

A California Toolkit to Transform Maternity Care

Improving Health Care Response to Obstetric Hemorrhage Version 2.0 A California Quality Improvement Toolkit

March 24, 2015

THIS COLLABORATIVE PROJECT WAS DEVELOPED BY:

THE OBSTETRIC HEMORRHAGE TASK FORCE

THE CALIFORNIA MATERNAL QUALITY CARE COLLABORATIVE

MATERNAL, CHILD AND ADOLESCENT HEALTH DIVISION; CENTER FOR FAMILY
HEALTH

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH



Improving Health Care Response to Obstetric Hemorrhage Version 2.0

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Suggested citation:

Lyndon A, Lagrew D, Shields L, Main E, Cape V. Improving Health Care Response to Obstetric Hemorrhage. (California Maternal Quality Care Collaborative Toolkit to Transform Maternity Care) Developed under contract #11-10006 with the California Department of Public Health; Maternal, Child and Adolescent Health Division; Published by the California Maternal Quality Care Collaborative, 3/17/15.

Funding for the development of this toolkit was provided by:

Federal Title V block grant funding from the California Department of Public Health; Maternal, Child and Adolescent Health Division and from Stanford University.

The California Toolkit to Transform Maternity Care called “Improving the Health Care Response to Obstetric Hemorrhage Version 2.0” was reviewed by the California Department of Public Health; Maternal, Child and Adolescent Health Division. This toolkit is considered a resource, but does not define the standard of care in California. 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.

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ACKNOWLEDGEMENTS

CMQCC would like to thank the California Department of Public Health; Maternal Child Health Division leaders Shabbir Ahmad, DVM, MS, PhD and Leona Shields, PHN, MN, NP, MFT, for their leadership to improve maternal health in California.

CMQCC would like to thank volunteer members of the Hemorrhage Task Force (HTF), the Task Force Co-Chairs, David Lagrew, MD, and Audrey Lyndon, PhD, RNC, FAAN.

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EXECUTIVE SUMMARY

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Early in the process of state level maternal mortality reviews, the California Department of Public Health Maternal Child and Adolescent Health Division, in collaboration with the California Maternal Quality Care Collaborative, identified obstetric hemorrhage as the leading cause of maternal mortality in California (2002-2004) and a cause of death with significant prevention potential.¹ This was the impetus for the first edition of *Improving Health Care Response to Obstetric Hemorrhage (California Maternal Quality Care Collaborative Toolkit to Transform Maternity Care)*, made publically available in July of 2010.²

While obstetric hemorrhage has been replaced by cardiovascular disease as the leading cause of maternal death, obstetric hemorrhage remains as one of the leading causes of severe maternal morbidity and mortality in California, the nation, and the world.³⁻⁷ Due to the widely accepted potential for interrupting the progression of hemorrhage to severe morbidity and mortality,^{1,8} the demonstrated usefulness of a standardized approach,^{9,10} and the need to plan ahead for rare but potentially catastrophic emergencies,¹¹ hemorrhage is one of the foci of the National Partnership for Maternal Safety initiatives. While the objectives and key recommendations of the original toolkit remain unchanged, this revision of the Obstetric Hemorrhage Toolkit clarifies and updates certain recommendations where there are new data, and aligns the approach of this toolkit to improving maternity care for obstetric

Table 1. Contents of CMQCC Obstetric Hemorrhage Toolkit in National Partnership for Maternal Safety Hemorrhage Bundle Sections (Bundle Components indicated with *)

(A) Readiness (every unit)

System level readiness

Carts, Kits, and Trays*
Simulation and Drills (includes debriefing)*
Sample Massive Transfusion Protocol*
Sample Emergency Transfusion Protocol*
Education*

Patient level readiness

Placenta Accreta and Percreta
Coagulation Disorders
Planning for women (Jehovah's Witness and others) who may decline transfusion

(B) Recognition (every patient)

Definition, Early Recognition and Triggers
Risk Assessment*
Cumulative Quantitative Assessment of Blood Loss*
Active Management of 3rd Stage of Labor*

(C) Response (every hemorrhage)

Emergency Management Plan*
Uterotonic Medications
Blood Product Replacement
Uterine Tamponade
Uterine Artery Occlusion
Patient and Family Support*
Resources for Clinicians after Severe Morbidity*
Discharge planning for women with complications
Preparedness Considerations for Small and Rural Hospitals
Anti-shock garments

(D) Reporting/Systems (every unit)

Debriefing Form*
OB Hemorrhage Measures for Hospital QI Projects*
[Bundle Elements not included in CMQCC Toolkit:]
Establish a culture of huddles for high-risk patients
Review all stage 3 hemorrhages for systems issues

hemorrhage with the National Partnership for Maternal Safety Hemorrhage Bundle as outlined in Table 1.

Melissa's Story

Melissa Price, the patient representative on the hemorrhage task force, had a late postpartum hemorrhage. Melissa ended up with a hysterectomy and about 12 units of blood transfused. While in the Emergency Department, Melissa recalls asking the nurses how they could tell how much blood she was losing – the nurses never weighed the blood, and dumped it from a bed pan into a portable toilet. After Melissa's OB got the bleeding to stop, she was left alone behind a curtain and checked on infrequently. Melissa tells of feeling sheer panic when the bleeding started up again with "enormous clots...I screamed and I will never forget the look on the nurse's face when she lifted up that blanket. After that, ER staff was running around everywhere. Rushing to call my OB, rushing to get an OR suite, rushing to figure out how to get my insulin pump turned off. I just kept thinking, 'God give them more time. They need more time to save me.' When I was going down the hallway to the OR suite, my OB was right next to me – running next to me. I grabbed his hand and said to him, 'Get me to the other side of this.' And he said, 'Melissa, I will do everything I can to get you there.' It haunts me to this day that had I passed out and not been able to scream and advocate for myself, things would likely have turned out very, very differently." (Story and name used with permission of Melissa Price, a patient representative of the Hemorrhage Task Force.)

WHY A HEMORRHAGE BUNDLE IS NEEDED FOR EVERY BIRTH FACILITY

Obstetric hemorrhage is a leading cause of maternal morbidity and mortality at the population level. In the United States the overall rate of postpartum hemorrhage increased 26% between 1994 and 2006. This increase was driven primarily by a 50% increase in cases of uterine atony.⁴ Rapid recognition and treatment are necessary to prevent progression of hemorrhage as women can lose large volumes of blood very quickly due to the physiologic changes of pregnancy. However, obstetric hemorrhage is also a low-volume, high-risk event for any given birth facility: without advance planning the probability of mounting a rapid, coordinated response is low. Indeed, maternal mortality reviews have consistently revealed problems with recognition, communication, and effective application of interventions as contributory factors in deaths from maternal hemorrhage.^{1,8,12} Birth facilities and health systems that have implemented systematic protocols for recognizing and responding to hemorrhage have demonstrated improved outcomes such as decreased use of both blood products and higher level interventions such as uterine artery embolization and hysterectomy.^{9,13} This toolkit is designed to assist birth facilities in demonstrating adoption of the National Partnership for Maternal Safety

Hemorrhage Bundle by developing systems that promote readiness, recognition, and response to obstetric hemorrhage.

SUMMARY OF KEY CHANGES IN THIS EDITION

Usability

We modified the format of the toolkit to improve usability by 1) providing the Emergency Management Plan documents at the front, 2) aligning the sections with the National Hemorrhage Bundle, and 3) providing an “Executive Summary” for each of the Best Practice Documents. Best practice documents review the evidence and rationale for toolkit recommendations. The executive summaries comprise 3-6 bullet points highlighting the most important concepts discussed in each document.

User Experience

“One of the major informal leaders came up to me and she said, ‘You know, every time you make us do a hemorrhage drill I know I roll my eyes but I think it really saved my patient’s life yesterday and I’m never going to roll my eyes at you again.’”

Highlights of Updated Content and Recommendations

- **Risk Assessment:** Added parameters for ongoing risk assessment at least at every shift or patient handoff.
- **Active management of third stage labor (AMTSL):** Emphasizes oxytocin as the main component and definitively states that AMTSL should not interfere with delayed cord clamping.
- **Medications:**
 - Continues to emphasize oxytocin as first line for prevention and treatment. There is no data to make a definitive recommendation for a second line recommendation. However, the key point for the second line agent is for facilities to agree on a standard second line agent.
 - Changes in misoprostol dosing recommendations.
- **Blood Product Replacement:**
 - Clarification: After the first two units of PRBC’s, early transfusion with FFP is correlated with improved survival from hemorrhage after trauma. There is ongoing debate as to the optimal ratio but most protocols recommend ratios between 1:1 and 1:2 (FFP:RBC) for initial resuscitation.
 - Additions: the importance of preventing low calcium, coagulopathy, acidosis, and hypothermia.
 - Further decrease in enthusiasm for rFactor VIIa.
- **Substantial expansion** of the section on patient and family support to address women’s experiences and psychological needs after an unexpected event.

- **Addition** of a resource list for staff support after a severe maternal morbidity.
- **Addition** of suggested structure, process, and outcome measures.
- **Examples** of how end-users have integrated key work such as risk assessment and cumulative quantification of blood loss into their electronic medical records.

National Safety Bundle Elements not included in the CMQCC Toolkit

The toolkit does not have specific guidance on establishing a culture of huddles (frequent, short briefings) for high-risk patients. Excellent support for this is publically available through the TeamSTEPPS program provided by the Agency for Healthcare Research and Quality at <http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/>.

Similarly, The Council on Patient Safety in Women's Health Care provides guidance on reviewing cases of severe maternal morbidity at <http://safehealthcareforeverywoman.org/get-smm-forms.php>

SUMMARY OF LESSONS FROM THE FIELD

With this second edition of the Obstetric Hemorrhage Toolkit we offer several principles for successful implementation gleaned from our end-users and literature on safety, quality improvement, and implementation science.

- **It takes a broad team to implement systematic change.**

Sites with the greatest success in implementing the recommended practices in this toolkit have recognized the need to engage all stakeholders in the project. It is important to think through who the stakeholders are in specific institutions. For example, some settings have their operating rooms run and staffed by surgical services rather than labor and delivery. In these settings it is important to bring surgical partners on board early. Similarly, most units will need to engage their Information Technology department and Electronic Medical Record programmers to achieve optimal workflow integration with documentation systems. Figure 1 shows an illustrative list of necessary partners to consider in developing implementation teams for obstetric hemorrhage.

Figure 1. Breadth of the Implementation Team	
Disciplines & Departments	Needed?
Obstetrics	YES
Nursing	
Anesthesia	
Blood Bank	
Laboratory	
Operating Room	
Support personnel	
IT/EMR	
Others unique to your setting?	

- **Easy wins matter.**

Demonstrating some early, straightforward successes builds confidence and enthusiasm for continued improvement. What constitutes an easy win will vary by institution, but implementation of hemorrhage carts and oxytocin at birth for active management of third stage of labor have often been ‘easy wins’ for our end-users.

- **Goals and timelines are very useful.**

An internal review of the experiences of hemorrhage collaborative participants revealed that highly motivated teams developed implementation plans with specific goals and timelines. Structuring their work in this way and assigning deliverables gave teams a sense of progress and momentum that was encouraging. Teams that had not structured their work this way identified this as a helpful strategy and adopted similar approaches. These observations are consistent with quality improvement literature and implementation literature.^{14,15}

- **Small tests of change matter.**

A key principle of implementation science is that fit between intervention and context is crucial.¹⁵ The core elements of an effective hemorrhage response plan are outlined in the National Hemorrhage Bundle. The exact manner in which these elements are deployed in a given institution needs to be adapted to each unit/birth facility. Development and field testing of these local adaptations is most effectively accomplished through small tests of change using quality improvement principles such as the Model for Improvement or FOCUS-PDSA.^{14,16}

- **Data matter.**

Data are needed to test changes, provide feedback, and answer the essential question, “How do we know the change was an improvement?” However, having extensive and difficult data collection processes can inhibit progress by draining the team’s energy and increasing the team’s frustration without adding much benefit. Langley, et al. recommend no more than 6 measures for an improvement project. Facilities should select a limited number of the highest quality meaningful and *feasible* measures available to them, monitor these measures frequently, and provide the team with regular feedback on progress and performance.^{14,16,17}

- **Administrative support matters.**

Teams that made the greatest progress had high-level administrative support. Successful bundle implementation requires staff time and budgetary resources for equipment, training, and data collection. Implementation teams may need administrative support in identifying organizational stakeholders and resources, purchasing supplies, moving order sets and protocols through committees, and obtaining compliance with agreed-upon practices. Facilities also need to provide resources and staff support for developing and streamlining data collection

systems. This will often involve working collaboratively with information technology and quality departments as well as some dedicated medical record review. Staff need release time or additional support to complete these activities successfully.

- **It takes time and persistence to get systems running smoothly.**

The scope of full implementation of the hemorrhage toolkit involves the careful coordination of multiple clinicians and departments. Therefore, everyone should realize that, while there will be some “quick wins”, overall success will often take significant time. In addition, we recognize that developing and refining systems are always works in progress. Staying the course requires steady pressure by committed leaders.

- **Champions are essential.**

Formal leaders, opinion leaders and early adopters are important to overall success since the changes can be uncomfortable and take a long time. Champions, however, are essential. Champions are individuals who actively associate with the project and dedicate themselves to driving implementation.⁹ Both nursing and physician champions are core components of successful implementation of the hemorrhage bundle. Nursing champions typically play a central role in testing, implementing, coordinating, and disseminating clinical changes. Physician champions are particularly important since they make the definitive diagnostic and treatment decisions, and are particularly visible stakeholders. Careful selection, clear identification, and motivation are critical to success of these leaders, whether they are administrative, physician, nursing or other clinicians.

The World Health Organization estimates that the US maternal mortality ratio (MMR) increased 136%, from 12 deaths per 100,000 live births in 1990 to 28 deaths per 100,000 live births in 2013.¹⁸ Other estimates of US MMR are more conservative, but also show an increase in contrast to decreasing MMRs in the majority of developed and developing nations.¹⁹ While maternal mortality is rare, the consequences are devastating and maternal mortality from hemorrhage is believed to be highly preventable. *Furthermore, severe morbidity affects 50 times more women, can also be devastating, and when related to hemorrhage is likely to be preventable with early recognition and action.* Implementation of hemorrhage bundles to improve safety in all birth facilities is a national priority, and implementation of this toolkit will achieve that goal.

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EMERGENCY MANAGEMENT PLANS

OBSTETRIC HEMORRHAGE EMERGENCY MANAGEMENT PLAN: CHECKLIST FORMAT

CMQCC

Obstetric Hemorrhage Emergency Management Plan: Checklist Format

Revision 9/10/14

Stage 0: All Births – Prevention & Recognition of OB Hemorrhage Prenatal Assessment & Planning

- ☐ **Identify and prepare for patients with special considerations:** Placenta Previa/Accreta, Bleeding Disorder, or those who Decline Blood Products
- ☐ **Screen and aggressively treat severe anemia:** if oral iron fails, initiate IV Iron Sucrose Protocol to reach desired Hgb/Hct, especially for at risk mothers.

Admission Assessment & Planning

Verify Type & Antibody Screen from prenatal record

If not available,

- ☐ Order Type & Screen (lab will notify if 2nd specimen needed for confirmation)

If prenatal or current antibody screen positive (if not low level anti-D from Rho-GAM),

- ☐ Type & Crossmatch 2 units PRBCs

All other patients,

- ☐ Send specimen to blood bank

- ☐ Evaluate for **Risk Factors** on admission, throughout labor, and postpartum. (At every handoff)

If medium risk:

- ☐ Order Type & Screen
- ☐ Review Hemorrhage Protocol

If high risk:

- ☐ Order Type & Crossmatch 2 units PRBCs
- ☐ Review Hemorrhage Protocol
- ☐ Notify OB Anesthesia

Identify women who may decline transfusion

- ☐ Notify OB provider for plan of care
- ☐ Early consult with OB anesthesia
- ☐ Review Consent Form

Ongoing Risk Assessment

- ☐ **Evaluate for development of additional risk factors in labor:**

- Prolonged 2nd Stage labor
- Prolonged oxytocin use
- Active bleeding
- Chorioamnionitis
- Magnesium sulfate treatment

- ☐ **Increase Risk level** (see below) **and convert to Type & Screen or Type & Crossmatch**

- ☐ **Treat multiple risk factors as High Risk**

- ☐ **Monitor women postpartum for increased bleeding**

Admission Hemorrhage Risk Factor Evaluation

Low (Clot only)	Medium (Type and Screen)	High (Type and Crossmatch)
No previous uterine incision	Prior cesarean birth(s) or uterine surgery	Placenta previa, low lying placenta
Singleton pregnancy	Multiple gestation	Suspected Placenta accreta or percreta
≤ 4 previous vaginal births	> 4 previous vaginal births	Hematocrit < 30 AND other risk factors
No known bleeding disorder	Chorioamnionitis	Platelets < 100,000
No history of PPH	History of previous PPH	Active bleeding (greater than show) on admit
	Large uterine fibroids	Known coagulopathy

All Births – Prophylactic Oxytocin, Quantitative Evaluation of Blood Loss, & Close Monitoring

Active Management of Third Stage

- ☐ Oxytocin infusion: 10-40 units oxytocin/1000 ml solution titrate infusion rate to uterine tone; or 10 units IM; do not give oxytocin as IV push

Ongoing Quantitative Evaluation of Blood Loss

- ☐ Using formal methods, such as graduated containers, visual comparisons and weight of blood soaked materials (1gm = 1ml)

Ongoing Evaluation of Vital Signs

If: Cumulative Blood Loss > 500ml vaginal birth or > 1000ml C/S with continued bleeding -OR-

Vital signs > 15% change or HR ≥ 110, BP ≤ 85/45, O2 sat < 95% -OR- Increased bleeding during recovery or postpartum, proceed to STAGE 1

STAGE 1: OB Hemorrhage Cumulative Blood Loss >500ml vaginal birth or >1000ml C/S with continued bleeding -OR- Vital signs >15% change or HR ≥110, BP ≤85/45, O2 sat <95% -OR- Increased bleeding during recovery or postpartum		
MOBILIZE	ACT	THINK
<p>Primary nurse, Physician or Midwife to:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Activate OB Hemorrhage Protocol and Checklist <p>Primary nurse to:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Notify obstetrician or midwife (in-house and attending) <input type="checkbox"/> Notify charge nurse <input type="checkbox"/> Notify anesthesiologist <p>Charge nurse:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Assist primary nurse as needed or assign staff member(s) to help 	<p>Primary nurse or designee:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Establish IV access if not present, at least 18 gauge Increase IV Oxytocin rate, 500 mL/hour of 10-40 units/500-1000 mL solution; Titrate infusion rate to uterine tone <input type="checkbox"/> Apply vigorous fundal massage <input type="checkbox"/> Administer Methergine 0.2 mg IM per protocol (if not hypertensive); give once, if no response, move to alternate agent; if good response, may give additional doses q 2 hr (If Misoprostol standard, misoprostol 800 mcg SL per protocol) <input type="checkbox"/> Vital Signs, including O2 sat & level of consciousness (LOC) q 5 minutes <input type="checkbox"/> Weigh materials, calculate and record cumulative blood loss q 5-15 minutes <input type="checkbox"/> Administer oxygen to maintain O2 sats at >95% <input type="checkbox"/> Empty bladder: straight cath or place Foley with urimeter <input type="checkbox"/> Type and Crossmatch for 2 units Red Blood Cells STAT (if not already done) <input type="checkbox"/> Keep patient warm <p>Physician or midwife:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Rule out retained Products of Conception, laceration, hematoma <p>Surgeon (if cesarean birth and still open)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Inspect for uncontrolled bleeding at all levels, esp. broad ligament, posterior uterus, and retained placenta 	<p>Consider potential etiology:</p> <ul style="list-style-type: none"> • Uterine atony • Trauma/Laceration • Retained placenta • Amniotic Fluid Embolism • Uterine Inversion • Coagulopathy • Placenta Accreta <p>Once stabilized: Modified Postpartum management with increased surveillance</p>
<p>If: Continued bleeding or Continued Vital Sign instability, and < 1500 mL cumulative blood loss proceed to STAGE 2</p>		

STAGE 2: OB Hemorrhage Continued bleeding or Vital Sign instability, and < 1500 mL cumulative blood loss		
MOBILIZE	ACT	THINK
<p>Primary nurse (or charge nurse):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Call obstetrician or midwife to bedside <input type="checkbox"/> Call Anesthesiologist <input type="checkbox"/> Activate Response Team: PHONE #: _____ <input type="checkbox"/> Notify Blood bank of hemorrhage; order products as directed <p>Charge nurse:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Notify Perinatologist or 2nd OB <input type="checkbox"/> Bring hemorrhage cart to the patient's location <input type="checkbox"/> Initiate OB Hemorrhage Record <input type="checkbox"/> If considering selective embolization, call-in Interventional Radiology Team and second anesthesiologist <input type="checkbox"/> Notify nursing supervisor <input type="checkbox"/> Assign single person to communicate with blood bank <input type="checkbox"/> Assign second attending or clinical nurse specialist as family support person or call medical social worker 	<p>Team leader (OB physician or midwife):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Additional uterotonic medication: Hemabate 250 mcg IM [if not contraindicated] OR Misoprostol 800 mcg SL <ul style="list-style-type: none"> o Can repeat Hemabate up to 3 times every 20 min; (note-75% respond to first dose) <input type="checkbox"/> Continue IV oxytocin and provide additional IV crystalloid solution <p>Do not delay other interventions (see right column) while waiting for response to medications</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bimanual uterine massage <input type="checkbox"/> Move to OR (if on postpartum unit, move to L&D or OR) <input type="checkbox"/> Order 2 units PRBCs and bring to the bedside <input type="checkbox"/> Order labs STAT (CBC/PLTS, Chem 12 panel, Coag Panel II, ABG) <input type="checkbox"/> Transfuse PRBCs based on clinical signs and response, do not wait for lab results; consider emergency O-negative transfusion <p>Primary nurse (or designee):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Establish 2nd large bore IV, at least 18 gauge <input type="checkbox"/> Assess and announce Vital Signs and cumulative blood loss q 5-10 minutes <input type="checkbox"/> Set up blood administration set and blood warmer for transfusion <input type="checkbox"/> Administer meds, blood products and draw labs, as ordered <input type="checkbox"/> Keep patient warm <p>Second nurse (or charge nurse):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Place Foley with urimeter (if not already done) <input type="checkbox"/> Obtain portable light and OB procedure tray or Hemorrhage cart <input type="checkbox"/> Obtain blood products from the Blood Bank (or send designee) <input type="checkbox"/> Assist with move to OR (if indicated) <p>Blood Bank:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Determine availability of thawed plasma, fresh frozen plasma, and platelets; initiate delivery of platelets if not present on-site <input type="checkbox"/> Consider thawing 2-4 FFP (takes 30 min), use if transfusing > 2 units PRBCs <input type="checkbox"/> Prepare for possibility of massive hemorrhage 	<p>Sequentially advance through procedures and other interventions based on etiology:</p> <p>Vaginal birth If trauma (vaginal, cervical or uterine):</p> <ul style="list-style-type: none"> • Visualize and repair <p>If retained placenta:</p> <ul style="list-style-type: none"> • D&C <p>If uterine atony or lower uterine segment bleeding:</p> <ul style="list-style-type: none"> • Intrauterine Balloon <p>If above measures unproductive:</p> <ul style="list-style-type: none"> • Selective embolization (Interventional Radiology if available & adequate experience) <p>C-section:</p> <ul style="list-style-type: none"> • B-Lynch Suture • Intrauterine Balloon <p>If Uterine Inversion:</p> <ul style="list-style-type: none"> • Anesthesia and uterine relaxation drugs for manual reduction <p>If Amniotic Fluid Embolism:</p> <ul style="list-style-type: none"> • Maximally aggressive respiratory, vasopressor and blood product support <p>If vital signs are worse than estimated or measured blood loss: possible uterine rupture or broad ligament tear with internal bleeding; move to laparotomy</p> <p>Once stabilized: Modified Postpartum management with increased surveillance</p>
<p align="center">Re-Evaluate Bleeding and Vital Signs If cumulative blood loss > 1500ml, > 2 units PRBCs given, VS unstable or suspicion for DIC, proceed to STAGE 3</p>		

STAGE 3: OB Hemorrhage Cumulative blood loss > 1500ml, > 2 units PRBCs given, VS unstable or suspicion for DIC		
MOBILIZE	ACT	THINK
<p>Nurse or Physician:</p> <p><input type="checkbox"/> Activate Massive Hemorrhage Protocol</p> <p>PHONE #: _____</p> <p>Charge Nurse or designee:</p> <p><input type="checkbox"/> Notify advanced Gyn surgeon (e.g. Gyn Oncologist)</p> <p><input type="checkbox"/> Notify adult intensivist</p> <p><input type="checkbox"/> Call-in second anesthesiologist</p> <p><input type="checkbox"/> Call-in OR staff</p> <p><input type="checkbox"/> Ensure hemorrhage cart available at the patient's location</p> <p><input type="checkbox"/> Reassign staff as needed</p> <p><input type="checkbox"/> Call-in supervisor, CNS, or manager</p> <p><input type="checkbox"/> Continue OB Hemorrhage Record (In OR, anesthesiologist will assess and document VS)</p> <p><input type="checkbox"/> If transfer considered, notify ICU</p> <p>Blood Bank:</p> <p><input type="checkbox"/> Prepare to issue additional blood products as needed – stay ahead</p>	<p>Establish team leadership and assign roles</p> <p>Team leader (OB physician + OB anesthesiologist, anesthesiologist and/or perinatologist and/or intensivist):</p> <p><input type="checkbox"/> Order Massive Hemorrhage Pack (RBCs + FFP + 1 apheresis pack PLTS—see note in right column)</p> <p><input type="checkbox"/> Move to OR if not already there</p> <p><input type="checkbox"/> Repeat CBC/PLTS, Coag Panel II STAT and Chem 12 panel q 30-60 min</p> <p>Anesthesiologist (as indicated):</p> <p><input type="checkbox"/> Arterial blood gases</p> <p><input type="checkbox"/> Central hemodynamic monitoring</p> <p><input type="checkbox"/> CVP or PA line</p> <p><input type="checkbox"/> Arterial line</p> <p><input type="checkbox"/> Vasopressor support</p> <p><input type="checkbox"/> Intubation</p> <p><input type="checkbox"/> Calcium replacement</p> <p><input type="checkbox"/> Electrolyte monitoring</p> <p>Primary nurse:</p> <p><input type="checkbox"/> Announce VS and cumulative measured blood loss q 5-10 minutes</p> <p><input type="checkbox"/> Apply upper body warming blanket if feasible</p> <p><input type="checkbox"/> Use fluid warmer and/or rapid infuser for fluid & blood product administration</p> <p><input type="checkbox"/> Apply sequential compression stockings to lower extremities</p> <p><input type="checkbox"/> Circulate in OR</p> <p>Second nurse and/or anesthesiologist:</p> <p><input type="checkbox"/> Continue to administer meds, blood products and draw labs, as ordered</p> <p>Third Nurse (or charge nurse):</p> <p><input type="checkbox"/> Recorder</p>	<p>Selective Embolization (IR)</p> <p>Interventions based on etiology not yet completed</p> <p>Prevent hypothermia, academia</p> <p>Conservative or Definitive Surgery:</p> <ul style="list-style-type: none"> • Uterine Artery Ligation • Hysterectomy <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p>For Resuscitation:</p> <p>Aggressively Transfuse</p> <p>Based on Vital Signs, Blood Loss</p> <p>After the first 2 units of PRBCs use</p> <p>Near equal FFP and RBC for massive hemorrhage:</p> <p>4-6 PRBCs: 4 FFP: 1 apheresis Platelets</p> </div> <p>Unresponsive Coagulopathy:</p> <ul style="list-style-type: none"> • Role of rFactor VIIa is very controversial. After 8-10 units PRBCs and coagulation factor replacement with ongoing hemorrhage, may consider risk/benefit of rFactor VIIa in consultation with hematologist or trauma surgeon <p>Once Stabilized: Modified Postpartum Management with increased surveillance; consider ICU</p>

UTEROTONIC AGENTS for POSTPARTUM HEMORRHAGE

Drug	Dose	Route	Frequency	Side Effects	Contraindications	Storage
Pitocin® (Oxytocin) 10 units/ml	10-40 units per 500-1000 ml, rate titrated to uterine tone	IV infusion	Continuous	Usually none Nausea, vomiting, hyponatremia ("water intoxication") with prolonged IV admin. ↓ BP and ↑ HR with high doses, esp IV push	Hypersensitivity to drug	Room temp
Methergine® (Methylergonovine) 0.2 mg/ml	0.2 mg	IM (<u>not</u> given IV)	-Q 2-4 hours -If no response after first dose, it is unlikely that additional doses will be of benefit	Nausea, vomiting Severe hypertension, esp. if given IV, which is not recommended	Hypertension, Preeclampsia, Cardiovascular disease Hypersensitivity to drug Caution if multiple doses of ephedrine have been used, may exaggerate hypertensive response w/possible cerebral hemorrhage	Refrigerate Protect from light
Hemabate® (15-methyl PG F2a) 250 mcg/ml	250 mcg	IM or intra- myometrial (<u>not</u> given IV)	-Q 15-90 min -Not to exceed 8 doses/24 hrs -If no response after several doses, it is unlikely that additional doses will be of benefit.	Nausea, vomiting, Diarrhea Fever (transient), Headache Chills, shivering Hypertension Bronchospasm	Caution in women with hepatic disease, asthma, hypertension, active cardiac or pulmonary disease Hypersensitivity to drug	Refrigerate
Cytotec® (Misoprostol) 100 or 200 mcg tablets	600-800 mcg	Sublingual or oral	One time	Nausea, vomiting, diarrhea Shivering, Fever (transient) Headache	Rare Known allergy to prostaglandin Hypersensitivity to drug	Room temp

BLOOD PRODUCTS

Packed Red Blood Cells (PRBC) (approx. 35-40 min. for crossmatch—once sample is in the lab and assuming no antibodies present)	Best first-line product for blood loss 1 unit = 200 ml volume If antibody positive, may take hours to days. for crossmatch, in some cases, such as autoantibody crossmatch compatible may not be possible; use "least incompatible" in urgent situations
Fresh Frozen Plasma (FFP) (approx. 35-45 min. to thaw for release)	Highly desired if > 2 units PRBCs given, or for prolonged PT, PTT 1 unit = 180 ml volume
Platelets (PLTS) Local variation in time to release (may need to come from regional blood bank)	Priority for women with Platelets < 50,000 Single-donor Apheresis unit (= 6 units of platelet concentrates) provides 40-50 k transient increase in platelets
Cryoprecipitate (CRYO) (approx. 35-45 min. to thaw for release)	Priority for women with Fibrinogen levels < 80 10 unit pack (or 1 adult dose) raises Fibrinogen 80-100 mg/dl Best for DIC with low fibrinogen and don't need volume replacement Caution: 10 units come from 10 different donors, so infection risk is proportionate.

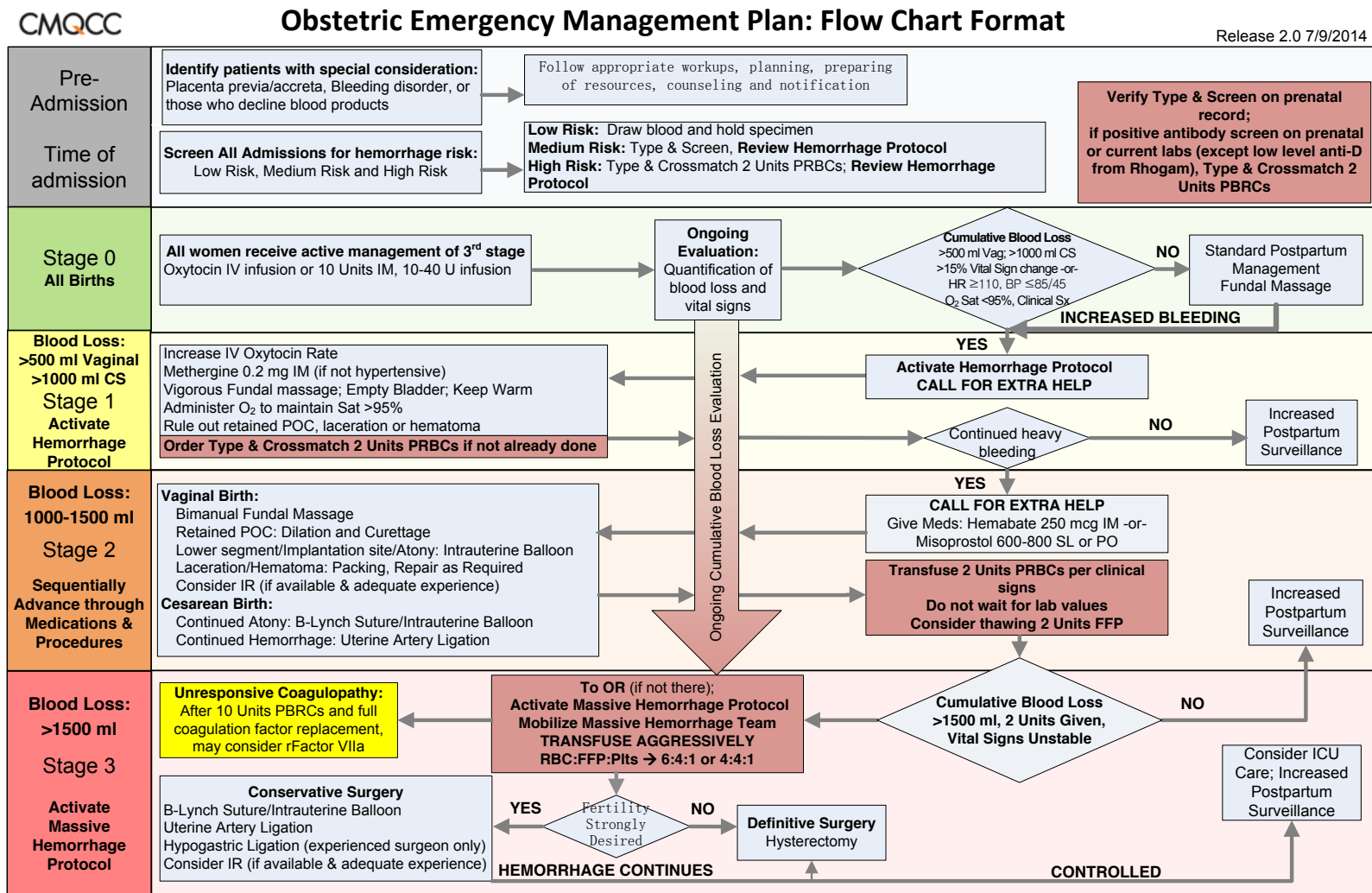
OBSTETRIC HEMORRHAGE EMERGENCY MANAGEMENT PLAN: TABLE CHART FORMAT



Obstetric Hemorrhage Emergency Management Plan: Table Chart Format
version 2.0

	Assessments	Meds/Procedures	Blood Bank
Stage 0	Every woman in labor/giving birth		
<i>Stage 0 focuses on risk assessment and active management of the third stage.</i>	<ul style="list-style-type: none"> Assess every woman for risk factors for hemorrhage Measure cumulative quantitative blood loss on every birth 	Active Management 3rd Stage: <ul style="list-style-type: none"> Oxytocin IV infusion or 10u IM Fundal Massage-vigorous, <u>15 seconds min.</u> 	<ul style="list-style-type: none"> If Medium Risk: T & Scr If High Risk: T&C 2 U If Positive Antibody Screen (prenatal or current, exclude low level anti-D from RhoGam):T&C 2 U
Stage 1	Blood loss: > 500ml vaginal or >1000 ml Cesarean, or VS changes (by >15% or HR ≥110, BP ≤85/45, O2 sat <95%)		
<i>Stage 1 is short: activate hemorrhage protocol, initiate preparations and give Methergine IM.</i>	<ul style="list-style-type: none"> Activate OB Hemorrhage Protocol and Checklist Notify Charge nurse, OB/CNM, Anesthesia VS, O2 Sat q5' Record cumulative blood loss q5-15' Weigh bloody materials Careful inspection with <u>good exposure</u> of vaginal walls, cervix, uterine cavity, placenta 	<ul style="list-style-type: none"> IV Access: at least 18gauge Increase IV fluid (LR) and Oxytocin rate, and repeat fundal massage Methergine 0.2mg IM (if not hypertensive) May repeat if good response to first dose, BUT otherwise move on to 2nd level uterotonic drug (see below) Empty bladder: straight cath or place foley with urimeter 	<ul style="list-style-type: none"> T&C 2 Units PRBCs (if not already done)
Stage 2	Continued bleeding with total blood loss under 1500ml		
<i>Stage 2 is focused on sequentially advancing through medications and procedures, mobilizing help and Blood Bank support, and keeping ahead with volume and blood products.</i>	OB back to bedside (if not already there) <ul style="list-style-type: none"> Extra help: 2nd OB, Rapid Response Team (per hospital), assign roles VS & cumulative blood loss q 5-10 min Weigh bloody materials Complete evaluation of vaginal wall, cervix, placenta, uterine cavity Send additional labs, including DIC panel If in Postpartum: Move to L&D/OR Evaluate for special cases: <ul style="list-style-type: none"> -Uterine Inversion -Amn. Fluid Embolism 	2nd Level Uterotonic Drugs: <ul style="list-style-type: none"> Hemabate 250 mcg IM <u>or</u> Misoprostol 800 mcg SL 2nd IV Access (at least 18gauge) Bimanual massage Vaginal Birth: (typical order) <ul style="list-style-type: none"> Move to OR Repair any tears D&C: r/o retained placenta Place intrauterine balloon Selective Embolization (Interventional Radiology) Cesarean Birth: (still intra-op) (typical order) <ul style="list-style-type: none"> Inspect broad lig, posterior uterus and retained placenta B-Lynch Suture Place intrauterine balloon 	<ul style="list-style-type: none"> Notify Blood Bank of OB Hemorrhage Bring 2 Units PRBCs to bedside, transfuse per clinical signs – do not wait for lab values Use blood warmer for transfusion Consider thawing 2 FFP (takes 35+min), use if transfusing > 2u PRBCs Determine availability of additional RBCs and other Coag products
Stage 3	Total blood loss over 1500ml, or >2 units PRBCs given or VS unstable or suspicion of DIC		
<i>Stage 3 is focused on the Massive Transfusion protocol and invasive surgical approaches for control of bleeding.</i>	<ul style="list-style-type: none"> Mobilize team <ul style="list-style-type: none"> -Advanced GYN surgeon -2nd Anesthesia Provider -OR staff -Adult Intensivist Repeat labs including coags and ABG's Central line Social Worker/ family support 	<ul style="list-style-type: none"> Activate Massive Hemorrhage Protocol Laparotomy: <ul style="list-style-type: none"> -B-Lynch Suture -Uterine Artery Ligation -Hysterectomy Patient support <ul style="list-style-type: none"> -Fluid warmer -Upper body warming device -Sequential compression stockings 	Transfuse Aggressively Massive Hemorrhage Pack <ul style="list-style-type: none"> Near 1:1 PRBC:FFP 1 PLT apheresis pack per 4-6 units PRBCs Unresponsive Coagulopathy: After 8-10 units PRBCs and full coagulation factor replacement: may consult re rFactor Vlla risk/benefit

OBSTETRIC EMERGENCY MANAGEMENT PLAN: FLOW CHART FORMAT



OB HEMORRHAGE TOOLKIT POCKET CARD



NCPPOP-Northeastern
California Perinatal
Outreach Program

OB Hemorrhage Toolkit Pocket Card

This project was developed by RPPC Region 2, Northeastern California Perinatal Outreach Program (NCPPOP) with Title V funding through the CDPH/MCAH, 2010. Adapted with permission from the California Department of Public Health Toolkit: "Improving the Health Care Response to Obstetric Hemorrhage" by Lyndon A. Lagrew D, Shields L, et al and the California Maternal Quality Care Collaborative, 2010. Funding for development of the toolkit and this poster was provided by the federal Title V block grant from the California Maternal, Child and Adolescent Health Division. (Updated 5/2014 for v 2.0)

Identify Risk on Admission

OB Hemorrhage—No Denial—No Delay		
Low Risk:	Hold Specimen	
<ul style="list-style-type: none"> No previous uterine incision Singleton Pregnancy ≤ 4 previous vaginal births No known bleeding disorder No history of PPH 		
Medium Risk:	Type and Screen	
<ul style="list-style-type: none"> Prior c/s or uterine surgery Multiple gestation > 4 previous vaginal births Chorioamnionitis History of previous PPH Large uterine fibroids 		
High Risk:	Type and Cross	
<ul style="list-style-type: none"> Placenta Previa, or low lying Suspected accreta or percreta HCT < 30 AND other risk factors Platelets < 100,000 Active bleeding on admit Known coagulopathy 		

Stage 0

Stage 0
<ul style="list-style-type: none"> Active management with oxytocin infusion of 10-40 units/500-1000 mL titrated; or 10 units IM
Action
<ul style="list-style-type: none"> Quantitative evaluation of cumulative blood loss: use of graduated containers, visual comparisons, and weighing blood soaked materials after delivery of placenta. 1gm = 1mL
<ul style="list-style-type: none"> Ongoing evaluation of vital signs per hospital protocol; more if needed per patient condition.
<p>Proceed to STAGE 1 if:</p> <ul style="list-style-type: none"> cumulative blood loss > 500 mL for vaginal or > 1000 mL for C/S OR VS > 15% change (HR ≥ 110, BP ≤ 85/45, O₂ sat < 95%) OR ↑ bleeding during recovery or postpartum

Stage 1

Stage 1
Continued bleeding and Blood loss: > 500 ml vaginal or > 1000 ml C/S, OR VS changes (by > 15% or HR ≥ 110, BP ≤ 85/45) sat < 95% OR increased bleeding during recovery period.
Mobilize
<ul style="list-style-type: none"> Notify OB/CNM Notify Charge RN Notify Anesthesia provider
Actions
<ul style="list-style-type: none"> Establish 16g IV Infuse oxytocin 500mL/hr (10-40 units/500-1000 mL) Vigorous fundal massage Administer 2nd uterotonic Vital signs including O₂ sat q 5 minutes Weigh and calculate blood loss Administer O₂ to keep sats >95% Empty bladder – foley with urimeter Type and Cross for 2 units PRBCs Keep patient warm
<p>Consider potential etiologies: atony, trauma, laceration, retained placenta, AFE, inversion, coagulopathy, accreta</p> <p>Proceed to STAGE 2 if:</p> <ul style="list-style-type: none"> Continued bleeding or continued VS instability, & < 1500 mL cumulative blood loss

Stage 2

Stage 2
Continued bleeding or Vital Sign instability, and < 1800 mL cumulative blood loss
Mobilize
<ul style="list-style-type: none"> OB/CNM at bedside; 2nd OB or perinatologist & anesthesiologist called to assist; Charge nurse: assign recorder and runner, notify nursing supervisor, call radiology to prepare for IR if available, and call for second anesthesiologist Notify Rapid Response Team Assign a 2nd RN to communicate with blood bank and offer family support
Actions
<ul style="list-style-type: none"> Administer hemabate or misoprostil Move to OR Transfuse 2 U PRBC (do not wait for lab results); blood warmer; request for blood bank to thaw FFP Order STAT CBC/plts, Chem 12, Coag panel, and ABG Start 2nd IV Weigh & calculate cumulative blood loss Announce vital signs Ready essential equipment.
<p>*THINK: Prepare for procedures/interventions based on etiology for: balloon, selective embolization with IR (atony), repair (trauma), B-lynch suture for (C/S), etc. Proceed to STAGE 3 if:</p> <ul style="list-style-type: none"> still bleeding, cumulative blood loss > 1800 mL, > 2 units PRBCs given, VS unstable or suspicion for DIC

Stage 3

Stage 3
Cumulative blood loss > 1800 mL, > 2 U PRBCs given, VS unstable or suspect DIC
Mobilize
<ul style="list-style-type: none"> Activate Massive Transfusion Protocol Notify GYN/Onc Surgeon Call in OR staff (anesthesia assist) Call in supervisor, CNS, Manager Blood bank to stay ahead of blood products
Actions
<ul style="list-style-type: none"> Announce VS and cumulative blood loss Assist anesthesiologist with art line, PA or CVP line, or intubation. Use fluid warmer and/or rapid infuser Keep patient warm. Apply sequential compression stockings to lower extremities. Repeat labs q 30-60 minutes.
<p>*THINK:</p> <ul style="list-style-type: none"> Selective Embolization (IR) Interventions based on etiology from previous stage not yet completed: prevent hypothermia, acidemia, and hypocalcemia Surgeries: uterine artery ligation or hysterectomy For resuscitation: aggressively transfuse based on VS, and blood loss. <p>After first 2 units PRBC, near equal FFP and PRBC for massive hemorrhage</p> <p>4-6 PRBC:4FFP:1 apheresis platelets</p> <ul style="list-style-type: none"> Once stable: modify postpartum management consider ICU

Blood Products

Packed Red Blood Cells (PRBCs)

- Best first line product
- 1 unit = 200 ml volume
- If antibody positive, may take 1-24 hrs for crossmatch

Fresh Frozen Plasma (FFP)

- Approximately 35-45 min to thaw
- Highly desired if > 2 units PRBCs given, or for prolonged PT, PTT
- 1 unit = 18 ml volume

Platelets (PLTs)

- Priority for women with platelets < 50,000
- Single—donor apheresis unit (= 6 units of platelet concentrates) provides 40-50 K transient increase in platelets

Cryoprecipitate (CRYO)

- Approximately 35-45 min to thaw
- Priority for women with Fibrinogen levels < 80
- 10 unit pack raises Fibrinogen 80-100 mg/dl
- Best for DIC with low Fibrinogen and don't need volume replacement
- Caution: 10 units come from 10 different donors, so infection risk is proportionate
- Warm upper body with blankets or warming device
- Sequential compression stockings

Uterotonic Agents

Drug/Dose	Route/Frequency	Side Effects	Contraindications
Pitocin (Oxytocin) 10 units/mL 10-40 units per 500-1000 mL titrated to uterine tone	Continuous IV infusion	Usually none; nausea/vomiting, hypotension ("water intoxication") with prolonged IV; 1 BP and 1 HR with high doses, esp IV push	Hypersensitivity to drug
Methergine (Methylergonovine) 0.2 mg/mL 0.2 mg	IM only/every 2-4 hours	Nausea/vomiting, severe hypertension, esp with rapid administration or in patients with HTN or Preeclampsia	HTN, Preeclampsia, heart disease; hypotensive drug Caution: if multiple doses of ergot alkaloids have been used, may exaggerate hypertensive response w/ possible cerebral hemorrhage
Hemabate (15-methyl PG F2a) 250 mcg/mL 250 mcg	IM only or intramyometrial on-ly/every 15-90 min, NTE 8 doses in 24 hours	Nausea/vomiting, diarrhea, fever (transient), headache, chills, shivering, HTN, bronchospasm	Caution in women with hepatic disease, asthma, HTN, active cardiac or pulmonary disease; hypersensitivity to drug
Cytotec 100 or 200 mcg tablets 500-500 mcg	Sublingual (SL) or Orally (PO)/ One time	Nausea/vomiting, diarrhea, shivering, fever (transient), headache	Rare; known allergy to prostaglandin; hypersensitivity to drug

SYSTEMS LEVEL READINESS

OB HEMORRHAGE: CARTS, KITS AND TRAYS

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EXECUTIVE SUMMARY

- Several lists of suggested materials for standardized carts, kits, and trays are provided to use in preparing for obstetric hemorrhage.

