# Postpartum Hemorrhage: Review, Update and Novel Strategies

## New England Obstetrical and Gynecological Society
## Annual Spring Meeting
## April 20, 2022

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Vice Chair for Quality & Patient Safety
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Associate Dean for Professionalism

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NewYork-Presbyterian

# Disclosures

- Haymarket PPH Educational Video
- Cooper Surgical Obstetrical Safety Council
- Laborie Speaker
- Organon Expert Consultant
- PI for Jada Pivotal Trial and Post Market Registry

# Learning Objectives

- Affirm awareness of PPH as a critical maternal health issue
- Describe the Obstetric Hemorrhage Patient Safety Bundle
- Understand key bundle elements and identify implementation opportunities
- Practical management pearls

# What Is Postpartum Hemorrhage?

- Postpartum hemorrhage (PPH) is the leading cause of maternal death worldwide[1]
- Majority of PPH-associated deaths could be avoided by the use of appropriate treatment[1]
- Considered an obstetric emergency
- Defined as cumulative blood loss ≥1000 mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours of vaginal or cesarean delivery[2,3]

  Both reVITALize and the ACOG highlight that a blood loss of 500–999 mL should trigger increased supervision and potential interventions as clinically indicated

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1. WHO recommendations: Uterotonics for the prevention of postpartum haemorrhage. Web annex 7: Choice of uterotonic agents: Evidence to Decision framework. Geneva: World Health Organization; 2018 (WHO/RHR/18.34). Licence: CC BY-NC-SA 3.0 IGO.
2. ACOG. *Obstet Gynecol*. 2017;130:e168-e186.
3. Atallah F, Goffman D. *Risk Manag Healthc Policy*. 2020;13:35-42.

# PPH: A Time Sensitive Diagnosis

- **Every minute counts during PPH:** a woman can lose her **entire blood volume within 14 minutes**
- **Delays** in recognition and treatment are frequent causes of **preventable** harm and death

MMRIA BUILDING U.S. CAPACITY TO REVIEW AND PREVENT MATERNAL DEATHS

Distribution of Preventability Among Pregnancy-Related Deaths

**25%**
Not Preventable

**70%**
Preventable

**5%**
Unable to Determine

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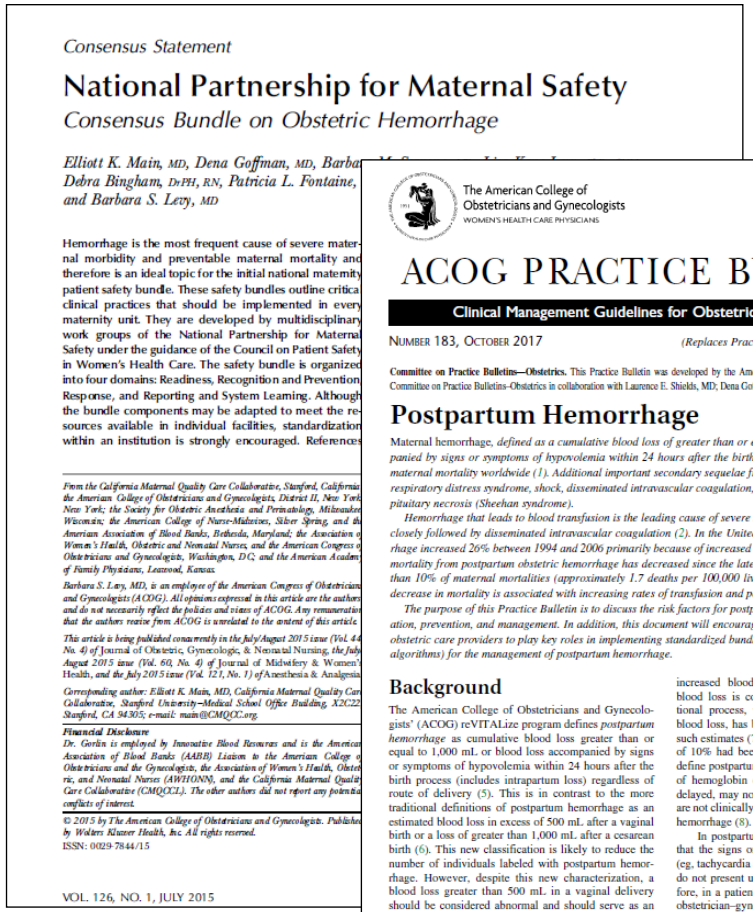
Building US capacity to review and prevent maternal deaths. 2018. Report from nine maternal review committees. http://reviewtoaction.org/Report_From_Nine_MMRCs.

