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While obstetric hemorrhage has been replaced by cardiovascular disease as the leading cause of maternal death, obstetric hemorrhage remains as one of the leading causes of severe maternal morbidity and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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