BACKGROUND AND LITERATURE REVIEW

Postpartum hemorrhage (PPH) is a commonly encountered obstetrical emergency on labor and delivery units throughout California.¹ Although medical management is often successful in treating PPH, the obstetrician may have to resort to surgical measures. For ideal response to the emergency, the obstetrician should have rapid access to surgical instruments and tools designed to treat PPH. Equipment and instruments compiled on an obstetrical hemorrhage “cart” is designed to treat vaginal/cervical lacerations and perform uterine tamponade or uterine/ovarian artery ligation. In short, the cart would have all the instruments necessary to treat PPH before hysterectomy is considered. The reader is referred to other guidelines in this toolkit that depict the use of these techniques. For more in-depth details about the hemorrhage cart, the reader is referred to articles by TF Baskett.^{2,3}

RECOMMENDATIONS

1. Labor and delivery units construct a sterile tray that provides rapid access to instruments used to surgically treat PPH.
2. Hysterectomy trays are separately available.

EVIDENCE GRADING

Level of Evidence: III C. Opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees. Recommendations based primarily on consensus and expert opinion.

Level of Evidence: II-3. Evidence obtained from multiple time series with or without intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. Strong quality improvement data such as statistical process control, or other well-designed analysis.

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1. Lu MC, Fridman M, Korst LM, et al. Variations in the incidence of postpartum hemorrhage across hospitals in California. *Maternal Child Health Journal*. September 2005;9(3):297-306.
2. Baskett TF. Equipment tray for postpartum hemorrhage in A Textbook of PostPartum Hemorrhage. (ed C. B-Lynch et al). *Sapiens Publishing 2006 (III)*. 2006.
3. Baskett TF. Surgical management of severe obstetric hemorrhage: experience with an obstetric hemorrhage equipment tray. *J Obstet Gynaecol Can*. Sep 2004;26(9):805-808.

CHECKLIST: CARTS, KITS, TRAYS

OB Hemorrhage Cart: Recommended Instruments

- ☐ Set of vaginal retractors (long right angle); long weighted speculum
- ☐ Sponge forceps (minimum: 2)
- ☐ Sutures (for cervical laceration repair and B-Lynch)
- ☐ Vaginal Packs
- ☐ Uterine balloon
- ☐ Banjo curettes, several sizes
- ☐ Long needle holder
- ☐ Uterine forceps
- ☐ Bright task light on wheels; behind ultrasound machine
- ☐ Diagrams depicting various procedures (e.g. B-Lynch, uterine artery ligation, Balloon placement)

OB Hemorrhage Medication Kit: Available in L&D and Postpartum Floor

PYXIS/refrigerator

- ☐ Pitocin 10-40 units per 500-1000 mL NS 1 bag
- ☐ Hemabate 250 mcg/mL 1 ampule
- ☐ Cytotec 200 mcg tablets 5 tabs
- ☐ Methergine 0.2 mg/mL 1 ampule

OB Hemorrhage Tray: Available on Postpartum Floor

- ☐ IV start kit
- ☐ 16 gauge angiocath
- ☐ 1 liter bag lactated Ringers
- ☐ IV tubing
- ☐ Sterile Speculum
- ☐ Urinary catheter kit with urimeter
- ☐ Flash light
- ☐ Lubricating Jelly
- ☐ Assorted sizes sterile gloves
- ☐ Lab tubes: red top, blue top, tiger top

Labor and Delivery Emergency Hysterectomy Tray: Available in L&D OR Suite

☐ 4 Towel Clips, Backhaus (perforating) 5 1/4"

☐ 4 Mosquito, Curved, 5"

☐ 2 Clamp, Mixer 9"

☐ 2 Clamp, Tonsil

☐ 2 Clamp, Allis, Extra long 10"

☐ 2 Clamp, Allis 6"

☐ 2 Clamp, Babcock 8"

☐ 2 Clamp, Babcock 6 1/4"

☐ 2 Clamp, Lahey 6"

☐ 2 Clamp, Heaney-Rezak, Straight, 8"

☐ 8 Kelly, Curved 5 3/4"

☐ 2 Kelly, Straight 5 3/4"

☐ 8 Pean Curved, 6 1/4"

☐ 2 Forceps, Debakey, 9 1/2"

☐ 1 Forceps, Tissue with teeth 9 3/4"

☐ 1 Forceps, Russian 8"

☐ 1 Forceps, Smooth 8"

☐ 1 Forceps, Ferris Smith

☐ 2 Forceps with Teeth, 6 "

☐ 1 Forceps, Russian 6"

☐ 2 Forceps, Adson with Teeth

☐ 1 Forceps, Tissue, Smooth, 7"

☐ 2 Kocher, Straight, 8"

☐ 6 Forceps, Heaney, Curved, 8 1/4"

☐ NH, Mayo Hegar, 8"

☐ 4 Sponge Stick, 9 1/2"

☐ 1 Scissor, Jorgensen, Curved, 9"

☐ 1 Scissors, bandage 7"

☐ 1 Scissors, curved dissecting, Metzenbaum

☐ 1 Scissors, Mayo, curved

- ☐ 1 Scissors, sharp/blunt, Straight, 5 1/2"
- ☐ 1 Scissors, Curved Metzenbaum 12"
- ☐ 1 Scissors, Mayo Straight 11"
- ☐ 1 Scissors, Mayo Curved 11"

- ☐ 1 Knife Handle #3
- ☐ 1 Knife Handle #4
- ☐ 1 Knife Handle #3, Long

- ☐ 1 Retractor, Kelly, large
- ☐ 1 Retractor, Deaver, Large, 3" x 12"
- ☐ 1 Retractor, Deaver, Medium
- ☐ 2 Retractor, Med/large Richardson
- ☐ 1 Retractor, Balfour Blades
- ☐ 2 Retractor, Goulet, 7 1/2"

- ☐ 1 Suction, Yankauer Tip
- ☐ 1 Suction, Pool Tip

SIMULATIONS & DRILLS

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EXECUTIVE SUMMARY

- Interdisciplinary drills are useful for improving communication and coordination among team members in emergency situations.
- Drills can also be used to assess system weaknesses, identify opportunities for improvement, and test new or modified policies and procedures.
- Human factor training is essential for maximizing learning and team building. It should be incorporated into simulation/drills programs for effective debriefing of drills and critical incidents.
- Both low and high fidelity simulation can be of benefit. Access to a simulation center is not required for the development of an effective simulation program.

BACKGROUND AND LITERATURE REVIEW

Medical simulation drills of obstetrical hemorrhage cases can assess system weaknesses and strengths, test policies and procedures for coping with hemorrhage and improve teamwork and communication skills of staff members. Drills that include all disciplines (obstetrics, anesthesia, pediatrics and nursing) can be especially effective in improving communication and coordination among team members.

Drills are practice sessions of relatively uncommon but critical events, such as antenatal or postpartum hemorrhage and amniotic fluid embolism. Critical Event Training simulations for all physicians, midwives, anesthesiologists and nurses may improve neonatal outcomes.¹ Implementing a rapid response team and addressing systems' issues for management of obstetrical hemorrhage has been shown to decrease maternal mortality and improve outcomes.² The Joint Commission recommends team training in their 2005 Executive Summary of Strategies to Improve the Medical Liability System and Prevent Patient Injury.³

Human factors training can improve communications and teamwork. Such training includes briefings, handoffs, time-outs and situational awareness for the team, which is a shared understanding of what is happening now and what happens next. Explicit communication skills to be taught include: addressing team members by name, making eye contact, repeating back orders and confirming that you are responding to an order, and not speaking to the room and assuming that you were heard. In addition, the concept of "Just Culture" or a similar environment should be implemented in all health care settings so that all team members feel respected and comfortable with asserting

observations, suggestions and opinions. Team training may include practicing worst case scenarios, back up behavior (assisting a teammate in completion of a task), and performance monitoring (monitoring a teammate and providing constructive feedback).⁴ Improving communications skills among caregivers is one of the Joint Commission 2012 National Patient Safety Goals.

Scenarios for simulation should be designed for the needs of the learners (nurses, physicians, residents, respiratory therapy, etc.) and tailored to available resources. Interdisciplinary training should include all disciplines involved in the care of obstetric patients. Simulation can be low tech—using live models—or high tech, using complex computerized simulators or a combination of both. The objective of simulation is to create situations that are as similar to “real life” as possible. Simulation in situ may improve ability to address systems issues and provides practice in one’s own hospital setting with familiar resources. A study of neonatology in situ and lab simulation training over a 19-month period found that in situ simulation identified safety threats more readily, leading to documented improvements in neonatal care.⁵ Simulation in a computerized simulation center offers high technology in an environment similar to real life, but without the distractions of the hospital. The choice of high or low fidelity simulation is institution dependent; both can work well for hemorrhage scenarios. For practicing complex events requiring a maternal cardiorespiratory arrest, high fidelity may be a better choice since chest compressions cannot be performed on a live model, for example. Some institutions use a combination of both types. Simulation of obstetric hemorrhage has been used to teach quantification of blood loss, bimanual compression technique, inspection for lacerations, and medical treatment of atony.⁶

Debriefing is appropriate both for simulation drills and for live events. Video taken during simulation serves as a realistic debriefing tool to explore what went well and what needs improvement after a scenario is performed. One method of debriefing developed by simulation experts in Cambridge, Massachusetts divides debriefing into three stages: Reactions (clear the air, review facts), Understanding (explore what happened, apply judgment and teach skills, generalize lessons to real life situations), and Summarize (review lessons learned which can be applied to future events).⁷ To facilitate debriefing, provide a safe private area for discussion, acknowledge value of all input and importance of reflection, and clarify that debriefing is confidential.⁸

Evaluation tools such as checklists for expectations of each participant in their role and for team and individual performances can provide an objective approach to debriefing. Similarly, follow-up evaluation ensures that specific goals and objectives for each level of participant are met. The Ottawa Crisis Resource Management Global Rating Scale and Mayo High Performance Teamwork Scale are examples.^{9,10}

RECOMMENDATIONS

All hospitals adopt regularly scheduled simulation drills for practicing response to obstetric hemorrhage. The choice of high or low fidelity drills is institution dependent; both can work well for hemorrhage scenarios.

EDUCATIONAL TOOLS

1. Guidelines for Simulation Scenario Development
2. Obstetric Hemorrhage Sample Scenario 1: Drill for Uterine Atony
3. Obstetric Hemorrhage Sample Scenario 2: Drill for Hemorrhage and Pulseless Electrical Activity in the OR (see Appendix B)
4. Kaiser Evaluation Form for Drills; Debriefing Tool: "Labor and Delivery/Family Centered Care, Mock Obstetrical Hemorrhage, Roles and Responsibilities of Staff Skills Validation"

EVIDENCE GRADING

Level of Evidence: II-3 B. Evidence obtained from multiple time series with or without intervention. Well-done QI studies with statistical process control analyses (or the like) fall into this category. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. Recommendations based on limited or inconsistent evidence.

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SIMULATIONS AND DRILLS: EDUCATIONAL TOOL #1: GUIDELINES FOR SIMULATION SCENARIO DEVELOPMENT

(Used with permission of Kaiser Permanente)

The scenario is the structure of simulation-based training (SBT). In general, scenarios are comprised of an overview, set up instructions for the simulation, guidelines for running the scenario for participants, debriefing aids and the documents that support the content in the scenario. Below is a brief discussion of the components of the scenario with suggestions and examples for generation of new scenarios or the alteration of existing scenarios to better meet the needs of your participants (learners). For more in depth review and instruction on scenario development we recommend you attend a simulation instructor program.

SCENARIO OVERVIEW

The scenario overview provides basic information about the scenario. Contents of the overview include the patient history or story, learning objectives, target audience (participants the scenario is written for) and approximate time of the scenario.

The patient history or story can be taken directly from an existing scenario or from an actual patient case. Of all the information contained in the scenario, the most important is the learning objectives. Learning objectives guide development of the scenario. They assist the simulation instructors in determining what cues are needed in the scenario, what type of manikin or task trainer should be used, how many actors are needed in the scenario, what critical behaviors should be accomplished by the participants in the scenario and they directly guide debriefing questions that set the stage for the participants to engage in discussion that promotes learning. Below are examples of learning objectives that are specific to hemorrhage. These learning objectives can be used as is or altered to meet the specific learning needs of your participants.

Learning objectives are broken down into three categories based on the skills that should be demonstrated in the scenario or drill. Selection of learning objectives should be based on who is being trained, what you want them to learn and what areas for improvement are being targeted. Target areas are identified by risk management data, patient safety data, and data collection from the patient care unit or root cause analysis. Also, different disciplines may require additional learning objectives specific to their skill set or role. Limiting the number of learning objectives per category to no more than three (additional discipline specific learning objectives may be added as stated above) helps to keep the scenario from becoming too lengthy and facilitates thorough debriefing.

In addition, consider providing information found in the cognitive learning objectives in advance (unit policies, bulletins, monographs or current literature) for participant review to allow more debriefing time to focus on technical and behavioral skills. You may also want

to consider the addition of metrics or measurements in the scenario to illuminate unit issues, issues with unit policies or procedures or for report generation on the simulation training session(s). Open-ended questions are listed with each set of learning objectives that can be used during debriefing.

EXAMPLES OF LEARNING OBJECTIVES FOR HEMORRHAGE

Cognitive Skills (what you want participants to know)

Sample Learning Objectives

- Knowledge of signs and symptoms of hemorrhage during pregnancy
- States major causes of hemorrhage in pregnancy
- Lists changes in maternal physiology that may mask symptoms of hemorrhage
- Knowledge of hospital policies and procedures for hemorrhage management, placement of tamponade devices and blood transfusion particularly massive transfusion

Metrics

- Test for fund of knowledge on hemorrhage or a specific policy such as the massive transfusion guideline
Use in report on simulation training: identify gaps in knowledge to help prioritize learning objectives for next training session, guide on-going education plan for participants

Debriefing questions

- What is your assessment of this patient at this time?
- What could cause this or what is your differential diagnosis at this time?
- How do the changes in maternal physiology affect the signs and symptoms of hemorrhage?
- Based on this assessment, what are your priorities for patient care OR what is your plan for care?
- What prevented you from carrying out the priorities for care or your management plan? *(This question also has implications for behavioral skill discussion, for example was there not enough help, what prevented the team from calling for help?)*

Technical Skills (what you want participants to be able to do)

Sample Learning Objectives

- Provide adequate and continuous uterine massage
- Administer uterotonic medications in correct dose, route and time
- Application of devices (tamponade devices, uterine packing) to control bleeding per policy
- Quantify blood loss
- Order blood components or massive transfusion bucket according to policy
- Set up and initiate rapid blood transfuser

Metrics

- Measurements of time
 - Time of diagnosis of hemorrhage to administration of first medication
 - Time help paged to time help arrived in room
 - Amount of time uterine massage was stopped unless directed by physician
 - Time from request for tamponade device to completion of insertion
 - Time from request for blood to blood in patient room
 - Time from request for rapid infuser to start of volume infusion

Excessive lengths of time for a task may indicate a knowledge gap, lack of system support or flawed policy
- Measurement of ability to accurately complete current policy/procedure
 - Key points from policy placed in a checklist that is reviewed during scenario or after

Helpful to see where it is difficult for learners to comply with policy and can guide adjustments to unit to better support patient care
- Correct measurement of volume of blood loss
 - Comparison of the amount of blood used in scenario to the amount measured by participants during the scenario

Helpful to see where unit or system can be adjusted to better support adoption of blood loss measurement

Debriefing questions

- What supported or prevented continuous uterine massage?
- What facilitated or delayed medication administration?
- What uterotonic medications have major contraindications?
- Why would a uterine tamponade device be considered at this time?
- What blood loss management strategies are options for this patient?
- How was the quantified blood loss information used in this situation?
- What supported or hampered measurement of blood loss?
- What is the massive transfusion policy in this institution?

- Under what circumstances would this policy be activated?
- What supported or delayed implementation of the massive transfusion policy?
- What is a fast process for getting rapid transfuser in room and setting it up?

Behavioral Skills (*how you want the team to perform*)

Sample Learning Objectives

- Communication between team members is directed to a person and acknowledged
- Communication during hand off is acknowledged by the receiver
- Concerns voiced about the patient or management plan are acknowledged by the team leader
- The team leader announces assumption of the role
- Team leader assigns roles if not already assigned or key role not filled
- Team leader communicates plan of care to the team
- All team members assume a role or ask leader how they can assist

Metrics

- Number of thin air or open air commands
- Number of thin air or open air communications
- Number of people in scenario without a role
- Roles not assigned or not filled during scenario
- Number of questions or concerns voiced about the management plan
- Number of changes in leaders

Information obtained from these metrics can be used to report adoption of key behavioral skills, recommend further training or educational offerings or alteration of unit practices

Debriefing questions

- How was team communication?
- How did communication improve or delay care of the patient?
- How did the communication between the leader and the team member giving report to leader impact patient care?
- Who is the leader at this point?
- Why did the role of leader change hands?
- What roles are filled and unfilled at this time?
- What strategies can the team use to fill key roles that are currently not filled?

SCENARIO SET-UP

This section of the scenario describes how the simulation area should be set up for the scenario. If several simulation training sessions are going to occur that require consistency taking a picture of the set up can be helpful. Having a list of items needed for the scenario and keeping those items in a bag or bin will facilitate set up. Clear directions should be included for set up of the manikin or task trainer. These directions should include any 'moulage' or make-up that is required. For hemorrhage scenarios this may include making artificial blood or using a red cloth to simulate bleeding.

RUNNING THE SCENARIO

This section gives clear direction to the person running the manikin or providing vital sign information to the participants. There should also be discussion with the person responsible for video recording to insure they are aware of the key parts of the scenario that should be captured on video. Actors or the voice of the patient will need clear roles and instruction. Lastly, be sure to designate where in the scenario the objectives are achieved to the point that the scenario can be stopped. For example, in a hemorrhage scenario this may be when 'blood' arrives for administration to the patient or when the 'blood' has been loaded into a rapid infuser.

DEBRIEFING AIDS

Developing open-ended questions in advance based on the learning objectives will help guide debriefing. In addition, use of metrics and critical behavior checklists will also assist in generating discussion pertinent to the learning objectives.

EVIDENCE FOR SCENARIO CONTENT

The last section of the scenario includes the evidence that supports the content in the scenario. Evidence may be in the form of unit policies and procedures, current literature or association guidelines such as those found in Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), the American College of Obstetricians and Gynecologists (ACOG) or the American Society of Anesthesiologists (ASA).

SIMULATIONS AND DRILLS: EDUCATIONAL TOOL #2: SAMPLE SCENARIO #1: DRILL FOR UTERINE ATONY

Center for Advanced Pediatric and Perinatal Education Julie Arafeh MSN, RN



SCENARIO OVERVIEW

Name of Scenario: Post-partum Hemorrhage (Uterine Atony)

Patient description: Renee Harper, 32 yo G2 P1, 38 weeks gestation, admitted for spontaneous labor, OB history remarkable for previous postpartum hemorrhage requiring transfusion. Labor Course: Epidural for pain management, spontaneous vaginal delivery after five-hour labor. No complications for mother or infant during delivery, delivery occurred 30 minutes ago, epidural catheter removed, patient is holding infant.

History:

Medical: Unremarkable, OB history remarkable for previous post-partum hemorrhage

Surgical: Unremarkable

Social: Smoker for 5 years, stopped before first pregnancy

Baseline Lab values: Labs WNL except Hct 24

Learning Objectives

Cognitive:

- States major causes of hemorrhage in pregnancy
- Lists changes in maternal physiology that may mask symptoms of hemorrhage
- Knowledge of policies and procedures for hemorrhage management, placement of tamponade devices and blood transfusion particularly massive transfusion

Technical:

- Provide adequate and continuous uterine massage.
- Administer uterotonic medications in correct dose, route and time
- Application of tamponade device to control bleeding per policy
-

Behavioral:

- Communication during hand off is acknowledged by the receiver
- Concerns voiced about the patient or management plan are acknowledged by the team leader
- Team leader assigns roles if not already assigned or key role not filled

Target Trainees Obstetricians, L&D/PP nurses

Anticipated Duration: 10 minutes

SCENARIO SET-UP

Room configuration: LDR bed against right wall, manikin in bed, IV pump with mainline, fetal monitor and patient monitor next to bed, wooden bedside cabinet next to bed

Equipment:

- Manikin, neonatal manikin swaddled
- IV (1000 mL LR with 20 units Pitocin) with IV pump set up with dump bucket
- Monitor for maternal VS (BP cuff, pulse oximeter)
- Red fabric
- Postpartum hemorrhage medication kit
- Tamponade device with stopcock, tubing, fluid for inflation

Manikin/task trainer preparations: Manikin in bed with thin amount of baby powder on face to give appearance of paleness, red cloth in uterus with approximately ½ yard in bed, Uterus boggy, starts to firm with medication administration, firm after tamponade device placed

Presets

Patient monitor: BP 120/90 ⇒ 80-40, P 120 ⇒ 140, RR 32 ⇒ 24, with resolution of bleeding BP SaO2 92%⇒ 96%

Pumps: Mainline IV at 125 cc/hr

Initial Presentation: Patient in recovery room with infant, pale and shaky, diaphoretic

Miscellaneous: Medication cabinet for medication kit, second IV with blood tubing available if ordered

Chart Contents: Summary of L&D

Demonstration Items needed in Debriefing Room: Tamponade device with items for placement, pelvis to demonstrate placement

SCENARIO LOGISTICS (Running the Scenario)

Expected interventions:

- Fundal massage, extraction of clots
- Administration of medications (misoprostol, Methergine)

- Order and placement of uterine tamponade device
- Assessment of patient response using clinical exam, VS, laboratory tests

Likely progression:

- Bedside nurse assesses patient, detects hemorrhage, starts uterine massage
Calls for help
- Help arrives, hand off given to leader
- Roles established for other responders
- Medications given as ordered
- Bleeding continues and vital signs not responding
- Uterine tamponade device placed
- Patient improves

Expected endpoint: Tamponade device in place

Distracters (if needed):

- Uncooperative family member

Additional/optional challenges (if needed):

- Delayed response to tamponade device, massive transfusion activated

Videotape Guidelines (Priorities to capture on videotape)

- Maternal vital signs
- Bleeding from pelvis
- Team communication
- Administration of medications
- Placement of tamponade device

Confederate Roles

- Family member (responsible for pushing red cloth out of uterus)

Trainee Roles

- Bedside RN
- Help: OB physician, 2-3 RNs

DEBRIEFING QUESTIONS

Cognitive:

- What could cause this or what is your differential diagnosis at this time?
- How do the changes in maternal physiology affect the signs and symptoms of hemorrhage?
- Based on this assessment, what are your priorities for patient care OR what is your plan for care?
- What prevented you from carrying out the priorities for care or your management plan?

Technical:

- What supported or prevented continuous uterine massage?
- What facilitated or delayed medication administration?
- What uterotonic medications have major contraindications?
- Why would a uterine tamponade device be considered at this time?
- What blood loss management strategies are options for this patient?

Behavioral:

- How was team communication?
- How did communication improve or delay care of the patient?
- How did the communication between the leader and the team member giving report to leader impact patient care?
- What roles are filled and unfilled at this time?
- What strategies can the team use to fill key roles that are currently not filled?

SCENARIO SUPPORT MATERIALS

Reference List

- Unit policies and procedures
- Postpartum Hemorrhage. ACOG Practice Bulletin No. 76.
American College of Obstetricians and Gynecologists Obstet
Gynecol 2006; 108:1039-1047
- AWHONN Monograph: Obstetric Hemorrhage (2012)

A. Critical Behavior Checklist

B. Metrics List

C. Visual aids/cognitive aids: Manufacturer guidelines from uterine tamponade device used on your unit

SCENARIO SUPPORT MATERIALS

A. Critical Behaviors Checklist

Behavior	Met	Unmet	Comment
Detection of hemorrhage			
Call for help, asks for specific help needed			
Uterine massage begins upon detection of boggy uterus, stopped upon physician order			
Handoff given in SBAR format			
Leader announces role to team			
Team roles are assumed			
Uterotonic medications given per policy			
Uterine tamponade device inserted per procedure			
Leader acknowledges team concerns			

SCENARIO SUPPORT MATERIALS

B. Uterine Atony Metrics

Metric Item	Measurement	Measurement	Comment
Time of diagnosis of hemorrhage to administration of first medication	Time Started:	Time Complete:	
Time help paged to time help arrived in room	Time Started:	Time Complete:	
Amount of time uterine massage was stopped unless directed by physician	Time Started:	Time Complete:	
Time from request for tamponade device to completion of insertion	Time Started:	Time Complete:	
Number of thin air or open air commands	#		
Number of thin air or open air communications	#		
Number of people in scenario without a role	#		
Roles not assigned or not filled during scenario	#		
Number of questions or concerns voiced about the management plan			

SCENARIO SUPPORT MATERIALS

C. Visual aids/cognitive aids: Place the manufacturer guidelines from uterine tamponade device used on your unit here

SIMULATIONS AND DRILLS: EDUCATIONAL TOOL #3: SAMPLE SCENARIO #2: DRILL FOR HEMORRHAGE AND PULSELESS ELECTRICAL ACTIVITY IN THE OR

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Anita Nadwarny, RN, Kaiser Permanente San Diego Medical Center

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This scenario document will be found in Appendix B at the end of the toolkit.
It includes:

Part 1: General Information

Part 2: Objectives

Part 3: Patient and Background Information

Part 4: Equipment / Materials List

Part 5: Program Algorithm and operator notes

SIMULATIONS AND DRILLS: EDUCATIONAL TOOL #4: KAISER EVALUATION FORM FOR DRILLS; DEBRIEFING TOOL

LABOR AND DELIVERY/FAMILY CENTERED CARE, MOCK OBSTETRICAL
HEMORRHAGE, ROLES AND RESPONSIBILITIES OF STAFF SKILLS VALIDATION
(Used with permission from: Lawrence Lurvey, MD, Kaiser Permanente, West Los
Angeles)

SHIFT _____

DATE: _____

CRITICAL ELEMENTS	Met	Not Met	Comments
A. Primary Surgeon, MD or CNM			
• Recognizes the need to activate the hemorrhage protocol and ensures its immediate activation			
• Updates nursing team and the team leader of blood products needed.			
• Cancels the hemorrhage protocol as indicated			
B. Charge Nurse or designated Team Leader			
•Assesses the patient, source of bleeding, color, amount			
•Cont. monitor VS			
•Stays with the patient at all times			
•Performs all nursing interventions			
•Call MD using SBAR format			
•Initiates the hemorrhage protocol per MD order			
•Ensures IV access patent			
•Ensures collection of a Blood Bank specimen and its immediate transport to the blood bank			
•Assigns a person who will communicate with the Blood Bank for the duration (Communicator)			
•Maintains communication with the physician, surgeon or designee, using SBAR			
•Explains all procedures to patient			
•Obtains transfusion consent			
•Arranges transportation to L&D			
•Ensures cancellation of the protocol, as directed per policy and prompt return of unused blood products to the Blood Bank			

CRITICAL ELEMENTS	Met	Not Met	Comments
C. Designated team leader or staff			
•Calls the Blood Bank stat @ extension [XXXX]			
•Tells the Blood Bank technician “Hemorrhage protocol is in effect for patient (state patient’s name), medical record # (give patient’s MRN), in room # (give patient’s location/unit)			
•Gives telephone extension for return calls and further communication			
•Immediately transports the blood specimen and lab slip directly to the Blood Bank via transporter			
•Initiates electronic or manual orders for all Blood products as they are requested by the attending MD/CNM			
•Relays to the blood bank any information and or instructions from the MD			
D. The communicator (person assigned to communicate with the Blood Bank), usually the Ward Clerk or Transporter			
•Completes orders for blood products (electronic or manual) and <i>Blood Release Verification</i> forms for pick up of products.			
•Transports blood bank specimen to the Blood Bank immediately if transporter is unavailable			
•Receives blood products from the Blood Bank and delivers to patient location immediately if transporter is unavailable			
•Maintains close communication with the Blood Bank			
•Waits for additional instructions from the Charge Nurse or team leader			
•Notify the Blood Bank if hemorrhage Protocol is cancelled by the MD/CNM			
E. The Transporter (if available) will:			
•Bring the blood specimen (a red top Corvac) and the complete release form to the Blood Bank			
•Pick up 4 units O negative (blood type of patient) PRBC or			
•Pick up additional blood products as ordered			

CRITICAL ELEMENTS	Met	Not Met	Comments
F. The Blood Bank Technologist (CLS):			
• Prepares 4 units of uncross-matched O negative RBC for immediate issue			
• Completes uncross-matched Waiver for MD signature			
• Immediately calls the telephone extension of the unit given for pick-up of the blood product and the waiver			
• Notifies a lab supervisor as needed			
• If requested, begin to thaw at least 2 units of type specific frozen plasma. If ABO/Rh is not known at this time thaw AB plasma			
• Immediately performs type and screen			
• Verifies ABO/Rh result with previous record otherwise have another technologist verify ABO/Rh			
• While antibody screen is incubating, immediately spins crossmatch 4 units of type specific RBC			
• Checks blood inventory and orders, additional blood products for immediate delivery			
• Processes requested blood products as soon as telephone orders received			
• Sets aside the labeled donor unit segments of issued blood products for later recording and/or maintenance			
• Compare pertinent paperwork			
• Standby for additional instructions			
• When protocol is cleared/cancelled: complete paperwork and update patient's computer record			
• Restores unused blood products in the computer and the refrigerator			
G. Scrub Tech/RN:			
• Scrubbed and in OR within 1-2 minutes			
• Sets up equipment in OR/DR			
• Prepares D&C/Hysterectomy tray			
H. Other RN:			
• Assists with patient transfer to OR			
• May be 3 rd nurse to assist anesthesiology or scrub tech prn			

PATIENT LEVEL READINESS

PLACENTA ACCRETA AND PERCRETA: INCIDENCE, RISKS, DIAGNOSIS, COUNSELING AND PREPARATION FOR DELIVERY

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EXECUTIVE SUMMARY

- The risk of placenta accreta is highest in women with a history of prior cesarean and current placenta previa.
- The risk of placenta accreta increases proportionally with each subsequent cesarean.
- Ultrasound and MRI can both be effective diagnostic tools and may be complimentary when imaging is inconclusive.
- Advance planning for birth in a center with access to surgeons experienced in complex pelvic surgery, full anesthesiology coverage, and capacity for rapid access to massive transfusion is essential for women with strong suspicion for placenta accreta.
- Delivery is advised prior to the onset of labor.
- ACOG suggests placenta accreta be delivered between 34 0/7-35 6/7 weeks gestation.

BACKGROUND AND LITERATURE REVIEW

The rising incidence of placenta accreta is due to the rapidly rising numbers of primary and repeat cesarean births.¹ The most recent data in California shows that 32.8% of all births are by cesarean section.² One study at The University of Chicago showed that between 1982 and 2002 (before the greatest rise in cesarean births) the overall incidence of placenta accreta was 1 in every 533 deliveries.³

A placenta accreta occurs when there is abnormally firm attachment of placental villi to the uterine wall with the absence of the normal intervening deciduas basalis and Nitabuch's layer. There are three variants of this condition: 1) *accreta*: the placenta is attached to the myometrium; 2) *increta*: the placenta extends into the myometrium; and 3) *percreta*: the placenta extends through the entire myometrial layer and uterine serosa.

RISK

The risk of placenta accreta is highest in patients with both prior cesarean birth and placenta previa (placenta previa also increases with prior cesarean births). Silver, et al. reported proportionally increased risk of placenta accreta with higher numbers of prior cesareans in women with or without placenta previa (See Table 1).⁴

Table 1: Placenta Previa and Placenta Accreta by Number of Cesarean Deliveries

Cesarean Delivery	Previa	Previa*: Accreta† N (%)	No Previa‡: Accreta† N (%)
First§	398	13 (3.3%)	2 (0.03%)
Second	211	23 (11%)	26 (0.2%)
Third	72	29 (40%)	7 (0.1%)
Fourth	33	20 (61%)	11 (0.8%)
Fifth	6	4 (67%)	2 (0.8%)
≥ 6	3	2 (67%)	4 (4.7%)

*Percentage of accreta in women with placenta previa

†Increased risk with increasing number of cesarean deliveries; $P < .001$

‡Percentage of accreta in women without placenta previa

§Primary cesarean

DIAGNOSIS

A diagnosis of accreta can be confirmed with tissue histology; however, medical imaging can be an effective diagnostic tool. Ultrasound can detect the presence of accreta (80-90% sensitivity) and absence of accreta (95% specificity).^{5-8,9} Furthermore, ultrasound has been used to predict the degree of placental invasion.¹⁰ Warshak, et al. reported that in cases with suspicious or inconclusive ultrasonography results, MRI accurately predicted placenta accreta with 88% sensitivity and 100% specificity.⁷ While MRI's specificity is enhanced when gadolinium is used, its effects on the fetus remain uncertain; many researchers believe benefits of its use outweigh risks associated with mis- or undiagnosed placenta accreta.⁷ A recent Stanford study suggests that high-resolution sonography and MRI give similar results but are complimentary when one modality is inconclusive.⁸ Another meta-analysis demonstrated similar sensitivities and specificities for ultrasound and MRI detection of placenta accreta.¹¹

Second trimester Maternal Serum Alpha-Fetoprotein (MSAFP) may also be helpful. In one recent study of patients with placenta previa, MSAFP was elevated in 45% of those with accreta, and not in those without accreta.¹²

COUNSELING

Providers caring for patients with prenatally suspected placenta accreta should counsel patients extensively about potential risks and complications well in advance of their estimated due date. Patients with accreta are at increased risk for hemorrhage, blood transfusion, bladder/ureteral damage, infection, need for intubation, prolonged hospitalization, ICU admission, need for reoperation, thromboembolic events and death.^{4,8,12,13} Discussions should involve relative likelihood for hysterectomy and subsequent infertility.

DELIVERY TIMING

In patients with strong suspicion for placenta accreta, it is strongly advised to perform the delivery before labor begins or hemorrhaging occurs.¹² In patients with a suspected placenta accreta who have antenatal vaginal bleeding, uterine contractions, or PPRM, the risk for unscheduled delivery prior to a planned delivery date increases.¹⁴ The presence of these factors should be included when planning delivery. Consideration should be given to performing the cesarean birth electively and prematurely, either after antenatal corticosteroids treatment (ATC) for fetal lung maturation or after documentation of fetal lung maturity. A decision analysis demonstrated optimized outcomes with delivery at 34 weeks gestation without amniocentesis for both mother and fetus in the setting of a stable placenta previa/accreta.¹⁵ ACOG suggests placenta accreta be delivered between 34 0/7-35 6/7 weeks gestation.¹⁶

DELIVERY PREPARATIONS

Advance planning with anesthesia, blood bank, nursing (OB and OR) and advanced surgeons is an essential first step. Advanced surgeons are gynecology oncologists or experienced pelvic surgeons familiar with the operative management of complex pelvic surgeries. A Massive Transfusion Pack with 4-6 units PRBCs, FFP and Platelets should be available (see OB Hemorrhage Care Guidelines: Checklist Format and Blood Product Replacement Best Practice Article). At the time of cesarean, the hysterotomy should be made away from the location of the placenta. In all but those with focal accretas, a hysterotomy —without disturbance of the placenta—is strongly advised.^{12,17} Blood salvage equipment should also be considered where available.¹⁸ The results of conservative surgery have been recently reviewed with many complications noted (e.g. infection, delayed hemorrhage, re-operation requiring hysterectomy, disseminated intravascular coagulation) and should only be considered in the most select situations.¹⁹ Consultation with experienced surgeons (e.g. gynecologic oncologist) or referral to appropriate facilities is required when a provider lacks appropriate support services or surgical experience with managing placenta accreta. The use of prophylactic intravascular balloon catheters for cesarean hysterectomy for placenta accreta is controversial.²⁰ A large case control study (UC Irvine/Long Beach Memorial) showed no

benefit.²¹ If a focal placenta accreta is found (typically in the lower uterine segment at the delivery of a placenta previa) management options are broader and include over-sewing, fulguration and placement of an intrauterine compression balloon (with drainage through the cervix/vagina) for 24 hours. Pelvic arterial embolization has also been used in the management of hemorrhage for placenta accreta, but its effectiveness and safety is still subject to debate.^{20,22}

RECOMMENDATIONS

Screen

1. Screen all women with prior cesarean birth for placenta previa with ultrasound.⁴ (C)
2. Screen all women with placenta previa for accreta first with ultrasound, then with MRI if ultrasound results are suspicious or inconclusive.⁶ (B)

Counsel

1. Counsel all patients with placenta accreta about delivery risks and complications and future infertility if hysterectomy is performed. (C)

Prepare

1. Prepare a multi-disciplinary approach for delivery, including a plan for emergent surgery prior to scheduled delivery.
 - a. Planning should include primary OB surgeon, blood bank, perinatologist, anesthesiologist, gynecologic oncologist/experienced pelvic surgeon, labor & delivery nursing, operating room personnel, nursery and pediatric teams. (C)
2. Consider early delivery (34-35 6/7 weeks) before labor and after pretreatment with antenatal corticosteroids for fetal benefit. (C)
3. Perform the delivery surgery in main OR with a surgical scrub team. (C)
4. Actively involve surgeon(s) with advanced skills for controlling heavy pelvic bleeding and repairing bladder or ureteral injury. (C)
5. Strongly consider hysterectomy (without removal of placenta) if no further children are desired. (C)
6. Notify blood bank for potential of massive hemorrhage and ensure immediate availability of 4-6 units of PRBC, FFP, and platelets. (C)

7. The Committee was divided on the desirability for pre-placement of internal iliac artery balloon catheters with a recent large case control study (UC Irvine/Long Beach Memorial) showing no benefit.²¹ (B)

EVIDENCE GRADING

Level of Evidence: II-3 B. Evidence obtained from multiple time series with or without intervention. Well-done QI studies with statistical process control analyses (or the like) fall into this category. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. Recommendations based on limited or inconsistent evidence

Level of Evidence: III C. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. Recommendations based primarily on consensus and expert opinion

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INHERITED COAGULATION DISORDERS IN PREGNANCY

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EXECUTIVE SUMMARY

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

BACKGROUND AND LITERATURE REVIEW

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 pregnancy, such abnormalities can lead to maternal hemorrhage events during antepartum, birth or postpartum and can have deleterious effects on the mother's and baby's health. Identifying patients with inherited coagulation disorders and carefully planning their care is crucial for optimal outcomes. Although postpartum hemorrhage can occur in these patients, coagulation defects are sufficiently rare that routine screening in patients with postpartum hemorrhage will not identify a large number of these patients.^{1,2} Though incidence is low, this is an important group of individuals to identify and prepare for.³⁻¹²

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.¹³⁻¹⁵

von Willebrand Disease (vWD) is the most common hereditary coagulation abnormality described in humans with a prevalence of 1% in the general population.^{3,16,17} 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, 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.¹⁸ Type 1 individuals make up 60-80% of all vWD cases and have a quantitative defect (heterozygous for the defective gene) but may not have clearly impaired clotting function. 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). Type 2 vWD patients (20-30% of all vWD cases) have a qualitative defect and the tendency to bleed varies between individuals. Individuals with Types I and II are usually mildly affected by the disorder and pass the trait in an autosomal dominant fashion.