# Obstetric Hemorrhage: Key Resources



*Consensus Statement*

## National Partnership for Maternal Safety

*Consensus Bundle on Obstetric Hemorrhage*

*Elliott K. Main, MD, Dena Goffman, MD, Barba*
*Debra Bingham, DrPH, RN, Patricia L. Fontaine,*
*and Barbara S. Levy, MD*

Hemorrhage is the most frequent cause of severe mater-
nal morbidity and preventable maternal mortality and
therefore is an ideal topic for the initial national maternity
patient safety bundle. These safety bundles outline critica
clinical practices that should be implemented in every
maternity unit. They are developed by multidisciplinary
work groups of the National Partnership for Maternal
Safety under the guidance of the Council on Patient Safety
in Women's Health Care. The safety bundle is organized
into four domains: Readiness, Recognition and Prevention,
Response, and Reporting and System Learning. Although
the bundle components may be adapted to meet the re-
sources available in individual facilities, standardization
within an institution is strongly encouraged. References

*From the California Maternal Quality Care Collaborative, Stanford, California; the American College of Obstetricians and Gynecologists, District II, New York, New York; the Society for Obstetric Anesthesia and Perinatology, Milwaukee, Wisconsin; the American College of Nurse-Midwives, Silver Spring, and the American Association of Blood Banks, Bethesda, Maryland; the Association of Women's Health, Obstetric and Neonatal Nurses, and the American Congress of Obstetricians and Gynecologists, Washington, DC; and the American Academy of Family Physicians, Leawood, Kansas.*

*Barbara S. Levy, MD, is an employee of the American Congress of Obstetricians and Gynecologists (ACOG). All opinions expressed in this article are the authors' and do not necessarily reflect the policies and views of ACOG. Any remuneration that the authors receive from ACOG is unrelated to the content of this article.*

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*Corresponding author: Elliott K. Main, MD, California Maternal Quality Care Collaborative, Stanford University–Medical School Office Building, X2C22, Stanford, CA 94305; e-mail: main@CMQCC.org.*

**Financial Disclosure**

*Dr. Gorlin is employed by Innovative Blood Resources and is the American Association of Blood Banks (AABB) Liaison to the American College of Obstetricians and the Gynecologists, the Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN), and the California Maternal Quality Care Collaborative (CMQCC2L). The other authors did not report any potential conflicts of interest.*



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The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

ACOG PRACTICE BUL

Clinical Management Guidelines for Obstetrician–Gy

NUMBER 183, OCTOBER 2017 (Replaces Practice Bulleti

Committee on Practice Bulletins—Obstetrics. This Practice Bulletin was developed by the American College
Committee on Practice Bulletins-Obstetrics in collaboration with Laurence E. Shields, MD; Dena Goffman, MD; an

## Postpartum Hemorrhage

Maternal hemorrhage, *defined as a cumulative blood loss of greater than or equal to 1,0*
*panied by signs or symptoms of hypovolemia within 24 hours after the birth process,*
*maternal mortality worldwide (1). Additional important secondary sequelae from hemor*
*respiratory distress syndrome, shock, disseminated intravascular coagulation, acute rena*
*pituitary necrosis (Sheehan syndrome).*

*Hemorrhage that leads to blood transfusion is the leading cause of severe maternal m*
*closely followed by disseminated intravascular coagulation (2). In the United States, th*
*rhage increased 26% between 1994 and 2006 primarily because of increased rates of ate*
*mortality from postpartum obstetric hemorrhage has decreased since the late 1980s and*
*than 10% of maternal mortalities (approximately 1.7 deaths per 100,000 live births) i*
*decrease in mortality is associated with increasing rates of transfusion and peripartum h*

*The purpose of this Practice Bulletin is to discuss the risk factors for postpartum hem*
*ation, prevention, and management. In addition, this document will encourage obstetric*
*obstetric care providers to play key roles in implementing standardized bundles of care*
*algorithms) for the management of postpartum hemorrhage.*