Type III vWD is the most severe form; it is autosomal recessive and severely affected individuals are homozygous for the defective gene. Patients 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.

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 (random inactivation of the X chromosome). Usually women have 50% activity but if inactivation of the “normal” gene occurs in greater frequency, lower levels can be seen.¹⁹ Of note, Factor VIII activity usually increases during pregnancy.²⁰

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 the least common form of hemophilia (sometimes called “Christmas Disease,” after the first afflicted patient), occurring in about 1:30,000 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 (less than 1:100,000) but more common in Ashkenazi Jewish patients, and it can occur in both males and females.^{7,21} 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%.

Rarer Disorders Congenital Factor XIII deficiency is a rare autosomal recessive disorder who when identified can be successfully followed and treated in pregnancy with replacement factor.¹³ Patients with congenital fibrinogen deficiency will require monitoring of levels and replacement with targets of > 0.5-1.0 g/L in the antepartum, intrapartum and postpartum periods.¹⁴ Inherited dysfibrinogenemia requires similar replacement of fibrinogen to maintain levels > 100 mg/dl and in addition should be given anticoagulation.¹⁵

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.²² When a patient with an inherited coagulation disorder delivers, one must be concerned about extra-uterine bleeding and hematomas and the effect of the disorder on the fetus. Cesarean section is rarely recommended.^{4,5,23} 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 for patients with suspected disorders^{18,19}:
 - von Willebrand Disorder: 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

Other tests performed for patients with bleeding problems: complete blood count (especially platelet counts), APTT (activated partial thromboplastin time), prothrombin time, thrombin time and fibrinogen level. Note that patients with von Willebrand disease 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.^{4,5}

4. Obtain perinatal and anesthesia consultation for planning and coordination of antepartum and intrapartum management.^{4,5} In general regional anesthesia must be given with caution given the risks of spinal hematoma. Route of delivery for most patients with carrier status which may cause neonatal coagulation disorders, e.g. Factor VIII deficiency, should still be reserved for obstetrical indications since studies have not shown a protective effect of cesarean section.^{4,5} Individualized decisions should be made in a multidisciplinary fashion.
5. Refer patients for genetic counseling regarding possible testing and evaluation of the fetus and newborn.^{4,5,23}
6. 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^{4,5}
 - von Willebrand Disorder: Mild forms can be treated with desmopressin acetate (DDAVP) but more severe forms require vWF and VIII factor replacement.¹² DDAVP challenge testing can identify whether patients will respond to this medication.
 - Hemophilia A/B: Concentrates of clotting factor VIII (for Hemophilia A) or clotting factor IX (for Hemophilia B) are slowly dripped in or injected into a vein. Consider DDAVP adjunctive therapy.
 - Hemophilia C: FFP is the first product used to treat patients with hemophilia C. The main advantage of FFP 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: III C. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. Recommendations based primarily on consensus and expert opinion.

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PLANNING FOR WOMEN (JEHOVAH'S WITNESSES AND OTHERS) WHO MAY DECLINE BLOOD AND BLOOD PRODUCTS

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EXECUTIVE SUMMARY

- It is important to assess a woman's stance toward blood products well in advance of labor or planned surgery.
- After personal discussion, approximately half of the Jehovah's Witness community may be willing to accept some blood products such as Fresh Frozen Plasma, Erythropoietin, Cell-Saver re-infusion, and even some will accept red cells in the face of death.
- Prenatal optimization of hemoglobin and developing a detailed management plan for delivery are critical steps for women who may decline transfusion of some or all blood products.

BACKGROUND AND LITERATURE REVIEW

Given the known rate of obstetric hemorrhage, it is very unsettling to many obstetricians and anesthesiologists to have a patient decline a potentially life-saving treatment. Fortunately, discussions regarding limits to intervention generally occur in advance of emergencies in pregnant women whose belief systems preclude blood transfusion.

The goals of the interaction with the woman who is declining transfusion are the following: 1) to find common ground to manage the birth as safely as possible; 2) to build trust or if not possible, to transfer to a program amenable with the plans; and 3) to develop a well thought out delivery plan to minimize blood loss and maximize decisive decisions. A large study in New York of 391 live births among Jehovah's Witnesses found 2 maternal deaths from hemorrhage (512 maternal deaths per 100,000 births).¹

With regard to goal #3 listed above, there is a broad movement in the United States to develop skills and promote the concepts of "Bloodless Surgery." While this may sound a bit utopian, there are case series of open-heart surgeries and liver transplants without transfusions. The principles of this approach are listed below:²

General Principles of Bloodless Medicine Management

- Employ a multidisciplinary treatment approach to blood conservation
- Formulate a plan of care for avoiding/controlling blood loss
- Consult promptly with senior specialist experienced in blood conservation

- Promptly investigate and treat anemia
- Decisive intervention, including surgery
- Be prepared to modify routine practice when appropriate
- Restrict blood drawing for laboratory tests
- Decrease or avoid the use of anticoagulants and antiplatelet agents
- Stimulate erythropoiesis
- Transfer a stabilized patient, if necessary, to a major center before the patient's condition deteriorates

Not all blood products are “off the table”

There is a wide range of acceptable blood interventions within the Jehovah's Witness community—50% will actually take some form of blood transfusions. Therefore it is imperative to begin discussions prenatally to educate and review all possible options to be available at the time of delivery.^{3,4}

RECOMMENDATIONS

Prenatal Care

1. Comprehensive discussion with a checklist specifying acceptable interventions⁵
2. Aggressively prevent anemia (goal: maintain HCT: 36-40%)
 - Iron—PO or IV (iron sucrose or ferric carboxymaltose) (+Folate and B12)
 - rh-Erythropoietin 600 u/kg SQ 1-3x per weekly (each dose contains 2.5mL of albumin so is not always acceptable)
3. Line-up Consultants (consider MFM, Hematology, Anesthesiology)

Labor and Delivery

Early anesthesia consultation

1. Reassessment of hemorrhage risk and discussion of options (e.g. Surgery, Interventional Radiology)
2. Review specific techniques (e.g. Options Checklist and Fibrin/Thrombin glues)⁶
3. Review references—Have a Plan!⁷
4. Be decisive

Postpartum

1. Maintain volume with crystalloids and blood substitutes
2. Aggressively treat anemia
 - Iron—IV (iron sucrose or ferric carboxymaltose)
 - Rh-Erythropoietin 600 u/kg SQ weekly (3x week); RCT's show benefit in Critical Care units

DISSEMINATION STRATEGY

Since patients who decline blood products are uncommon in California, providers will often be unfamiliar with these issues. It is important to identify local physician resources (often perinatologists) and to have these protocols (informed consent and checklist, blood product management checklist and the Iron sucrose protocol) available on the unit and online via access to the CMQCC website (www.CMQCC.org). Education about this topic should be introduced in venues such as Grand Rounds.

EDUCATIONAL TOOLS, SAMPLE DOCUMENTS

1. Jehovah's Witness Consent Form and Management Checklist⁸
2. Specific Checklist for Management of Pregnant Women Who Decline Transfusions
3. IV Iron Sucrose and Ferric Carboxymaltose Protocols

EVIDENCE GRADING

Level of Evidence: III C. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. Recommendations based primarily on consensus and expert opinion.

JEHOVAH'S WITNESS BLOOD PRODUCT AND TECHNIQUE INFORMED CONSENT / DECLINE CHECKLIST

My signature below indicates that I request no blood derivatives other than the ones that I have designated in this consent be administered to me during this hospitalization. My attending physician, _____ M.D. has reviewed and fully explained to me, ***the risks and benefits*** of the following blood products and methods for alternative non-blood medical management and blood conservation available to me. My attending physician _____ M.D. has also **fully explained to me the potential risks associated by not authorizing blood and / or non-blood management during this hospitalization.**

	ACCEPT	DO NOT ACCEPT
COMPONENTS OF HUMAN BLOOD		
Red Blood Cells	_____	_____
Fresh Frozen Plasma	_____	_____
Platelets	_____	_____
Cryoprecipitate	_____	_____
Albumin	_____	_____
Plasma Protein Fraction	_____	_____
INTRAVENOUS FLUIDS WHICH ARE NOT COMPONENTS OF HUMAN BLOOD		
Hetastarch	_____	_____
Balanced Salt Solutions	_____	_____
MEDICATIONS WHICH CONTAIN A FRACTION OF HUMAN BLOOD		
Rhogam	_____	_____
Erythropoietin	_____	_____
Human Immunoglobulin	_____	_____
Tisseel	_____	_____
TECHNIQUES FOR BLOOD CONSERVATION / PROCESSING		
Hemodilution	_____	_____
Cell Saver	_____	_____
Autologous Banked Blood	_____	_____
Cardiopulmonary Bypass	_____	_____
Chest Drainage Autotransfusion	_____	_____
Plasmapheresis	_____	_____
Hemodialysis	_____	_____
Other_____	_____	_____

PLEASE CIRCLE WHICH ONE APPLIES

I do (do not) have a durable power of attorney.

I accept (do not accept) this consent as an addendum to my durable power of attorney.

I fully understand the options available to me and hereby release the hospital, its personnel, the attending physician and any other person participating in my care from any responsibility whatsoever for unfavorable reactions or any untoward results due to my decision not to permit the use of blood or its derivatives. The possible risks and consequences of such refusal on my part have been fully explained to me by my attending physician. I fully understand such risks and consequences may occur as a result of my decision.

DATE:_____ **TIME:**_____

SIGNATURE:_____
(patient/parent/guardian/conservator)

RELATIONSHIP:_____

WITNESS:_____

SPECIFIC CHECKLIST FOR MANAGEMENT OF PREGNANT WOMEN WHO DECLINE TRANSFUSIONS

Prenatal Care

- ☐ Comprehensive discussion with a checklist specifying acceptable interventions
- ☐ Aggressively prevent anemia (goal: HCT: 36-40%)
 - ☐ Iron—PO or IV (iron sucrose or ferric carboxymaltose) with Folate and B12 as needed
 - ☐ rh-Erythropoietin 600 u/kg SQ 1-3x per weekly as needed (most preparations have 2.5 mL of albumin so may be refused by some Jehovah's Witnesses but others do accept)
- ☐ Line-up Consultants (consider MFM, Hematology, Anesthesiology)

Labor and Delivery

- ☐ Anesthesia consultation early
- ☐ Reassessment of hemorrhage risk and discussion of options (e.g. Surgery, Interventional Radiology)
- ☐ Review specific techniques (e.g. Options Checklist and Fibrin/Thrombin glues)
- ☐ Review references—Have a Plan!!
- ☐ Be decisive

Postpartum

- ☐ Maintain volume with Crystalloids and Blood substitutes
- ☐ Aggressively treat anemia
 - ☐ Iron—IV (iron sucrose or ferric carboxymaltose)
 - ☐ Rh-Erythropoietin 600 u/kg SQ weekly (3x week)
RCT's show benefit in Critical Care units

IRON SUCROSE PROTOCOL

Iron Sucrose (Venofer[®]) is a safe intravenous preparation of iron for those who need iron and do not respond or cannot take oral iron.

Side Effects

Iron sucrose has been rarely associated with anaphylaxis, which has made it preferred over older preparations for parenteral iron supplementation. Occasional patients (10%) may have a transient metallic taste in their mouth, nausea, muscle cramps and hot flashes.^{9,10} Additional patients (as many as 10-30%) will experience transient hypotension, dizziness, and feeling very tired. This appears to be more common with higher doses and more rapid administration.

Indications

Selected patients with the following:

1. Severe antepartum iron deficient anemia non-responsive (or intolerant) to oral iron replacement
2. Anemia in a high-risk setting requiring quick replacement of iron stores:
 - a) placenta previa/accreta
 - b) Jehovah's Witness or other decliners of blood transfusions
3. Severe anemia from obstetric hemorrhage
4. Post autologous donation with need for rapid replenishment

In indications 2-4, there is additional consideration for recombinant human erythropoietin (EPO) (300 u/kg SQ, once), which combined with iron sucrose gives the most rapid response.

Administration

Option 1:

300-500 mg Iron Sucrose in NS 250 mL administered over three (3) hours; may repeat as needed in 3-7 days to reach 1 gm. We have found the lower dose to be better tolerated in the second half of gestation.

Option 2:

200 mg in NS 100 mL administered over 20-30 minutes; may repeat every other day to reach target.

Fe need: see below.

Calculate Fe (Iron sucrose) need:

$$\text{Fe need} = \text{wt (kg)} \times 0.24 \times \Delta\text{Hgb (gm/L)} + 500 \text{ mg}$$

↑
= target - current

Example: 70 kg woman with Hgb of 7.0 gm/dL and a target of 11 gm/L

$$= 70 \text{ kg} \times 0.24 \times (\text{target: } 11 \text{ gm/L} - \text{actual: } 7 \text{ gm/L}) + 500 \text{ mg}$$

Remember: 7 gm/dL = 70 gm/L

Remember: Use **pre-pregnancy** weight (kg)

$$= 672 \text{ mg} + 500 \text{ mg} = 1172 \text{ mg} \quad (\text{This is usually rounded off to 100 or 200 mg increments})$$

IRON FERRIC CARBOXYMALTOSE PROTOCOL

Ferric Carboxymaltose (Injectafer®) was recently approved by the FDA (July 2013) and may have some advantages over Venofer. It is well tolerated and may have less hypotension (< 2%) and allows for a greater iron administration in a single setting. It represents a safe intravenous preparation of iron for those who need iron and do not respond or cannot take oral iron. There is limited experience reported in the United States.¹¹

Side Effects

Anaphylaxis has been reported in 2 of 1775 women receiving Ferric Carboxymaltose. While hypotension was noted less commonly (< 2%), transient hypertension with nausea has been reported in 6% of women.

Indications

Selected patients with the following:

1. Severe antepartum iron deficient anemia non-responsive (or intolerant) to oral iron replacement
2. Anemia in a high-risk setting requiring quick replacement of iron stores:
 - a) placenta previa/accreta
 - b) Jehovah's Witness or other decliners of blood transfusions
3. Severe anemia from obstetric hemorrhage
4. Post-autologous donation with need for rapid replenishment

In indications 2-4, there is additional consideration for recombinant human erythropoietin (EPO) (300 u/kg SQ, once), which combined with Ferric Carboxymaltose gives the most rapid response.

Administration

750 mg IV (mixed with 250mL of normal saline, administered over 15-30 minutes) may be repeated 7 days later with second 750 mg dose; not to exceed cumulative dose of 1500 mg per course.

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RECOGNITION

DEFINITION, EARLY RECOGNITION AND RAPID RESPONSE USING TRIGGERS

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EXECUTIVE SUMMARY

- Early recognition is critical for early intervention and prevention of progression to severe hemorrhage.
- Initial signs and symptoms of blood loss can be difficult to detect due to compensatory responses, increased circulating volume in pregnant women, and circulatory changes that occur with delivery of the placenta.
- Changes in laboratory values such as hemoglobin and hematocrit take too long to be useful in real-time determination of severity of blood loss.
- Cumulative blood loss of 500 mL in a vaginal birth should alert the clinician to the need for increased surveillance, and rapid intervention is indicated if bleeding continues or changes in clinical signs are detected.
- The revised ACOG definition of obstetric hemorrhage is cumulative EBL > 1,000 mL for either vaginal or cesarean birth with enhanced surveillance and early interventions, as needed, for 500-1,000 mL.

BACKGROUND

The risk of obstetric hemorrhage is present in every pregnancy. Early identification of abnormal blood loss creates the potential to intervene and prevent major blood loss.¹ Early intervention requires: 1) recognition of risk factors leading to heightened surveillance; 2) appropriate preparation; 3) a standardized approach to accurately determine cumulative blood loss; and 4) recognition of clinical findings suggestive of or indicating hypovolemia. To have the best chance of preventing the progression of heavy bleeding to massive hemorrhage which carries the risk of more devastating sequelae, all four areas need to be integrated into care of the woman giving birth.

A comprehensive obstetric hemorrhage protocol should include mechanisms for risk identification, early recognition and rapid response as well as treatment. Challenges for

risk identification and early recognition are due in part to the broad range of clinical risk factors for obstetric hemorrhage, lack of standardized methods for determining blood loss and lack of a “gold standard” for defining obstetric and especially postpartum hemorrhage.²⁻⁶ This document focuses on: 1) providing a consensus definition of significant blood loss in pregnant and postpartum women; 2) outlining clinical signs of hypovolemia to quickly identify and respond to heavy bleeding. Identification of risk factors and stratification is found elsewhere in this toolkit. (See Risk Factor Assessment article, pg. 75.)

TRIGGER: DEFINITION OF SIGNIFICANT BLOOD LOSS

Whether hemorrhage occurs prior to birth, early postpartum (within first 24 hours) or late postpartum (≥ 24 hours postpartum), no single definition of hemorrhage exists that is widely accepted or useful alone. A commonly used definition of > 500 mL for a vaginal birth and $> 1,000$ mL for a Cesarean birth is obviously inconsistent and not clearly related to morbidity, but may be useful as an alarm trigger. In healthy women, blood loss is generally tolerated without vital sign changes until the total loss exceeds 1,000 mL. Traditional definitions have been based on estimated blood loss, changes in measured blood values and clinical signs. Problems exist with all of these quantifiers. Estimation of blood loss has been shown to be inaccurate particularly when blood loss is excessive.^{5,7} Changes in blood values such as hemoglobin level or hematocrit are often delayed following hemorrhage and therefore are not helpful with early recognition and treatment.⁸ Approximately four hours after acute blood loss changes in these measured laboratory values can be seen, with the peak change occurring as late as 48-72 hours after birth.⁸ Moreover, changes in vital signs can be subtle in the initial stages of hemorrhage based on a young healthy person’s ability to compensate for loss of volume. This is particularly true during pregnancy when increased circulating blood volume may further conceal loss.^{3,4}

Different approaches to measuring standard blood loss during birth have led to different estimates of normal. The most widely accepted values are those of Pritchard, et al. They measured blood loss following vaginal birth, repeat cesarean birth and repeat cesarean with hysterectomy using photometry. Following vaginal birth the majority of women had a blood loss less than 500 mL but 5% lost > 1000 mL. Around 60% of women lost 500-1000 mL after repeat cesarean birth and approximately 50% of women lost over 2500 mL following repeat cesarean with hysterectomy.^{3,9}

In light of the above considerations, ACOG (as part of the reVITALize project) has recently endorsed a revised definition:

Cumulative blood loss of ≥ 1000 mL OR blood loss accompanied by sign/symptoms of hypovolemia within 24 hours following the birth process (Cumulative blood loss of 500-999 mL alone should trigger increased supervision and potential interventions as clinically indicated).

TRIGGER: CLINICAL SIGNS OF HYPOVOLEMIA

In response to blood loss several compensatory mechanisms work to move venous blood into the central circulation, pump blood more forcefully, and redirect blood to essential organs.¹⁰ In a state of health, the body can successfully compensate for as much as 20-25% blood loss before prominent clinical signs of hypovolemia are present. Typical signs of blood loss or hypovolemia include elevated heart rate and respiratory rate, decrease in blood pressure, drop in urine output, dizziness, altered level of consciousness and pallor. Table 1 below correlates clinical signs with the amount of blood loss. Note that many clinical signs do not occur until the blood loss reaches very high levels.

Table 1: Clinical Signs of Hypovolemia

Amount of Blood Loss	Clinical Signs
1000 mL	Slight change in blood pressure, heart rate normal, palpitations, respiratory rate normal, dizziness, normal urine output
1500 mL	Narrowed pulse pressure*, heart rate over 100, respiratory rate 20-30, diaphoretic, weak, urine output 20-30 mL/hr
2000 mL	Hypotension, narrowed pulse pressure, heart rate over 120, respiratory rate 30-40, pale, extremities cool, restlessness, urine output 5-15 mL/hr
≥ 2500 mL	Profound hypotension, heart rate over 140, respiratory rate over 40, slight urine output or anuria

*Pulse pressure is the difference between the systolic and diastolic blood pressure. With hemorrhage a rise in the diastolic pressure reflects vasoconstriction and narrows the pulse pressure.^{4,11}

When risk factors for hemorrhage are present or hemorrhage is suspected, careful and accurate assessment of the clinical parameters above is essential to detect signs of decompensation. When medical conditions exist such as anemia or preeclampsia, signs of decompensation can occur with smaller amounts of blood loss. Signs of hypovolemia

may only be clearly apparent when the body is no longer able to successfully compensate, therefore response needs to be rapid, particularly during pregnancy.

The National Health System of the United Kingdom has published a detailed “Obstetric Early Warning Chart” that assists with recognition of signs of decompensation. The chart provides a colored checklist for vital status and a guide for intervention when a patient “triggers” in one red or two yellow scores at any one time and makes use of both numeric and visual clues for care providers (See Best Practice article “Blood Loss: Clinical Techniques for Ongoing Quantitative Measurement”).¹² While the overall concept is quite attractive, the exact numbers for the triggers are currently undergoing validation in a number of American centers.

RECOMMENDATIONS

Aggressive treatment of women at clinical trigger points has the potential to limit the overall blood loss and prevent hemorrhage complications such as Disseminated Intravascular Coagulation (DIC). To address this CMQCC recommends the following:

1. Use the following as **alert and action triggers** for obstetric hemorrhage:
Cumulative blood loss greater than 500 mL for vaginal birth and greater than 1000 mL for cesarean birth warrants heightened surveillance for continued bleeding (these would be considered alert triggers), and in the presence of **ongoing bleeding** or any evidence of vital sign changes additional steps (Stage1) should be considered (these would be considered action triggers).
2. Use the following as a standard clinical definition of obstetric hemorrhage for **safety/quality monitoring**: Blood loss of ≥ 1000 mL **OR** blood loss accompanied by signs/symptoms of hypovolemia within 24 hours following birth processes including intrapartum blood loss.^{6,8}
3. Birthing facilities adopt and maintain protocols addressing:
 - a) Objective Quantification of blood loss at all births (See Best Practice article “Cumulative, Quantitative Assessment of Blood Loss”, pg. 72).
 - b) Management of all women with cumulative blood loss ≥ 500 mL and continued bleeding (Refer to Obstetric Hemorrhage Emergency Management Plan -Checklist Format, page 14.)
 - ii. Clinical Triggers: surveillance and intervention:
 1. Heart Rate ≥ 110
 2. Blood Pressure $\leq 85/45$ ($> 15\%$ drop)
 3. Oxygen Saturation $< 95\%$

- c) It is the responsibility and authority of all licensed health care team members, including RNs, to call for help and activate maternal hemorrhage response as clinically indicated.
4. Hospitals and other health care organizations debrief and review cases for all women with cumulative blood loss > 1000 mL.
5. The Joint Commission and others are now (January 2014) recommending that every obstetric hemorrhage case that requires 4 or more units of blood products have an intensive case review (Root Cause Analysis) to look for improvement opportunities.

EVIDENCE GRADING

Level of Evidence: II 2. One prospective cohort study; expert consensus opinion (WHO, NHS)

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RISK FACTOR ASSESSMENT

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EXECUTIVE SUMMARY

- Routine risk assessment improves the clinical team's readiness to respond to obstetric hemorrhage.
- Risk factors for obstetric hemorrhage should be formally assessed prenatally, on admission, and at each patient handoff through at least 24 hours postpartum.
- Identified risk factors must be clearly communicated to the clinical team caring for the woman in labor and postpartum.

BACKGROUND AND LITERATURE REVIEW

Prevention of postpartum hemorrhage starts with preparation. Although more than half of women who hemorrhage due to uterine atony have no known risk factors, identification of associated risk factors during the antenatal and intrapartum periods can improve readiness to respond for those with known risks.¹ There is no literature identified to support when and how often to assess for risk factors during the course of pregnancy through the postpartum period. However, there are numerous studies that identify risk factors associated with hemorrhage throughout these periods.¹⁻³ Furthermore, certain modes of birth, including instrumented and cesarean birth are associated with increased risk for postpartum hemorrhage.

Early identification of risk factors for postpartum hemorrhage can lead to advanced planning and increased surveillance following birth that may prevent adverse outcomes. The plan of care can be individualized for each patient, based on her risk factor identification and as their condition changes. Interventions may include pre-transfusion testing (i.e. clot to blood bank, type and screen, type and crossmatch) on admission or during labor, having medications readily available at time of delivery, having scales available to weigh blood-soaked items, and notification of personnel to be available to assist if needed. The risk levels at which pre-transfusion testing is indicated may be facility dependent. The pre-transfusion testing strategy should be developed in collaboration with the blood bank recognizing local capabilities and policies: for example, in some laboratories, automated type and screen has made that test very inexpensive and feasible to collect for all obstetric admissions. For other settings testing may not be inexpensive, but the threshold for pre-transfusion testing may need to be set at a fairly low risk level if the time to cross match and blood product availability is longer. On the

other hand, some facilities with very rapid testing and access may set the threshold for pre-transfusion testing higher to conserve resources when their infrastructure allows them to do so without significant delays in obtaining blood products when needed. The strategy for risk-based pre-transfusion testing should be standardized within each obstetric service to minimize confusion and potential error.

Various studies report multiple risk factors for postpartum hemorrhage.¹⁻³ One study specifically examined the predictive validity of the CMQCC risk factor stratification in the original CMQCC Obstetric Hemorrhage Toolkit.⁴ This study found that the risk for hemorrhage did increase across the three categories of low, medium, and high risk; BMI and macrosomia were not associated with postpartum hemorrhage risk, and inclusion of additional risk criteria did not significantly improve the sensitivity of the risk factors identified.⁴ Similarly, BMI was not associated with significant risk for hemorrhage in a recent UK population-based study.⁵ The literature is mixed on a number of factors including BMI, race/ethnicity, hypertension, and maternal age, which are variously reported. Thus the committee cannot make a clear recommendation about inclusion of these risk factors at this time. The committee emphasizes that risk assessment should be an ongoing process throughout labor and birth, not a static admission assessment. Our previous risk stratification (minus BMI and estimated fetal weight > 4 kg) and pre-transfusion testing strategy seems to hold for the average community hospital setting:

Table 1: Pregnancy/Admission risk factors

Low (Clot only)	Medium (Type and Screen)	High (Type and Crossmatch)
No previous uterine incision	Prior cesarean birth(s) or uterine surgery	Placenta previa, low lying placenta
Singleton pregnancy	Multiple gestation	Suspected placenta accreta, percreta, increta
≤ 4 previous vaginal births	> 4 previous vaginal births	Hematocrit < 30 <u>AND</u> other risk factors
No known bleeding disorder	Chorioamnionitis	Platelets < 100,000
No history of post partum hemorrhage	History of previous post partum hemorrhage	Active bleeding (greater than show) on admit
	Large uterine fibroids	Known coagulopathy

Additional **risk factors that may develop in labor** include:

- Prolonged second stage
- Prolonged oxytocin use
- Active bleeding
- Chorioamnionitis
- Magnesium Sulfate treatment

Additional **third stage/postpartum risk factors** for hemorrhage stemming from the birth process include:^{1,5}

- Vacuum- or forceps-assisted birth
- Cesarean birth (especially urgent/emergent cesarean)
- Retained placenta

RECOMMENDATIONS

1. Perform initial risk factor identification during the prenatal period and document findings in the prenatal record and have available upon admission to labor and delivery.
2. Risk factors should be reviewed from the prenatal records upon admission to labor and delivery and patient is assigned a risk category.
3. Assessment of risk factors may change during the course of labor and should be performed at least once per shift until time of delivery.
4. The next assessment should occur at the time of delivery and any modifications to the plan of care made based on risk category.
5. The final assessments should occur during the postpartum period for the first 24 hours at least once per shift.
6. Assessments can be done more frequently as patient conditions may change during the course of stay.

EVIDENCE GRADING

Level of Evidence: II-2 B. Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

Recommendations based on limited or inconsistent evidence

Level of Evidence: III A. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. Recommendations based on high quality and consistent evidence.

Level of Evidence: III C. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. Recommendations based primarily on consensus and expert opinion.

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CUMULATIVE QUANTITATIVE ASSESSMENT OF BLOOD LOSS

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EXECUTIVE SUMMARY

- Measuring blood loss as accurately as possible is essential to identifying and responding to hemorrhage.
- Visual estimation significantly underestimates large volumes by 35-50%.
- Estimation can be improved with training, but skills decay over time.
- Measurement via calibrated drape correlates with photospectrometry values.
- Routine quantification of blood loss with standardized processes is strongly recommended for all births.

BACKGROUND AND LITERATURE REVIEW

Accurate measurement of blood loss is essential for 1) recognizing potentially life-threatening hemorrhage and 2) managing blood product replacement. While multiple methods for estimating blood loss are available, most are either impractical (e.g., acid hematin; chromium tagged RBCs) or inaccurate (e.g., visual estimation).^{1,2-5} Visual estimation has consistently been shown to significantly underestimate large volume blood loss by 33%-50% when compared to direct measurement.²⁻⁶ Visual estimation of blood loss may also be complicated by the presence of a large volume of amniotic fluid, stool or sponges. Several studies demonstrate that while visual estimation of blood loss is inaccurate, especially for larger volumes, it can be improved with training and by quantification of blood loss using calibrated under-buttocks drapes to collect blood.^{2-5,7} However, training to improve visual estimation has also been shown to deteriorate over time.⁸ Moreover, measurement of blood loss by calibrated drape at vaginal birth was highly correlated with photospectrometry values.^{9,10} Replacing estimation with quantification of blood loss at birth has been proposed as one of seven safety objectives of the National Maternal Health Initiative.¹¹ We recommend routine quantification of blood loss (QBL) at all births as a best practice.

Challenges in implementing routine QBL may include clinician's concerns for the workflow changes involved in routine QBL and desire to reserve QBL for the severe hemorrhage. Clinicians may also be concerned that QBL will not provide an exact quantification, especially in cases where there is a lot of amniotic fluid or irrigation.

Rationale for routine quantification: Delay in recognition of large blood losses is a common finding in cases of maternal morbidity and mortality from hemorrhage and a policy of waiting to quantify blood loss only after the excessive loss is appreciated does not address this problem.^{12,13} Standardization of procedures is an important aspect of improving safety and quality, and if QBL is used only for severe cases, staff may be unfamiliar with the procedures and less likely to obtain valid data. With practice and routine adoption, quantification of blood loss generally requires only minutes to perform in the majority of births.¹⁴ Standardization of the processes involved, and building the experience of team members through obtaining this measure in all routine cases develops the skills needed to quantify blood loss in an actual hemorrhage situation. The purpose of quantification of blood loss is not to obtain an "exact" number as there will always be a degree of imprecision of this measurement. Instead, the goal is to improve evaluation of large blood losses compared to estimation techniques, which are known to be inaccurate. QBL is meant to promote early recognition of large volume blood loss and is just one component of an overall strategy to facilitate effective response to hemorrhage.

Average amniotic fluid volumes have been described across gestational ages from 8-43 weeks and can be approximated using a published nomogram when necessary.¹⁵ The specific materials used to collect blood and the presence of clots may also affect accuracy of blood loss measurement.¹⁰ Measurement of blood loss by weight is the most accurate and practical method for determining the volume of blood not captured in graduated containers. This can be accomplished by subtracting the dry weight of absorbing materials (pads, sponges, etc.) from the weight of blood-containing materials and using the conversion 1 gm weight = 1 mL to quantify the blood volume contained in the materials. Use of simple applications, such as a calculator embedded within an electronic medical record or a spreadsheet which includes standard dry weights for any items used during cesarean or vaginal birth, can facilitate easier determination of quantified blood loss.

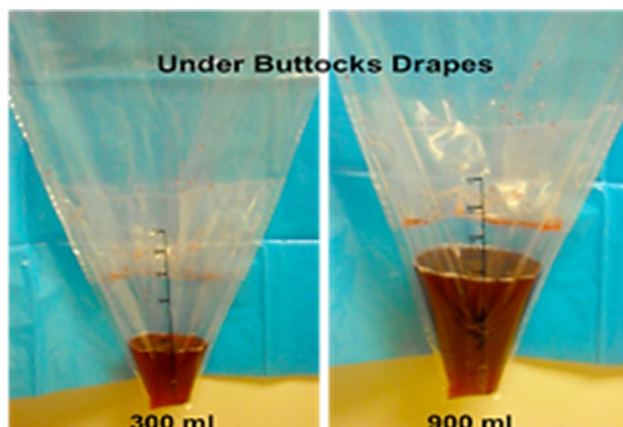
RECOMMENDATIONS

1. All facilities provide chart tools and **regularly scheduled standardized training** in formal quantitative measurement of blood loss, which is critical for early recognition of and response to maternal hemorrhage. (Level I B)
2. Quantitative measurement of blood loss should be a collaborative effort that includes nurses, anesthesia and obstetric providers.

3. For vaginal birth:
 - a. Use under-buttock drapes, preferably with graduated markers, to collect blood with vaginal birth. (Level I B)
 - b. Immediately after the birth of the baby, stop to assess the amount of fluid in the under-buttock calibrated drape. This value becomes the 'baseline' and all subsequent fluid represents blood loss.
 - c. At the completion of the delivery/recovery period weigh all blood clots and blood soaked materials to determine cumulative volume. See Appendices I, J and K for supporting material.
4. For cesarean birth:
 - a. After birth of the baby, suction all amniotic fluid and stop to assess the amount of collected fluid before delivery of the placenta. This value is the 'baseline'. All subsequent fluid represents blood loss (except use of measured irrigation fluid volume).
 - b. In addition to counting lap sponges, the circulating nurse should assess volume of blood loss by weight or saturation assessment techniques
5. For birth without prior rupture of membranes, the following volumes can be used to estimate the contribution of amniotic fluid at term: Brace, et al. found normal fluid volume 700 mL; oligohydramnios 300 mL; polyhydramnios 1400 mL. (Level III A)¹⁵
6. Unusual visual and auditory cues to excessive bleeding should be urgently investigated. Such cues include blood on the floor, walls, or ceiling, blood dripping off of the bed, table, or stretcher, continuously vibrating suction tubing or continuous full suction. (Level III C)
7. **For all cases of ongoing hemorrhage, intake and output measurements should be** documented, tallied, and reported to the team at frequent intervals. (Level III C) This data provides important direction to the team.
8. Trigger tools such as the **NHS Obstetric Early Warning Chart** (Appendix E, printed with permission Fiona McIlveney, PhD) should be used for all women to assist staff in recognizing and responding to concealed hemorrhage.^{16,17} (Level III C)

EDUCATIONAL TOOLS, SAMPLE DOCUMENTS

1. **Posters** with volumes collected on materials commonly used in Labor and Delivery, **Techniques for Ongoing Quantitative Assessment of Blood Loss** (Appendix F) (L&D)²



(Photos courtesy of Bev VanderWal, and used with permission)

2. **Gram scales** readily available in US L&D settings:
 - a. Blood soaked materials should be placed in precautionary container system, such as red-bagging, but kept accessible during an acute bleed to allow a visual cue to blood volume loss and to facilitate resolution of any discrepancies in blood volume loss assessment. (Level III C)
 - b. Dry weight of materials must be subtracted from weight of blood soaked materials. The best technique for accounting for dry weight may depend on the circumstances and volume of material. Strategies include:
 - i. Zeroing the scale with comparable dry material
 - ii. Subtracting known weight of dry materials from the total weight
 - c. Facilities should keep an updated list of standard dry weights for materials available in-patient care areas.
3. **Under-buttocks calibrated drapes** with measurement marks on collection pouches

United States Manufacturer: Medline

www.medline.com

Product pdf: surgical gowns and drapes:

http://www.medline.com/international/lit/european%20catalog/english/proxi_ma_english.pdf

4. **Simulations and Drills of OB Hemorrhage:** Blood-red-colored cloth (challis fabric or synthetic silk works well; 3 yards) used during drills and simulations in lieu of imitation blood is recommended; it works effectively as a visual cue, is easy to transport and requires no clean-up. Tuck the fabric into the mannequin's pelvis with one corner hanging out onto the bedsheets/chux; an actor in the simulation then pushes/pulls the rest of the cloth out of the pelvis as the hemorrhage continues. See Appendices B and C for supporting materials on drill and debriefing.
5. See Emergency Management Plan, Checklist Format for approximate volumes for blood product replacements
6. Template for trigger tool such as *NHS Obstetric Early Warning Chart*, Appendix E.

EVIDENCE GRADING

Level of Evidence: I B. Evidence obtained from at least one properly designed randomized controlled trial. Recommendations based on limited or inconsistent evidence.

Level of Evidence: III A. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. Recommendations based on high quality and consistent evidence.

Level of Evidence: III C. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. Recommendations based primarily on consensus and expert opinion.

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ACTIVE MANAGEMENT OF THIRD STAGE LABOR

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EXECUTIVE SUMMARY

- We previously recommended a package of interventions including oxytocin infusion, cord clamping and cutting, controlled cord traction, and vigorous fundal massage, commonly referred to as active management of the third stage of labor (AMTSL).
- New data and recent systematic reviews have identified significant risk of bias in previous studies and called the efficacy of various components of AMTSL into question.
- Evidence based analysis has established that AMTSL can reduce maternal hemorrhage, but studies evaluating the individual components have confirmed only oxytocin administration as effective, particularly in high resource settings and in low risk women.
- Delayed cord clamping does not increase the risk for hemorrhage, and any components of AMTSL that may be used should not interfere with the practice of delayed cord clamping for newborn benefit.

BACKGROUND AND LITERATURE REVIEW

A 2011 Cochrane review of active management of the third stage of labor (AMTSL) was designed to consider the benefits versus potential harms of the components of AMTSL, and specifically to tease out differences in effect based on low- versus high-resource settings.¹ The review included 8247 women enrolled in seven studies conducted in six high-income countries and one low-income country. Four of the studies compared active management with expectant management of the third stage. Three studies compared active management with a “mixture of managements.” The primary outcomes for the review were postpartum hemorrhage > 1000 mL, postpartum hemorrhage > 2500 mL, and maternal death. The authors concluded that active management reduced the risk of bleeding, but that this reduction in risk may be due to oxytocin alone. They also found increased risk of hypertension, return to hospital for bleeding, and a possible decrease in average newborn blood volume in the active management group. There was no difference in the rate of severe bleeding (defined as ≥ 1000 mL blood loss) between groups in low-risk women. The authors noted that the sample sizes for all included studies were below those needed for optimal information, and the GRADE scores for primary outcomes were low.

Sheldon, et al. conducted a secondary analysis of data from 2 clinical trials that were conducted in Egypt, Ecuador, Turkey, Vietnam, and Burkina Faso.² This analysis included 39,202 women and evaluated the probability of blood loss > 700 mL under various combinations of the component interventions used in AMTSL. They found that when oxytocin prophylaxis was administered intramuscularly, controlled cord traction significantly reduced the risk of bleeding, but cord traction was not beneficial in the setting of intravenous oxytocin prophylaxis. Uterine massage increased the risk of bleeding, and the combination of controlled cord traction and uterine massage doubled the predicted probability of blood loss over 700 mL in the setting of intravenous oxytocin prophylaxis. The authors conclude that there is no benefit to uterine massage, and other decisions about AMTSL protocols need to take the availability and route of oxytocin administration into account. In hospital settings using IV oxytocin prophylaxis, controlled cord traction may not be necessary. Other studies support the focus on oxytocin as the main ingredient contributing the effect of AMTSL.³

Deneux-Tharaux, et al. conducted a randomized controlled trial five high-resource maternity units in France comparing the incidence of hemorrhage with controlled cord traction without awaiting placental separation versus “standard placenta expulsion.”⁴ Standard expulsion was described as spontaneous separation and expulsion through maternal efforts, assisted if needed by fundal pressure and “soft tension” on the cord. Length of third stage was shorter and manual removal of the placenta was less frequent in the controlled traction arm. However, there was no difference in mean blood loss between groups at either > 500 mL or > 1000 mL in the immediate period of birth and initial recovery, nor in mean peripartum change in hematocrit. The authors conclude that controlled cord traction had no effect on postpartum blood loss in the high-resource context. They note that it is difficult to evaluate the impact on manual removal of the placenta because the policy in France is to intervene to remove the placenta if it is not expelled within 30 minutes, and that controlled cord traction is incompatible with delayed cord clamping.

In a Cochrane collaboration systematic review of delayed cord clamping that included 15 trials and 3911 women, there was no difference in hemorrhage risk between the early and delayed cord clamping groups.⁵

RECOMMENDATIONS

Evidence based analysis has established a clear benefit of oxytocin prophylaxis in the third stage of labor for reducing maternal hemorrhage, but studies evaluating the individual components have not clearly demonstrated benefit of non-oxytocin components of AMTSL including uterine massage, immediate cord clamping, and cord traction in low risk women. The benefit of this technique appears to be the combination of oxytocin, careful attention to possible hemorrhage and prompt intervention. Therefore management protocols should continue to support variations of AMTSL in all women but not allow the

various components to interfere with the labor processes outside of the use of oxytocin. The World Health Organization recommends prophylactic oxytocin for all women, against sustained uterine massage for hemorrhage prevention when prophylactic oxytocin has been used, and delayed cord clamping for all births unless there is an immediate need for neonatal resuscitation.⁶ Further research, with larger numbers of patients in various subgroups and more vigorous methods of determining blood loss, would be helpful to clarify which patients would benefit from other measures. Finally, it is important to make distinctions between management for *prevention* of hemorrhage (AMTSL components) versus *treatment* of hemorrhage which will initially entail similar measures.

1. Prophylactic oxytocin is the prevention strategy of choice in high-resource settings.
2. Other aspects of active management of the third stage of labor are less well supported in the literature and some may increase risk of bleeding.
3. The benefits of delayed cord clamping for the newborn are believed to outweigh any benefit that might be obtained from other components of AMTSL.
4. Similarly, skin-skin care after birth is of known benefit to the newborn and any components of AMTSL that are used should not delay skin-skin care.

EVIDENCE GRADING

Level of Evidence: I A Evidence obtained from at least one properly designed randomized control trial. Recommendations based on high quality and consistent evidence.

Level of Evidence: I B. Evidence obtained from at least one properly designed randomized control trial. Recommendations based on limited or inconsistent evidence.

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RESPONSE OBSTETRIC HEMORRHAGE EMERGENCY MANAGEMENT PLAN CHECKLIST

CMQCC

Obstetric Hemorrhage Emergency Management Plan: Checklist Format

Revision 9/10/14

Stage 0: All Births – Prevention & Recognition of OB Hemorrhage Prenatal Assessment & Planning

- ☐ **Identify and prepare for patients with special considerations:** Placenta Previa/Accreta, Bleeding Disorder, or those who Decline Blood Products
- ☐ **Screen and aggressively treat severe anemia:** if oral iron fails, initiate IV Iron Sucrose Protocol to reach desired Hgb/Hct, especially for at risk mothers.

Admission Assessment & Planning

Verify Type & Antibody Screen from prenatal record

If not available,

- ☐ Order Type & Screen (lab will notify if 2nd specimen needed for confirmation)

If prenatal or current antibody screen positive (if not low level anti-D from Rho-GAM),

- ☐ Type & Crossmatch 2 units PRBCs

All other patients,

- ☐ Send specimen to blood bank

- ☐ Evaluate for **Risk Factors** on admission, throughout labor, and postpartum. (At every handoff)

If medium risk:

- ☐ Order Type & Screen
- ☐ Review Hemorrhage Protocol

If high risk:

- ☐ Order Type & Crossmatch 2 units PRBCs
- ☐ Review Hemorrhage Protocol
- ☐ Notify OB Anesthesia

Identify women who may decline transfusion

- ☐ Notify OB provider for plan of care
- ☐ Early consult with OB anesthesia
- ☐ Review Consent Form

Ongoing Risk Assessment

- ☐ **Evaluate for development of additional risk factors in labor:**

- Prolonged 2nd Stage labor
- Prolonged oxytocin use
- Active bleeding
- Chorioamnionitis
- Magnesium sulfate treatment

- ☐ **Increase Risk level** (see below) **and convert to Type & Screen or Type & Crossmatch**

- ☐ **Treat multiple risk factors as High Risk**

- ☐ **Monitor women postpartum for increased bleeding**

Admission Hemorrhage Risk Factor Evaluation

Low (Clot only)	Medium (Type and Screen)	High (Type and Crossmatch)
No previous uterine incision	Prior cesarean birth(s) or uterine surgery	Placenta previa, low lying placenta
Singleton pregnancy	Multiple gestation	Suspected Placenta accreta or percreta
≤ 4 previous vaginal births	> 4 previous vaginal births	Hematocrit < 30 AND other risk factors
No known bleeding disorder	Chorioamnionitis	Platelets < 100,000
No history of PPH	History of previous PPH	Active bleeding (greater than show) on admit
	Large uterine fibroids	Known coagulopathy

All Births – Prophylactic Oxytocin, Quantitative Evaluation of Blood Loss, & Close Monitoring

Active Management of Third Stage

- ☐ Oxytocin infusion: 10-40 units oxytocin/1000 ml solution titrate infusion rate to uterine tone; or 10 units IM; do not give oxytocin as IV push

Ongoing Quantitative Evaluation of Blood Loss

- ☐ Using formal methods, such as graduated containers, visual comparisons and weight of blood soaked materials (1gm = 1ml)

Ongoing Evaluation of Vital Signs

If: Cumulative Blood Loss > 500ml vaginal birth or > 1000ml C/S with continued bleeding -OR-

Vital signs > 15% change or HR ≥ 110, BP ≤ 85/45, O2 sat < 95% -OR- Increased bleeding during recovery or postpartum, proceed to STAGE 1

STAGE 1: OB Hemorrhage Cumulative Blood Loss >500ml vaginal birth or >1000ml C/S with continued bleeding -OR- Vital signs >15% change or HR ≥110, BP ≤85/45, O2 sat <95% -OR- Increased bleeding during recovery or postpartum		
MOBILIZE	ACT	THINK
<p>Primary nurse, Physician or Midwife to:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Activate OB Hemorrhage Protocol and Checklist <p>Primary nurse to:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Notify obstetrician or midwife (in-house and attending) <input type="checkbox"/> Notify charge nurse <input type="checkbox"/> Notify anesthesiologist <p>Charge nurse:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Assist primary nurse as needed or assign staff member(s) to help 	<p>Primary nurse or designee:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Establish IV access if not present, at least 18 gauge Increase IV Oxytocin rate, 500 mL/hour of 10-40 units/500-1000 mL solution; Titrate infusion rate to uterine tone <input type="checkbox"/> Apply vigorous fundal massage <input type="checkbox"/> Administer Methergine 0.2 mg IM per protocol (if not hypertensive); give once, if no response, move to alternate agent; if good response, may give additional doses q 2 hr (If Misoprostol standard, misoprostol 800 mcg SL per protocol) <input type="checkbox"/> Vital Signs, including O2 sat & level of consciousness (LOC) q 5 minutes <input type="checkbox"/> Weigh materials, calculate and record cumulative blood loss q 5-15 minutes <input type="checkbox"/> Administer oxygen to maintain O2 sats at >95% <input type="checkbox"/> Empty bladder: straight cath or place Foley with urimeter <input type="checkbox"/> Type and Crossmatch for 2 units Red Blood Cells STAT (if not already done) <input type="checkbox"/> Keep patient warm <p>Physician or midwife:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Rule out retained Products of Conception, laceration, hematoma <p>Surgeon (if cesarean birth and still open)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Inspect for uncontrolled bleeding at all levels, esp. broad ligament, posterior uterus, and retained placenta 	<p>Consider potential etiology:</p> <ul style="list-style-type: none"> • Uterine atony • Trauma/Laceration • Retained placenta • Amniotic Fluid Embolism • Uterine Inversion • Coagulopathy • Placenta Accreta <p>Once stabilized: Modified Postpartum management with increased surveillance</p>
<p>If: Continued bleeding or Continued Vital Sign instability, and < 1500 mL cumulative blood loss proceed to STAGE 2</p>		

STAGE 2: OB Hemorrhage Continued bleeding or Vital Sign instability, and < 1500 mL cumulative blood loss		
MOBILIZE	ACT	THINK
<p>Primary nurse (or charge nurse):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Call obstetrician or midwife to bedside <input type="checkbox"/> Call Anesthesiologist <input type="checkbox"/> Activate Response Team: <p>PHONE #: _____</p> <ul style="list-style-type: none"> <input type="checkbox"/> Notify Blood bank of hemorrhage; order products as directed <p>Charge nurse:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Notify Perinatologist or 2nd OB <input type="checkbox"/> Bring hemorrhage cart to the patient's location <input type="checkbox"/> Initiate OB Hemorrhage Record <input type="checkbox"/> If considering selective embolization, call-in Interventional Radiology Team and second anesthesiologist <input type="checkbox"/> Notify nursing supervisor <input type="checkbox"/> Assign single person to communicate with blood bank <input type="checkbox"/> Assign second attending or clinical nurse specialist as family support person or call medical social worker 	<p>Team leader (OB physician or midwife):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Additional uterotonic medication: Hemabate 250 mcg IM [if not contraindicated] OR Misoprostol 800 mcg SL <ul style="list-style-type: none"> o Can repeat Hemabate up to 3 times every 20 min; (note-75% respond to first dose) <input type="checkbox"/> Continue IV oxytocin and provide additional IV crystalloid solution <p>Do not delay other interventions (see right column) while waiting for response to medications</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bimanual uterine massage <input type="checkbox"/> Move to OR (if on postpartum unit, move to L&D or OR) <input type="checkbox"/> Order 2 units PRBCs and bring to the bedside <input type="checkbox"/> Order labs STAT (CBC/PLTS, Chem 12 panel, Coag Panel II, ABG) <input type="checkbox"/> Transfuse PRBCs based on clinical signs and response, do not wait for lab results; consider emergency O-negative transfusion <p>Primary nurse (or designee):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Establish 2nd large bore IV, at least 18 gauge <input type="checkbox"/> Assess and announce Vital Signs and cumulative blood loss q 5-10 minutes <input type="checkbox"/> Set up blood administration set and blood warmer for transfusion <input type="checkbox"/> Administer meds, blood products and draw labs, as ordered <input type="checkbox"/> Keep patient warm <p>Second nurse (or charge nurse):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Place Foley with urimeter (if not already done) <input type="checkbox"/> Obtain portable light and OB procedure tray or Hemorrhage cart <input type="checkbox"/> Obtain blood products from the Blood Bank (or send designee) <input type="checkbox"/> Assist with move to OR (if indicated) <p>Blood Bank:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Determine availability of thawed plasma, fresh frozen plasma, and platelets; initiate delivery of platelets if not present on-site <input type="checkbox"/> Consider thawing 2-4 FFP (takes 30 min), use if transfusing > 2 units PRBCs <input type="checkbox"/> Prepare for possibility of massive hemorrhage 	<p>Sequentially advance through procedures and other interventions based on etiology:</p> <p>Vaginal birth</p> <p>If trauma (vaginal, cervical or uterine):</p> <ul style="list-style-type: none"> • Visualize and repair <p>If retained placenta:</p> <ul style="list-style-type: none"> • D&C <p>If uterine atony or lower uterine segment bleeding:</p> <ul style="list-style-type: none"> • Intrauterine Balloon <p>If above measures unproductive:</p> <ul style="list-style-type: none"> • Selective embolization (Interventional Radiology if available & adequate experience) <p>C-section:</p> <ul style="list-style-type: none"> • B-Lynch Suture • Intrauterine Balloon <p>If Uterine Inversion:</p> <ul style="list-style-type: none"> • Anesthesia and uterine relaxation drugs for manual reduction <p>If Amniotic Fluid Embolism:</p> <ul style="list-style-type: none"> • Maximally aggressive respiratory, vasopressor and blood product support <p>If vital signs are worse than estimated or measured blood loss: possible uterine rupture or broad ligament tear with internal bleeding; move to laparotomy</p> <p>Once stabilized: Modified Postpartum management with increased surveillance</p>
<p align="center">Re-Evaluate Bleeding and Vital Signs If cumulative blood loss > 1500ml, > 2 units PRBCs given, VS unstable or suspicion for DIC, proceed to STAGE 3</p>		

STAGE 3: OB Hemorrhage Cumulative blood loss > 1500ml, > 2 units PRBCs given, VS unstable or suspicion for DIC		
MOBILIZE	ACT	THINK
<p>Nurse or Physician:</p> <p><input type="checkbox"/> Activate Massive Hemorrhage Protocol</p> <p>PHONE #: _____</p> <p>Charge Nurse or designee:</p> <p><input type="checkbox"/> Notify advanced Gyn surgeon (e.g. Gyn Oncologist)</p> <p><input type="checkbox"/> Notify adult intensivist</p> <p><input type="checkbox"/> Call-in second anesthesiologist</p> <p><input type="checkbox"/> Call-in OR staff</p> <p><input type="checkbox"/> Ensure hemorrhage cart available at the patient's location</p> <p><input type="checkbox"/> Reassign staff as needed</p> <p><input type="checkbox"/> Call-in supervisor, CNS, or manager</p> <p><input type="checkbox"/> Continue OB Hemorrhage Record (In OR, anesthesiologist will assess and document VS)</p> <p><input type="checkbox"/> If transfer considered, notify ICU</p> <p>Blood Bank:</p> <p><input type="checkbox"/> Prepare to issue additional blood products as needed – stay ahead</p>	<p>Establish team leadership and assign roles</p> <p>Team leader (OB physician + OB anesthesiologist, anesthesiologist and/or perinatologist and/or intensivist):</p> <p><input type="checkbox"/> Order Massive Hemorrhage Pack (RBCs + FFP + 1 apheresis pack PLTS—see note in right column)</p> <p><input type="checkbox"/> Move to OR if not already there</p> <p><input type="checkbox"/> Repeat CBC/PLTS, Coag Panel II STAT and Chem 12 panel q 30-60 min</p> <p>Anesthesiologist (as indicated):</p> <p><input type="checkbox"/> Arterial blood gases</p> <p><input type="checkbox"/> Central hemodynamic monitoring</p> <p><input type="checkbox"/> CVP or PA line</p> <p><input type="checkbox"/> Arterial line</p> <p><input type="checkbox"/> Vasopressor support</p> <p><input type="checkbox"/> Intubation</p> <p><input type="checkbox"/> Calcium replacement</p> <p><input type="checkbox"/> Electrolyte monitoring</p> <p>Primary nurse:</p> <p><input type="checkbox"/> Announce VS and cumulative measured blood loss q 5-10 minutes</p> <p><input type="checkbox"/> Apply upper body warming blanket if feasible</p> <p><input type="checkbox"/> Use fluid warmer and/or rapid infuser for fluid & blood product administration</p> <p><input type="checkbox"/> Apply sequential compression stockings to lower extremities</p> <p><input type="checkbox"/> Circulate in OR</p> <p>Second nurse and/or anesthesiologist:</p> <p><input type="checkbox"/> Continue to administer meds, blood products and draw labs, as ordered</p> <p>Third Nurse (or charge nurse):</p> <p><input type="checkbox"/> Recorder</p>	<p>Selective Embolization (IR)</p> <p>Interventions based on etiology not yet completed</p> <p>Prevent hypothermia, acidemia</p> <p>Conservative or Definitive Surgery:</p> <ul style="list-style-type: none"> • Uterine Artery Ligation • Hysterectomy <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p style="text-align: center;">For Resuscitation: Aggressively Transfuse Based on Vital Signs, Blood Loss After the first 2 units of PRBCs use Near equal FFP and RBC for massive hemorrhage: 4-6 PRBCs: 4 FFP: 1 apheresis Platelets</p> </div> <p>Unresponsive Coagulopathy:</p> <ul style="list-style-type: none"> • Role of rFactor VIIa is very controversial. After 8-10 units PRBCs and coagulation factor replacement with ongoing hemorrhage, may consider risk/benefit of rFactor VIIa in consultation with hematologist or trauma surgeon <p>Once Stabilized: Modified Postpartum Management with increased surveillance; consider ICU</p>

UTEROTONIC AGENTS for POSTPARTUM HEMORRHAGE

Drug	Dose	Route	Frequency	Side Effects	Contraindications	Storage
Pitocin® (Oxytocin) 10 units/ml	10-40 units per 500-1000 ml, rate titrated to uterine tone	IV infusion	Continuous	Usually none Nausea, vomiting, hyponatremia ("water intoxication") with prolonged IV admin. ↓ BP and ↑ HR with high doses, esp IV push	Hypersensitivity to drug	Room temp
Methergine® (Methylergonovine) 0.2 mg/ml	0.2 mg	IM (not given IV)	-Q 2-4 hours -If no response after first dose, it is unlikely that additional doses will be of benefit	Nausea, vomiting Severe hypertension, esp. if given IV, which is not recommended	Hypertension, Preeclampsia, Cardiovascular disease Hypersensitivity to drug Caution if multiple doses of ephedrine have been used, may exaggerate hypertensive response w/possible cerebral hemorrhage	Refrigerate Protect from light
Hemabate® (15-methyl PG F2a) 250 mcg/ml	250 mcg	IM or intra- myometrial (not given IV)	-Q 15-90 min -Not to exceed 8 doses/24 hrs -If no response after several doses, it is unlikely that additional doses will be of benefit.	Nausea, vomiting, Diarrhea Fever (transient), Headache Chills, shivering Hypertension Bronchospasm	Caution in women with hepatic disease, asthma, hypertension, active cardiac or pulmonary disease Hypersensitivity to drug	Refrigerate
Cytotec® (Misoprostol) 100 or 200 mcg tablets	600-800 mcg	Sublingual or oral	One time	Nausea, vomiting, diarrhea Shivering, Fever (transient) Headache	Rare Known allergy to prostaglandin Hypersensitivity to drug	Room temp

BLOOD PRODUCTS

Packed Red Blood Cells (PRBC) (approx. 35-40 min. for crossmatch—once sample is in the lab and assuming no antibodies present)	Best first-line product for blood loss 1 unit = 200 ml volume If antibody positive, may take hours to days. for crossmatch, in some cases, such as autoantibody crossmatch compatible may not be possible; use "least incompatible" in urgent situations
Fresh Frozen Plasma (FFP) (approx. 35-45 min. to thaw for release)	Highly desired if > 2 units PRBCs given, or for prolonged PT, PTT 1 unit = 180 ml volume
Platelets (PLTS) Local variation in time to release (may need to come from regional blood bank)	Priority for women with Platelets < 50,000 Single-donor Apheresis unit (= 6 units of platelet concentrates) provides 40-50 k transient increase in platelets
Cryoprecipitate (CRYO) (approx. 35-45 min. to thaw for release)	Priority for women with Fibrinogen levels < 80 10 unit pack (or 1 adult dose) raises Fibrinogen 80-100 mg/dl Best for DIC with low fibrinogen and don't need volume replacement Caution: 10 units come from 10 different donors, so infection risk is proportionate.

UTEROTONIC MEDICATIONS FOR PREVENTION AND TREATMENT OF POSTPARTUM HEMORRHAGE

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EXECUTIVE SUMMARY

- Oxytocin is the medication of choice for **BOTH prophylaxis and treatment** of postpartum hemorrhage in high resource settings (i.e. hospitals in the United States and other developed countries), and has a favorable side effect profile relative to other uterotonics.
 - Oxytocin dosing is typically 10-40 units/500-1000 mL IV fluid or 10 units IM.
 - The most frequently studied prophylactic dose is 10 units/500 mL over 1 hour.
- Second line therapy for **treatment** of hemorrhage is a choice between Methergine[®] (methylergonovine maleate), Hemabate[®] (carboprost or 15 methyl PGF2 alpha) and Cytotec[®] (misoprostol) with the choice being made on institution assessment of availability and contraindications.
- Medication protocols for both **prophylaxis** and **treatment** should be standardized within each institution to provide ease of access and timely administration of medication according to processes that are well understood by all intrapartum and postpartum staff.

Table 1: Medications Summary

Prevention	Treatment
Oxytocin or 10-40 units/500-1000 mL IV infusion titrated to uterine tone OR Oxytocin 10 u IM when no IV access	Rapid infusion of IV oxytocin 10-40 units/500-1000 mL at ≥ 500 mL/hour, titrated to response
	Choose a standard second line agent from: Methergine 0.2 mg IM Hemabate 250 mcg IM or intramyometrially Misoprostol 600 mcg orally, 800 mcg sublingually

BACKGROUND

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 rate of infusion should be sufficient to maintain uterine contractility. 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. The drug may be stored at room temperature.

Experts appear to agree that oxytocin is still considered the prophylactic drug of choice in the developed world.¹⁻⁴ A 2013 Cochrane systematic review stated that prophylactic usage of oxytocin, 10 units intravenous infusion or intramuscular injection, is still the most effective medication with the fewest side effects compared to ergot alkaloids (nausea and vomiting) and misoprostol (hyperpyrexia).³ The WHO recommendations state that oxytocin intravenous infusion and bolus are acceptable, although if given by bolus it should be given slowly to avoid side effects.¹ If intravenous access is not available, intramuscular oxytocin 10 units can be given.¹ There is not a clear recommendation on the specific dosing, as studies utilize a different concentrations and rates. The most frequently studied prophylactic dose is 10 units/500 mL over 1 hour. A 2014 Cochrane Review also concludes that oxytocin is the first line agent of choice for treatment of primary postpartum hemorrhage.⁵

Alternative approaches to dosing of oxytocin at cesarean birth are an area of active investigation in the literature. Three discussions oxytocin dosing at cesarean suggest slow, small IV boluses of 1-3 units oxytocin over 15-30 seconds to initiate uterine contractility followed by ongoing infusion of 4–10 units per hour.⁶⁻⁸ Concern for the hemodynamic effects of oxytocin has increased in recent years, especially in relation to historical practices of administering a 5-10 units IV bolus of oxytocin after delivery of the infant at cesarean in some settings. While the most commonly noted side effects are nausea, flushing, and hypotension, significant hemodynamic changes may be observed after IV boluses, including tachycardia, increased cardiac output and cardiac work, and myocardial ischemia.⁶ These potential adverse effects are of increasing concern when the population of childbearing women is older and has more co-morbidities and cardiovascular disease is becoming a leading cause of pregnancy-related mortality.⁹ Rapid IV boluses should be avoided in all patients and the use of small boluses of oxytocin should be used with caution in women with preexisting cardiovascular disease.

- **Side Effects:** The drug should not to 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.

- **Contraindications:** The only postpartum contraindication to use of oxytocin would be hypersensitivity to the drug.

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 ampoules 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 ampoule) 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.

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." In the first iteration of the CMQCC guidelines, the taskforce recommended Methergine as the primary second line agent for treatment of uterine atony, since the third line agent, misoprostol was of a similar therapeutic class to Hemabate, and therefore would theoretically be providing efficacy by different physiologic pathways (CMQCC guideline version 1). This ambiguity in efficacy clearly supports more research to determine the most effective therapy.

- **Side Effects:** Side effects are rare in the absence of prolonged use. 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). In these settings, there may be an exaggerated blood pressure response to the use of this agent. Care should also be taken when 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 ampoules

containing 250 mcg of the drug. The dose is one ampoule given as an IM injection. The peak plasma level of the drug is reached about 30 minutes after injection. A successful clinical response is expected after a single injection in about 75% of cases. 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. It should be noted that other uterotonic agents are also less effective in the setting of chorioamnionitis. The drug must be refrigerated when stored.

- **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. Despite anecdotal evidence of efficacy, studies of the efficacy of misoprostol for prevention and treatment of obstetric hemorrhage have had mixed results. For the treatment of postpartum hemorrhage from uterine atony, Gibbons, et al. cited two large randomized controlled trials which demonstrated oxytocin had the best efficacy, for both prophylaxis and first-line treatment of postpartum hemorrhage caused by uterine atony, without the side effects of fever seen commonly (22-58%) with misoprostol.² They also noted that the second study found the addition of misoprostol to oxytocin did not improve outcomes.²

The drug is water-soluble and is quickly absorbed after sublingual, oral, vaginal, and rectal use. The time to peak plasma concentration is shortest for sublingual administration and the plasma concentration is higher than when given rectally. However, after rectal administration, plasma concentrations are maintained for a longer period. 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. One of the major advantages of this agent is that the drug does not need to be refrigerated and may be easily stored on labor and delivery hospital units. Treatment of postpartum hemorrhage with 800 mcg sublingually 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.¹

Historically misoprostol was commonly administered rectally at a dose of 800-1000 mcg in US settings. Since our initial review, several articles have been published on the utilization of sublingual/oral misoprostol to treat and prevent postpartum hemorrhage, and there are relatively few studies using rectal misoprostol. Most of the research has been conducted outside the United States where the use of misoprostol is more prevalent due to its low cost, easy storage and availability.¹⁰⁻¹² In all the reports, shivering and temperature elevation, known side effects of misoprostol, were found to be increased in exposed patients. It appears to have more side effects than oxytocin and therefore will not replace oxytocin for prophylaxis therapy in most U.S. settings, where oxytocin is readily available.^{3,13}

For cesarean birth a recent meta-analysis suggests the combination of oxytocin and 400 mcg sublingual misoprostol may be of benefit for prevention.¹⁴ The four studies used for this comparison were all done overseas. The authors suggest the apparent effectiveness of the combined use of oxytocin and misoprostol may be explained by the differences in timing of onset and duration of action between the two medications. The committee strongly urges more study of equivalence and dosing of various medications and their efficacies in populations more reflective of our patients so that the proper medication, route, amounts and combinations can be determined. These findings are consistent with other recommendations.^{1,15}

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

RECOMMENDATIONS

1. All labor and delivery and postpartum units should have a standardized medications regimen.
2. All relevant uterotonic medications should be readily available for emergent use.
3. Special preparation for treatment such as kits and carts should be in place in all labor & delivery and postpartum units.
4. Clinicians should stay abreast of emerging literature regarding the use of uterotonic agents.

Prophylaxis

1. The first line agent for hemorrhage prophylaxis is an intravenous infusion of oxytocin, with the most commonly recommended and studied dose being 10 units/500 mL over one hour.
2. Intramuscular administration of 10 units is recommended when IV access is not available.

Treatment

1. For treatment of hemorrhage due to uterine atony the first line medication remains oxytocin.
2. Institutions should select a standard medication for second line treatment. Options include Methergine[®] (methylergonovine maleate), Hemabate[®] (carboprost or 15 methyl PGF2 alpha) and Cytotec[®] (misoprostol).
3. Sublingual misoprostol appears to be effective and may offer benefit over rectal administration, but misoprostol has not been demonstrated as effective as oxytocin in the most recent systematic review of treatment of primary postpartum hemorrhage.

EVIDENCE GRADING:

Level of Evidence: I B. Evidence obtained from at least one properly designed randomized controlled trial. Recommendations based on limited or inconsistent evidence.

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BLOOD PRODUCT REPLACEMENT: OBSTETRIC HEMORRHAGE

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EXECUTIVE SUMMARY

- Outcomes are improved with early and aggressive intervention.
- Both emergency blood release and massive transfusion protocols should be in place.
- In the setting of significant obstetric hemorrhage, resuscitation transfusion should be based on vital signs and blood loss and should not be delayed by waiting for laboratory results.
- Calcium replacement will often be necessary with massive transfusion due to the citrate used for anticoagulation in blood products.
- During massive transfusion resuscitation, the patient's arterial blood gas, electrolytes, and core temperature should be monitored to guide clinical management and all transfused fluids should be warmed; direct warming of the patient should be initiated as needed to maintain euthermia and to avoid added coagulopathy.

BACKGROUND AND LITERATURE REVIEW

After the first several units of packed red blood cells (PRBCs) and in the face of continuing or worsening hemorrhage, aggressive transfusion therapy becomes critical. This report covers the experience with massive transfusion protocols. Lessons from military trauma units as well as civilian experience with motor vehicle accidents and massive obstetric hemorrhage have identified new principles such as earlier use of plasma (FFP/thawed plasma/plasma frozen within 24 hours/liquid plasma) and resuscitation transfusion while laboratory results are pending.

Life-threatening maternal hemorrhage occurs in approximately 1-2% of births and is a leading cause of maternal death in both industrial and developing countries.¹⁻³ Delays in recognizing and treating hemorrhage frequently lead to inadequate blood product

replacement and concomitant development of disseminated intravascular coagulation (DIC). Both of these factors significantly contribute to maternal morbidity and mortality. Furthermore, delayed treatment increases the likelihood that the patient will require multiple units of blood products and, if available, activation of massive hemorrhage protocols.⁴ This section reviews blood component replacement therapy in the context of significant maternal hemorrhage.

At the time of the first release of this toolkit nine massive hemorrhage protocols tailored specifically to obstetrics were evaluated.^{1,2,5-10} No formal clinical trials were available and all of the protocols were developed in consultation with experts in obstetrics and hematology/transfusion. Only one center has published a case series of their results.⁸ The salient feature of each protocol was an attempt to address three primary problems: 1) delayed diagnosis; 2) underestimated blood loss; and 3) treatment and prevention of fulminant disseminated intravascular coagulation (DIC).¹⁰ To address these problems, the use of “obstetrical hemorrhage packs,” which included all needed blood components (i.e. PRBCs, plasma, cryoprecipitate, platelets) was recommended. None of the protocols recommended routine use of recombinant factor VIIa as part of initial therapy.

Since publication of our initial recommendations, an additional report of an obstetric specific protocol has been published⁴ and an additional report in abstract form¹¹ have been presented that follow many of the guidelines originally outlined in the first release of the CMQCC hemorrhage toolkit. The findings and conclusions from both of the reports confirm that with aggressive early intervention patient outcomes are improved.⁴ These reports and the original recommendations within the toolkit are consistent with Recommendations by the American Society of Anesthesiologists Task Force on Perioperative Blood Loss are consistent with the protocols reviewed here and with recommendations outlined below. The American College of Obstetrics and Gynecology has no specific recommendation for the use of blood components for treating postpartum hemorrhage.^{12,13}

BLOOD PRODUCT REPLACEMENT

PACKED RED BLOOD CELLS (PRBCS)

The majority of protocols recommended four-six units of PRBCs be prepared and available and the patient’s hematocrit be maintained minimally at 21-24% (hemoglobin 7-8g/dL).^{1,5,7,9,14} Ideally, the use of a single unit of PRBCs should increase the hematocrit by approximately 3-4% (1g/dL increase in hemoglobin) in a 70 kg patient.¹⁵ However, the expected increase in hematocrit may be slightly less in patients at term due to expanded blood volume during pregnancy. As noted elsewhere in this toolkit, any patient with continued bleeding after initial measures have failed (Stage 2) should be transfused with multiple units of PRBCs based on clinical signs and response to treatments. If these are not readily available, consideration should be given for the use of emergency released

uncross-matched group O negative blood while the blood bank is completing the patient's type, antibody screen and crossmatch. Note: For women with a negative antibody screen, virtually all type compatible units will also be crossmatch compatible. Consistent with recommendations from this toolkit, for any patient that reaches Stage 3, a massive OB hemorrhage pack, which includes 3 to 6 units of PRBCs as pre-arranged with the blood bank for massive transfusion protocol, should be prepared and transfused based on vital signs and blood loss. Good communication with the laboratory regarding the urgency of the situation is essential.

FRESH FROZEN PLASMA (FFP)

Fresh frozen plasma contains nearly all coagulation factors and can be used up to 24 hours after thawing and up to 5 days if relabeled as "thawed plasma." The type of plasma that is available can vary from institution to institution. Concomitant use of FFP and PRBCs is recommended during massive hemorrhage. Other acceptable choices for plasma include FP24, which is plasma that has been frozen within 24 hours of collection (instead of 8 hours as in FFP), and liquid (never frozen) plasma. FP24 is used virtually the same as FFP and can be stored up to 5 days if labeled "thawed" as well. Liquid plasma must be collected in a closed system and may contain cellular elements increasing the risk for CMV and therefore, perhaps a less desirable choice in this setting.

After the first two units of PRBC's, early transfusion with FFP is correlated with improved survival from hemorrhage after trauma. There is ongoing debate as to the optimal ratio but most protocols recommend ratios between 1:1 and 1:2 (FFP:RBC) for initial resuscitation. Similar recommendations have been established at centers with existing massive OB hemorrhage protocols with the goal of maintaining the INR at < 1.5-1.7.^{1,5,9,16,17} If diffuse bleeding is noted, or there is laboratory evidence of DIC and the patient's blood type is unknown, AB plasma is recommended. AB plasma is often in short supply. If AB plasma were not available, 2-3 units of mismatched plasma is usually well tolerated by adults while patient type is completed.¹⁸ FFP usually requires 20-30 minutes to thaw and may not be available immediately.

PLATELETS

All protocols in our review recommended transfusion of a single donor apheresis unit or a pool of 6 whole blood-derived platelets when platelet levels varied between are below 100K during Stage 3.^{6,8,9} Platelet pheresis units are the standard equivalent of 5-6 units of whole blood-derived pooled platelets and may increase the platelet count in a 70 kg patient by approximately 40-50,000/uL¹⁵

In the face of massive maternal hemorrhage, platelet transfusions should maintain platelet count between 50,000-100,000/uL. However, platelet counts should be used only as a guide and should be interpreted in conjunction with the patient's clinical condition.

These recommendations are consistent with those of the American Society of Anesthesiologists Task Force on Perioperative Blood Loss.¹⁹ Some protocols have suggested higher platelet counts for initiating transfusion and maintaining appropriate platelet levels. These suggestions are based on the assumption that unless bleeding and DIC have been controlled, the patient will experience ongoing platelet loss.^{2,5} Platelets do not require crossmatching and are not always type specific. Rh negative platelets (at least those from whole blood) are preferentially given to patients with an Rh negative blood type because of the small risk of sensitization to the D-antigen. However, a dose of Rh-Immune Globulin may be given and is protective if Rh negative platelets are unavailable. As a general rule, apheresis platelets rarely are significantly contaminated with red cells and therefore the observed seroconversion rate following Rh (D) + units in Rh (D) negative patients is vanishingly low if only receiving apheresis platelets.^{20,21}

CRYOPRECIPITATE AND FIBRINOGEN

In the face of hypofibrinogenemia (fibrinogen levels < 100-125 mg/dL and ongoing bleeding), fibrinogen should be used in addition to FFP. Transfusion recommendations were based on maintaining a fibrinogen concentration above 100 mg/dL. Cryoprecipitate released from the Blood Bank is often in pools of 4-10 units. Each unit provides ≥ 150 mg of fibrinogen for a total of at least 1500 mg in a pool of 10 units in a total volume of approximately 80-100 cc. A pooled “ten-unit” pack would be expected to increase the fibrinogen level of a 70 kg patient by approximately 75 mg/dL. It is worth noting that a 10-unit pool represents 10 separate donor exposures. Improved manufacturing techniques are making smaller pools with equivalent fibrinogen dose common. This reduces the donor exposure risk, where available. If continued bleeding and hypofibrinogenemia is present, additional units of cryoprecipitate should be used. In the presence of severe abruption or amniotic fluid embolism the initial request for blood products should include cryoprecipitate as both of these conditions are associated with significant fibrinogen depletion.

CALCIUM

Hypocalcemia is one of the most clinically significant electrolyte disturbances noted in massive transfusion. Both PRBCs and FFP contain the anticoagulant citrate, which binds calcium. Although this can be cleared in a short amount of time by the liver in optimal conditions, hepatic function may be impaired by significant hypotension, hypothermia, preexisting liver disease, or may be overwhelmed by the rate of blood product transfusion and dilution. Calcium is necessary for adequate clotting and myocardial contraction. Ionized calcium should be frequently monitored and replaced to keep levels within a normal physiologic range.

COAGULOPATHY, ACIDOSIS & TEMPERATURE

The coagulopathy frequently associated with massive hemorrhage may be further exacerbated by hypothermia and acidosis. Worsening acidosis often results from hypoperfusion of multiple organs and an increase in lactate levels. Activity of clotting factors is significantly reduced (> 50% reduction) at a pH of 7.0, compared to a pH of 7.4 and electrolytes are frequently abnormal.²²

Hypothermia associated with the infusion of cold fluids (including blood products) is the main cause of heat loss during massive transfusion. In trauma patients, each 1°C drop in temperature is associated with a 10% drop in clotting factor activity, and a core temperature below 33°C is associated with a > 50% reduction in normal factor activity.²² Acidosis and hypothermia are associated with increased morbidity and mortality in trauma patients. During massive transfusion resuscitation, the patient's arterial blood gas, electrolytes, and core temperature should be monitored to guide clinical management, all transfused fluids should be warmed, and direct warming of the patient should be initiated as needed to maintain euthermia.

RECOMBINANT FACTOR VIIa

Factor VII is a vitamin K-dependent serine protease with a pivotal role in coagulation. After reconstitution with sterile water, each vial contains approximately 0.6 mg/mL (600 µg/mL). It's approved indication for use is in patients with hemophilia A and B. The role of rfVIIa in primary postpartum hemorrhage is controversial.²³⁻²⁵ It has been reported (anecdotally) to significantly improve hemostasis in hemorrhaging obstetrical patients, but may also result in life-threatening thrombosis.²⁶ The committee reviewed the literature and it appears that the use of Factor VII in obstetrical patients continues to be very rare and other specialty areas seem to be moving away from their use of the medication. We therefore cannot recommend its usage but recognize that in patients where all other efforts fail this may be a last ditch option (see editorial in Annals of Internal Medicine).²⁷ Continued concern over the medication causing venous thrombosis prevents recommending usage outside this narrow range of patients.^{28,29} If rfVIIa is to be used, treatment should be provided in consultation with a local and/or regional expert in the area of massive hemorrhage, such as a hematologist, transfusion medicine specialist, or trauma surgeon. There is not a consensus on dosing recommendations in obstetrical hemorrhage patients.

TRANEXAMIC ACID

Tranexamic acid is a lysine analog and antifibrinolytic agent, which has been shown to modestly reduce blood loss in multiple studies of surgical patients. The hemostatic process is reliant on a combination of coagulation factors and a tight net of fibrin covering the damaged areas. There are limited studies in obstetrical patients to demonstrate efficacy and safety. Preliminary data suggest only modest benefit and we recommend

waiting for results of a large multicenter trial is being undertaken in Europe, the WOMAN trial, which is designed to evaluate usage in obstetrical patients.^{12,30}

SUMMARY

During obstetrical hemorrhage, the primary goals are to provide adequate and early blood product replacement and to either prevent or correct DIC. The literature and protocols reviewed provided remarkable consensus related to therapy in the setting of massive obstetrical hemorrhage.

RECOMMENDATIONS

For transfusion in the setting of massive obstetrical hemorrhage, use a ratio of PRBCs to FFP to platelets that is 4-6 units PRBC: 4 units FFP: 1 unit apheresis platelets.

STAT LABS

If bleeding exceeds expected volume for routine delivery and there is no response to initial therapy, request stat laboratory analysis for the following:

1. CBC with platelets
2. PT(INR) /PTT
3. Fibrinogen and ionized calcium

Repeat labs 1-3 every 30 minutes until patient is stable.

PBRCs

1. Initial request: 3-6 units of RBCs
2. O-negative or type-specific blood initially until cross match units are released

FFP

1. Initial goal of RBCs to FFP ratio should be 3:2
2. Infuse FFP to maintain INR < 1.5-1.7

PLATELETS

1. Prefer single donor apheresis platelet
2. Infuse to maintain platelet count > 50,000-100,000/uL in the face of ongoing hemorrhage

CRYOPRECIPITATE

1. Initial request: 6-10 units cryoprecipitate if fibrinogen is less than 100 mg/dL
2. Initial request: 10 units cryoprecipitate if severe abruption or amniotic fluid embolism is suspected (in some institutions one adult dose may contain fewer units with equivalent amount of fibrinogen)
3. Additional units to maintain fibrinogen concentration \geq 100-125 mg/dL

TRANEXAMIC ACID:

Currently under investigation³¹

RECOMBINANT ACTIVATED FACTOR VII (rFVIIA)

Not universally recommended

EDUCATIONAL TOOLS, SUPPORT DOCUMENTS

TABLE 1: Adverse Reactions to Transfusions (See Table 1 below)

EVIDENCE GRADING

Level of Evidence: II-3 C: Evidence obtained from multiple time series with or without intervention. Well-done QI studies with statistical process control analyses (or the like) fall into this category. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. Recommendations based primarily on consensus and expert opinion.

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TABLE 1: ADVERSE REACTIONS TO TRANSFUSIONS - BLOOD PRODUCT REPLACEMENT: OBSTETRIC HEMORRHAGE

Used with permission from Holli Mason, MD

Acute Adverse Effects of Transfusion (Onset within minutes or hours)			
Type of Reaction	Incidence	Usual Cause	Signs or Symptoms
Hemolysis-Immunologic (Acute Hemolytic transfusion reaction)	1:25,000	Red cell incompatibility, usually ABO	Fever, chills, renal failure, DIC, pain, hypotension, tachycardia, anxiety, hemoglobinemia, hemoglobinuria, cardiac arrest.
Hemolysis-Physical or Chemical	Unknown	Overheating, freezing, addition of hemolytic drugs or solutions.	Asymptomatic hemoglobinuria, rarely DIC, renal failure, hypotension
Febrile Nonhemolytic	0.5-1.5%	Recipient antibodies to donor leukocytes; or preformed cytokines in blood product	Fever, chills
Anaphylaxis	1:20,000-47,000	IgA deficient recipient with antibodies to IgA in donor plasma; antibodies to other plasma proteins, WBCs and platelets.	Respiratory obstruction and cardiovascular collapse, angioedema, anxiety, chills, agitation.
Urticarial	1-3%	Antibody to donor plasma proteins	Pruritus and hives
Transfusion Related Acute Lung Injury (TRALI, Non-cardiogenic Pulmonary Edema)	Reported 0.001%, 0.02%, 0.34%	Donor antibody to recipient leukocytes or patient antibody to donor specific HLA or granulocytes	Respiratory distress, pulmonary edema and hypoxemia with normal wedge pressures. "White out" on CXR
Congestive Heart Failure	6:1000*	Volume overload	Respiratory distress
Septic Complication	1:1000-7:1000	Bacterial contamination	Usually gram negative sepsis when the transfusion is red cells, gram positive cocci are most common in platelet transfusion
Hypothermia	Unknown	Rapid infusion of cold blood	Chills without fever
Hyperkalemia	Unknown	RAPID infusion of stored red cell	Cardiac dysfunction (usually problematic only in infants or those with compromised renal function)
Hypocalcemia	Unknown	Rapid and massive transfusion of stored blood products containing citrate.	Cardiac dysfunction and coagulopathy (usually problematic only in patients with significant hypocalcemia)**

*Reference for this statement: ³²

**Reference for this statement: ³³

Delayed Adverse Effects of Transfusion (Onset within days to years)			
Type of Reaction	Incidence	Usual Cause	Signs or Symptoms
IMMUNOLOGIC			
Delayed Hemolytic Transfusion Reaction	1:4000-7000	Alloantibody to RBC antigen, usually anamnestic	Fever, chills, jaundice, pain, uncommonly renal failure days to weeks following transfusion
Graft vs. Host Disease	Unknown but rare	Lymphocytes from blood donor mount an immune response to host antigens, usually in an immune- compromised host	Fever, rash, anorexia, diarrhea, -LFTs, PROFOUND PANCYTOPENIA which leads to death
Post-transfusion Purpura	Rare	Alloantibody to platelet antigen (usually anti-HPA-1a)	Thrombocytopenia and generalized purpura
Red Cell Alloimmunization	»2% of transfused patients	Exposure to foreign red cell antigens	May cause delayed hemolytic reactions on subsequent transfusions
Platelet-refractoriness	»30% of patients requiring multiple platelet transfusions	Exposure to foreign HLA antigens, sepsis, depressed hematopoiesis, splenic sequestration.	Poor response to platelet transfusions
Immunomodulation	Unknown	Leukocytes in transfused products	May increase risk of infection or tumor recurrence.
NONIMMUNOLOGIC			
Iron Overload	Dependent on number of red cell transfusion	Iron in transfused red cells, usually need 60+ units in an adult patient	Hemochromatosis, cardiac dysfunction

Delayed Adverse Effects of Transfusion (Onset within days to years)			
Type of Reaction	Incidence	Usual Cause	Signs or Symptoms
INFECTIOUS			
HIV	1:2,135,000		
Hepatitis B	1:200,000 - 1:500,000		
Hepatitis C	1:1,935,000		
HTLV I/II	1:2,993,000		
CMV	< 1% of seropositive units transmit disease		
Protozoal infections (Malaria, Babesia, Chagas disease)	Rare		
Parvovirus B19	40-60% of donors are seropositive but viremia occurs only during acute phase of infection	A non-enveloped single strand DNA virus which is not inactivated by solvent- detergent methods of viral inactivation. Has been detected in pooled factor concentrate products	Intrauterine infection: may lead to hydropsfetalis and fetal demise, children: Fifth's disease, patients with chronic hemolytic syndromes or Immune deficiency: aplastic crisis
Potential or Theoretical Risks			
Creutzfeld-Jacob Disease (Theoretical risk)	Rare	Abnormal prion which behaves as an infectious particle	Progressive dementia resulting in death
As yet unknown infections (Potential risk)	Unknown	Infectious agents which may be detected in the future	Unknown morbidity and mortality

IMMEDIATE STEPS FOR ALL REACTIONS:

1. Stop transfusion.
2. Keep IV open with 0.9% NaCl.
3. Notify Attending Physician and Blood Bank.

If transfusion is terminated:

1. Send freshly collected blood and any necessary urine samples to Blood Bank.
2. Send blood unit and administration set to Blood Bank.
3. Fill out COMPLETELY and send to Blood Bank the Transfusion Reaction section of the blood tag.