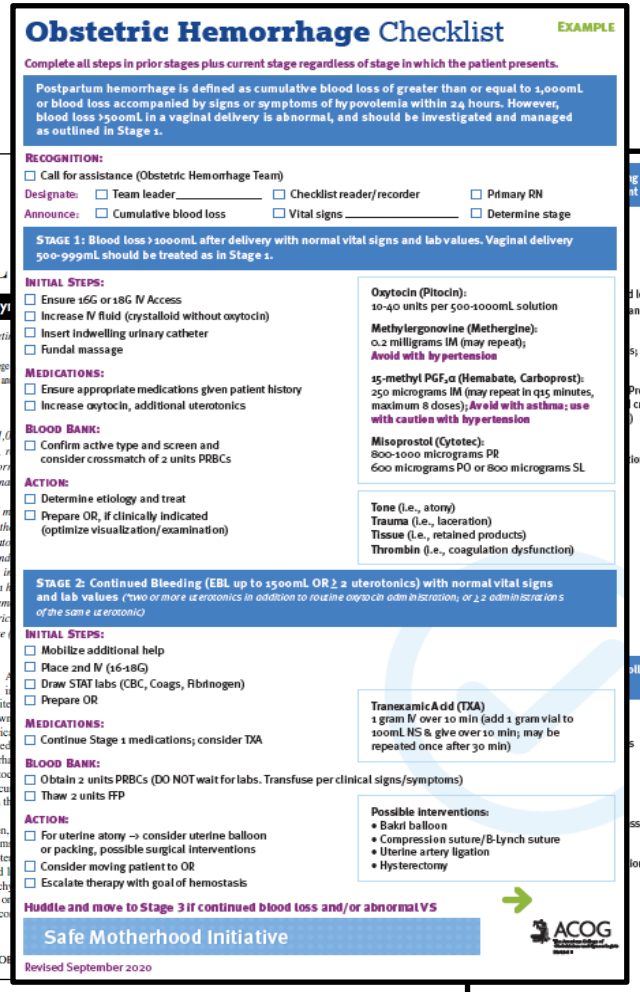
### Background

The American College of Obstetricians and Gynecologists' (ACOG) reVITALize program defines *postpartum hemorrhage* as cumulative blood loss greater than or equal to 1,000 mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after the birth process (includes intrapartum loss) regardless of route of delivery (5). This is in contrast to the more traditional definitions of postpartum hemorrhage as an estimated blood loss in excess of 500 mL after a vaginal birth or a loss of greater than 1,000 mL after a cesarean birth (6). This new classification is likely to reduce the number of individuals labeled with postpartum hemorrhage. However, despite this new characterization, a blood loss greater than 500 mL in a vaginal delivery should be considered abnormal and should serve as an indication for the health care provider to investigate the

increased blood deficit. A
blood loss is considered i
tional process, with limite
blood loss, has been shown
such estimates (7). Historic
of 10% had been proposed
define postpartum hemorrh
of hemoglobin or hemato
delayed, may not reflect cu
are not clinically useful in th
hemorrhage (8).

In postpartum women,
that the signs or symptom
(eg, tachycardia and hypote
do not present until blood l
fore, in a patient with tachy
obstetrician–gynecologist o
should be concerned that co





## Obstetric Hemorrhage Checklist EXAMPLE

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

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

**RECOGNITION:**
- ☐ Call for assistance (Obstetric Hemorrhage Team)

Designate: ☐ Team leader_____ ☐ Checklist reader/recorder ☐ Primary RN
Announce: ☐ Cumulative blood loss ☐ Vital signs _____ ☐ Determine stage

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

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

**MEDICATIONS:**
- ☐ Ensure appropriate medications given patient history
- ☐ Increase oxytocin, additional uterotonics

**BLOOD BANK:**
- ☐ Confirm active type and screen and consider crossmatch of 2 units PRBCs

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

**Oxytocin (Pitocin):** 10-40 units per 500-1000mL solution

**Methylergonovine (Methergine):** 0.2 milligrams IM (may repeat); **Avoid with hypertension**

**15-methyl PGF$_2\alpha$ (Hemabate, Carboprost):** 250 micrograms IM (may repeat in q15 minutes, maximum 8 doses); **Avoid with asthma; use with caution with hypertension**

**Misoprostol (Cytotec):** 800-1000 micrograms PR, 600 micrograms PO or 800 micrograms SL

**Tone** (i.e., atony)
**Trauma** (i.e., laceration)
**Tissue** (i.e., retained products)
**Thrombin** (i.e., coagulation dysfunction)

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

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

**MEDICATIONS:**
- ☐ Continue Stage 1 medications; consider TXA

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

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

**ACTION:**
- ☐ For uterine atony → consider uterine balloon or packing, possible surgical interventions
- ☐ Consider moving patient to OR
- ☐ Escalate therapy with goal of hemostasis