(Source: Harbor-UCLA Medical Center Appendix to Hospital Policy for Informed Consent for Blood and Blood Products, initially developed by Priscilla Figueroa, MD 8/1998 and most recently revised by Holli M. Mason, MD 1/2010; based on information from the American Association of Blood Banks)

UTERINE TAMPONADE FOR OBSTETRIC HEMORRHAGE: INTERNAL BALLOONS AND EXTERNAL COMPRESSION STITCHES

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EXECUTIVE SUMMARY

- Uterine tamponade can be a simple and effective intervention for bleeding from the placental implantation site.
- WHO recommends the use of uterine balloon tamponade for treatment of uterine atony-related hemorrhage in situations where uterotonics have not been effective or are not available.
- Uterine balloon insertion 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.
- The potential for concealed intra-abdominal bleeding must be kept in mind. It is essential to carefully inspect for unrepaired lacerations prior to balloon 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 sharing this chapter, watching the video and practicing during a drill or simulation.

BACKGROUND

Direct pressure or tamponade on a bleeding site is a long established approach for many types of hemorrhage. In obstetric hemorrhage the large majority of cases involve bleeding from the placental implantation site. A secondary source to always keep in mind is bleeding from trauma (laceration) to the vaginal sidewall, cervix or the uterus itself. These lacerations generally require direct repair. There are three approaches to uterine tamponade: intrauterine packing, intrauterine balloons and uterine (myometrial) compression sutures.

Uterine packing with systematically placed gauze, which is retrieved through the vagina 24 hours later has some disadvantages compared to the use of a balloon; however it might remain a low cost option in resource poor areas, or in experienced hands. Reported disadvantages include the need to pack the uterine cavity tightly and methodically which requires operator experience and adequate anesthesia. Further, there remains concern regarding a delay in recognizing ongoing hemorrhage until the blood loss has saturated

many yards of packing material. Although recent case reports suggest that uterine packing might still play a role, in its updated 2012 guidelines for the treatment of postpartum hemorrhage, WHO recommended against its use.^{1,2}

Uterine balloon tamponade has emerged as a simpler and effective option that can easily be learned. There are many reported retrospective series of uterine balloon tamponade. The postpartum uterine cavity requires a balloon of sizable volume to adequately apply pressure against its walls. The Rusch urologic balloon, designed for bladder tamponade and the Sengstaken-Blakemore esophageal tube were initially used. There are now three commercially available devices designed specifically for uterine balloon tamponade available including 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. The filled balloons are easily visualized with bedside trans abdomen ultrasound, which may be useful to assess development of intrauterine blood and clots or balloon extrusion through a dilated cervix into the vagina. In 2012, WHO updated its guidelines for the management of postpartum hemorrhage to state, “The use of intrauterine balloon tamponade is recommended for the treatment of PPH due to uterine atony. This recommendation is now stronger than the previous guidelines. It can be used for women who do not respond to uterotonics or if uterotonics are not available.”²

The exact mechanism of action of balloon uterine tamponade is not yet clear. Reduction of uterine bleeding may occur by reduction of uterine artery perfusion pressure, by application of pressure directly to the placental bed, or both.³

Successful use of a balloon catheter is defined in most case series as diminished bleeding such that no additional non-pharmacologic interventions are needed. The reported success rates range from 68%-88%, derived from recent cases series ranging from 15-50 patients in a total of 204 women.⁴⁻¹⁰ These case series specifically describe use of the Bakri™ Postpartum Balloon. Some authors have noted a higher rate of success in women who were delivered vaginally compared to by cesarean section.^{4,6,9} Because an intrauterine balloon can fairly rapidly be placed (typically less than 5-8 minutes), even if the balloon is ultimately not successful in completely controlling the hemorrhage, its placement may diminish bleeding while other therapeutic resources are mobilized, such as transferring the patient to the operating room or to an interventional radiology suite. One author noted a significant decrease in the rate of invasive procedures needed among vaginally delivered women once an intrauterine balloon was introduced into the postpartum hemorrhage protocol.⁷

Placement of the balloon via a transvaginal route can be accomplished by holding the balloon in the palm of the operator's hand and manually guiding it through the dilated

cervix and into the uterine cavity, with the patient in a dorsal lithotomy position. The balloon must typically be manually held within the uterine cavity to prevent extrusion through the dilated cervix until the balloon is filled to at least 300 cc or even more. Care should be taken not to inadvertently “kink” the short length of tubing connecting the fill device (syringe or IV bag) and stopcock to the main balloon catheter. Once the balloon is optimally filled, gentle traction on the stem should seat the balloon within the lower uterine segment. This process may involve the operator holding the catheter in place and assessing the uterine filling and tone; and an assistant who draws up the saline syringes, turns the stopcocks and pushes the fluid. Others need to record the fluid placed into the balloon, number of vaginal packs if used, and the blood loss out. 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. *Note: such packing must be tied to the balloon catheter so that it is removed at the same time, preventing retained vaginal packing.* The Ebb[®] tamponade system has a separate vaginal balloon which may be inflated to facilitate a vaginal packing effect. The maximal uterine balloon fill volumes are reported to be from 500 cc (Bakri[™] and BT-Cath[®]) to 750 cc (Ebb[®]). 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.

Placement of the Bakri[™] balloon at the time of cesarean section involves threading the catheter end of the device through the abdomen incision, into the uterine cavity, and down through the cervix into the vagina. Care should be taken to ensure that the catheter is threaded through the cervix and is not inadvertently coiled within the lower uterine segment. An assistant, underneath the surgical drapes and with a gloved hand in the vagina may facilitate proper placement of the catheter tube. This assistant can ensure the retention of the balloon within the uterus as the uterine incision is closed and the balloon is then inflated. Inflation of the balloon prior to closure of the uterus can risk needle puncture of the balloon. In contrast, the Ebb[®] tamponade system with its multiple catheters, needs to be placed from the vagina upwards. This can be accomplished with an assistant but usually requires placing the woman in lithotomy position to feed the catheter as cleanly as possible through the cervix.

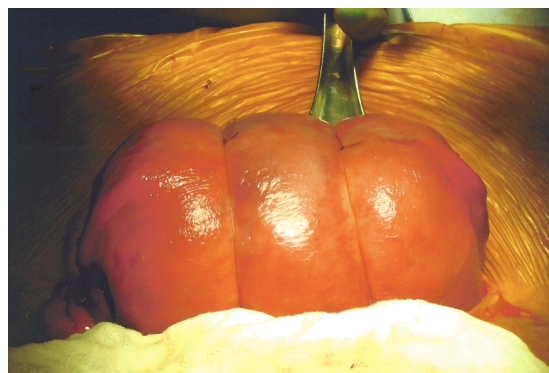
Post-procedure monitoring includes continuing with the hemorrhage protocol and checklist with the addition of measurement of draining blood. The next 20-30 minutes should be devoted to creating a plan for next steps should the bleeding not be controlled. Fortunately, in 60-80% of cases, the balloon will be the last major intervention needed. 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 remains in the uterus (usually up to 24 hours maximum) and some have suggested

soaking any vaginal packing used in povidone iodine or antibiotic solution. Whether these measures are necessary is unknown.

Several caveats should be kept in mind: (1) lack of vaginal bleeding does not necessarily mean that the bleeding is controlled—hemorrhage may continue intra-abdominally thru a laceration and be obscured by the balloon. Close attention to vital signs is critical. (2) Uterine atony and lower segment bleeding from a poorly contracted placental implantation site are the most recognized indications for an intrauterine balloon. Experience with focal abnormally adherent placenta (partial accreta) has been mixed, some claim great success others have noted failure with significant obscured blood loss. (3) A critical first step is a thorough and well-lit examination for lacerations. Often this is best done in the operating room with surgical stirrups, long retractors, assistants and multiple OR lights. This is also the opportunity to rule out retained placental fragments. If it is to be done in a delivery room, one should assemble similar resources.

Another approach that should be available in every institution is the use of uterine compression sutures. B-Lynch “suspender-style” suturing with heavy gauge absorbable suture such as 1-Chronic 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 accretas). 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 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 after a B-Lynch suture has been successfully reported in a small number of cases. The combination of external and internal compression can be very effective.

(Photo courtesy of Elliott Main, MD and used with permission)



RECOMMENDATIONS

1. An intrauterine balloon tamponade device should be available on all obstetrical units.
2. All delivery providers (physicians, midwives and nurses) at the institution should be familiar with the technique and instruments for placement of both the intrauterine balloon and the B-Lynch suture, including physically practicing the steps. Appropriate protocols for the timing and method of placement should be added to institutional policies and procedures. (Diagrams with the technique and indications for use may be helpful if clearly posted in the labor and delivery units as well as available in large laminated size in an obstetric hemorrhage kit.) Viewing a manufacturer's commercial animation may also be useful.¹¹
3. The critical first step for evaluation of obstetric hemorrhage should always be a careful and well-visualized examination of the vagina and cervix.

EVIDENCE GRADING:

Level of Evidence: II-3 B. Evidence obtained from multiple time series with or without intervention. Well-done QI studies with statistical process control analyses (or the like) fall into this category. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. Recommendations based on limited or inconsistent evidence.

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UTERINE ARTERY OCCLUSION AND EMBOLIZATION

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EXECUTIVE SUMMARY

- Vaso-occlusive balloon insertion and uterine artery embolization may be an option for intervention to control hemorrhage in centers with interventional radiologists experienced in these procedures.
- Literature on the efficacy and safety of these procedures has been mixed.
- Severe complications, including uterine necrosis are possible.
- Vaso-occlusive and embolization techniques should only be performed by experienced interventional radiologists, in patients stable enough for transport to the IR suite, and after full review of risks and benefits.

BACKGROUND AND LITERATURE REVIEW

Many authors have written on their experience with arterial balloon occlusion and embolization as an alternative to other conservative measures or hysterectomy for controlling postpartum hemorrhage.¹⁻³ Temporary arterial occlusion is typically used as a prophylactic measure when conditions such as placenta accreta 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 literature describing the efficacy and safety of these techniques is limited to several case reports and small series. A review article of 46 studies of conservative measures found that they were effective but fell behind balloon catheters and hemostatic uterine sutures in efficacy. The success rates for controlling obstetrical hemorrhage were as follows: 90.7% (95% confidence interval [CI], 85.7%-94.0%) for arterial embolization, 84.0% (95% CI, 77.5%-88.8%) for balloon tamponade, 91.7% (95% CI, 84.9%-95.5%) for uterine compression sutures, and 84.6% (81.2%-87.5%) for iliac artery ligation or uterine devascularization.^{4,5} The major limitation in these studies was the difficulty in assessing operator experience across various studies, and, unfortunately, the results have not always demonstrated clear-cut efficacy.⁶

There is the possibility of severe complications from arterial balloon occlusion and embolization. One complication is uterine necrosis.⁷ In one case-control study the authors found that 3 out of 19 subjects (15.8%) had complications from catheter placement and two required stent placement and/or arterial bypass.⁸ Other serious complications such as thromboembolic events, fistulae⁹ and in one series fetal bradycardia requiring immediate delivery (15.4%) occurred.¹⁰ 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 until large registries can determine more precise risks.¹¹

RECOMMENDATIONS

1. Vaso-occlusive balloons and embolization techniques appear to be another option in centers with adequate interventional radiology expertise.
2. The indications, potential complications and effectiveness of these techniques are not well established and therefore must be approached with caution.
3. If utilized the patient must be in stable condition for transport to the interventional radiology suite and should be accompanied by a nurse skilled in the assessment and treatment of obstetrical hemorrhage should the patient's status suddenly decline.
4. Obstetrical staff should keep abreast of further research developments as to the most effective technique and indications for these procedures.

EVIDENCE GRADING

Level of Evidence: II-2. Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

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WOMEN'S EXPERIENCE OF OBSTETRIC HEMORRHAGE: INFORMATIONAL, EMOTIONAL AND PHYSICAL HEALTH NEEDS

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EXECUTIVE SUMMARY

- Women and families need information and emotional support during and after an obstetric hemorrhage.
- Women need to experience being listened to and have their experience acknowledged from their own, rather than the clinicians' perspective.
- Women need to know what happened to them, and why. Formal discussions about their experience and prognosis should occur throughout their hospitalization and during postpartum follow up visits.
- After a severe hemorrhage, maternity clinicians should be alert for behavior or emotional states in women that are outside the normal range of postpartum responses. Such reactions may include detachment, dissociation, and intrusive thoughts.
- The experience of traumatic birth after hemorrhage is individual; not all women respond the same way. Factors affecting the development of traumatic reactions may include the woman's sense of threat to her or her baby, loss of control, or loss of trust in caregivers. Women's reactions may not correspond with clinicians' perception of the level of the severity, or resolution of the complication.
- Tailored and specific discharge planning for women and their families who have experienced hemorrhage should include assessment for women's physical and emotional recovery, and referrals for counseling and support in the community.

BACKGROUND AND LITERATURE REVIEW

There is little research on women's experience of hemorrhage in the United States. However, international research and published first person narratives provide insights into women's experience of severe maternal morbidity. These insights suggest we can better meet the needs of women and families regarding information and emotional support during and after a severe maternal hemorrhage.^{1-8,11}

After a traumatic birth event, women seek to understand what happened to them, make sense of the reasons behind their experience, and think about implications for their long-term health and possible future childbearing. Research on women's experience of

obstetric hemorrhage from studies conducted in Australia, the United Kingdom and other countries shows that a significant proportion of women report not receiving adequate information about their condition and recovery.^{2,3,9} While women report feeling grateful to health professionals for the life saving care provided to them and their babies, women often report feelings of anger and frustration at not receiving sufficient information and/or at the quality of the emotional care they received.^{4,5}

In a study of 206 Australian women who had significant postpartum hemorrhage, twenty percent of the women reported they did not receive care that consistently met their needs for acknowledgement, reassurance, and information while in the hospital⁷, and 37% believed the hemorrhage might have been prevented with different care. A participant in an ongoing study of U.S. women's experiences of maternal complications recalled:

*I must have used the portable toilet four times in that Emergency Room. The nurse never weighed that blood. And that's a common thing: people don't realize you're hemorrhaging because they don't even keep track. (Beth)*¹⁰

These and other findings suggest that women are attuned to delays in recognition of and response to hemorrhage, and may be further traumatized by perceptions of sub-optimal care. Such experiences may intensify the need for a formal discussion, including review of events and prognosis, with a health care provider who was present during the event.

In the case of language barriers, provision should be made for professional (non-family) translators, preferably with experience in obstetrics. A study of Swedish immigrant women's experience of maternal morbidity found that women felt health care providers underestimated their complaints, did not provide women with adequate information about their diagnosis and treatment options nor their risks for the complications they experienced, and this was especially marked among women with low education levels¹¹.

After a significant morbidity, referral for follow-up counseling and mental health services is also recommended.² Physician and nursing providers may not know how women have perceived their experience, thus assessment and discharge planning for follow-up care are essential for all women who have experienced severe hemorrhage or other potentially traumatic birth experiences.

Finally, it is important to note that there are no specific organizations that support the unique needs of women who have experienced a severe obstetric hemorrhage but there are resources that address medical crises and the impact of trauma in childbirth.

INFORMATIONAL, EMOTIONAL AND PHYSICAL HEALTH NEEDS

Key informational, emotional and physical health needs particular to specific time periods are summarized in Table 1 (found directly before the references) and briefly elaborated below.

Before the Critical Event

Women who communicate with providers or present to care with a concern about their symptoms should be listened to respectfully and given full, complete information about their concerns. All women who have been identified to be at high risk for obstetric hemorrhage should be counseled early in their prenatal course about the likelihood of blood transfusions. The discussion, patient preferences and plan regarding treatment should be documented and communicated to the facility where the woman will give birth. In complex cases, the primary maternity provider should ensure that all relevant disciplines (e.g. anesthesia, nursing, and sub-specialty services as appropriate to the woman's condition) are included in care planning.

During the Critical Event

Families and other close support persons are an integral part of the birth process, often providing strength and support for patients in managing unexpected health crises. During childbirth, health crises are especially unexpected and family members need information and support; they may wish to stay with their loved one throughout the course of care. Health care providers are often uncomfortable with family presence during procedures and resuscitation due to fears of distraction, interference by family members, psychological distress for family members and liability concerns.¹²⁻¹⁴ However, studies suggest these fears are unfounded, and family members, patients and clinicians benefit from family presence, even during resuscitation.¹⁵⁻²¹ Survey data revealed patients and families overwhelmingly wanted the option of family presence at resuscitations.²² There is no evidence to support health care providers' perceptions or concerns that family members are disruptive during invasive procedures or resuscitations, or that family presence increases malpractice risk.^{17,20,22} A recent clinical trial suggests psychological benefit for family members present during CPR.^{20,22,23} Support for family presence during invasive procedures and resuscitations is formally endorsed by the Society for Critical Care Medicine, American Academy of Pediatrics, American College of Emergency Physicians, American Association of Critical Care Nurses, and the Emergency Nurses Association.^{22,24-26}

Patient and family expectations and desires for presence during urgent medical care and resuscitation should be ascertained and supported.²⁷ It is generally appropriate for a family member or other close personal support person to remain with the patient during resuscitation if they wish to do so. Family members who witnessed resuscitations in patients who ultimately died reported easier adjustment to death and grieving and felt

their presence was beneficial to their loved ones. Patients who have survived resuscitations witnessed by family members also report this was beneficial.^{12,13,18,20,22} Hospitals should have a clear, formal policy for family presence during emergencies and resuscitations in obstetric units. Such policies should include a designated support person for the family member.^{19,26}

Recovery after the Critical Event (In hospital)

Although clinicians may feel relief that the clinical situation was successfully managed, it is important to remember that the patient has a potentially long and challenging recovery ahead of her, as well as the need to care for her new baby. If she is in a critical care unit, it is important to create a calm, healing environment. When the prognosis is relatively positive, clinicians can sometimes lose focus and talk about their own reactions or chat about extraneous events while providing clinical care. This can have the effect of denying the humanity of the patient and her current reality. Michelle Flaum Hall remembers feeling erased as a person when a clinician chatted casually about weekend plans while hanging a bag of blood:

I needed my providers to maintain a caring and professional focus on me, which means not allowing one's own "stuff" to get in the way of sensitive and respectful communication. Experiencing medical trauma can be dehumanizing; treating patients as competent, resilient people restores their humanity.⁴

It is critical that health care providers be especially careful in the manner and language used to communicate with women after a critical event, especially when there has been an unexpected or unwanted outcome, such as a hysterectomy.

I can remember waking up and feeling...I was just mad. I was angry that it [a hysterectomy] had happened. I don't remember how I knew that everything had happened. I was told that a nurse had told me. She didn't know that I didn't know, that I wasn't going to be able to have any more kids. I had no clue what she was talking about and no one wanted to tell me at that point because I still wasn't stable and I guess this nurse kind of messed up and told me. And apparently I screamed and I was angry and I made her cry. (Jennifer)¹⁰

An unexpected physical trauma may affect women's preferences regarding self and newborn care. As with all support, it is important to follow women's lead. For example, some women are grateful for breastfeeding assistance, such as pumping, in the ICU; others report difficulty in obtaining appropriate support. Still others may be worried about how lactation may affect their own healing, or may find that the physical challenges of healing supersede their prior preferences. It is important not to make assumptions about what women need, can, or "should" do during this time. Shared decision-making using

high quality information should be used to support the mother in her decisions and actions regarding feeding and other newborn care.

Maternity clinicians should assess women's emotional state and pay attention to signs of trauma and negative emotional states, such as depression or dissociation. If available at the facility, on-site referrals to mental health professionals may be useful. Clinical counselor Michelle Flaum Hall developed a sample tool for maternity clinicians to assess women's acute stress levels after a severe morbidity (see Appendix G, page 172-176).

Recovery after the Critical Event (At home)

Women with moderate or severe morbidity related to an obstetric hemorrhage are faced with their own physical recovery needs but also the responsibility of caring for a newborn at home. It is important to assess women's needs for, and access to, in-home support and care. Women who have experienced a significant morbidity as a result of childbirth should receive specific discharge planning reflecting their needs for physical and emotional recovery in addition to the routine discharge planning and teaching regarding care of themselves and newborn(s). A sample discharge planning tool is available on page 139-140.

Some women fear being alone at home with the baby, especially if the hemorrhage began during the postpartum period and they remember passing out or calling paramedics.¹⁰ Many women may be physically weak and require additional help at home. Family members may not live nearby, and those who came from a distance for the birth may be unable to extend their stay. Partners may have to work and may not have sufficient time off to stay with women after they are discharged home.

Women who have experienced a life-threatening event experience an existential crisis as well as a medical one.^{2,3,9,10} They need to process the event yet often find that family members and friends wish to put the ordeal behind them.

There are times...when people say, "Oh, you should just be thankful you're alive." Well, I totally agree with that, but there are times you still...you know, it's hard. I guess every once and awhile you need a pity party and just to feel bad because I would've had more children. I feel like I was cheated in that way. (Jennifer)¹⁰

Family members and friends are often emotionally overwhelmed and can be unable or uncertain how best to provide support once the woman has been discharged home. Lack of support from family members can create lasting rifts:

And my father-in-law said, "What happened to you was obviously supposed to. Beth, you need to move on." And I was thinking, "Oh my god, if I was talking about this three years later, maybe someone should say that. But this has been three weeks. I've had two major abdominal surgeries in eight days of each other. I almost died and that's your response?" (Beth)¹⁰

Even with the highest quality of care, women may be at risk of developing traumatic stress reactions and acute stress disorder after a severe hemorrhage. These stress reactions may occur when people experience events in which there was an actual or perceived threat of death or severe injury. While not all women who have an obstetric emergency experience will develop PTSD, when it does develop, it can be debilitating and greatly impair functioning in many life domains.^{2,28} Women and their families should be informed of the signs and symptoms of PTSD (for both the woman and her partner) and provided with referrals for counseling before they leave the hospital. Sensitive care may support resiliency and reduce the development of severe emotional distress if staff understand that the experience of traumatic birth is individual and may be more related to the woman's sense of threat, loss of control, loss of trust in caregivers, or other factors rather than the clinical severity or clinical resolution of the complication. This is why it is essential to assess for signs of trauma reaction before discharge, and to provide referrals and resource lists for all women who experience severe morbidity. See the Educational Tool #1 for a list of resources for birth and general trauma support and resiliency models.

RECOMMENDATIONS

1. Women who experience obstetric hemorrhage need to be
 - a. Given full information about their medical condition as it happens and their prognosis;
 - b. Observed for signs and symptoms of acute trauma and referred to psychological counseling resources while in hospital and/or post discharge.
2. Families and support persons should be given the opportunity to remain present during resuscitation efforts, and be given information and emotional support.
3. More research is needed on women's experience. There is little research on women's experience of obstetric hemorrhage and no research investigating predictors of trauma experience following hemorrhage or factors contributing to or interfering with emotional healing after obstetric hemorrhage with or without peripartum hysterectomy.

EDUCATIONAL TOOLS, SAMPLE DOCUMENTS

1. Educational Tool #1: Resources For Women, Families and Clinicians After and Obstetric Emergency and Resources for Maternity Clinicians after a Severe Maternal Morbidity.
2. Educational Tool #2: Discharge Planning For Women With Complications During The Birth Hospital Stay.
3. A Guide to Recognizing Acute Stress Disorder in Postpartum Women in the Hospital Setting (Appendix G).

**TABLE 1:
INFORMATIONAL, EMOTIONAL & PHYSICAL HEALTH NEEDS AMONG WOMEN (AND THEIR FAMILIES) WHO
EXPERIENCE MATERNAL HEMORRHAGE**

	PRENATAL/ before critical event	INTRAPARTUM/ during critical event	POSTPARTUM/ in hospital recovery	DISCHARGE	POSTPARTUM/ at HOME
	Information needs				
Women	<ul style="list-style-type: none"> What is normal bleeding postpartum When to seek medical care and where to go IF HIGH RISK: Develop a plan and include information about blood donation ahead of time Provide professional translator, when applicable 	Factual data: <ul style="list-style-type: none"> What is happening What is being done Orient to hemorrhage as emergent event Provide professional translator, when applicable throughout hospital stay 	<ul style="list-style-type: none"> Read the chart! Know the facts before speaking to patient Sensitively and empathetically provide information about what has happened and her current condition Keep focused on patient needs; avoid personal or social conversations with colleagues while with patient 	<ul style="list-style-type: none"> Formal discussion: chain of events; what caused hemorrhage Balance women's need to know with hospital policy around disclosure Recognize possible conflict of interest Provide referrals to psychological counselor or social worker 	<ul style="list-style-type: none"> Risks in future pregnancy (if applicable) Formal discussion about what happened and prognosis at follow up postpartum visit
Partner, Family, Support team	Same as above	Same as above, and <ul style="list-style-type: none"> Assign support to Partner Keep updated frequently Keep in the room, even during emergency care if the person wishes to stay 	Same as above, and <ul style="list-style-type: none"> Assign support to Partner Keep updated frequently 	Same as above	Same as above

	PRENATAL/ before critical event	INTRAPARTUM/ during critical event	POSTPARTUM/ in hospital recovery	DISCHARGE	POSTPARTUM/ at HOME
	Emotional support				
Women		Reassurance: <ul style="list-style-type: none"> ○ Baby: Where is the baby; How is the baby ○ Provide pictures of the baby if separated for medical reasons ○ Woman: <i>"We are doing everything to take care of you"</i> 	<ul style="list-style-type: none"> ○ It may be helpful to minimize loud noises, bright lights if possible. Take the patient's lead regarding TV, visitors, etc. ○ Pay attention to signs of trauma, depression. Seek consultation with a mental health professional if necessary ○ Present information of trauma behaviors, ways to support herself in a caring, nurturing manner 	<ul style="list-style-type: none"> ○ Normalize postpartum experiences without discounting severe event 	<ul style="list-style-type: none"> ○ Pay attention to signs of trauma, depression ○ Seek consultation with a mental health professional if necessary
Partner, Family, Support team		Same as above	<ul style="list-style-type: none"> ○ Ask how partner/family members are doing ○ Remember the partner is also processing the experience ○ Present information of trauma behaviors, ways to support mother and family in a caring, nurturing manner 	<ul style="list-style-type: none"> ○ Referral to postpartum care needs ○ Counseling and PTSD warning signs for self and woman 	<ul style="list-style-type: none"> ○ Referral to postpartum care needs ○ Counseling and PTSD warning signs for self and woman

	PRENATAL/ before critical event	INTRAPARTUM/ during critical event	POSTPARTUM/ in hospital recovery	DISCHARGE	POSTPARTUM/ at HOME
	Physical/Health Care				
Women		<ul style="list-style-type: none"> Keep mom and baby together if possible 	<ul style="list-style-type: none"> Support breastfeeding if desired and provide breast pump and certified lactation consultant Don't assume medications make breastfeeding contraindicated Assess strength and ability to perform activities of daily living 	<ul style="list-style-type: none"> Refer to Outpatient lactation support Referral to physical therapy as indicated 	<ul style="list-style-type: none"> Postpartum follow up within 10 days; formal discussion about what happened and prognosis
Partner, Family, Support team		<ul style="list-style-type: none"> Comfortable place to sleep Private place to make calls for additional support and updates 	<ul style="list-style-type: none"> Comfortable place to sleep Private place to make calls for additional support and updates 	<ul style="list-style-type: none"> Counsel about need for extra physical support for woman at home 	<ul style="list-style-type: none"> Counsel about need for extra physical support for woman at home

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EDUCATIONAL TOOL #1

RESOURCES FOR WOMEN, FAMILIES AND CLINICIANS AFTER AN OBSTETRIC EMERGENCY

After an obstetric emergency, many women seek to understand what happened to them and to find a supportive community. Increasingly, online resources provide a space for women who experience these rare events to gather and share stories and information. While not all these may apply to severe hemorrhage, many of the resources are useful after any obstetric emergency.

BIRTH TRAUMA RESOURCES FOR WOMEN & FAMILIES

- **PATTCh:** (<http://pattch.org/>) PATTCh is a collective of birth and mental health experts dedicated to the prevention and treatment of traumatic childbirth. Resources for women, families and health care providers, including a comprehensive **Traumatic Birth Prevention & Resource Guide**.
- **Solace for Mothers:** <http://www.solaceformothers.org/> Solace for Mothers is an organization designed for the sole purpose of providing and creating support for women who have experienced childbirth as traumatic. Contact: info@solaceformothers.org
 - *Comforting a Woman Traumatized by her Birth Experience:* Article from <http://theunnecesarean.com/>, *Women from the Solace for Mothers message boards collaborated to create this list of common things said to women in the postpartum period and how they might be interpreted by women who feel traumatized by their birth and/or have postpartum depression or PTSD.*
- **Improving Birth:** <http://www.improvingbirth.org/traumatoolkit/> Toolkit: Trauma, Traumatic Birth, and Recovery

CONDITION-SPECIFIC RESOURCES WITH GENERAL APPLICABILITY FOR WOMEN & FAMILIES

- **Obstetric Hemorrhage:** (no organizations specific to this issue)
- **Amniotic Fluid Embolism Foundation:** (<http://afesupport.org/>) This foundation is the only patient advocacy organization serving those affected or devastated by amniotic fluid embolism. Their mission is to fund research, raise public awareness and provide support for those whose lives have been touched by this often-fatal maternal health complication. Online Guides: Families in Crisis; Families Grieving the Loss of a Loved One; Fathers Grieving the Loss of a Spouse; Families Grieving the Loss of an Infant; etc.

- **Preeclampsia Foundation:** (<http://www.preeclampsia.org/>) The Preeclampsia Foundation is an empowered community of patients and experts, with a diverse array of resources and support. They provide support and advocacy for the people whose lives have been or will be affected by the condition – mothers, babies, fathers and their families. Online resources and tools for women, families and clinicians.
- **Cardiomyopathy:** My Heart Sisters (<http://www.myheartsisters.com/>)
- **MITSS (Medically Induced Trauma Support Services)** (<http://www.mitss.org/>) is a non-profit organization whose mission is “To Support Healing and Restore Hope to patients, families, and clinicians impacted by medical errors and adverse medical events.”
 - Toolkit for staff support: www.mitsstools.org/tool-kit-for-staff-support-for-healthcare-organizations.html

GENERAL MEDICAL AND TRAUMA RESOURCES FOR CLINICIANS

- **ACOG:** "Healing Our Own: Adverse Events in Obstetrics and Gynecology" Available to ACOG members only via website
- **Risking Connection:** (<http://www.riskingconnection.com/>) Risking Connection® teaches a relational framework and skills for working with survivors of traumatic experiences. The focus is on relationship as healing, and on self-care for service providers. Some information here is helping provider recognize trauma the patient brings with her but the issues presented-safety, empowerment, etc. apply in any trauma situation.
- **Health Care Toolbox:** (<http://healthcarettoolbox.org/index.php/what-providers-can-do/d-e-f-protocol-for-trauma-informed-pediatric-care.html>) This is for pediatric patients but it is evidenced-based, and is simply and clearly presented. "A-B-C" orients providers to the crucial first steps to save a life (Airway, Breathing, Circulation). "D-E-F" can help providers remember the key initial steps for children's emotional recovery from illness or injury. Health care providers are experts in treating illness, restoring functioning, and saving lives.
- **Women's Health Research at Yale:** (<http://medicine.yale.edu/whr/research/cores/trauma.aspx#page1>) The Trauma Core of *Women's Health Research at Yale* studies issues unique to female veterans, women, and children. Lots of information and resources.

EDUCATIONAL TOOL #2

DISCHARGE PLANNING FOR WOMEN WITH COMPLICATIONS DURING THE BIRTH HOSPITAL STAY

Call your doctor or midwife if you have:

- Bleeding soaking a pad an hour
- Large blood clots
- Feeling dizzy when you stand up
- A headache that does not go away with Tylenol
- Visual changes (blurry vision or seeing spots)
- Abdominal pain - If you had surgery, this means more pain than you have been having from surgery
- Feeling detached, numb, afraid, depressed, anxious, or very stressed

Routine follow-up care:

1. Early postpartum check-up scheduled with:

_____ on _____

- Women who have had a significant complication such as hemorrhage, preeclampsia, ICU admission, or unplanned or extensive surgery may need early post-partum follow-up to assess their physical and emotional recovery.
- This visit should be scheduled within 3-7 days (or even sooner) for women who are on anti-hypertensive medication at hospital discharge.

2. Breastfeeding support scheduled with: _____ or ☐ Not applicable

_____ on _____

3. 6 week postpartum check-up scheduled with:

_____ on _____

(Continued on page 2)

Specialty follow-up care:

Is follow-up with a specialist needed? ☐ Yes ☐ No

If yes, follow-up with:

	Name	Phone Number	When?
<input type="checkbox"/> Lactation			
<input type="checkbox"/> Your Cardiologist (Heart)			
<input type="checkbox"/> Your Endocrinologist			
<input type="checkbox"/> Your Nephrologist (Kidney)			
<input type="checkbox"/> Your Rheumatologist			
<input type="checkbox"/> Your Pulmonologist (Lungs)			
<input type="checkbox"/> Your Urogynecologist			
<input type="checkbox"/> Counseling			
<input type="checkbox"/> Support group			
<input type="checkbox"/> Psychiatry/Psychology			
<input type="checkbox"/> Other:			

PREPAREDNESS CONSIDERATIONS FOR SMALL AND RURAL HOSPITALS

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EXECUTIVE SUMMARY

- Considerations for birth at a tertiary hospital should be discussed for women with prenatal conditions that put them at high risk for hemorrhage.
- Communication and collaboration between departments and between disciplines are essential to providing optimal hemorrhage care.
- Smaller and more rural hospitals may face special challenges in preparing for and responding to obstetric hemorrhage.
- Deliberate processes need to be in place for communicating with the entire team when emergencies occur during labor and birth.
- All staff need a clear picture of response times, and teams should be mobilized early for high risk situations.
- Blood product availability and time to obtain blood products should be clearly communicated to all members of the birth team.

Multidisciplinary and multi-departmental collaboration are critical to facilitating the highest quality of care for women undergoing a postpartum hemorrhage. During a hemorrhage, availability of resources such as personnel, equipment, and blood products may pose unique challenges for smaller hospitals.¹ These hospitals should proactively identify challenges and modify processes to optimize outcomes for their patients. A massive hemorrhage should be considered an emergency similar to a respiratory or cardiac arrest and elicit the same hospital emergency response and resources.

Women with high-risk conditions such as a placenta previa with a prior cesarean section, multiple prior cesarean sections, or a history of postpartum hemorrhage should be considered for delivery at a tertiary hospital where the appropriate resources are immediately available. The hospital should identify transfer resources and options including a possible transfer agreement with a tertiary hospital.

Many smaller and critical access hospitals are located in rural areas and may be prone to severe weather conditions. Adjustments to processes should be made to account for delays related to distance and weather, and these facilities may wish to consider including non-pneumatic anti-shock garments² in their emergency supplies and training for postpartum hemorrhage. Small hospitals planning to deliver women with known high-risk

conditions or have women present with high-risk conditions should develop a multidisciplinary plan of care.

Planned delivery of women at high risk for a postpartum hemorrhage at tertiary hospitals will not prevent all postpartum hemorrhages from occurring at small hospitals. Women will present with active bleeding to the closest hospital and some women with no identified risk factors, will develop a postpartum hemorrhage. Emergency scenarios should be discussed and a plan developed in order to facilitate an optimal response.

Communication

Early and frequent communication throughout the birth process is essential to facilitate the best care for a woman during a postpartum hemorrhage emergency. Risk factors should be identified early in the pregnancy and hospital admission. Risk assessments should be performed on admission and at patient handoffs, and communicated to the entire birth team even if they are not physically present in the hospital. Offsite providers will need to be notified of evolving high-risk situations in order to actively participate in the development of a plan of care.

The entire birth team should have a shared mental model of the emergency resources available within the hospital. Dialogue regarding time frames needed for mobilization of equipment and personnel should occur prior to an emergency situation. Communication related to available resources can be accomplished by developing unit specific plans, performing multidisciplinary drills, and huddles.

Personnel

There may be limited nursing resources available in the labor and delivery suite, operating room, and general hospital emergency personnel. Operating room personnel may not be in house at all times especially during nights, weekends and holidays. There should be an expectation that operating room personnel and staff home on call will be called in early in the event of a hemorrhage and for high risk situations, not just when an emergency is well in progress.

Consider all hospital staff when mobilizing resources during a hemorrhage emergency. A nursing supervisor or administrator may be able to assist with mobilizing personnel from other areas of the hospital or from home. A nursing supervisor may facilitate space in the operating room, post anesthesia care unit or a bed in the intensive care unit. Nurses from the emergency room and intensive care unit have critical care skills that are helpful during a hemorrhage emergency. Medical surgical nurses may be able to care for postpartum patients during an emergency or be a scribe during a hemorrhage emergency.

Anesthesia providers may be available in the operating room or at home but not to labor and delivery without a time delay. Surgical specialties such as gynecologic oncologists or vascular surgeons that may provide benefit to complicated emergent surgical situations but may be limited or not available. Available provider resources and pathways for activating emergency response from them should be identified prior to an emergency hemorrhage situation. A clear and simple process to contact providers should be developed and practiced during hemorrhage drills.

Equipment and Supplies

A significant hemorrhage is rare. Developing and maintaining hemorrhage supplies in an easily moveable container expedites care during hemorrhage emergencies. Since a hemorrhage may occur in multiple locations throughout the hospital it is optimal to have a designated hemorrhage cart that can be easily transported to the woman.

Emergency equipment may need to be brought from other areas of the hospital. A plan should be in place to mobilize emergency equipment that is not located in labor and delivery. Personnel with the responsibility to mobilize emergency equipment should be identified prior to an emergency hemorrhage. Mobilization of equipment should be practiced during postpartum hemorrhage drills to identify barriers within the process.

Blood Products

All types of blood products may not be stored at a facility, for example platelets may need to be brought in from a central regional location outside of the hospital. The hospital should identify the availability of each type of blood product, the processing time frames for each and communicate this information to the birth team. This information should be posted in an easily accessible location on the birth unit. Plans and criteria should be developed to guide pre-transfusion preparation for high-risk patients and for obtaining blood products in massive transfusion situations. Any changes to the availability of blood products should be immediately communicated to key participants of the birth team.

RECOMMENDATIONS

1. A multidisciplinary, multi-department team should be convened to evaluate readiness for managing obstetric hemorrhage.
2. Identify high-risk antenatal conditions that would be appropriate for planned birth at tertiary facility and review periodically.
3. Consider all potential personnel resources within the facility and include departments such as the operating room in planning response strategy.

4. Small hospitals should carefully map the response process for obstetric hemorrhage to identify availability of equipment, personnel, and blood products.
5. Risk assessment pre-transfusion testing (hold clot vs. type and screen vs. type and cross-match) strategies should be modified to account for potentially longer time to conduct tests and obtain blood products.
6. Conducting routine inter-departmental obstetric hemorrhage drills may assist the team in developing a shared mental model of response times and in identifying opportunities for system improvement.

EVIDENCE GRADE

Level of Evidence III C: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees. Recommendations based primarily on consensus and expert opinion.

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ANTI-SHOCK GARMENTS: NON-PNEUMATIC ANTI-SHOCK GARMENT (NASG) AND PNEUMATIC ANTI-SHOCK GARMENT (PASG)

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EXECUTIVE SUMMARY

- The non-pneumatic anti-shock garment (NASG) is a non-pneumatic compression device that can reduce bleeding and reverse shock secondary to obstetric hemorrhage.
- Although it is mainly used in low-resource settings it has applications in developed countries as well, anytime there is intractable hemorrhage or delays in accessing blood and/or surgery.
- The NASG can be used for obstetric hemorrhage occurring in rural areas where women have to be transported by ambulance or by air.
- The NASG can be used for out-of-hospital birth centers or home births.
- NASGs can reduce blood loss and reverse shock for women with intractable hemorrhage while awaiting arterial embolization.
- The NASG has been used as a “last-ditch” technology for women with intractable hemorrhage where hysterectomy is to be avoided.