**Possible interventions:**
- Bakri balloon
- Compression suture/B-Lynch suture
- Uterine artery ligation
- Hysterectomy

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

Safe Motherhood Initiative

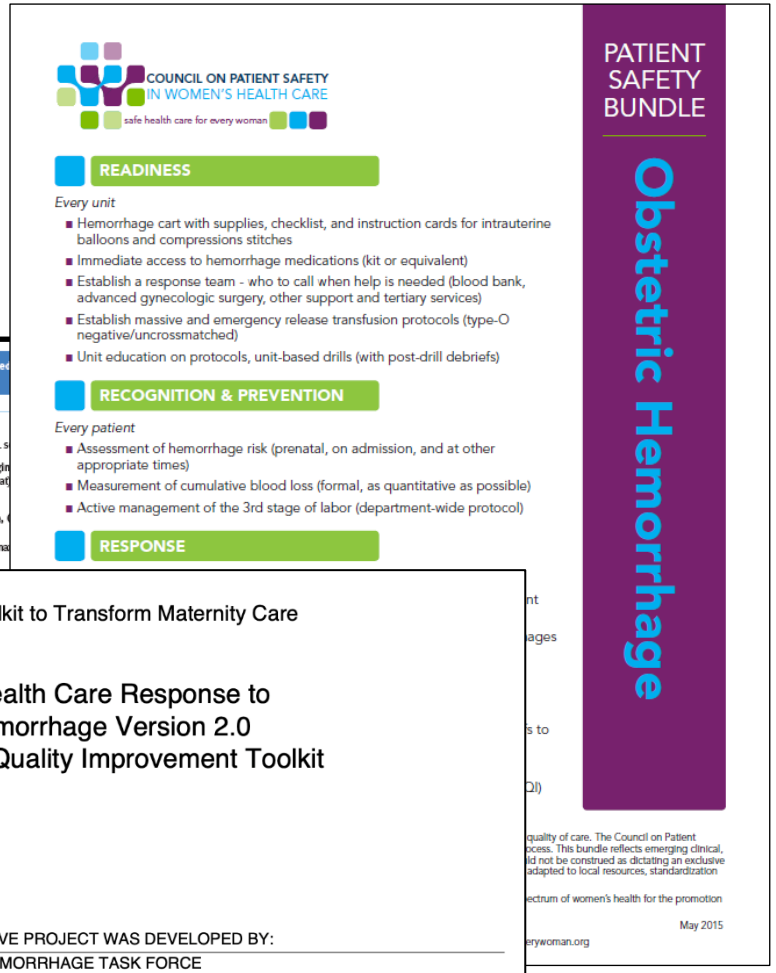
ACOG

Revised September 2020



Revised September 2020

Safe Motherhood Initiati



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PATIENT SAFETY BUNDLE

**Obstetric Hemorrhage**

**READINESS**

*Every unit*
- Hemorrhage cart with supplies, checklist, and instruction cards for intrauterine balloons and compressions stitches
- Immediate access to hemorrhage medications (kit or equivalent)
- Establish a response team - who to call when help is needed (blood bank, advanced gynecologic surgery, other support and tertiary services)
- Establish massive and emergency release transfusion protocols (type-O negative/uncrossmatched)
- Unit education on protocols, unit-based drills (with post-drill debriefs)

**RECOGNITION & PREVENTION**

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

**RESPONSE**

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May 2015

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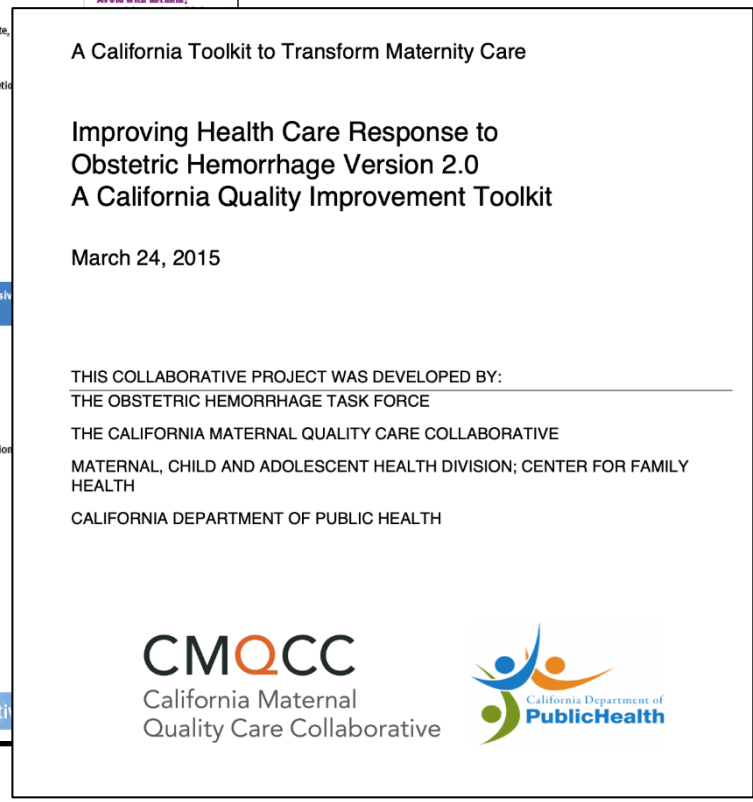

A California Toolkit to Transform Maternity Care

## 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

CMQCC California Maternal Quality Care Collaborative

California Department of PublicHealth

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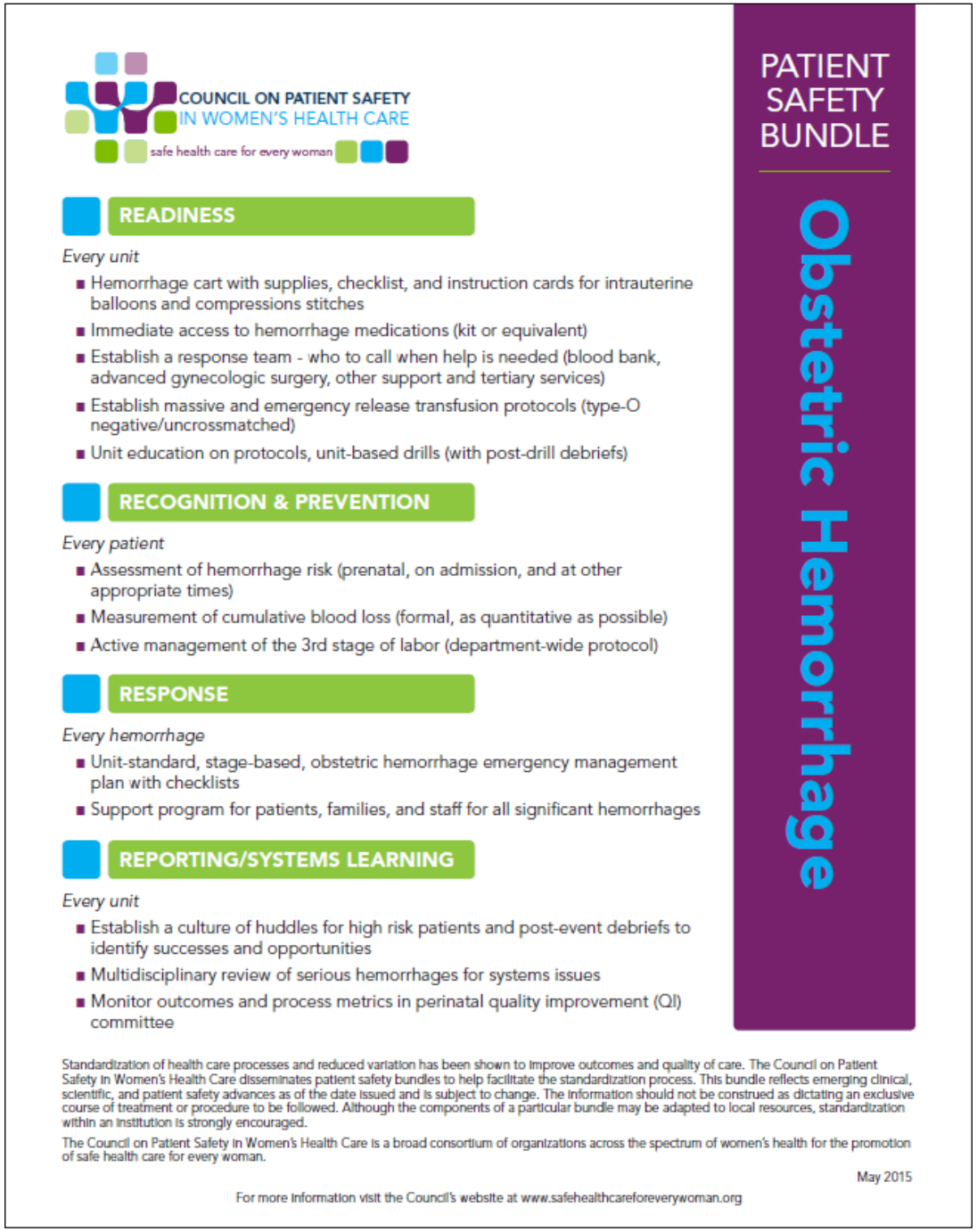

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## RESPONSE

*Every hemorrhage*

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

## REPORTING/SYSTEMS LEARNING

*Every unit*

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities
- Multidisciplinary review of serious hemorrhages for systems issues
- Monitor outcomes and process metrics in perinatal quality improvement (QI) committee

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

The Council on Patient Safety in Women's Health Care is a broad consortium of organizations across the spectrum of women's health for the promotion of safe health care for every woman.

May 2015

For more information visit the Council's website at www.safehealthcareforeverywoman.org

**Bundle updates coming soon from AIM…**

**IHI Change Package coming soon to augment implementation opportunities…**

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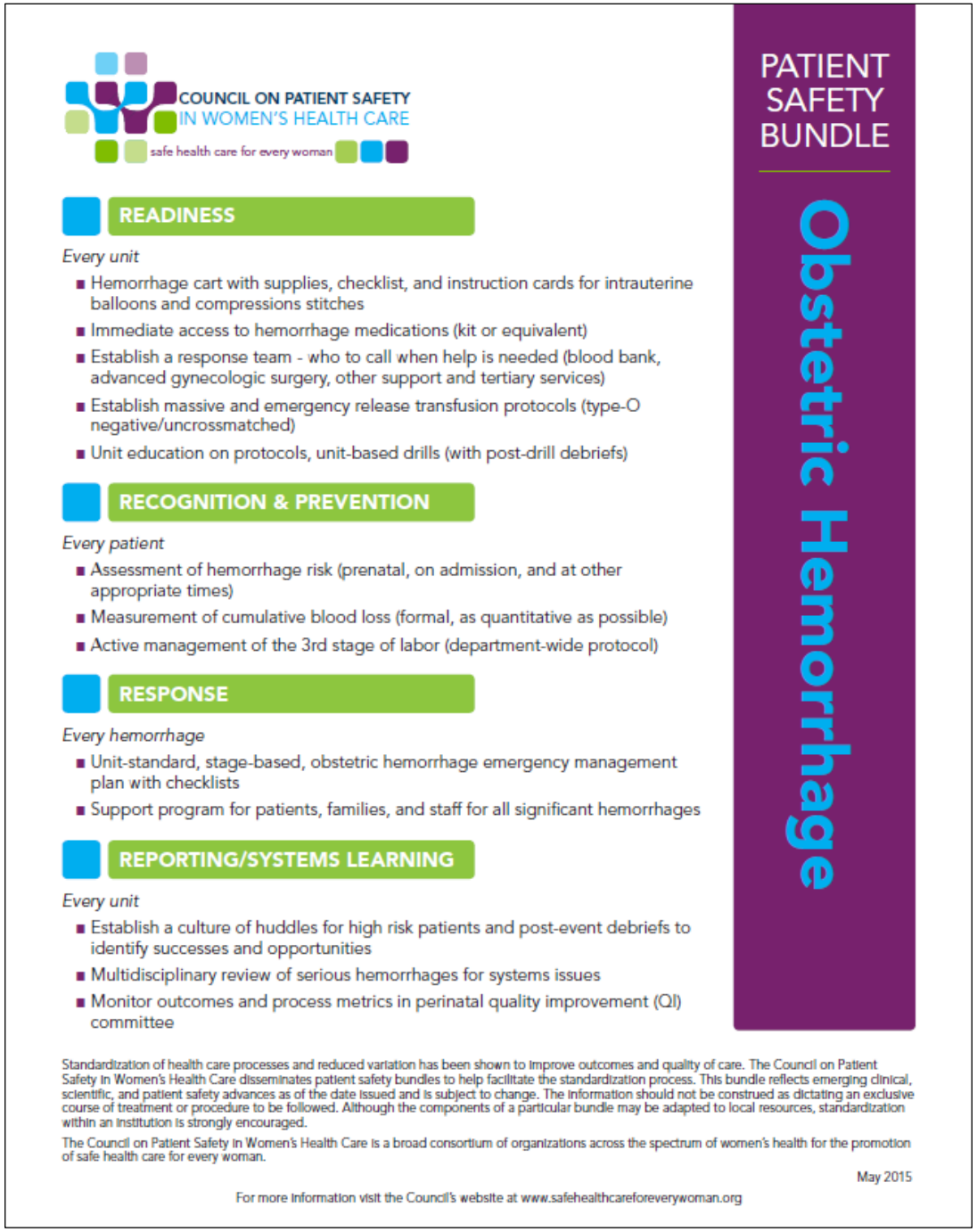