BACKGROUND

In 2006, the Joint Statement of the International Confederation of Midwives (ICM) and the International Federation of Gynecology and Obstetrics (FIGO) recommended research on anti-shock garments to reduce mortality among women suffering postpartum hemorrhage.^{1,2} Currently, there are two types of anti-shock garments in use. The pneumatic anti-shock garment, or PASG, was developed in the 1970s and used to transport wounded soldiers during the Vietnam War, hence its other name, Medical Anti-Shock Trousers, or MAST. The other type of anti-shock garment is a non-pneumatic version. While the PASG is not often used for obstetric hemorrhage, the non-pneumatic anti-shock garment (NASG) has been used for obstetric hemorrhage in low-resource settings for the past ten years. The NASG is a first-aid device that reverses hypovolemic shock and decreases obstetric hemorrhage. It consists of articulated segments of neoprene that close tightly with Velcro, increasing blood flow from the lower body to the core organs, elevating blood pressure and increasing preload and cardiac output. Following ten years of research and evaluation, the World Health Organization (WHO) added the NASG to their “Recommendations for Prevention and Treatment of PPH”^{3,4},

FIGO likewise included the NASG in their 2012 “FIGO Guidelines: Prevention and Treatment of PPH in Low-Resource Settings”.⁵

NASG

The NASG was developed in 1971 by teams associated with the National Aeronautics and Space Administration/Ames Research Center (NASA/Ames) in order to overcome some of the deficiencies of the PASG, such as over-inflation, compartment syndrome, and ischemia.⁶ In 1991, the NASG (Zoex Corporation, Ashland, OR, USA) was granted a United States Food and Drug Administration (US FDA) 510(k) medical device regulations number. Based on the same principle as the PASG, circumferential counter-pressure, but without air bladders, manometers, stopcocks, foot pumps and tubing, and without the associated risks of over-inflation and excessive pressures, the NASG is a promising first-aid treatment for hypovolemic shock resulting from obstetric hemorrhage.^{7,8}

NASG MECHANISMS OF ACTION AND NASG BLOOD FLOW STUDIES

Theoretically, all anti-shock garments work on the same principle: a compression suit which restricts blood flow to the lower body while increasing the blood pressure and cardiac output in the non-compressed area, where the oxygen-dependent core organs (heart, lungs, brain) benefit from increased blood flow. Doppler flow studies of the NASG in twelve healthy adult volunteers showed a mean decrease in blood flow in the distal aorta of 33% or 0.65 l/min ($p = 0.04$).⁹ Lester et al studied blood flow in healthy postpartum volunteers and found an increased Resistive Index (RI) in the internal iliac vessels with full application of the NASG, indicating reduced flow, from 0.83 to > 1.05 , Wilcoxon matched pairs signed rank test ($p = 0.02$).¹⁰ A more complete description of the mechanisms of action can be found elsewhere.¹¹

QUASI-EXPERIMENTAL NASG STUDIES FOR OBSTETRIC HEMORRHAGE

The first comparative NASG study was a pre-post pilot of severe obstetric hemorrhage in four Egyptian tertiary-level hospitals. All 364 women (158 pre-intervention phase, 206 post-intervention/NASG phase) had ≥ 750 mL EBL with signs of shock (pulse > 100 BPM, SBP < 100 mmHg) at study entry. All were treated with a standardized protocol; during the post-intervention phase, women also received the NASG. The NASG-treated women had better outcomes, with a statistically significant lower median measured blood loss (500 mL pre-intervention vs. 250 mL post-intervention, median difference -200, 95% CI -250 to -120, $p < 0.001$) and a non-statistically significant 69% decrease in extreme adverse outcomes (mortality and severe morbidity combined).^{12,13}

Further analysis of this data found that NASG-treated women experienced decreased shock recovery times, indicated by return to normal Shock Index (SI). Median SI recovery

time in 249 obstetric hemorrhage cases was significantly shorter in the NASG group (75 vs. 120 minutes, $p = 0.003$), independent of standard treatments, such as volume of IV fluids and/or waiting time for blood transfusions.¹⁴

Miller and colleagues have conducted a larger pre-intervention phase/NASG intervention phase study set in two tertiary facilities in Egypt and four tertiary facilities in Nigeria, $n = 1442$.¹⁵ In both phases of the trial, women with obstetric hemorrhage and hypovolemic shock (see criteria above) were treated with a standardized hemorrhage/shock protocol. Women in the NASG phase also received the NASG. Despite being in worse condition at the study start, negative maternal health outcomes were significantly reduced among women treated with the NASG. Mean measured blood loss after study entry was reduced 50% (median mL 400 vs. 200, $p < 0.0001$), maternal mortality decreased from 6.3% in the pre-intervention phase to 3.5% in the NASG phase (RR 0.56, 95% CI = 0.35 – 0.89), and emergency hysterectomy decreased from 8.9% in the pre-intervention phase to 4.0% in the NASG phase (RR 0.44, 95% CI = 0.23 – 0.86). In multiple logistic regression, there was a 55% reduced odds of mortality during the NASG (aOR 0.45, 95% CI = 0.27 – 0.77). A number of sub-analyses were conducted, based on hemorrhage etiologies or study country, with similar findings of reduced mortality.¹⁶⁻¹⁹

Using data from the pre-intervention phase/ NASG intervention phase study in Nigeria and Egypt¹⁵, Sutherland, et al. combined the data with costs from the study sites to conduct a cost-effectiveness analysis.²⁰ Results showed that providing NASGs to women in severe shock resulted in decreased mortality and morbidity, averting 357 DALYs in Egypt and 2,063 DALYs in Nigeria, with a net savings of \$9,489 in Egypt and a net cost of \$3.13/DALY averted in Nigeria.

El Ayadi and colleagues combined data from studies set in Nigeria/Egypt¹⁵, Zambia²¹, Zimbabwe²², and India²³, and used meta-analytic techniques to describe outcomes of NASG use on 3,561 women across a variety of tertiary care facilities.²⁴ They evaluated pooled odds ratios (POR). The POR for mortality for women treated with the NASG was 38% lower (POR 0.62, 95% CI = 0.44–0.86). For women in more severe shock, the NASG was associated with a 59% reduced odds of mortality (POR 0.41, 95% CI = 0.20–0.83).

RANDOMIZED CLUSTER TRIAL (RCT) OF NASG AT PRIMARY HEALTH CARE LEVEL

A cluster RCT was conducted in Zimbabwe and Zambia to determine if early application of the NASG by midwives at the Primary Health Care (PHC) level, prior to transfer to a referral hospital, decreased extreme adverse outcomes (EAO), mortality or severe-end organ failure morbidity, ClinicalTrials.gov number NCT00488462.²⁵ The study also analyzed potential side effects of the NASG. Entry criteria were estimated vaginal blood

loss ≥ 500 mL and at least one other sign of hemodynamic instability (pulse > 100 or SBP < 100 mmHg). Thirty-eight PHCs were randomly assigned to providing women in hypovolemic shock to either standard obstetric hemorrhage/shock protocols or to the same protocols plus NASG prior to transport to the referral hospital (RH) for definitive treatment. All women received the NASG at the RH, $n=5$ RHs. In an intent-to-treat analysis, the intervention was associated with a non-significant 46% reduced odds of mortality (OR 0.54, 95% CI = 0.14–2.05, $p = 0.37$) and 54% reduction in composite EAO (OR 0.46, 95% CI 0.13–1.62, $p = 0.22$). Women with NASGs recovered from shock significantly faster (HR 1.25, 95% CI = 1.02–1.52, $p = 0.03$). No differences were observed in negative effects.²⁵

Despite a lack of statistical significance, the 54% reduced odds of EAO, the significantly faster shock recovery, and the similarity in decreased mortality rates of approximately 50% across a variety of settings, facility levels, and OH etiologies, suggest there might be treatment benefits from early application of NASGs for delays obtaining definitive treatment for hypovolemic shock. A pragmatic study with rigorous evaluation is suggested for further research. A presentation by the authors of the above study examined the per-protocol analysis; while still not statistically significant due to small sample size, women who actually received the NASG experienced a 64% reduced odds of mortality (OR = 0.36, 95% CI 0.08–1.57, $p = 0.17$).²⁶

CASE REPORT OF NASG FOR PPH IN HIGH-RESOURCE SETTINGS

While the NASG is being studied for efficacy in reducing maternal mortality and morbidity in low-resource settings, it can also be used in high-resource settings. El Sayed, et al. reported on an 18-year-old woman with intractable PPH at the Lucile Packard Children's Hospital, Stanford University, California, USA.²⁷ The woman, bleeding profusely after vaginal twin delivery, received multiple interventions, including Ringer's Lactate infusions, each with 35 units of oxytocin per liter; two doses of 0.2 mg methergine IM; three doses of 250 mcg hemabate IM; 800 mcg misoprostol per rectum; and transfusions of packed RBCs, recombinant factor VII, uterine massage, and uterine curettage. Having exhausted standard treatment measures, the surgeons packed the uterus and applied the NASG. Within minutes of NASG placement, bleeding subsided, pulse decreased, and blood pressure rose. The patient remained hemodynamically stable with normal vaginal bleeding. The NASG was removed on postpartum day 1, without complications or recurrent bleeding. Indications for use in high-resource settings include transport from rural areas to areas capable of treating severe PPH; use while awaiting arterial embolization team, operating room, or anesthesiology; anytime there is a delay in achieving definitive treatment; and/or as in the El Sayed case report, when all else has failed, as a "last-ditch" effort to stabilize and resuscitate.

RECOMMENDATIONS

Given that WHO and FIGO have now added the NASG to their guidelines for PPH²⁸⁻³⁰, and WHO is adding the NASG to their list of Essential Devices for 2014 (personal communication, Velazquez Burumen, 2013), it is no longer necessary to conduct expensive and lengthy efficacy trials. Implementation science and pragmatic operations research are needed to answer a number of remaining questions:

- Hemodynamics
 - The mechanism of action in pregnancy/postpartum is not clear. How much blood flow is decreased to the uterus? Is blood only decreased in the lower body or is there actually blood shunted to upper body? If blood is shunted, what volume of blood is shunted?
 - What is the effect on cardiac output? SPR? Stroke Volume?
- Practical Applications
 - Would equipping ambulances serving rural populations with NASGs have any effect on maternal health outcomes? What about air transports for extremely remote areas?
 - Should the NASG, if introduced into California hospital protocols, be used on women with placenta previa and a viable fetus?
 - Is there a role for NASG in management of women with heavy bleeding from second trimester abortion? Post-caesarean hemorrhage?

EDUCATIONAL TOOLS AND SAMPLE DOCUMENTS

Note that the NASG is not FDA-approved, but does have FDA 510(k) certification, and is substantially similar to an FDA-approved device, the Pneumatic Anti-Shock Garment (PASG), so that it can be marketed in the US and internationally.

NASGs can be obtained from BlueFuzion Group: NASG@bfgroup.asia

A training video and other training materials, links to research publications, and other information about the NASG can be found at www.lifewraps.org.

EVIDENCE GRADING

Level of Evidence: II-3 A. Evidence obtained from multiple time series with or without intervention. Well-done QI studies with statistical process control analyses (or the like) fall into this category. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. Recommendations based on high quality and consistent evidence

Level of Evidence: II-3 B. Evidence obtained from multiple time series with or without intervention. Well-done QI studies with statistical process control analyses (or the like) fall into this category. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence. Recommendations based on limited or inconsistent evidence

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REPORTING SYSTEMS

OB HEMORRHAGE MEASURES FOR HOSPITAL QI PROJECTS

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EXECUTIVE SUMMARY

- Total number of blood products used and the number of mothers who require large transfusions (≥ 4 units of packed red blood cells) have been validated by several large multi-hospital obstetric hemorrhage QI collaboratives as useful quality improvement measures.
- These measures are not designed or validated for use in comparing inter-hospital performance.

BACKGROUND

Quality improvement metrics can be divided into (1) outcome measures (identifying improvement of the health of the population at risk, e.g. reduced morbidity/mortality), (2) process measures (improving elements of care that are linked to improved outcomes, e.g. better risk assessment or estimation of blood loss), and (3) structural measures (ensuring that basic supporting features are in place within the institution, e.g. policies, equipment, staff training).

The focus of CMQCC and other obstetric hemorrhage QI collaboratives to date has been to reduce maternal morbidity by early identification and a standardized and timely response. Two measures, total number of blood products used and the number of mothers who require large transfusions (≥ 4 units of packed red blood cells), have been validated by several large multi-hospital obstetric hemorrhage QI collaboratives. These collaboratives have found that reduction in use of blood products of 20-30% is achievable.¹⁻³

A concern with using the rate of mothers receiving blood transfusion as a quality indicator is a possible unintended consequence of discouraging use of needed blood transfusions. We find that the focus on total number of units overall used for OB patients and the number of mothers who received ≥ 4 units of PRBCs minimizes this concern. Importantly, this measure is harmonized with the new Joint Commission definition of an Obstetric Sentinel Event that includes transfusion of ≥ 4 units of PRBCs. This will reinforce the importance of and the collection of this measure. The appropriate transfusion of 1-2 units of PRBC may actually lower overall blood product usage if early intervention prevents

further deterioration. Large transfusions of blood products are necessary and life-saving in massive hemorrhage situations. However, progression to massive hemorrhage may indicate situations that could be preventable if recognized and aggressively managed earlier. Thus focusing on this population of patients as an opportunity for improvement is important. Large numbers of units used also can have significant impact on costs as these interventions are expensive.

Note: these measures were designed and recommended for collaboratives and similar QI projects (including Hospital Engagement Networks) that utilize time course designs (same hospital comparisons over time). **They are not designed or validated as inter-hospital quality measures.** It is also anticipated that many collaboratives may also want to use other locally designed process measures and “deliverable lists” to support the change process.

OUTCOME MEASURES

Obstetric morbidity is uncommon so large numbers of patients must be observed to show improvement.^{4,5} Therefore, for practical use the hospital-level measures described below are designed to be collected from administrative data sets.⁶ These measures are under consideration to be used throughout the country as part of the National Partnership for Maternal Safety. An additional approach is use of the CDC metric for severe maternal morbidity for both the overall population and within those with OB hemorrhage.

1. Total number of transfusions

- Short Description: Total number of blood products transfused per 1,000 mothers
- Denominator: All women giving birth > 20 weeks (birth hospitalization)
- Numerator: Total number of PRBCs
- Expected Baseline Rate: 40-60 units per 1,000 mothers
- Source: Hospital blood bank data sets or ChargeMaster
- Collection steps: Identify maternity patients either by diagnosis related group (DRGs) or obstetric ICD-9/10 codes, then query the ChargeMaster (or blood bank) data set to determine the total number of blood products used

2. Number of massive transfusions

- Short Description: Number of mothers receiving 4 or more units of Packed Red Blood Cells per 1,000 mothers
- Denominator: All women giving birth > 20 weeks (birth hospitalization)
- Numerator: Women who received ≥ 4 units of PRBCs (This is also the new definition of an Obstetric Joint Commission Sentinel Event so it is likely to be captured)

- Expected Baseline Rate: 2-4 cases per 1,000 mothers (may be higher)
- Source: Hospital blood bank data sets or ChargeMasters
- Collection steps: Identify maternity patients either by DRGs or obstetric ICD9/10 codes, then query the ChargeMaster (or blood bank data set) to identify the women who received ≥ 4 units of blood products

COMMENTS

1. The typical maternity MS-DRGs (765, 766, 767, 768, 770, 774, 775) can be used to restrict the denominator to the typical labor and delivery population (≥ 20 weeks of gestation). While earlier pregnancies do have hemorrhages (e.g. ectopic and late miscarriages), these are quite uncommon and typically have different etiologies and would require a different QI project with a focus on different care venues (office, ER, OR). Furthermore, there is no good way of properly identifying the denominator population for earlier gestations, i.e. — all pregnancies? or all pregnancies beyond 8 weeks? Etc.
2. The numerator identifies all blood products rather than just RBCs. This is the definition used by the Joint Commission and supported by an ACOG/CDC/SMFM consensus committee (in press).
3. Units of blood products is a reasonable measure to collect using blood bank databases or ChargeMaster. A survey of California hospitals found that with little effort, an analyst can create a monthly report of patients transfused with the number of units per patient.
4. The Joint Commission revised definition of ≥ 4 units of blood units transfused as an OB Sentinel Event (January 28, 2014) will be a powerful tool to help drive this quality initiative and it will be important to have coordinated outcome measures.
5. Blood products are very expensive and most hospitals currently have projects underway to carefully scrutinize utilization. Therefore this project may be able to piggy-back on those efforts.

OB HEMORRHAGE STRUCTURE AND PROCESS MEASURES

Structure and process measures are also important but are often quite dependent on the specific QI project so they will not be specified here. They are much more difficult to collect with administrative data so often require chart reviews (however this is usually able to be accomplished with a sample). Structure measures usually are a check-off yes or no for a list of key features that need to be implemented for the intervention to work.

Examples of OB Hemorrhage process measures that are being used in collaboratives include: a) Rate of mothers who had a hemorrhage risk assessment on admission to L&D (chart review of a sample); b) Rate of debriefs after a hemorrhage (first identifying hemorrhages over 1,000 mL (or other trigger such as transfusion(s)) and then determining whether they had a debrief); c) Rate of adherence to the hospital hemorrhage protocol (chart review of a sample); and d) the proportion of medical and nursing staff that have completed a course on OB hemorrhage.

Examples of structure measures include: (Yes/No) has the institution... Implemented a hemorrhage cart? Implemented a hemorrhage protocol? Implemented a massive transfusion protocol? Instituted drills based on the hemorrhage protocol?

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APPENDICES

APPENDIX A: STAGES OF HEMORRHAGE POSTER FOR CART (Miller Children's Hospital Long Beach) (Used with permission)

STAGE 1 QBL > 500 ml VD or >1000 ml CS <u>OR</u> Increased bleeding during recovery	
S T A G E 1	<ul style="list-style-type: none"> <input type="checkbox"/> Notify Coordinator; Notify OB and Anesthesiologist <input type="checkbox"/> Hemorrhage cart and scale to room <input type="checkbox"/> Verify IV ACCESS (at least 18 gauge) <input type="checkbox"/> Increase Oxytocin Rate - Run wide open (20-40 units per liter) <input type="checkbox"/> Vigorous Fundal Massage <input type="checkbox"/> METHERGINE 0.2mg IM – <i>Do not give if hypertensive</i> <input type="checkbox"/> Apply Pulse Oximeter <input type="checkbox"/> Vital Signs & O2 Sat Q 5-15 min <input type="checkbox"/> QBL Q 5-15 minutes; weight of bloody items <input type="checkbox"/> Empty Bladder; (consider Foley with urimeter) <input type="checkbox"/> T&C 2 UNITS Stat (if not done) <input type="checkbox"/> Administer Oxygen to keep O2 Sat > 95% <input type="checkbox"/> Apply Warm Blankets

STAGE 2
Continued bleeding or VS instability
QBL < 1500 ml

**S
T
A
G
E
2**

- ☐ **OB TO BEDSIDE**
- ☐ **Announce Vital Signs & O2 Sat Q 5-10 minutes**
- ☐ **Announce QBL Q 5-10 minutes, weight of bloody items**
- ☐ **HEMABATE 250 mcg IM or MISOPROSTOL 1000 mcg PR**
- ☐ **2nd IV access (16 gauge preferred)**
- ☐ **Bimanual uterine massage**
- ☐ **LABS: CBC, Basic Metabolic Panel, PT, PTT, Fibrinogen, ABG prn O2 sat less than 95%**
- ☐ **Bring 2 units PRBC to bedside**
- ☐ **TRANSFUSE PRBCs per clinical signs and response – Do NOT wait for lab values**
- ☐ **Blood Warmer for Transfusion**
- ☐ **Insert Foley with urimeter (if not previously done)**
- ☐ **Move to OR / IR**

STAGE 3

QBL > 1500 ml VS unstable or suspicion of DIC

S T A G E 3

“ALL HANDS ON DECK!”

- ☐ **MOBILIZE TEAM** – MFM, GYN
Surgeon, 2nd Anesthesia provider
- ☐ **Activate MTP**
- ☐ **Apply Bair Hugger**
- ☐ **Blood/Fluid Warmer and Rapid Infuser**
- ☐ **TRANSFUSE AGGRESSIVELY (1 PRBC: 1 FFP)**
- ☐ **Consider Interventional Radiology**
- ☐ **Announce Vital Signs & O2 Sat Q 5-10 minutes**
- ☐ **Announce QBL Q 5-10 minutes**
- ☐ **LABS:** CBC, PT, PTT, Fibrinogen, ionized Calcium (repeat after every 8 units PRBC) ABG prn O2sat less than 95%
- ☐ **Apply SCD'S**
- ☐ **Assign staff to family support; Call Social Worker, Chaplain**

APPENDIX B: SAMPLE SCENARIO #2 CRITICAL EVENT TEAM TRAINING

(Kaiser San Diego – Used with permission of authors)



Hemorrhage & PEA in the OR

CETT L&D, San Diego

Post-Partum Hemorrhage in the OR and PEA

Part 1 – General Information

Authors: Mark Meyer MD, KP San Diego Medical Center
Leslie Casper MD, KP San Diego Medical Center
Anita Nadworny RN, KP San Diego Medical Center

Scenario	Post Partum Hemorrhage in the OR and PEA
Scenario Time	15-20 minutes
Debriefing Time	40 minutes
Target Group	OB physicians, nurses, and techs For teaching ACLS, anesthesia and pediatric teams not required
Case Summary	<p>This is a case of severe hemorrhage during an elective cesarean section. Despite standard treatment for post-partum hemorrhage, the patient's blood loss is so severe that she suffers cardiac arrest and pulseless electrical activity (PEA).</p> <p>The team must manage hemorrhage per CMQCC guidelines and PEA per AHA ACLS protocols. Some of the OB participants will expect anesthesia to run the code in this scenario. However, the OB team should work WITH anesthesia to run the code when it occurs. Whoever plays the role of anesthesia in the room e.g. (confederate with ACLS expertise, CRNA, or Anesthesiologist), must not take control of the room entirely. They should be working with the OB surgeons and nursing staff, making suggestions re: management and communicating with the OB surgeons to get updates on what is happening away from the head of the bed. OB staff should be providing CPR and updates re: patient information. In this case, the massive hemorrhage is the cause of the PEA and must be communicated to anesthesia.</p> <p>The patient will respond with a stable cardiac rhythm and improved hemodynamic status when the team treats per ACLS protocols and begins transfusion of blood products.</p>
Teaching Personnel (Total # required will depend on expertise of training staff)	<ol style="list-style-type: none"> 1 OB MD For clinical expertise during debriefing Instructor staff must be able to complete the following tasks during the case (Note that one person may take on more than one task e.g. GUI operator and voice of patient) <ol style="list-style-type: none"> a. Give the participant team information re: whether the fundus is firm, boggy, etc. DURING the case. b. Give the participant team information re: status of bleeding e.g. has it stopped after treatment, etc. In the OR, EBL will be estimated based upon "blood" in suction container, in drape, and from number of soaked laps. c. GUI operator – Qualified simulation instructor to operate scenario in L&D. d. Note teamwork and communication skills and medical management for debriefing purposes. e. Voice of patient – use SimMan microphone system. 3. ACLS clinical expert who can act as anesthesia confederate if no anesthesia staff available.
Participants	<p>2 OB MD's 3 L&D nurses 1 scrub tech 1 Certified Nurse Midwife (optional) 1 Anesthesiologist or CRNA (optional)</p>
Learning Objectives	<ol style="list-style-type: none"> 1. Demonstrate Crisis Resource Management (CRM) skills and recognize their effect on team performance. 2. Identify maternal hemorrhage and estimate blood loss (EBL) based upon clinical condition. 3. Demonstrate knowledge of CMQCC maternal hemorrhage classification (based upon EBL and VS). 4. Treat maternal hemorrhage per CMQCC guidelines. 5. Assess ABC's and respond according to ACLS guidelines. 6. Improve the response/resuscitation of the critical patient by improving coordination of anesthesia, surgeons, nursing, and OR staff during critical events.

Post-Partum Hemorrhage in the OR and PEA

Part 2 – Objectives

Authors: Mark Meyer MD, KP San Diego Medical Center
Leslie Casper MD, KP San Diego Medical Center
Anita Nadworny RN, KP San Diego Medical Center

Cognitive Skills/Medical Management	<ol style="list-style-type: none"> 1. Assess ABC's and respond accordingly. 2. Demonstrate familiarity with code cart equipment/medications. 3. Identify maternal hemorrhage and estimate blood loss (EBL) based upon clinical condition (careful inspection and vital signs). 4. Identify progression of CMQCC Class 0 to Class 3 hemorrhage and treat per guidelines: <ol style="list-style-type: none"> a. Increased pitocin b. Fundal massage c. Methergine d. Type and Cross e. Establish 2nd IV f. Aggressive volume resuscitation g. Hemabate h. Misoprostol i. Call <i>Code Purple</i> and transfuse ASAP 5. Identify Pulseless Electrical Activity (PEA) and consider causes of PEA per AHA ACLS guidelines- in this case, hypovolemia secondary to hemorrhage. 6. Treat PEA with epinephrine, atropine (HR <60) as indicated and transfuse ASAP. 7. Provide high quality CPR with assisted ventilations and chest compressions while treating PEA. 8. Manage the patient per ACLS protocols as a coordinated effort between anesthesia, surgeons, nursing, and OR staff. 9. Demonstrate successful strategies to deal with concerned family members who may become an obstruction to patient care.
Psychomotor Skills	<ol style="list-style-type: none"> 1. Complete C-section delivery. 2. Calculate, prepare, and administer accurate medication doses. 3. Demonstrate competency with defibrillator/ monitor. 4. Provide high quality chest compressions/CPR. 5. Assist ventilations with mask ventilation and/or intubation-ventilation.
Critical Actions	<ol style="list-style-type: none"> 1. 100% O2, IV, monitor. 2. Identify PEA and unresponsive patient. 3. Anesthesia needs to call a code. 4. Treat PEA per AHA ACLS protocols. 5. High quality CPR while treating PEA. 6. Appropriate management of maternal hemorrhage per CMQCC guidelines.

Hemorrhage and PEA in the OR

Part 3 – Patient Background Information

Authors: Mark Meyer MD – KP San Diego Medical Center
Leslie Casper MD – KP San Diego Medical Center
Anita Nadworny RN – KP San Diego Medical Center

Patient Information and Background OPTION #1	
Age	27 y/o
Weight	80 kg
HPI	27 y/o G2P1 at 37 wks GA with complete placenta previa. She had a small bleeding episode at 33 weeks but has done well at bedrest since then. Previous pregnancy term SVD.
PMHx/PSHx	PMHx: None PSHx: T&A
Medications	PNV, iron bid
Allergies	Sulfa causes rash
Social Hx	Married housewife Tobacco – None EtOH – None
Presentation	In OR for elective CS, spinal in place, prepped and draped when team arrives
Vital Signs	T 97.2 P 84 BP 120/70 R 14

Patient Information and Background OPTION #2	
Age	38 y/o
Weight	110 kg
HPI	38 y/o G5P4 for elective repeat C-section and BTL at 39 weeks GA.
PMHx	Gestational diabetes A2 on glyburide, previous C-section x 2
Medications	PNV, glyburide, iron once daily
Allergies	None
Social Hx	Married, housewife Smokes 1-2 cigs per day, tried to quit. No EtOH or drugs.
Presentation	In OR for elective C-section, spinal in, prepped and draped when team arrives
Vital Signs	T 98.2 P 92 BP 130/80 R 12

Patient Information and Background OPTION #3	
Age	16 y/o
Weight	70 kg
HPI	17 y/o G1P0 at 39 weeks GA presents for elective C-section for breech.
PMHx/PSHx	PMHx: Mild childhood asthma, no recent inhaler use PSHx: None
Medications	PNV, iron twice a day (when she remembers)
Allergies	PCN causes hives
Social Hx	Single, boyfriend supportive Independent study program for pregnant teens Tobacco: None EtOH: None
Presentation	Presents in OR with spinal in, prepped and draped when team arrives
Vital Signs	T 98.4 P 96 BP 96/64 R 16

Post Partum Hemorrhage & PEA in OR

Part 4 – Equipment/Materials List

Simulation Equipment:

SimMan standard configuration	
Monitor, link box & laptop	
Philips defibrillator cable adapter (<i>Laerdal cat. Number: 945004. If not available, attach metal discs supplied with mannequin to defibrillation outputs on sternum and apex of SimMan</i>)	
VGA extension cable (<i>6ft or longer</i>) depending on location of patient monitor/touch screen	
Microphone for GUI operator to simulate patient's voice (<i>if using SimMan</i>)	
Resuscitation Infant wrapped for C-Section delivery (<i>carpet lining</i>)	
For video debriefing:	Webcam
	6-12 ft of USB extensions depending on distance between laptop and webcam location
	Additional laptop with Laerdal's Debrief Viewer software installed
	Digital Projector
	Flash drive to transfer Debrief Viewer files between laptops
Power strip	
Foam tape	

Patient Care Equipment:

ID Band on SimMan
BP, SPO2 monitor, ECG monitor (Anesthesia set up)
IV lock in place, attached IV tubing, running LR on Baxter IV pump
C-Section Set up w/blade
Adult crash cart with advance airway equipment, defibrillator, medications
Adult size bag-valve mask
Adult size oxygen mask w/tubing
Suction module, canister, tubing and yankauer tip
Blood tubing
Normal Saline
10-25 laps soaked with blood (should be handed to the surgeons during the case to help simulate ongoing hemorrhage)
Medical record/documentation tools

Medications:

Crash cart pharmacy tray: (<i>Epinephrine (1:10,000), Atropine included</i>)
Pitocine
Methergine
Hemabate
Misoprostol

Moulage

Consider misting down SimMan's, Noelle's face with a SMALL amount of water. Careful not to get electronics wet!!!
Blood clots (1800 ml)
6-10 laps soaked with blood consistent with approximately 500-1000 ml

Optional Equipment/Materials:

CO ₂ tank – required in order to get color change on capnometer. Requires valve/regulator from Laerdal mobility kit.
Mock Blood Bank O- uncrossed match blood

Post-Partum Hemorrhage in the OR and PEA **Part 5 – Program algorithm and operator notes**

Authors: *Mark Meyer MD, KP San Diego Medical Center
Leslie Casper MD, KP San Diego Medical Center
Anita Nadworny RN, KP San Diego Medical Center*

1. This is a case of severe hemorrhage during an elective cesarean section which leads to Pulseless Electrical Activity i.e. PEA. The team must manage hemorrhage per CMQCC guidelines and PEA per ACLS protocols.
2. The patient is initially awake and draped for C-section with a spinal in place in the OR.
3. Either a CRNA or anesthesiologist or confederate acting as anesthesia must be present
4. The team will deliver the infant via C-section which should take approx 5 min. When this is complete, one of the instructors will inform the team that the patient has a uterine atony and quickly hemorrhages approx 1000 ml (Start with 5-10 soaked laps, 500 mL in suction canister)
5. Click on "Cesarean delivery" below which will advance the case to the next frame where the hemorrhage continues and the patient's VS quickly deteriorate. The patient moves from Stage 0 to Stage 3 classification over approximately 4-5 minutes.

1. Note the OBPPH stage 0 to 3 trend running in this frame. In 4-5 minutes the patient's VS deteriorate to HR =143, BP= 68/30. The patient should become less responsive once the SBP reaches approximately 80.

2. The patient's hemorrhage will continue to 1800ml over the next few minutes. (Add additional 15 soaked laps and 500 ml more blood to suction canister making 1000 ml total.)
3. During this frame, the team should be managing PPH per CMQCC guidelines to include medications, fluid resuscitation, code purple, etc. Once the team has completed the appropriate interventions (except transfusion), the patient will go into PEA.
4. Click "Advance Next Frame" and the patient will go into PEA at a rapid rate. The patient will be unresponsive at this time. Anesthesia or the confederate acting as the CRNA must notify the team that the patient now has no pulses. The monitor will show sinus tachycardia, so the team must be told the patient is pulseless for the case to proceed.

The patient is now in PEA and unresponsive. The family member at the head of the bed should note that their loved one is no longer breathing. Dial down the O2 quickly to get anesthesia's attention. Note the trend "HR falling fast" running in this frame. The patient's rate will decrease as well so the team will have to treat unstable bradycardia as well.

Some of the OB participants will expect anesthesia to run the code in this scenario. The OB team should work WITH anesthesia to run the code. Whoever plays the role of anesthesia in the room e.g. (confederate with ACLS expertise, CRNA, or Anesthesiologist), must not take control of the room entirely. They should be working with the OB team, making suggestions re: management and communicating with the OB surgeons re: what is happening away from the head of the bed. OB staff should be providing CPR and updates re: patient information. The OB team must tell anesthesia about the hemorrhage that is the cause of the PEA and must be communicated to anesthesia.

The patient's PEA should be managed initially with epinephrine, but one dose will not be successful. This should prompt the team to give another medication, either a 2nd dose of epi or atropine. A 2nd dose of epi, atropine, or blood being transfused, will advance to the next frame and the patient will go back into sinus tachycardia and will be more responsive.

The patient is becoming more responsive and the HR and BP are recovering quickly. Stop the case once the VS have improved adequately by announcing that the code team has arrived and has taken over the management of the patient.

Debriefing Guide/Evaluation – Make comments below.

Note time of good or bad behavior for use during video debriefing

<p>Teamwork/Leadership</p> <ol style="list-style-type: none"> 1. Clearly established Physician & Nurse leadership 2. Clear role designation with role changes as needed 3. Encourages input from team 4. Calm and in control during times of stress 	<p>Situational Awareness</p> <ol style="list-style-type: none"> 1. Avoids task fixation 2. Reevaluates situation frequently 3. Demonstrates assertion when important information is identified
<p>Effective Communication Skills</p> <ol style="list-style-type: none"> 1. Complete SBAR to entire team 2. Shared Mental Model- "thinking out loud" 3. Uses names when possible, eye contact, non-verbal cues as needed 4. Readback of orders with units 5. Callout of orders as completed 6. Assertion is followed by closed loop communication 	<p>Cognitive Skills</p> <ol style="list-style-type: none"> 1. Quick assessment and management of ABC's 2. Frequently summarizes condition and response to treatment 3. Considers others diagnoses when patient does not respond to treatment or patient's condition changes 4. Utilizes appropriate infection control measures 5. Critical medical management actions completed in timely fashion (Specific for each case) 6. Avoids medication errors <p>For Pediatric Cases, note effective use of Broselow system</p>
<p>Psychomotor Skills (Specific for each case)</p> <ol style="list-style-type: none"> 1. Quickly locates critical equipment 2. Demonstrates competency with critical systems/equipment 	<p>Resource Utilization</p> <ol style="list-style-type: none"> 1. Avoids task saturation 2. Utilizes team resources effectively 3. Prioritizes tasks appropriately 4. Sets clear task priorities

APPENDIX C: DEBRIEFING TOOL

Directions: Form is to be completed immediately after patient situation by the designated team member. After completion, the form is given to _____ (designated by unit/hospital). After the debrief, team members who want to provide additional input are encouraged to complete an incident report.

Goal: Allow team a debrief mechanism to talk immediately about a patient care situation to capture what went well, what could have been done better and what prevented the team from caring for the patient effectively.

Patient Name: _____ Form completed by: _____

Date: _____ Time: _____

Team members attending debriefing (Print Names):

	Yes	No	
Team Attendance			Comments
1. Help arrived in a timely manner	<input type="checkbox"/>	<input type="checkbox"/>	
2. Team members assumed or were assigned needed roles	<input type="checkbox"/>	<input type="checkbox"/>	
3. Team members stayed in role through situation	<input type="checkbox"/>	<input type="checkbox"/>	
4. Adequate help was present	<input type="checkbox"/>	<input type="checkbox"/>	
Medication Administration	Yes	No	Comments
<input type="checkbox"/> N/A			
1. Medications arrived in a timely manner	<input type="checkbox"/>	<input type="checkbox"/>	
2. Medications were given in accordance with policy	<input type="checkbox"/>	<input type="checkbox"/>	
3. Adequate volume and type of medications were in room	<input type="checkbox"/>	<input type="checkbox"/>	
Device Placement	Yes	No	Comments
<input type="checkbox"/> N/A			
1. Device was placed correctly	<input type="checkbox"/>	<input type="checkbox"/>	
2. More than one device was used	<input type="checkbox"/>	<input type="checkbox"/>	

Fluid & Blood Product Administration	Yes	No	Comments
1. Second IV was started in a timely manner	<input type="checkbox"/>	<input type="checkbox"/>	
2. Was any type of blood product administered?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Blood arrived in a timely manner	<input type="checkbox"/>	<input type="checkbox"/>	
4. Was massive transfusion policy activated?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Was rapid transfuser used?	<input type="checkbox"/>	<input type="checkbox"/>	
6. Rapid transfuser arrived in a timely manner	<input type="checkbox"/>	<input type="checkbox"/>	
7. Rapid transfuser was used effectively and according to procedure	<input type="checkbox"/>	<input type="checkbox"/>	
8. Adequate amount of blood was available			
Surgical Treatment	Yes	No	Comments
1. Operating room ready in timely manner	<input type="checkbox"/>	<input type="checkbox"/>	
2. Adequate staff for procedure	<input type="checkbox"/>	<input type="checkbox"/>	
3. Support staff called to room arrived in time to assist with procedure	<input type="checkbox"/>	<input type="checkbox"/>	
4. Appropriate supplies for procedure were readily available	<input type="checkbox"/>	<input type="checkbox"/>	
	Yes	No	Comments
Other Issues to Report	<input type="checkbox"/>	<input type="checkbox"/>	

APPENDIX D: SAMPLES OF MASSIVE TRANSFUSION EVENT PROTOCOLS

Samples of Documents for Massive Transfusion Event Protocols are available on CMQCC's website here as a complete set or individual documents as titled:

1. Massive Transfusion Protocol
2. Massive Transfusion Event Protocol Policy
3. Emergency Transfusion of Uncross-matched Blood and Blood Products
4. Massive Transfusion Event Protocol Flowchart

These samples are from a California hospital that wishes to remain unnamed, and are used with permission.

APPENDIX E: NHS OBSTETRIC EARLY WARNING CHART

AN EXAMPLE OF AN OBSTETRIC EARLY WARNING CHART. REPRODUCED WITH THE KIND PERMISSION OF DR. FIONA MCILVENEY (1)

OBSTETRIC EARLY WARNING CHART (FOR MATERNITY USE ONLY)

Name: _____ DOB: _____
Ward: _____



CONTACT DOCTOR FOR EARLY INTERVENTION IF PATIENT TRIGGERS ONE RED OR TWO YELLOW SCORES AT ANY ONE TIME														
Date :														
Time :														
RESP (write rate in corresp. box)	>30												>30	
	21-30												21-30	
	11-20												11-20	
	0-10												0-10	
Saturations	95-100%												95-100%	
	<95%												<95%	
Administered O ₂ (L/min.)													%	
Temp	39												39	
	38												38	
	37												37	
	36												36	
	35												35	
HEART RATE	170												170	
	160												160	
	150												150	
	140												140	
	130												130	
	120												120	
	110												110	
	100												100	
	90												90	
	80												80	
	70												70	
	60												60	
	50												50	
	40												40	
	SYSTOLIC blood pressure	200												200
190													190	
180													180	
170													170	
160													160	
150													150	
140													140	
130													130	
120													120	
110													110	
100													100	
90													90	
80													80	
70													70	
60													60	
50												50		
DIASTOLIC blood pressure	130												130	
	120												120	
	110												110	
	100												100	
	90												90	
	80												80	
	70												70	
	60												60	
	50												50	
	40												40	
	URINE	passed (Y/N)												passed (Y/N)
		protein ++												protein ++
	Proteinuria	protein > ++												protein > ++
	Amniotic fluid	Clear / Pink												Clear / Pink
		Green												Green
NEURO RESPONSE (✓)	Alert												Alert	
	Voice												Voice	
	Pain												Pain	
	Unresponsive												Unresponsive	
Pain Score (no.)	0-1												0-1	
	2-3												2-3	
Lochia	Normal												Normal	
	Heavy / Fresh / Offensive												Heavy / Fresh / Offensive	
Looks unwell	NO (✓)												YES (✓)	
	YES (✓)												NO (✓)	
Total Yellow Scores														
Total Red Scores														

Requests for copies of the original chart in MS Excel format may be made to Dr Fiona McIlveney at: fiona.mcilveney@hsh.scot.nhs.uk

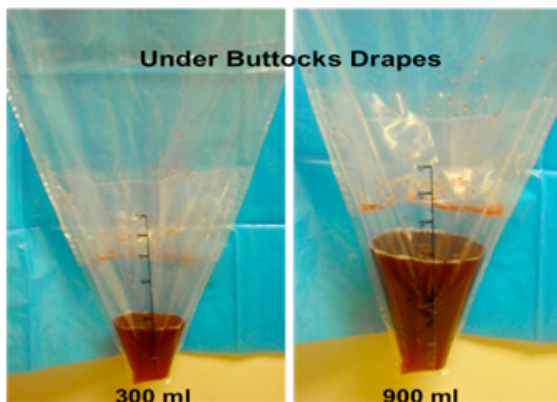
Reference

1. International Journal of Obstetric Anaesthesia (2006) 15, S1-S43 Abstracts of free papers presented at the annual meeting of the Obstetric Anaesthetists' Association, Glasgow 11-12 May, 2006.
"Early-warning scoring in obstetrics". P Harrison, C Hare, F McIlveney. Department of Anaesthesia, Stirling Royal Infirmary, Stirling, UK.

APPENDIX F: TECHNIQUES FOR ONGOING QUANTITATIVE ASSESSMENT OF BLOOD LOSS

Quantify blood loss by measuring

- Used graduated collection containers
- Account for other fluids (amniotic fluid, urine)
- At C/S hold irrigation until after blood loss



Quantify blood loss by weighing

- Establish dry weights of common items
- Standardize use of pads
- Make scales available in rooms
- Build weighing of pads into routine practice
- Build electronic calculator into documentation



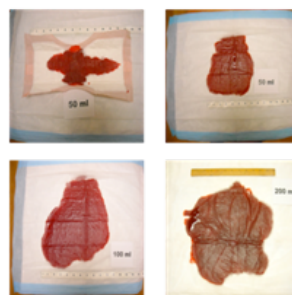
If weights unavailable, then use formal estimation

- Record percent (%) saturation of blood soaked items with the use of visual cues such as pictures/posters to determine blood volume equivalence of saturated/blood soaked pads

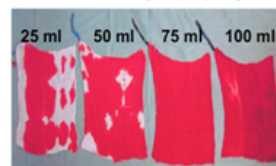
Photos courtesy of Beverly VanderWal and Jennifer McNulty and used with permission.