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May 2015

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# TJC Provision of Care, Treatment, and Services Standards for Maternal Safety

R³ Report | Requirement, Rationale, Reference
Issue 24, Aug. 21, 2019


## Provision of Care, Treatment, and Services chapter

**Standard PC.06.01.01: Reduce the likelihood of harm related to maternal hemorrhage.**

| | |
|---|---|
| Requirement | EP 1: Complete an assessment using an evidence-based tool for determining maternal hemorrhage risk on admission to labor and delivery and on admission to postpartum. (See also PC.01.02.01, EPs 1 and 2; PC.01.02.03, EP 3; RC.02.01.01, EP 2) |
| Rationale | Assessing and discussing patients' risks for hemorrhage allows the team to identify higher-risk patients and be prepared. The risk of hemorrhage may change during a patient's stay depending on the clinical situation. |
| Reference | Harvey CJ. "Evidence-Based Strategies for Maternal Stabilization and Rescue in Obstetric Hemorrhage." *Advanced Critical Care*. 2018;3(29):284-94. |
| Requirement | EP 2: Develop written evidence-based procedures for stage-based management of pregnant and postpartum patients who experience maternal hemorrhage that includes the following:<br>• The use of an evidence-based tool that includes an algorithm for identification and treatment of hemorrhage<br>• The use of an evidence-based set of emergency response medication(s) that are immediately available on the obstetric unit<br>• Required response team members and their roles in the event of severe hemorrhage<br>• How the response team and procedures are activated<br>• Blood bank plan and response for emergency release of blood products and how to initiate the organization's massive transfusion procedures<br>• Guidance on when to consult additional experts and consider transfer to a higher level of care<br>• Guidance on how to communicate with patients and families during and after the event |

# Recognition/Prevention opportunities: Risk Assessment

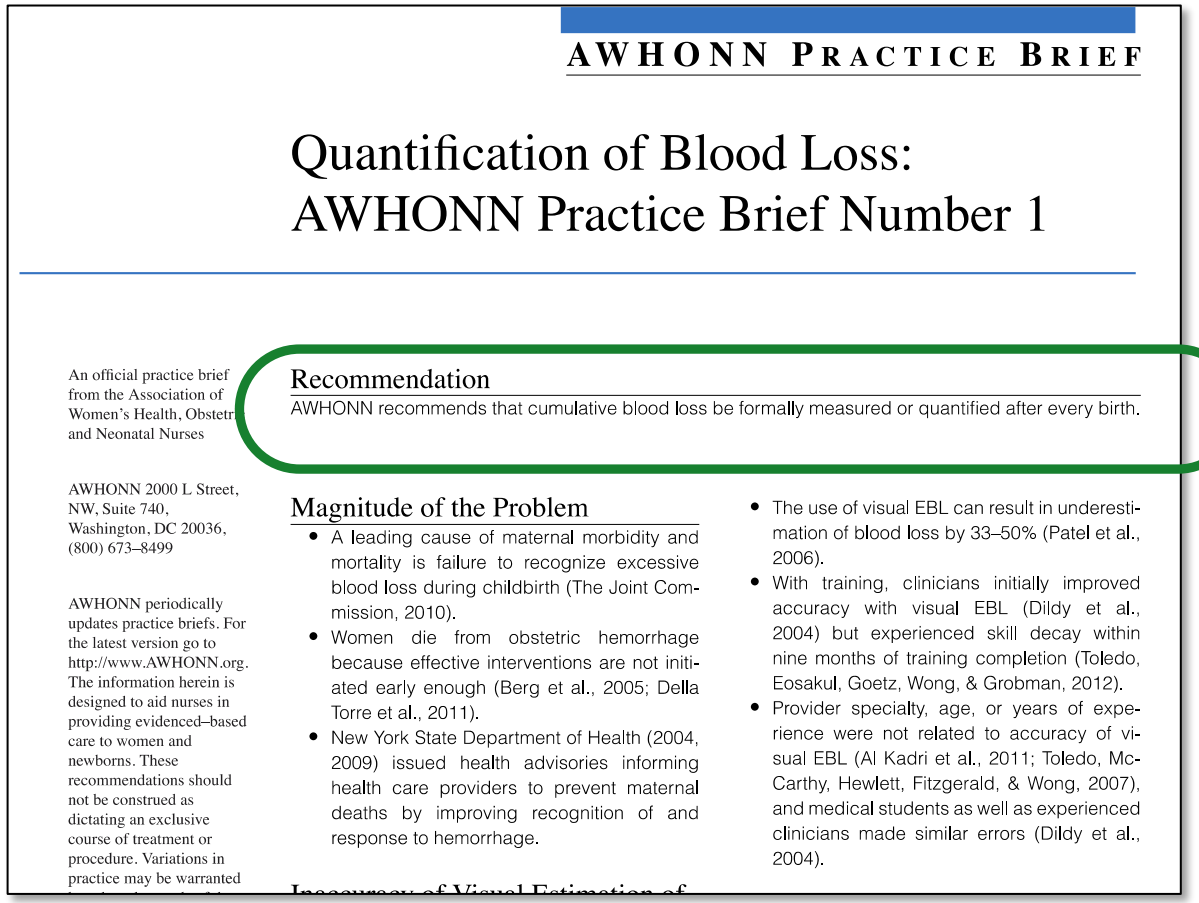
**Joint Commission standards** for perinatal safety aimed at reducing a patient's harm related to hemorrhage, a risk assessment must be performed on admission to labor and delivery and admission to postpartum.

Institutions have developed additional standardized time intervals:

- On admission to L&D *(completed by **provider**)*
- Pre-birth; at start of second stage *(completed by **L&D RN**)*
- Post-birth; following delivery in recovery phase *(completed by **L&D RN**)*
- Post-birth, on admission to the postpartum unit *(completed by **Postpartum RN**)*
- Concern for ongoing bleeding on postpartum *(completed by **Postpartum RN**)*

# Recognition/Prevention opportunities: Cumulative Quantitative Blood Loss

- Visually EBL is frequently significantly inaccurate, often underestimating large volume loss by 30%-50%
- **All clinicians regardless of training and experience** make the same EBL underestimation mistakes
- Underestimation of blood loss results in delayed treatment
- Delayed treatment is a frequent cause of death from obstetric hemorrhage



AWHONN PRACTICE BRIEF

Quantification of Blood Loss: AWHONN Practice Brief Number 1

An official practice brief from the Association of Women's Health, Obstetr and Neonatal Nurses

AWHONN 2000 L Street, NW, Suite 740, Washington, DC 20036, (800) 673–8499

AWHONN periodically updates practice briefs. For the latest version go to http://www.AWHONN.org. The information herein is designed to aid nurses in providing evidenced–based care to women and newborns. These recommendations should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted

Recommendation

AWHONN recommends that cumulative blood loss be formally measured or quantified after every birth.

Magnitude of the Problem

- A leading cause of maternal morbidity and mortality is failure to recognize excessive blood loss during childbirth (The Joint Commission, 2010).
- Women die from obstetric hemorrhage because effective interventions are not initiated early enough (Berg et al., 2005; Della Torre et al., 2011).
- New York State Department of Health (2004, 2009) issued health advisories informing health care providers to prevent maternal deaths by improving recognition of and response to hemorrhage.
- The use of visual EBL can result in underestimation of blood loss by 33–50% (Patel et al., 2006).
- With training, clinicians initially improved accuracy with visual EBL (Dildy et al., 2004) but experienced skill decay within nine months of training completion (Toledo, Eosakul, Goetz, Wong, & Grobman, 2012).
- Provider specialty, age, or years of experience were not related to accuracy of visual EBL (Al Kadri et al., 2011; Toledo, McCarthy, Hewlett, Fitzgerald, & Wong, 2007), and medical students as well as experienced clinicians made similar errors (Dildy et al., 2004).

Inaccuracy of Visual Estimation of

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Quantification of blood loss: AWHONN practice brief number 1. *J Obstet Gynecol Neonatal Nurs*. 2015;44(1):158-160.

# Recognition/Prevention Opportunity: Cumulative Blood Loss…Semi Quantitative?

| | |
|---|---|
| 4 x 4 gauze pad | 5 ml |
| Full & dripping chux | 80 ml |
| Fully soaked peripad | 70 ml |
| Partially soaked peripad | 50 ml |
| Full & dripping lap pad | 100 ml |
| Full lap pad (not dripping) | 75 ml |
| Half a lap pad | 40 ml |
| 12 ounce soda can | 355 ml |
| Fist or baseball sized clot | 60 ml |

# Recognition/Prevention Opportunity: Cumulative Quantitative Blood Loss

## QBL (Quantitative Blood Loss):

- Weighs and measures blood loss in real time
- Objective
- Drives prompt treatment
- Represents drastic culture and practice change
- Implementation is labor intensive and unlikely to succeed without buy-in from whole workforce

# Recognition Opportunity: Transition from EBL to QBL

## Estimation subjective assessment

- Subjective statements
  - **"She's bleeding a lot."**
  - **"She saturated 2 pads in 1 hr."**
- Lack of clarity affects the team response
- Terms like scant, small, minimal, moderate, heavy, or excessive for peripad assessment are subjective and vary from clinician to clinician.