Training Tools

Posters



18 X 18 inch Dry Lap Sponges



- 25 ml saturates about 50% area
- 50 ml saturates about 75% area
- 75 ml saturates entire surface
- 100 ml will saturate and 170

APPENDIX G: A GUIDE TO RECOGNIZING ACUTE STRESS DISORDER IN POSTPARTUM WOMEN IN THE HOSPITAL SETTING

Michelle Flaum Hall, EdD, LPCC-S, Xavier University

INTRODUCTION

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (APA, 2013) outlines the criteria for Acute Stress Disorder, beginning with the first criterion that a person must be exposed to actual or threatened death or serious injury; for many women, giving birth fits this standard. While some women can experience normal childbirth as traumatic, women who experience birth traumas such as postpartum hemorrhage and other complications are at an even greater risk of having a traumatic stress response following childbirth. In order to give postpartum women the services and support they need, it is imperative that healthcare professionals recognize the signs of Acute Stress Disorder, **note them accurately in the patient's chart**, and enlist the help of a mental health professional immediately. Because women who have experienced birth trauma must temporarily remain in the setting in which the trauma occurred (i.e., the hospital), it is vital that professionals recognize signs of traumatic stress early and provide necessary support.

Signs of Acute Stress Disorder

Symptom	Behavioral Signs	Support Needed
Intrusion Symptoms (Memories, dreams, flashbacks)	A woman can re-experience the birth trauma by having <i>involuntary</i> recurrent images, thoughts, illusions, dreams/nightmares, and/or flashbacks related to the event. Intrusive symptoms can be a cause of sleep difficulty and can exacerbate symptoms of anxiety and depression (such as poor concentration, hypervigilance, exaggerated startle response, and negative mood). Signs can include agitation upon waking and fitful sleep.	Do: If you suspect your patient is experiencing intrusive symptoms, consult with a mental health professional. Ask sensitive, open-ended questions about her current state, such as "I noticed you tossed and turned in your sleep last night. How was your sleep?" Avoid: Being insensitive, dismissive, or judgmental. Do not say things such as "it's over, just don't think about it," or "try to think happy thoughts before you fall asleep."

Symptom	Behavioral Signs	Support Needed
Distress with Exposure to Stimuli	While still in the hospital, a postpartum woman who has experienced birth trauma will be surrounded by stimuli related to the event. Signs of distress can be physical (accelerated heart rate, perspiration) or can manifest as irritability, fear, or unwillingness to comply with requests. Can show an exaggerated startle response to stimuli. Stimuli that can trigger distress include alarms/beeping or other sounds, medical instruments, medical professionals who were present during the trauma, bright lights, smells, and procedures.	<p>Do: Recognize that your patient has experienced a jarring medical event and that it could have been traumatic for her. Many aspects of the hospital environment were present during her traumatic event, and she is still in this environment. Be sensitive and use a warm voice when providing instructions, etc. Do not force any intervention. If patient shows signs of significant distress, contact a mental health professional.</p> <p>Avoid: Forcing any procedure, or saying things like “You just need to comply – it’s for your own (or your baby’s) good.”</p>
Negative Mood	Inability to experience positive emotions. The woman may show little to no joy during time with her baby or family. She may be detached or seem numb to the events happening around her; aloof; withdrawn. Women who have experienced birth trauma can feel a flood of different and sometimes conflicting emotions, including: Fear, sadness, terror, guilt, disappointment, happiness, anger, elation, joy, sorrow, embarrassment, and confusion. She may express these different emotions at times, or be overwhelmed by them and express nothing, seeming numb, cold, or detached.	<p>Do: Gently “check in” with your patient, inquiring about how she is feeling (not only physically, but emotionally). Ask her if she would like to speak to someone about her feelings, and try to normalize this for her (sometimes a woman might refuse because she feels a stigma for talking to a counselor). A woman can benefit from verbalizing her thoughts, feelings, and experiences about the trauma – if she feels safe in doing so.</p> <p>Avoid: Do not say things like: “Cheer up!” “Put on a happy face!” or “You should be glad or grateful that you survived/your baby survived/that the bad part is over.” These only minimize the patient’s feelings, and could shame her into staying silent about her inner experiences.</p>

Symptom	Behavioral Signs	Support Needed
Dissociative Symptoms (altered sense of reality or disturbance in memory)	<p>When dissociation occurs, it can seem like your patient is “out of it” or spacey, dazed, robotic, or confused about basic facts or her surroundings. Sometimes people lose concept of time (which can easily happen in the hospital setting). Some women might speak of an “out-of-body” experience, like floating above one’s own body or seeing the procedures happening to them. When patients experience flashbacks, they may have significant distress after seeing images, reacting as if the event were actually occurring.</p>	<p>Do: Be calm and clear with your communication, and be accurate when entering psychosocial comments in her records. Pay attention to her behaviors and document them appropriately. Dissociative symptoms exist on a continuum: your patient can seem a little dazed, or at the extreme, she can lose complete awareness of her surroundings. It is important to consult with a mental health professional immediately if you see signs of dissociation.</p> <p>Avoid: Minimizing or ignoring these symptoms, or trying to distract your patient from these experience by suggesting she “just watch TV to get her mind off of it.” Do not mistake dissociation for normal, compliant, or agreeable behavior. These are serious symptoms that need to be addressed by a mental health professional.</p>
Avoidance Symptoms (Avoiding distressing memories/thoughts/feelings or external reminders of the event)	<p>Women who have experienced birth trauma may attempt to avoid any memories or discussion about the birth experience, or may try to avoid reminders of the experience. She may refuse certain procedures, parts of the hospital, people who were present during the trauma – and at the extreme – she may want to avoid spending time with the baby.</p>	<p>Do: Be sensitive to your patient’s feelings, recognizing her current context. Stay focused on providing excellent care, and be calm and direct when requesting compliance. While it is important to be supportive, it may also be necessary to challenge your patient to follow her plan of care. You may need to consult with a mental health professional.</p> <p>Avoid: Forcing your patient to comply, or to “face her fears” regarding specific reminders of the trauma. Statements such as “There is nothing to be afraid of!” or “You just have to do it!” are not supportive of your patient.</p>

Symptom	Behavioral Signs	Support Needed
Arousal Symptoms		
Sleep Disturbance	Insomnia is common following a trauma. Signs of high arousal following a birth trauma can include fitful sleep or inability to go to sleep, which can indicate nightmares or an overly-active sympathetic nervous system.	<p>Do: Ask her how she slept, and if she is having any problems with both the amount and the quality of her sleep.</p> <p>Avoid: Assuming that because her eyes are closed, she is asleep. After a birth trauma, your patient may often need to lie quietly with her eyes closed – with little stimulation.</p>
Poor concentration	Because of the intense stimulation and activation of the sympathetic nervous system that occurs during a birth trauma, a woman may have difficulty concentrating on cognitive tasks or stimuli. She may ask you to repeat information or instructions several times or seem aloof with medical professionals or family/friends.	<p>Do: Be patient if you need to repeat information or instructions, recognizing her current emotional state. Ask her if she is having any difficulty concentrating, and if there is anything you can do to help.</p> <p>Avoid: Taking it personally, or getting agitated/impatient if you have to alter your communication to meet her current needs.</p>
Hypervigilance and Exaggerated Startle Response	Because of a birth trauma, a woman can become hypersensitive to stimuli around her. As a result, her behaviors can become exaggerated in an attempt to detect threats in the environment. Her sympathetic nervous system was likely activated for an extended period of time during the trauma, and her instinct is to protect herself at signs of threat. A traumatized individual can react instantly to stimuli that might not bother others, such as sudden noises or movements. Signs of exaggerated startle response include jumping, flinching, shaking, and accelerated heart rate in response to stimuli such as sudden speech or movements by others, noises from hallway, alarms or beeping, and physical connection.	<p>Do: Keep your movements careful. If you notice hypervigilance and an exaggerated startle response in your patient, you should slow down your pace and be mindful of noise, bright lights, and effects of physical touch. Ask her about preferences, and make accommodations if possible. This may include turning down alarms/monitors or dimming the lights. If you notice these symptoms, consult a mental health professional.</p> <p>Avoid: Doing “business as usual” when your patient is clearly negatively impacted by stimulation. Do not make off-hand remarks such as “Wow! Aren’t you jumpy today!” or any other statement that would minimize her current state.</p>

GENERAL SUGGESTIONS

If your patient has experienced a birth trauma, she has been through a difficult, painful, and scary experience. If she experienced a postpartum hemorrhage or other serious complication, she may have felt close to her own death and feared for the wellbeing of her newborn. *While these situations require the help and guidance of a mental health professional*, there are ways that medical professionals can help support the healing of women who have experienced birth traumas.

A few general guidelines include:

- Maintain empathy. Remain cognizant of the your patient's experience and of the many intense emotions she may be feeling;
- Communicate with warmth and patience;
- Stay focused on her treatment. Avoid engaging in sidebar conversations with other staff members;
- Minimize discomforts and harsh stimuli;
- Ask her how she is feeling – *emotionally*. Ask her if she would like to speak with someone; and
- Know the signs of Acute Stress Disorder and enlist the help of a mental health professional.

APPENDIX H : QBL CALCULATOR CESAREAN SECTION

QBL Calculator Cesarean Section

Cannister Volume cc	<input type="text"/>			0
Irrigation cc	<input type="text"/>			0
# of Lap Sleeves	<input type="text"/>	X	25 grams each	0
# of Lap Sponges	<input type="text"/>	X	20 grams each	0
Weight of Lap Sleeves plus Lap Sponges grams	<input type="text"/>			0
Weight of Kidney Basin + Blood grams	<input type="text"/>			0
Weight of Kidney Basin			20 grams	0
# of Blue Chux (30 X 30 cm)	<input type="text"/>	X	35 grams each	0
Weight of Bloody Chux grams	<input type="text"/>			0
Total QBL				0 cc

This is an example of an Excel spreadsheet that can be structured to auto-calculate the quantified blood loss. The spreadsheet will be available as a separate document on the CMQCC website.

This spreadsheet was created by Jennifer McNulty, MD and is used with her permission.

APPENDIX I: ROUTINE TWO STEP QUANTIFICATION OF BLOOD LOSS AT CESAREAN BIRTH

Routine Two Step Quantification of Blood Loss at CS

1 Suctioned blood

- a. Between delivery of infant and placenta;
 - i. OB suctioners drape of amniotic fluid
 - ii. Scrub staff directs Circulator to change suction tubing to second canister
 - iii. May omit switch to new canister if minimal amniotic fluid (patient is post AROM/SROM, in labor)
- b. Circulator records volume in second canister in spreadsheet calculator/EPIC calculator
 - i. Best to record before irrigation used OR
 - ii. If irrigation used and suctioned, Scrub staff communicates amount to Circulator to be subtracted from canister (but may lead to error if not all irrigation re-aspirated)
 - iii. Consider omitting irrigation use during routine cesarean section

2 Lap sponges

- a. During case, bloody lap sponges passed off scrub table by Scrub staff
- b. Circulator places in hanging lap sleeve bags (5 sponges/sleeve)
- c. Circulator weighs bloody sponges and lap sleeve bags *all together* near end of case (sponges left in sleeves)
- d. Total weight, # sponges weighed, # hanging sleeves weighed, entered in spreadsheet calculator/EPIC calculator

3 Spreadsheet calculator/EPIC calculator calculates QBL from entered data

Staff trained to account for other large sources of blood loss if indicated and add to QBL (examples: large amount expressed blood from uterus in emesis basin post op, large floor spill of blood, etc.)

APPENDIX J: QBL CALCULATOR IN EMR DELIVERY SUMMARY

QBL Calculator in EMR Deliver Summary

CESAREAN SECTION BLOOD LOSS	
Cannister Volume (blood volume only)	<input type="text"/>
Total Weight: Laps + Sleeves	<input type="text"/>
Lap Sleeves Used	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/> <input type="text" value="5"/> <input type="text" value="6"/> <input type="text" value="7"/> <input type="text" value="8"/> <input type="text" value="9"/> <input type="text" value="10"/>
# of Laps Used	<input type="text"/>
# of Chux Used	<input type="text"/>
Additional Source of Blood Loss Volume	<input type="text"/>
Add "Total Blood Loss Calculated" below to "Total Delivery Blood Loss" section (for I&O)	
TOTAL BLOOD LOSS CALCULATED	<input type="text" value="0"/>
VAGINAL DELIVERY BLOOD LOSS	
Method Of Quantification	<input type="button" value="EBL - Visual estimate only"/> <input type="button" value="QBL - Direct measure"/> <input type="button" value="QBL - Weight of blood soaked items"/>
TOTAL DELIVERY BLOOD LOSS (Vaginal or C/S)	
EBL/QBL During Delivery (mL)	<input type="text"/>

SLIDASET FOR PROFESSIONAL EDUCATION

Planning for and Responding to Obstetric Hemorrhage

**California Maternal Quality Care Collaborative
Obstetric Hemorrhage Version 2.0 Task Force**

This project was supported by Title V funds received from the California Department of Public Health; Maternal, Child and Adolescent Health Division

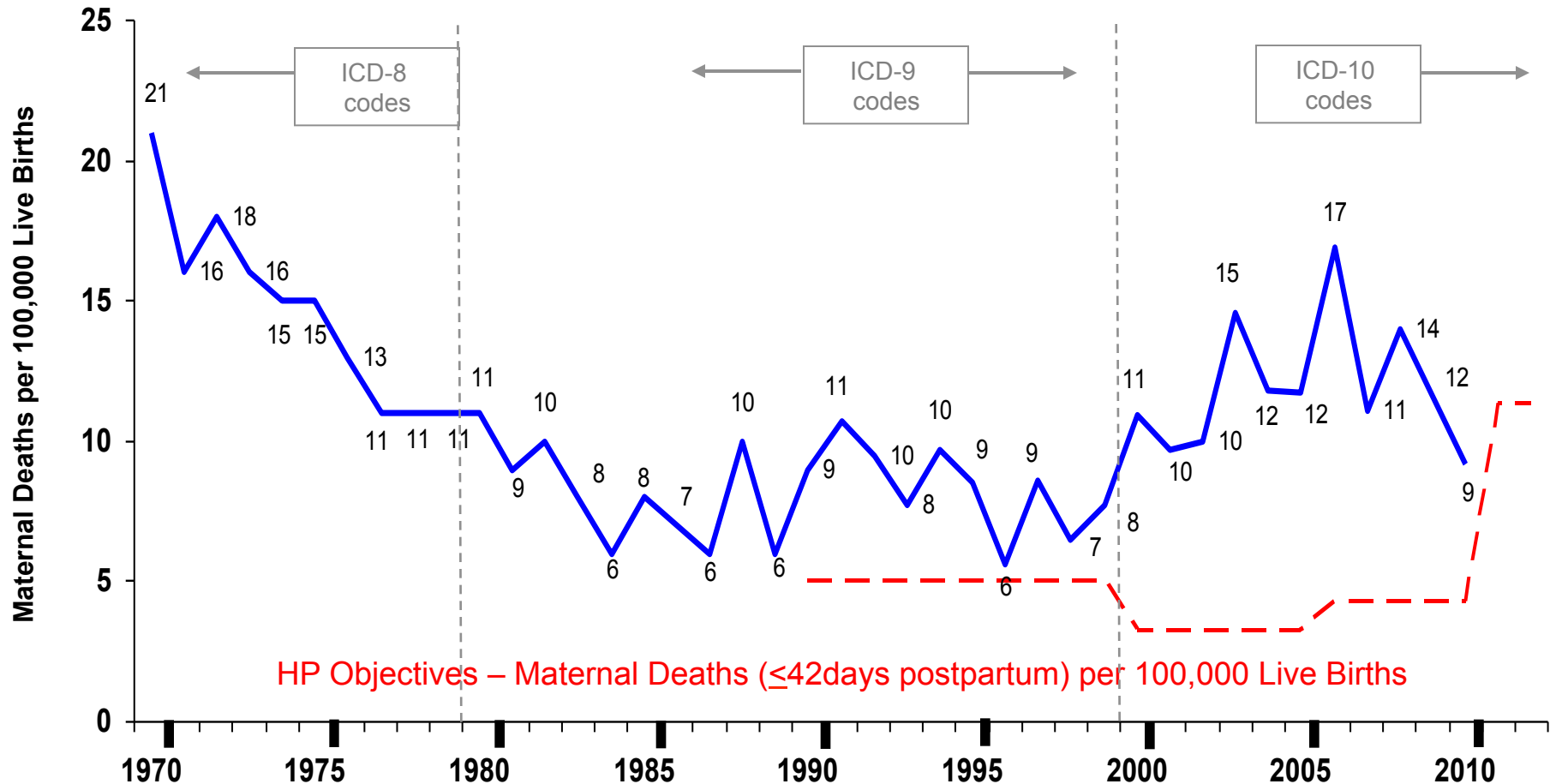


Instructions

- Please use the CMQCC template for any slide you use from the slide deck
- Please do not use the CMQCC or CDPH logos if you modify a slide – feel free to use your own logo in these situations
- If you add sides to the slide set please do not use the CMQCC or CDPH logos
- Slide set may be used as individual slides or in their entirety for educational purposes as long as credit is given to CDPH, CMQCC and the Hemorrhage Task Force.
- Please provide us feedback and recommendations for improving the slide set

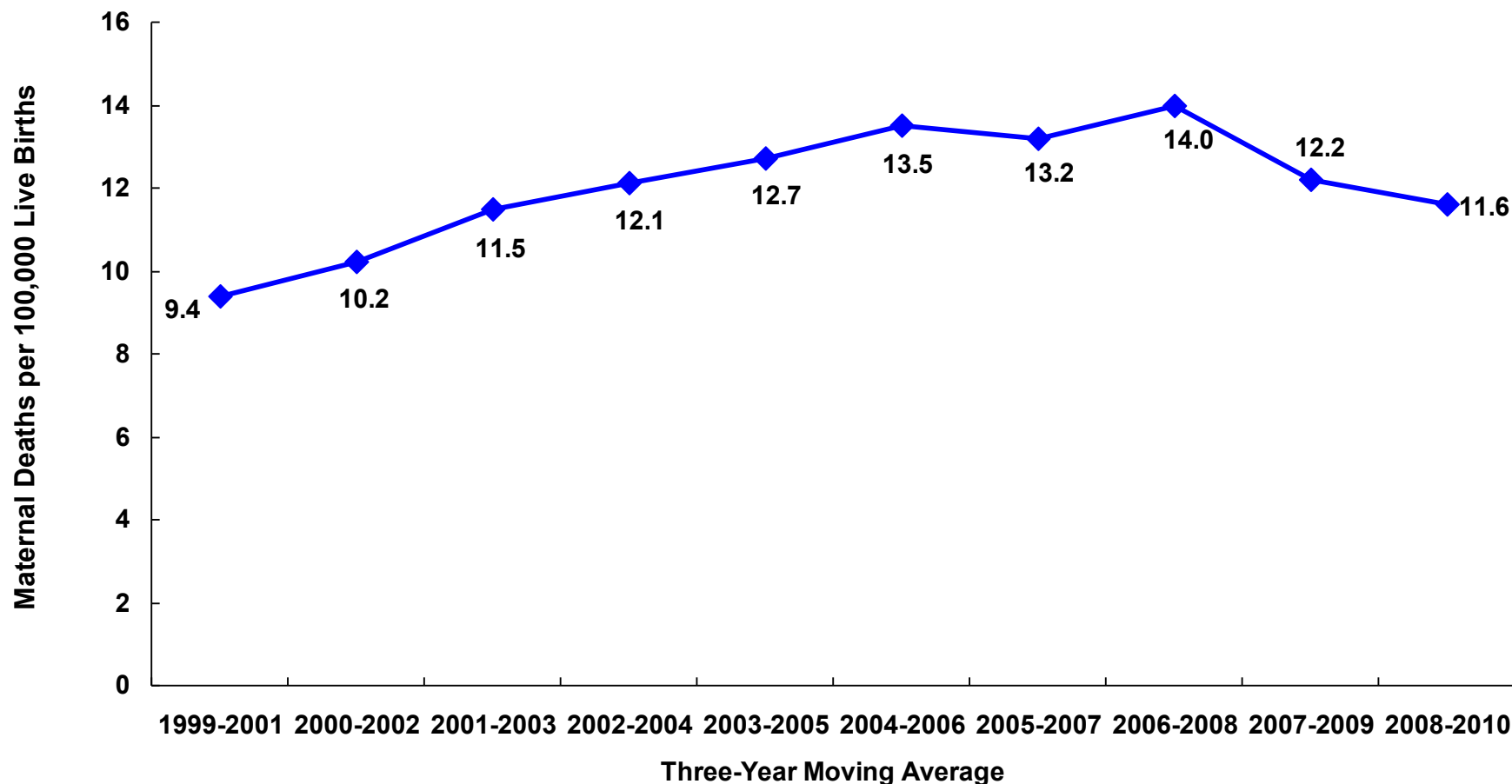


Maternal Mortality Rate, California Residents; 1970-2010



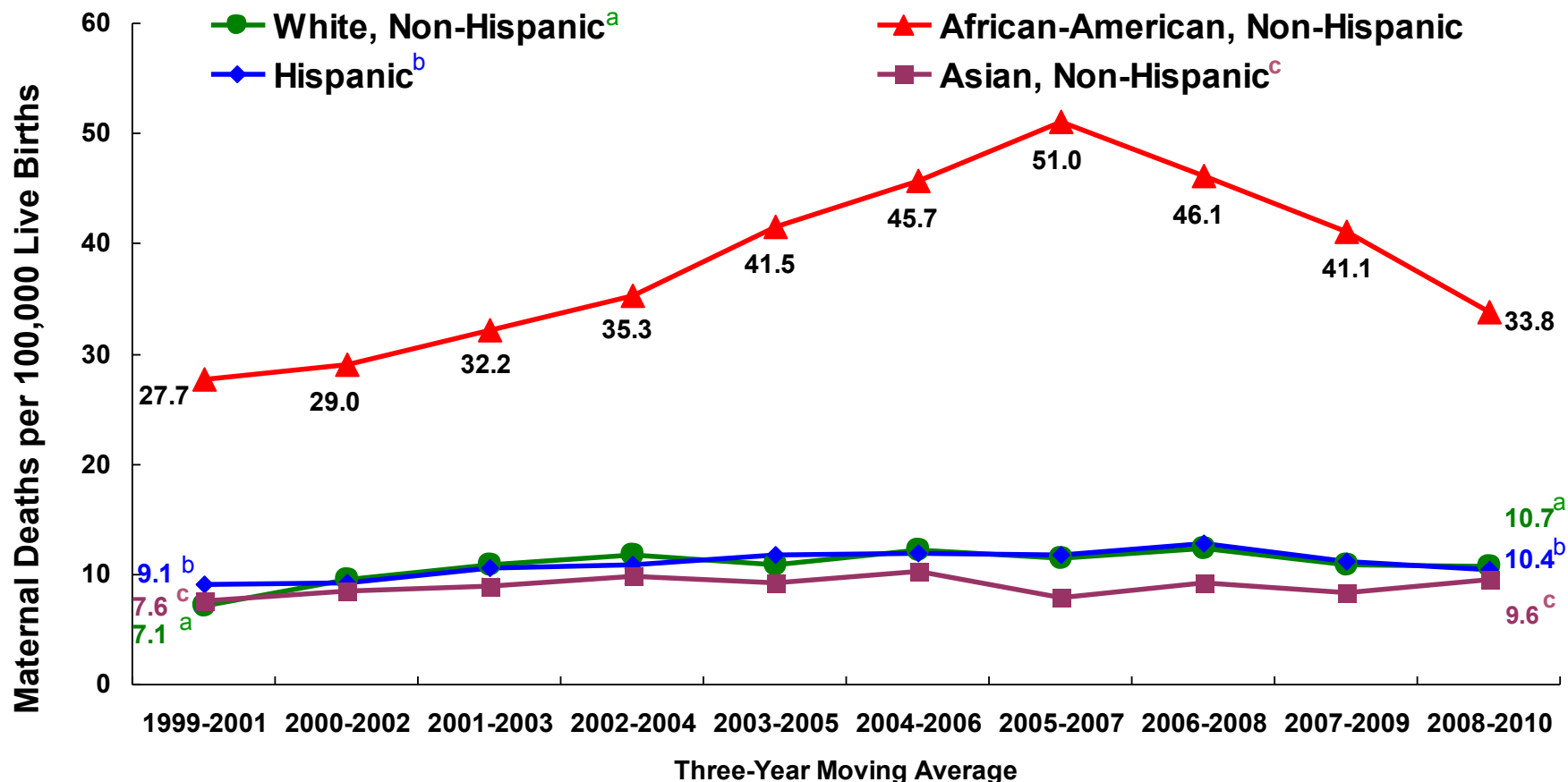
SOURCE: State of California, Department of Public Health, California Birth and Death Statistical Master Files, 1970-2010. Maternal mortality for California (deaths ≤ 42 days postpartum) was calculated using the ICD-8 cause of death classification for 1970-1978, ICD-9 classification for 1979-1998 and ICD-10 classification for 1999-2010. Healthy People Objectives: HP2000: 5.0 deaths per 100,000 live births; HP2010: 3.3 deaths, later revised to 4.3 deaths per 100,000 live births, and; HP2020: 11.4 deaths per 100,000 live births. Produced by California Department of Public Health, Center for Family Health, Maternal, Child and Adolescent Health Division, December, 2012.

Maternal Mortality Rates, Moving Average, California Residents; 1999-2010



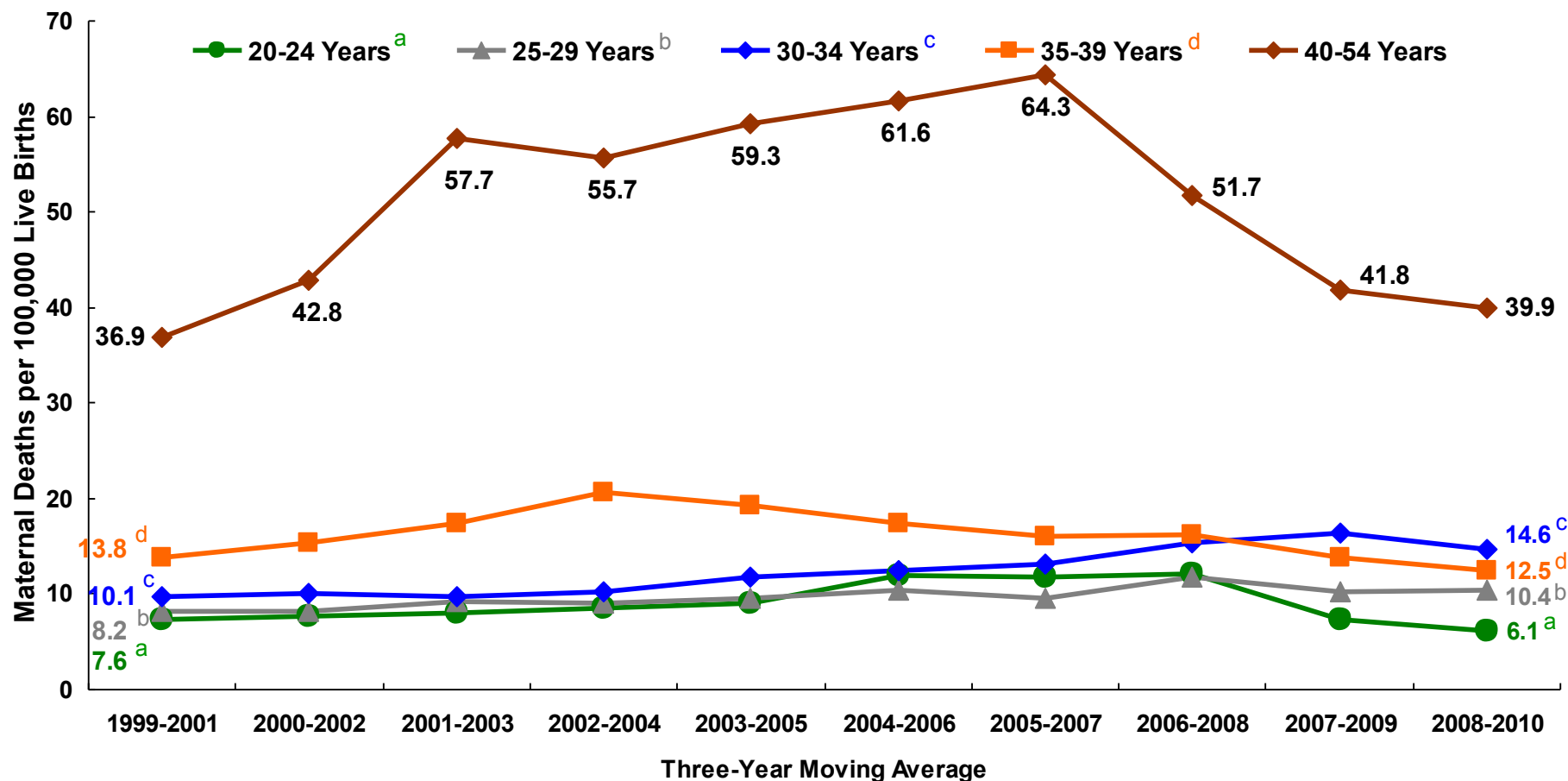
SOURCE: State of California, Department of Public Health, California Birth and Death Statistical Master Files, 1999-2010. Maternal mortality for California (deaths \leq 42 days postpartum) was calculated using ICD-10 cause of death classification (codes A34, O00-O95, O98-O99) for 1999-2010. On average, the mortality rate increased by 2% each year [(95% CI: 1.0%, 4.2%) $p=0.06$. Poisson regression] for a statistically significant increasing trend from 1999-2010 ($p=0.001$ one-sided Cochran-Armitage, based on individual year data). Produced by California Department of Public Health, Center for Family Health, Maternal, Child and Adolescent Health Division, December, 2012.

Maternal Mortality Rates by Race/Ethnicity, California Residents; 1999-2010



SOURCE: State of California, Department of Public Health, California Birth and Death Statistical Master Files, 1999-2010. Maternal mortality rates for California (deaths ≤ 42 days postpartum) were calculated using the ICD-10 codes for 1999 to 2010. Produced by California Department of Public Health, Center for Family Health, Maternal, Child and Adolescent Health Division, December, 2012.

Maternal Mortality Rates by Age Group, California Residents; 1999-2010



SOURCE: State of California, Department of Public Health, California Birth and Death Statistical Master Files, 1999-2010. Beginning in 1999, maternal mortality for California (deaths \leq 42 days postpartum) was calculated using ICD-10 cause of death classification (codes A34, O00-O95, O98-O99). Produced by California Department of Public Health, Center for Family Health, Maternal, Child and Adolescent Health Division, December, 2012.

National Partnership for Maternal Safety: “Three Bundles, Three Years”

- Multi-stakeholder effort built on consensus
 - Organizations representing public health, clinician providers, facilities, and safety and regulatory interests
 - www.safehealthcareforeverywoman.org
- Safety bundles at all birth facilities
 - Hemorrhage
 - Preeclampsia
 - Venous thromboembolism

Obstetric Hemorrhage Safety Bundle

- Readiness
- Recognition
- Response
- Reporting /
Systems Learning



Photo courtesy of David Lagrew,
MD and used with permission

Obstetric Hemorrhage Safety Bundle

Readiness: (every unit)

- Hemorrhage Cart / with Procedural Instructions (balloons, compression stiches)
- Rapid access to hemorrhage medications (kit or equivalent)
- Establish a response team: multiple partnerships // unit education, drills, debriefs
- Establish MTP and O-neg/uncrossmatched transfusion protocols

Recognition: (every patient)

- Assessment of hemorrhage risk (prenatal, on admission, ongoing in labor & PP)
- Measurement of CUMMULATIVE blood loss
- Active Management of 3rd Stage (oxytocin after birth)



Obstetric Hemorrhage Safety Bundle

Response: (every hemorrhage)

- Unit-standard, stage-based OB Hemorrhage Emergency Management Plan with checklist
- Support program for patients, families and staff

Reporting / Systems Learning: (every unit)

- Establish a culture of Huddles for high-risk patients and post-event debriefings
- Review all stage 3 hemorrhages for systems issues
- Monitor outcome and process metrics in perinatal QI committee



Why do we need this Toolkit?

- Incidence of obstetric hemorrhage is increasing
- Hemorrhage deaths reviewed generally have high “preventability” assessment
- Reviews indicate breakdowns at multiple points at least somewhat under our control: provider & facilities issues (vs. patient characteristics)

North Carolina: Mortality Mostly Preventable

Cause of Death (n=108)	% of All Deaths	% Preventable
Cardiomyopathy	21%	22%
Hemorrhage	14	93
PIH	10	60
CVA	9	0
Chronic condition	9	89
AFE	7	0
Infection	7	43
Pulmonary embolism	6	17

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



CA-PAMR Pregnancy-Related Deaths, Chance to Alter Outcome by Grouped Cause of Death; 2002-2004 (N=143)

Clinical Cause of Death	Chance to Alter Outcome (%)			
	Strong/Good	Some	None	Total N (%)
Obstetric hemorrhage	69	25	6	16 (11)
Deep vein thrombosis/ pulmonary embolism	53	40	7	15 (10)
Sepsis/infection	50	40	10	10 (7)
Preeclampsia/eclampsia*	50	50	0	24 (17)
Cardiomyopathy and other cardiovascular causes*	25	61	14	28 (19)
Cerebral vascular accident	22	0	78	9 (6)
Amniotic fluid embolism	0	87	13	15 (10)
All other causes of death	46	46	8	26 (18)
Total (%)	40	48	13	143*

* Two deaths lacked sufficient records to make determination (one from each cause of death).

INTERPRETATION:

The CA-PAMR Committee judged that there was a strong-to-good chance to have altered the fatal outcome in 40% of the pregnancy-related deaths in California in 2002 to 2004. Some pregnancy-related deaths may have had a better chance of being prevented, for example deaths from obstetric hemorrhage, compared to others, such as amniotic fluid embolism.

SOURCE:

The California Pregnancy-Associated Mortality Review, April 2012. © California Department of Public Health, Center for Family Health, Maternal, Child and Adolescent Health Division.

CA-PAMR: California Pregnancy Associated Mortality Review Advisory Committee



- ***Honoring Women's Lives***
- ***Honoring the Teams Caring for Women***
- ***Extracting Actionable Lessons***

Methodology:

Mitchell, C., Lawton, E., Morton, C., McCain, C., Holtby, S., & Main, E. (2013). California Pregnancy-Associated Mortality Review: Mixed Methods Approach for Improved Case Identification, Cause of Death Analyses and Translation of Findings. *Maternal Child Health Journal*. doi: 10.1007/s10995-013-1267-0

Composite Case: 24 y/o woman, G2 P1 at 38 wks gestation induced for “tired of being pregnant”

1. After 8 hr active phase and 2 hr 2nd stage, had a NSVD of an 8 lb. 6 oz. infant.
2. After placental delivery she had an episode of atony that firmed with massage. A second episode responded to IM methergine and the physician went home (now 1 am).
3. The nurses called the physician 30 min later to report more bleeding and further methergine was ordered.
4. 60 min after the call, the physician performed a D&C with minimal return of tissue. More methergine was given.

Composite Case: 24 y/o woman, G2 P1 at 38 wks gestation induced for “tired of being pregnant”

5. 45 min later a second D&C was performed, again with minimal returns. EBL now > 2,000.
6. Delays in blood transfusion because of inability to find proper tubing.
7. Anesthesia is delayed, but a second IV started for more crystalloid. VS now markedly abnormal, P=144, BP 80/30.
8. One further methergine given and patient taken for a 3rd D&C. Now she has received 2u PRBCs.
9. After completion, she had a cardiac arrest from hypovolemia /hypoxia and was taken to the ICU when she succumbed 3 hours later.

Another proto-typical case

G3P1, post dates induction: cervidil and oxytocin

Vacuum-assisted birth with immediate hemorrhage

1. Treatment within 20 minutes of delivery: improvement
Massage, Methergine, Hemabate, Curettage
2. OB leaves hospital
3. OB returns (35 minutes later) after continued bleeding and hypotension
Above steps repeated twice, plus packing
4. Delay in getting and administering blood and higher level medical attention
5. Patient codes
6. First unit of PRBC given **2½ hours** after hemorrhage starts
7. Multiple organ failure, anoxic brain injury, death 14 days PP

Key 2008 CMQCC Hemorrhage Task Force Survey Findings

- 40% of hospitals did not have a hemorrhage protocol
- Inconsistent definitions of hemorrhage were used among responding hospitals
- 70% of hospitals were not performing drills
 - MDs were not regularly participating in drills in hospitals that were doing them
- Most had access to all 4 uterotonics
- Many hospital reported they did not have access to alternative treatment methods, e.g., Balloons

Note: 173 hospitals responded to the first baseline survey. The response rate is 66.3% based on 173/261 hospitals (2008) with annual delivery volume > 50 births.



Quality Improvement Opportunities Identified through CA-PAMR & CMQCC HTF

- Reduce risks of hemorrhage
- Perform admission risk assessments
- Reduce Denial, Delay...
- Quantify blood loss
- Follow a step-by-step plan
- Increase use of non-pharmacologic treatments
- Improve treatments with blood products
 - “Too little, too late”—Resuscitation v. Treatment
 - “Old wine in new bottles”—“Whole blood” vs. PRBCs
- Enhance Teamwork and Communications!



Summary of Recommendations

- Quantification of blood loss for all
- Active management of the 3rd stage for all
- Vital sign triggers
- “Move along” on uterotonic medications
- Intrauterine balloon/B-Lynch suture
- A new approach to blood products
- The value of a formal protocol
- Toolkit at www.cmqcc.org/ob_hemorrhage

Hemorrhage: How Much is too Much?

- > 500 mL for vaginal delivery and > 750 mL for C/S
 - BUT 500 mL for NSVD is the **average**
 - 750 mL for C/S is **average**
 - And for most women well tolerated
- WHO defines
 - EBL of > 500 mL an “alert line”
 - > 1000 mL an “action line”
- ACOG (reVITALize)
 - Cumulative EBL > 1,000 mL for either vaginal or cesarean birth with enhanced surveillance and early interventions, as needed, for 500-1000 mL
- 4-5% of women > 1000 mL - A clinically significant amount!!

**1/3 of women
with > 1000 ml
NO risk factors**



Maternal Physiology: Cool Facts

- Blood volume
 - 60 kg gravid women about 6 L by 30 weeks
- Uterus weight
 - Pre pregnancy: 40 – 70 grams
 - Third trimester: 1,200 grams
- Uterine cavity capacity
 - Pre pregnancy: 10 mL
 - Third trimester: 5,000 mL
- **Blood Flow**
 - **Pre pregnancy: 2% cardiac output**
 - **Third trimester: 17% cardiac output: 600 – 800 mL/min**



Trauma Assessment of Blood Loss

Class	Blood Loss Volume	Total Deficit	Signs/Symptoms
I	<1000 mL	15%	Orthostatic Tachycardia
II	<1500 mL	15-25%	Resting tachycardia, orthostatic hypotension
III	<2,500 mL	25-40%	Resting hypotension, oliguria
IV	>2,500 mL	>40%	Obtunded, Cardiovascular collapse

Design Goals for Quality Improvement

- Make it easy to do the right thing
- Hardwire changes into routine practice:
 - Education, training, order sets, protocols, the environment
- All improvement is change, not all change is improvement.
- We must know the difference:
 - Build measurement into the process

Lessons from the Field

- **It takes a broad team**
- Easy wins matter
- Goals and timelines are very useful
- It takes time and persistence to get the systems running smoothly
- **Must have champions**

Disciplines & Departments	Needed?
Obstetrics	
Nursing	
Anesthesia	
Blood Bank	
Laboratory	
Operating Room	
Support personnel	
IT/EMR	
Others unique to your setting?	

Obstetric Hemorrhage Safety Bundle

Readiness: (every unit)

- Hemorrhage Cart / with Procedural Instructions (balloons, compression stiches)
- Rapid access to hemorrhage medications (kit or equivalent)
- Establish a response team: multiple partnerships // unit education, drills, debriefs
- Establish MTP and O-neg/uncrossmatched transfusion protocols

Recognition: (every patient)

- Assessment of hemorrhage risk (prenatal, on admission, ongoing in labor & PP)
- Measurement of CUMMULATIVE blood loss
- Active Management of 3rd Stage (oxytocin after birth)

Response: (every hemorrhage)

- Unit-standard, stage-based OB Hemorrhage Emergency Management Plan w/ checklist
- Support program for patients, families and staff

Reporting / Systems Learning: (every unit)

- Establish a culture of Huddles for high-risk patients and post-event debriefings
- Review all stage 3 hemorrhages for systems issues
- Monitor outcome and process metrics in perinatal QI committee



Selected Areas of Initial Focus for Hemorrhage Protocol

■ ***Likely* Easy Wins**

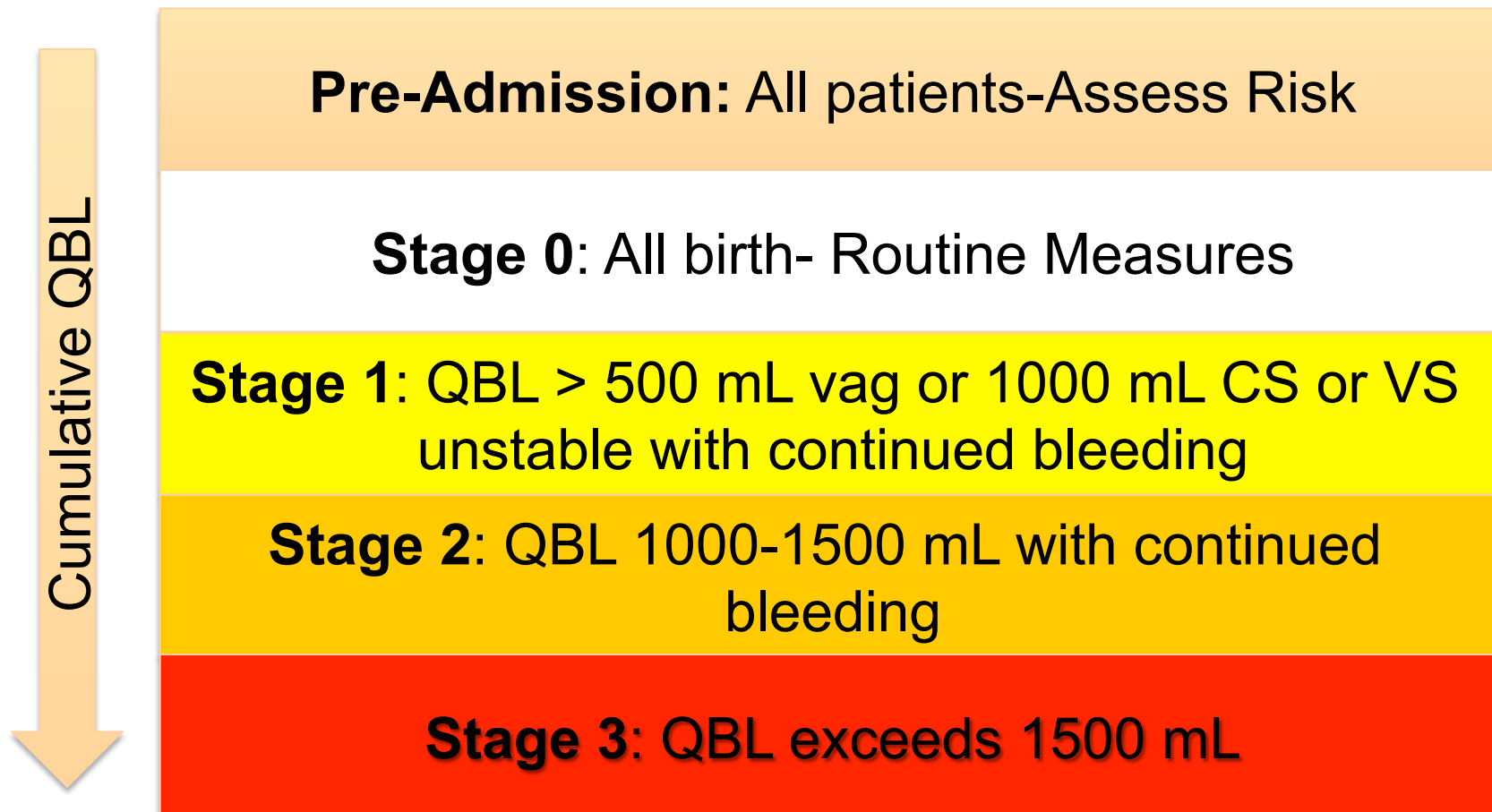
- ☐ Hemorrhage carts
- ☐ Active management (oxytocin at birth)

■ **Essential Elements, may take more time**

- ☐ Risk assessment
- ☐ Massive transfusion protocols
- ☐ Other overall protocol details (e.g. 2nd line meds)
- ☐ Replace EBL with QBL processes



Hemorrhage Guidelines: Staged Responses



CMQCC OB Hemorrhage Emergency Management Plan

CMQCC

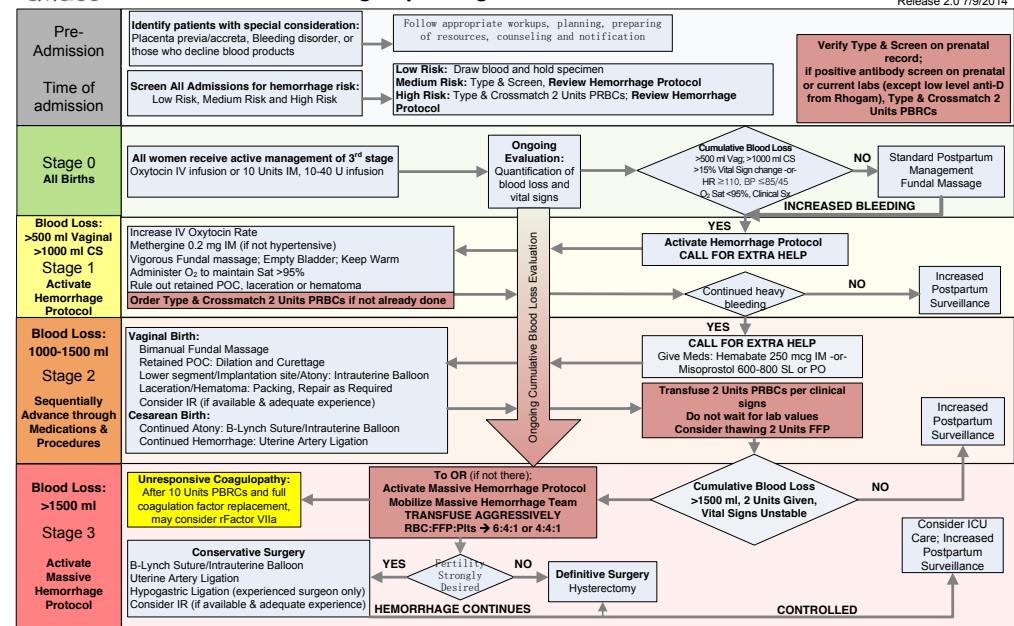
Obstetric Hemorrhage Emergency Management Plan: Table Chart Format
version 2.0

	Assessments	Meds/Procedures	Blood Bank
Stage 0	Every woman in labor/giving birth		
Stage 0 focuses on risk assessment and active management of the third stage.	<ul style="list-style-type: none"> Assess every woman for risk factors for hemorrhage Measure cumulative quantitative blood loss on every birth 	Active Management 3rd Stage: <ul style="list-style-type: none"> Oxytocin IV infusion or 10u IM Fundal Massage-vigorous, 15 seconds min. 	<ul style="list-style-type: none"> If Medium Risk: T & Scr If High Risk: T&C 2 U If Positive Antibody Screen (prenatal or current, exclude low level anti-D from RhoGam): T&C 2 U
Stage 1	Blood loss: > 500ml vaginal or >1000 ml Cesarean, or VS changes (by >15% or HR \geq 110, BP \leq 85/45, O2 sat <95%)		
Stage 1 is short: activate hemorrhage protocol, initiate preparations and give Methergine IM.	<ul style="list-style-type: none"> Activate OB Hemorrhage Protocol and Checklist Notify Charge nurse, OB/CNM, Anesthesia VS, O2 Sat q5' Record cumulative blood loss q5-15' Weigh bloody materials Careful inspection with good exposure of vaginal walls, cervix, uterine cavity, placenta 	<ul style="list-style-type: none"> IV Access: at least 18gauge Increase IV fluid (LR) and Oxytocin rate, and repeat fundal massage Methergine 0.2mg IM (if not hypertensive) May repeat if good response to first dose, BUT otherwise move on to 2nd level uterine drug (see below) Empty bladder: straight cath or place Foley with urimeter 	<ul style="list-style-type: none"> T&C 2 Units PRBCs (if not already done)
Stage 2	Continued bleeding with total blood loss under 1500ml		
Stage 2 is focused on sequentially advancing through medications and procedures, mobilizing help and Blood Bank support, and keeping ahead with volume and blood products.	<ul style="list-style-type: none"> OB back to bedside (if not already there) Extra help: 2nd OB, Rapid Response Team (per hospital), assign roles VS & cumulative blood loss q 5-10 min Weigh bloody materials Complete evaluation of vaginal wall, cervix, placenta, uterine cavity Send additional labs, including DIC panel If in Postpartum: Move to L&D/OR Evaluate for special cases: <ul style="list-style-type: none"> Uterine Inversion Amn. Fluid Embolism 	2nd Level Uterotonic Drugs: <ul style="list-style-type: none"> Hemabate 250 mcg IM or Misoprostol 800 mcg SL 2nd IV Access (at least 18gauge) Bimanual massage Vaginal Birth: (typical order) <ul style="list-style-type: none"> Move to OR Repair any tears D&C: r/o retained placenta Place intrauterine balloon Selective Embolization (Interventional Radiology) Cesarean Birth: (still intra-op) (typical order) <ul style="list-style-type: none"> Inspect broad lig, posterior uterus and retained placenta B-Lynch Suture Place intrauterine balloon 	<ul style="list-style-type: none"> Notify Blood Bank of OB Hemorrhage Bring 2 Units PRBCs to bedside, transfuse per clinical signs – do not wait for lab values Use blood warmer for transfusion Consider thawing 2 FFP (takes 35+min), use if transfusing > 2u PRBCs Determine availability of additional RBCs and other Coag products
Stage 3	Total blood loss over 1500ml, or >2 units PRBCs given or VS unstable or suspicion of DIC		
Stage 3 is focused on the Massive Transfusion protocol and invasive surgical approaches for control of bleeding.	<ul style="list-style-type: none"> Mobilize team <ul style="list-style-type: none"> Advanced GYN surgeon 2nd Anesthesia Provider OR staff Adult Intensivist Repeat labs including coags and ABG's Central line Social Worker/ family support 	<ul style="list-style-type: none"> Activate Massive Hemorrhage Protocol Laparotomy: <ul style="list-style-type: none"> B-Lynch Suture Uterine Artery Ligation Hysterectomy Patient support <ul style="list-style-type: none"> Fluid warmer Upper body warming device Sequential compression stockings 	Transfuse Aggressively Massive Hemorrhage Pack <ul style="list-style-type: none"> Near 1:1 PRBC:FFP 1 PLT apheresis pack per 4-6 units PRBCs Unresponsive Coagulopathy: <ul style="list-style-type: none"> After 8-10 units PRBCs and full coagulation factor replacement: may consult re Factor VIIa risk/benefit

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Obstetric Emergency Management Plan: Flow Chart Format

Release 2.0 7/9/2014



California Maternal Quality Care Collaborative (CMQCC), Hemorrhage Taskforce (2009) visit: www.CMQCC.org for details
This project was supported by funds received from the State of California Department of Public Health, Center for Family Health, Maternal, Child and Adolescent Health Division

Every hospital will need to customize the
protocol—but the point is every hospital
needs one



California OB Hemorrhage Guidelines

■ Stage 0 (BE PREPARED)

- Risk assessment on admission
- Active management 3rd stage of labor
- Antepartum care and counseling
 - Previa, accreta, Jehovah's witness, iron deficiency anemia
- Appropriate blood bank specimens on admission
- **Quantify** blood loss for all births



Admission Risk Assessment & Testing

Low (Clot only)	Medium (Type and Screen)	High (Type & Crossmatch)
No previous uterine incision	Prior cesarean birth(s) or uterine surgery	Placenta previa, low lying placenta
Singleton pregnancy	Multiple gestation	Suspected placenta accreta, percreta, increta
≤4 previous vaginal births	>4 previous vaginal births	Hematocrit <30 <u>AND</u> other risk factors
No known bleeding disorder	Chorioamnionitis	Platelets <100,000
No history of PPH	History of previous PPH	Active bleeding (greater than show) on admit
	Large uterine fibroids	Known coagulopathy
Pre-transfusion testing strategy should be standardized to facility conditions depending on blood bank resources, speed of testing, and availability of blood products.		

Ongoing Risk Assessment: At least q shift and at every handoff

During Labor

- Prolonged second stage
- Prolonged oxytocin use
- Active bleeding
- Chorioamnionitis
- Magnesium Sulfate treatment

Birth/Postpartum

- Vacuum- or forceps-assisted birth
- Cesarean birth (especially urgent/emergent cesarean)
- Retained placenta

Current Controversies: Active Management of Third Stage (AMTSL)

- Benefits vs. potential harms – are there unintended consequences?
- Appropriate candidates – do low-risk women benefit?
- Cord clamping – what about delayed clamping?
- Component elements – which aspects are effective?

Cochrane Review: AMTSL (2011)

- 7 studies, 8,247 women
- 6 high-income countries, 1 low-income
- 4 studies active vs. expectant
- 3 studies active vs “mixture of managements”
- Primary outcomes:
 - PPH >1000 mL; PPH >2500 mL; maternal death
 - Maternal Hb 9 g/dL 24-72 hours postpartum
- All sample sizes substantially smaller than optimal information size

AMTSL: Cochrane Review Conclusions

- Active management reduced risk of bleeding, but could be due to consistent uterotonics usage
- Increased rates of HTN, return to hospital for bleeding in active management group
- Possible decrease in average blood volume of newborns in active management group
- No difference in rate of severe bleeding in low-risk women
- GRADE scores for primary outcomes low

Additional new studies support these conclusions (e.g. Sheldon et al 2013 and the TRACOR trial)

Task Force Conclusions

- We previously recommended a package of interventions:
 - Oxytocin infusion, cord clamping and cutting, controlled cord traction, and vigorous fundal massage, commonly referred to as active management of the third stage of labor
- New data and recent systematic reviews
 - Identified significant risk of bias in previous studies and
 - Called the efficacy of various components of AMTSL into question

Task Force Conclusions

- Studies evaluating the individual components
 - Confirmed only **oxytocin administration** as effective
 - Particularly in high resource settings and in low risk women
- Delayed cord clamping does not increase the risk for hemorrhage
 - **AMTSL should not interfere** with the practice of delayed cord clamping for newborn benefit

Medication Recommendations 2.0

Prevention	Treatment
<p>Oxytocin or 10-40 international units/500-1000 mL IV infusion titrated to uterine tone</p> <p>OR</p> <p>Oxytocin 10 units IM when no IV access</p>	<p>Rapid infusion of IV oxytocin 10-40 IU/500-1000 mL at ≥ 500 mL/hour, titrated to response</p>
	<p><u>Choose a standard second line agent</u></p> <p>Methergine 0.2 mg IM</p> <p>Misoprostol 600 mcg orally or 800 mcg sublingually</p> <p>Hemabate 250 mcg IM or intramyometrially</p>

California OB Hemorrhage Guidelines

- **Stage 1:** EBL > 500 mL (vaginal) or > 1000 mL (C/S) or HR > 110, BP <85/45, O2 sat <95%; **AND STILL BLEEDING**
 - Activate hemorrhage protocol and check list
 - Find cause
 - Use a **standard** second line medication for atony
 - Initiate preparations
 - Get help: BUT primary RN STAY AT BEDSIDE
 - IV 16 gauge and baseline labs
 - Foley with urimeter
 - Blood bank: T and C 2 units
 - Quantify blood loss



Hemorrhage Medication Kits

OB Hemorrhage Cart: L&D and Postpartum

Labor and Delivery Emergency Hysterectomy

Tray for L&D OR Suite

Suggested medication and instrument lists available in
the CMQCC OB Hemorrhage Toolkit

Example OB Hemorrhage Cart

- Quick access to emergency supplies
- Refrigerator for meds
- Establish necessary items and par levels
- Label drawers/ compartments
- Include checklists
- Develop process for checking and restocking
- Educate nursing and physician staff



Example Obstetric Hemorrhage Cart:

Operating Room

- **IV start**
 - 16 gauge angiocaths
 - Blood draw tubes
 - Red top, blue top, tiger top
- IV pressure bags
- Foley with urimeter
- Sutures for B-lynch and modified B-lynch techniques
 - #1 Vicryl, standard x 2
 - #1 Monocryl, 36" long on curved 90 mm blunt needle
- **Laminated 8 x 11" diagram**
 - B-Lynch technique
 - Modified B-Lynch technique
- Hunter's curette
- Right angle retractors
- Eastman vaginal retractors
- Ring forceps x 4
- Short Allis tissue forceps x 2
- Bakri balloon
 - 500 cc fluid for filling
 - Bag for drainage collection
- Kerlex roll
- Vaginal pack



STAGE 2: OB Hemorrhage

Continued bleeding or Vital Sign instability, and < 1500 mL cumulative blood loss

MOBILIZE	ACT	THINK
<p>Primary nurse (or charge nurse):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Call obstetrician or midwife to bedside <input type="checkbox"/> Call Anesthesiologist <input type="checkbox"/> Activate Response Team: PHONE #: _____ <input type="checkbox"/> Notify Blood bank of hemorrhage; order products as directed <p>Charge nurse:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Notify Perinatologist or 2nd OB <input type="checkbox"/> Bring hemorrhage cart to the patient's location <input type="checkbox"/> Initiate OB Hemorrhage Record <input type="checkbox"/> If considering selective embolization, call-in Interventional Radiology Team and second anesthesiologist <input type="checkbox"/> Notify nursing supervisor <input type="checkbox"/> Assign single person to communicate with blood bank <input type="checkbox"/> Assign second attending or clinical nurse specialist as family support person or call medical social worker 	<p>Team leader (OB physician or midwife):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Additional uterotonic medication: Hemabate 250 mcg IM [if not contraindicated] OR Misoprostol 800 mcg SL <ul style="list-style-type: none"> o Can repeat Hemabate up to 3 times every 20 min; (note-75% respond to first dose) <input type="checkbox"/> Continue IV oxytocin and provide additional IV crystalloid solution <p>Do not delay other interventions (see right column) while waiting for response to medications</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bimanual uterine massage <input type="checkbox"/> Move to OR (if on postpartum unit, move to L&D or OR) <input type="checkbox"/> Order 2 units PRBCs and bring to the bedside <input type="checkbox"/> Order labs STAT (CBC/Plts, Chem 12 panel, Coag Panel II, ABG) <input type="checkbox"/> Transfuse PRBCs based on clinical signs and response, do not wait for lab results; consider emergency O-negative transfusion <p>Primary nurse (or designee):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Establish 2nd large bore IV, at least 18 gauge <input type="checkbox"/> Assess and announce Vital Signs and cumulative blood loss q 5-10 minutes <input type="checkbox"/> Set up blood administration set and blood warmer for transfusion <input type="checkbox"/> Administer meds, blood products and draw labs, as ordered <input type="checkbox"/> Keep patient warm <p>Second nurse (or charge nurse):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Place Foley with urimeter (if not already done) <input type="checkbox"/> Obtain portable light and OB procedure tray or Hemorrhage cart <input type="checkbox"/> Obtain blood products from the Blood Bank (or send designee) <input type="checkbox"/> Assist with move to OR (if indicated) <p>Blood Bank:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Determine availability of thawed plasma, fresh frozen plasma, and platelets; initiate delivery of platelets if not present on-site <input type="checkbox"/> Consider thawing 2-4 FFP (takes 30 min), use if transfusing > 2 units PRBCs <input type="checkbox"/> Prepare for possibility of massive hemorrhage 	<p>Sequentially advance through procedures and other interventions based on etiology:</p> <p>Vaginal birth If trauma (vaginal, cervical or uterine):</p> <ul style="list-style-type: none"> • Visualize and repair <p>If retained placenta:</p> <ul style="list-style-type: none"> • D&C <p>If uterine atony or lower uterine segment bleeding:</p> <ul style="list-style-type: none"> • Intrauterine Balloon <p>If above measures unproductive:</p> <ul style="list-style-type: none"> • Selective embolization (Interventional Radiology if available & adequate experience) <p>C-section:</p> <ul style="list-style-type: none"> • B-Lynch Suture • Intrauterine Balloon <p>If Uterine Inversion:</p> <ul style="list-style-type: none"> • Anesthesia and uterine relaxation drugs for manual reduction <p>If Amniotic Fluid Embolism:</p> <ul style="list-style-type: none"> • Maximally aggressive respiratory, vasopressor and blood product support <p>If vital signs are worse than estimated or measured blood loss: possible uterine rupture or broad ligament tear with internal bleeding; move to laparotomy</p> <p>Once stabilized: Modified Postpartum management with increased surveillance</p>

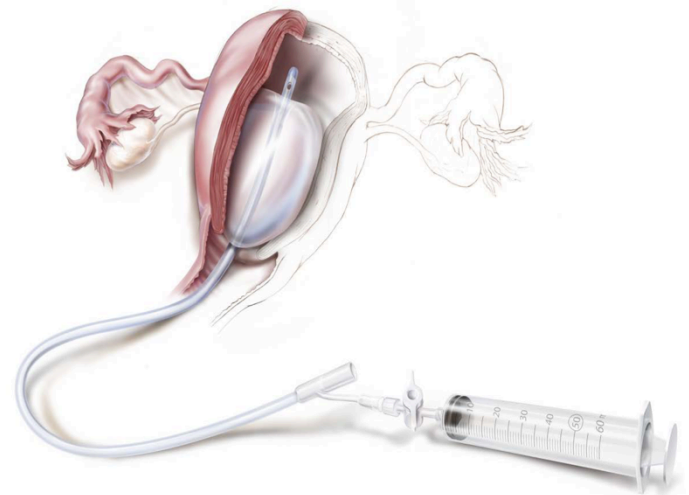
The Importance of IV Gauge

Get 2nd Line In Before Vasoconstriction Develops!

Gauge	Gravity Flow	Flow with Rapid Infuser
20	65 mL/min	
18	140 mL/min	250 mL/min
16	190 mL/min	350 mL/min
14	300 mL/min	500 mL/min

Cook “Bakri” Intrauterine Balloon

- There are now several balloons, but the most available in the US is the Cook “Bakri” Balloon
 - Specifically designed for this purpose
 - Double lumen (for drainage from above)
 - Silicone (non-latex)
 - Uterine contour shape
 - Good filling capacity (saline)
 - Inexpensive
 - Easy to use



Applications of Intrauterine Balloons

- Low-lying placental implantation site (esp placenta previa)
- Poorly contracting lower uterine segment
- Uterine atony
- Placenta accreta / percreta
- Cervical implantation
- DIC at term or after 2nd trimester loss
- In combination with Compression Suture at hysterotomy (“Sandwich technique”)
- Vaginal sidewall lacerations
- Easily placed when in stirrups for good exam for vaginal or cervical lacerations and for retained placenta

Intrauterine Balloon Should be First Step after Failure of Medical Therapy

- High success rate not different than other approaches
- Low-tech, fast, inexpensive, easy to utilize on any L&D Unit
- Least morbidity of any “next step”
- Can be used as “Tamponade Test” to temporize, determine needs and mobilize other resources

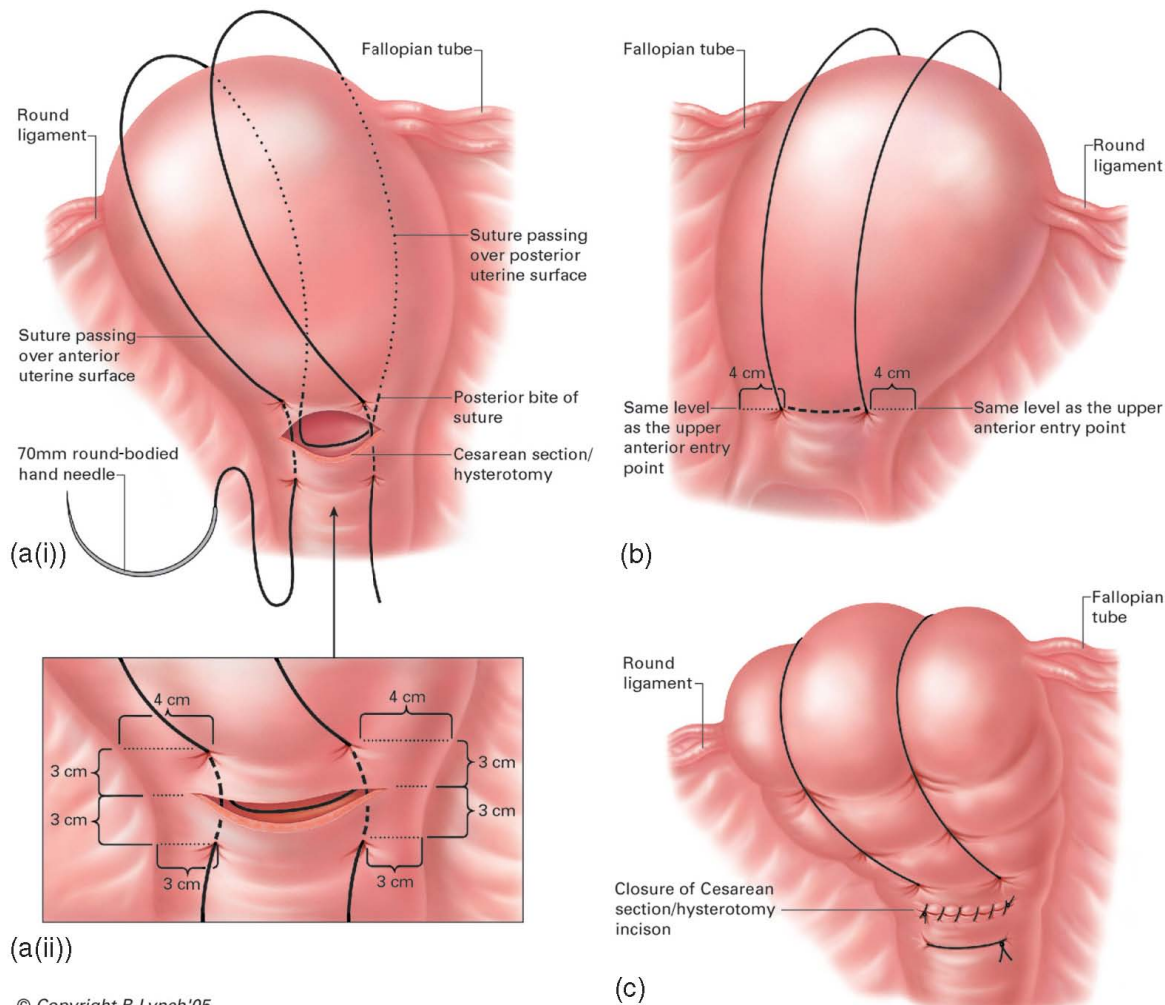
Issues for Balloons

- There are several balloons, but the most available in the US is the Cook “Bakri” Balloon
 - It is the balloon specifically designed for this purpose
 - Double lumen, silicone (non-latex), uterine contour shape, good filling capacity, inexpensive

Issues for Balloons

- There is some user learning—
 - How much to fill? (150-500 mL is a big range)
We recommend estimating the uterine volume bimanually --usually 250-300 mL is sufficient unless the uterus is very “floppy”
 - There can be “hour-glassing” of the balloon thru the cervix into the vagina. We recommend using vaginal packing if the cervix is more than 1-2cm dilated).

B-Lynch Compression Suture “Belt and Suspenders”



© Copyright B-Lynch'05

Used with permission from
Christopher B-Lynch



B-Lynch Suture completed



Photo courtesy of Elliott Main, MD
and used with permission

B-Lynch Suture

- Every Obstetrician should know how to do this (diagrams are in each OR)
- Quick (<2 minutes) and easy!
- Ideal at time of Cesarean birth for atony
- Can be combined with an intrauterine balloon for “Sandwich technique”

Perform B-Lynch within an hour

- Among 211 women treated with B-Lynch sutures
- Hysterectomy rate was 16% if done within an hour of delivery
- Hysterectomy rate was 42% with a delay of 2-6 hours

Move along a plan!

Kayem G, Kurinczuk JJ, Alfirevic Z, et al. Uterine compression sutures for the management of severe postpartum hemorrhage. *Obstet Gynecol*. Jan 2011;117(1):14-20.



California OB Hemorrhage Guidelines

- **Stage 3: STILL BLEEDING** and EBL >1500 mL or
> 2 u PRBCs given or VS unstable or suspect coagulopathy
 - **Massive transfusion protocol**
 - Transfuse aggressively
 - **Near 1:1 ratio PRBC: FFP**
 - Rapid use of FFP may be as important as ratio
 - 1 PLT pheresis pack per 4-6 units PRBC
 - Invasive surgical techniques
 - Mobilize help: Advanced surgeon (gyn, gyn onc, trauma, MFM)

Tip of the Spear: Lessons from Iraq and Afghanistan



**Lowest
losses ever
from
hemorrhage**

US Army Photo by Sgt. Dallas Walker
and used with permission



**Key: Increased FFP:RBC ratio
Forward units: carry PRBCs
and FFP even without
operating units**



CMQCC Transfusion Guidelines

- For massive ongoing hemorrhage
- Resuscitation transfusion not based on labs but clinical
- Seeks to AVOID coagulopathy
- Transfuse with uncrossed PRBCs until crossed blood available
- Goal near equal ratio of PRBC:FFP after first 2U
- One unit platelets (single platelet pheresis pack) given for every 4-6 units PRBCs
- Guidelines consistent with practice guidelines of the American Society of Anesthesiologists

The Lethal Coagulopathy Triad: Dilution, Hypothermia & Acidosis

■ Dilution

- Transfusion of crystalloid and packed cells devoid of clotting factors
- A problem once 1 – 1/2 total blood volume replaced

■ Hypothermia

- Significantly decreases platelet function: even if counts are adequate
- Keep patient warm (Bair Hugger®, fluid warmer)



The Lethal Coagulopathy Triad: Dilution, Hypothermia & Acidosis

■ Acidemia

- Occurs with massive hemorrhage due to hypovolemia, peripheral tissue hypoxia
- As hydrogen ion concentration increases, enzyme functions involved in coagulation pathway stop functioning
- VERY DIFFICULT TO REVERSE!
- Work to prevent metabolic acidosis



STAGE 3: OB Hemorrhage

Cumulative blood loss > 1500ml, > 2 units PRBCs given, VS unstable or suspicion for DIC

MOBILIZE

Nurse or Physician:

- ☐ Activate Massive Hemorrhage Protocol

PHONE #: _____

Charge Nurse or designee:

- ☐ Notify advanced Gyn surgeon (e.g. Gyn Oncologist)
- ☐ Notify adult intensivist
- ☐ Call-in second anesthesiologist
- ☐ Call-in OR staff
- ☐ Ensure hemorrhage cart available at the patient's location
- ☐ Reassign staff as needed
- ☐ Call-in supervisor, CNS, or manager
- ☐ Continue OB Hemorrhage Record (In OR, anesthesiologist will assess and document VS)
- ☐ If transfer considered, notify ICU

Blood Bank:

- ☐ Prepare to issue additional blood products as needed – **stay ahead**

ACT

Establish team leadership and assign roles

Team leader (OB physician + OB anesthesiologist, anesthesiologist and/or perinatologist and/or intensivist):

- ☐ **Order Massive Hemorrhage Pack** (RBCs + FFP + 1 pheresis pack PLTS—see note in right column)
- ☐ **Move to OR** if not already there
- ☐ Repeat CBC/PLTS, Coag Panel II STAT and Chem 12 panel q 30-60 min

Anesthesiologist (as indicated):

- ☐ Arterial blood gases
- ☐ Central hemodynamic monitoring
- ☐ CVP or PA line
- ☐ Arterial line
- ☐ Vasopressor support
- ☐ Intubation
- ☐ Calcium replacement
- ☐ Electrolyte monitoring

Primary nurse:

- ☐ Announce VS and cumulative measured blood loss q 5-10 minutes
- ☐ Apply upper body warming blanket if feasible
- ☐ Use fluid warmer and/or rapid infuser for fluid & blood product administration
- ☐ Apply sequential compression stockings to lower extremities
- ☐ Circulate in OR

Second nurse and/or anesthesiologist:

- ☐ Continue to administer meds, blood products and draw labs, as ordered

Third Nurse (or charge nurse):

- ☐ Recorder

THINK

Selective Embolization (IR)

Interventions based on etiology not yet completed

Prevent hypothermia, acidemia

Conservative or Definitive Surgery:

- Uterine Artery Ligation
- Hysterectomy

For Resuscitation:

Aggressively Transfuse

Based on Vital Signs, Blood Loss

After the first 2 units of PRBCs use
Near equal FFP and RBC for massive
hemorrhage:

4-6 PRBCs: 4 FFP: 1 apheresis Platelets

Unresponsive Coagulopathy:

- Role of rFactor VIIa is very controversial. After 8-10 units PRBCs and coagulation factor replacement with ongoing hemorrhage, may consider risk/benefit of rFactor VIIa in consultation with hematologist or trauma surgeon

Once Stabilized: Modified Postpartum Management with increased surveillance; consider ICU

Quantification of Blood Loss: QBL

- CMQCC Standard Recommendation
- All studies: We are VERY POOR at estimating blood loss with large volumes:
 - **Consistently underestimate**
- Every case review of maternal death in CA from hemorrhage, blood loss underestimated initially
 - Studies show we can get better with training but that **gains are partially lost over time and we are still poor at large volumes.**
 - Not related to experience of provider

Quantification of Blood Loss: QBL

- **DENIAL leads to DELAY**
- If its **not routine standard**, we don't **know how** to do it when we need it. And we don't recognize **WHEN** we need it until late in the game...



Routine QBL



- Goal is NOT a “perfect, precise” number
- Of course inaccuracies will persist
 - Amniotic fluid contamination, urine
 - Blood clots/other mixed with fluid in the drapes
- QBL increases our knowledge of blood loss and is more accurate than EBL
 - When patient has a hemorrhage, doing QBL is second nature for the team/staff/unit
 - “This is how we do it here....”
 - Allows for earlier recognition of excessive blood loss and improved communication among team members.
 - Avoid delay in management of excessive blood loss

QBL: Vaginal Birth

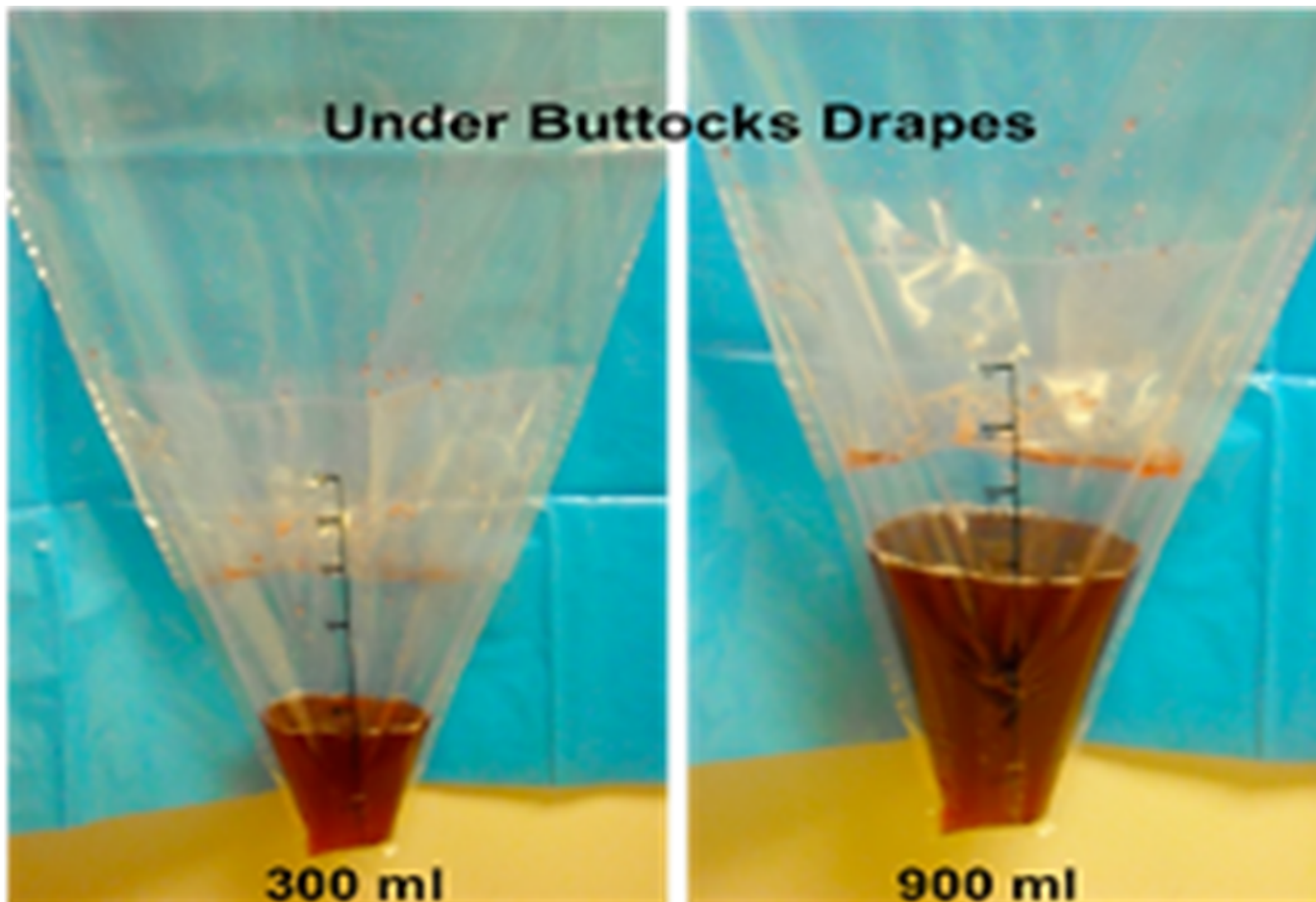


Photo courtesy of Bev VanderWal,
CNS and used with permission

QBL: Cesarean Birth

- Two step, quick process 95% of the time
- Need a calculator. Make it easy.
 - Build into EMR
 - Excel spreadsheet or equivalent
- Start with cases of one or two physician champions: small test of change
- Move to all scheduled cases
- Add unscheduled cases

Routine Two Step Quantification of Blood Loss at CS

1 Suctioned blood

- a. Between delivery of infant and placenta;
 - i. OB suction drains of amniotic fluid
 - ii. Scrub staff directs Circulator to change suction tubing to second canister
 - iii. May omit switch to new canister if minimal amniotic fluid (patient is post AROM/SROM, in labor)
- b. Circulator records volume in second canister in spreadsheet calculator/EPIC calculator
 - i. Best to record before irrigation used OR
 - ii. If irrigation used and suctioned, Scrub staff communicates amount to Circulator to be subtracted from canister (but may lead to error if not all irrigation re-aspirated)
 - iii. Consider omitting irrigation use during routine cesarean section

2 Lap sponges

- a. During case, bloody lap sponges passed off scrub table by Scrub staff
- b. Circulator places in hanging lap sleeve bags (5 sponges/sleeve)
- c. Circulator weighs bloody sponges and lap sleeve bags *all together* near end of case (sponges left in sleeves)
- d. Total weight, # sponges weighed, # hanging sleeves weighed, entered in spreadsheet calculator/EPIC calculator

3 Spreadsheet calculator/EPIC calculator calculates QBL from entered data

Staff trained to account for other large sources of blood loss if indicated and add to QBL (examples: large amount expressed blood from uterus in emesis basin post op, large floor spill of blood, etc.)



Photos courtesy of Jennifer McNulty,
MD and used with permission





Photo courtesy of Jennifer McNulty, MD and used with permission

EMR: QBL Calculator

QBL Calculator in EMR Deliver Summary

CESAREAN SECTION BLOOD LOSS	
Cannister Volume (blood volume only)	<input type="text"/>
Total Weight: Laps + Sleeves	<input type="text"/>
Lap Sleeves Used	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/> <input type="text" value="5"/> <input type="text" value="6"/> <input type="text" value="7"/> <input type="text" value="8"/> <input type="text" value="9"/> <input type="text" value="10"/>
# of Laps Used	<input type="text"/>
# of Chux Used	<input type="text"/>
Additional Source of Blood Loss Volume	<input type="text"/>
Add "Total Blood Loss Calculated" below to "Total Delivery Blood Loss" section (for I&O)	
TOTAL BLOOD LOSS CALCULATED	<input type="text" value="0"/>
VAGINAL DELIVERY BLOOD LOSS	
Method Of Quantification	<input type="button" value="EBL - Visual estimate only"/> <input type="button" value="QBL - Direct measure"/> <input type="button" value="QBL - Weight of blood soaked items"/>
TOTAL DELIVERY BLOOD LOSS (Vaginal or C/S)	
EBL/QBL During Delivery (mL)	<input type="text"/>

Importance of Drills / Simulations

Safety and QI Leader: Paul Preston, MD

“Medicine is the last high-risk industry that expects people to perform perfectly in complex, rare emergencies but does not support them with high-quality training and practice throughout their careers.”

“Certain individual and team skills require regular practice that cannot ethically occur in routine care.” [used with permission]

Melissa's Story

- Melissa Price had a late postpartum hemorrhage.
 - Melissa recalls asking the nurses how they could tell how much blood she was losing – the nurses never weighed the blood, and dumped it from a bed pan into a portable toilet.
- Melissa tells of feeling sheer panic when the bleeding started up again
 - *“enormous clots...I screamed and I will never forget the look on the nurse's face when she lifted up that blanket. I just kept thinking, ‘God give them more time. They need more time to save me.’”*
- Melissa ended up with a hysterectomy and about 12 units of blood transfused.

Melissa Price is a patient representative on the OB Hemorrhage Task Force and has given her permission to use her real name and story.



Creating a “Team For All Seasons”

- OB Hemorrhage is the prototypic OB emergency
- Many of the system changes are directly applicable to other obstetric emergencies
- Creating the team and systems to implement hemorrhage project makes other OB QI projects easier and more successful

Kaiser—Roseville (Northern California)

“We have learned that through debriefing, we talk about problems, and by talking about problems not only can we find solutions, but we can change outcomes.”

-John Vallee, MD, Perinatal Patient Safety Director, Kaiser Permanente-Northern CA (TPMG) [used with permission]

Salinas Valley Memorial Healthcare System—Salinas

“It's not just hemorrhage that we address here; we are trying to make L&D safer for moms and babies. As a result of processes we put into place, ALL births are safer.”

- Amen Ness, MD, Director of Perinatal Diagnostic Center [used with permission]

National Partnership for Maternal Safety Hemorrhage Outcome Measures

- Used by California, New York, and AWHONN Collaboratives; many HENs
- Goals:
 - Reduce overall and massive transfusions with early recognition and treatment
 - Do not discourage early appropriate transfusion
- Total # blood products per 1000 mothers
- Number of women receiving ≥ 4 units PRBCs

Callaghan WM, Grobman WA, Kilpatrick SJ, Main EK, D'Alton M. Facility-based identification of women with severe maternal morbidity: it is time to start. *Obstetrics and gynecology*. May 2014;123(5):978-981.



Business Case

- Blood products are VERY expensive
- Hemabate is ALSO VERY expensive
- R-Factor VIIa and Uterine Artery Embolization are VERY VERY expensive
- Math: more early interventions
=fewer hemorrhages that reach “massive”
=fewer high level (expensive) interventions



Examples of Success with Version 1.0!

- Saddleback Memorial
 - Reduction in hysterectomy with increased use of B-Lynch suture
- California Pacific Medical Center
 - Substantial reductions in blood product usage with protocol
- Dignity Health
 - Substantial reductions in blood product usage with protocol (Shields, et al 2013)
- Indiana University
 - 33% reduction in postpartum hemorrhage over 10 quarters with implementation of protocol



Version 2.0 Change Summary

- Oxytocin primary for AMTSL
- Dosage/route differences for misoprostol
- Minor modifications to blood product guidance
 - “Near equal” vs. Fixed 1:1 ratio PRBCs:FFP
 - Consider calcium, electrolytes
- Expanded resources for maternal and family support
- Resources for staff support

OB Hemorrhage: We Can Do Better

- Most maternal mortalities and near misses due to hemorrhage are preventable
- 1/3 of patients will have no risk factors prior to labor
 - Must be prepared for every patient
 - QBL every delivery so can respond early
- Requires reliance not on individuals but on team approach



OB Hemorrhage: We Can Do Better

- Preparation key
 - What resources are available
 - What resources need to be developed
 - Do all team members know what they are and how to deploy/utilize these resources
- Early recognition of triggers: empowering any team member to activate protocol and call for help
- Sequential utilization of patient monitoring, evaluation, medications, and procedures
 - Aggressive early therapy including transfusion when bleeding continues



Obstetric Hemorrhage Version 2.0 Task Force

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OB Hemorrhage Version 2.0 Toolkit
(www.cmqcc.org/ob_hemorrhage)