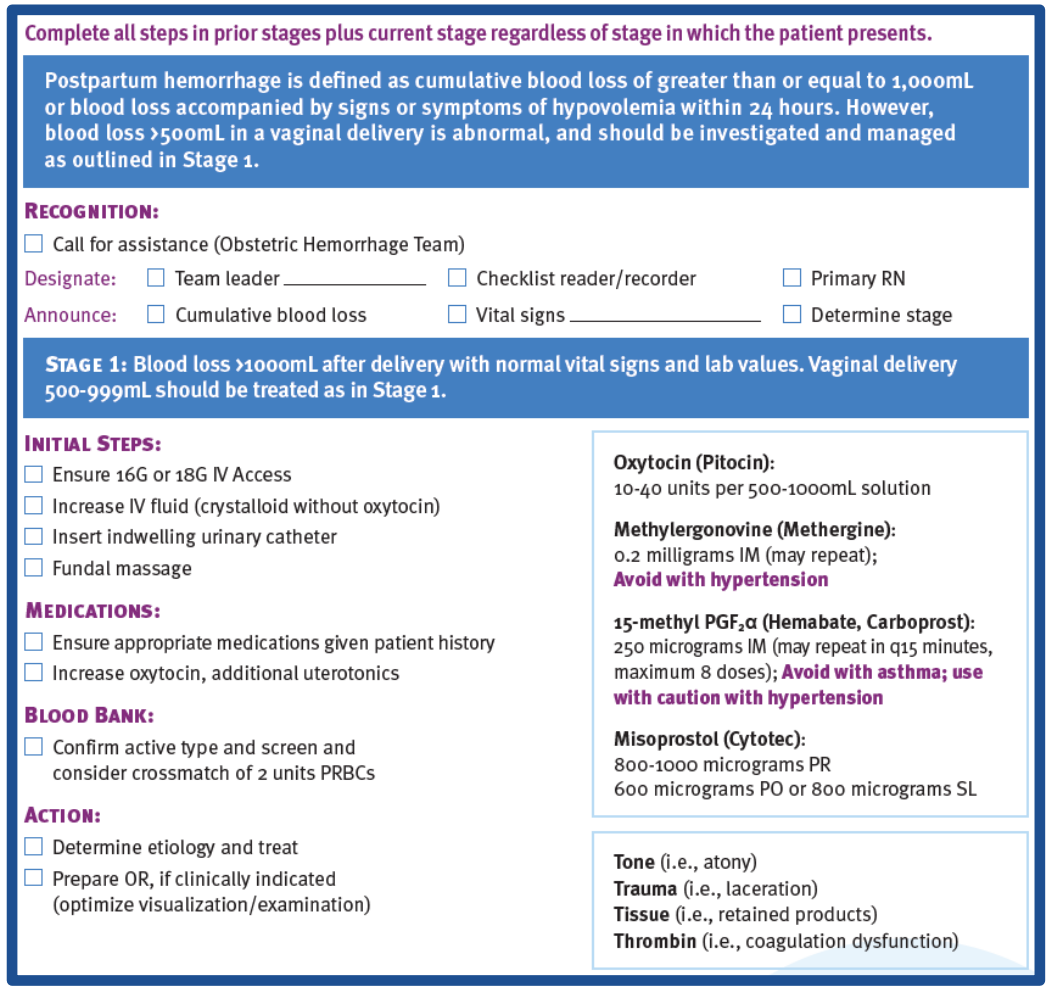
## Quantification objective assessment

- Objective statements
  - **"She has a QBL of 1240 ml."**
  - **"She has a Stage 2 PPH."**
- Reporting QBL gives the team a more accurate sense of current blood loss
- Basing care on objective information will likely improve communication, team situational awareness and prompt an early, appropriate team response.



Bingham D. *J Obstet Gynecol Neonatal Nurs*. 2012;41(4):540-548; quiz 549-550. Gabel KT, Weeber TA. *J Obstet Gynecol Neonatal Nurs*. 2012;41(4):551-558.

# Response Opportunity:
# Stage-based PPH Management Plan



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

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**RECOGNITION:**

☐ Call for assistance (Obstetric Hemorrhage Team)

Designate: ☐ Team leader _____ ☐ Checklist reader/recorder ☐ Primary RN

Announce: ☐ Cumulative blood loss ☐ Vital signs _____ ☐ Determine stage

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

**INITIAL STEPS:**

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

**MEDICATIONS:**

☐ Ensure appropriate medications given patient history
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**ACTION:**

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

**Oxytocin (Pitocin):**
10-40 units per 500-1000mL solution

**Methylergonovine (Methergine):**
0.2 milligrams IM (may repeat);
**Avoid with hypertension**

**15-methyl $PGF_2\alpha$ (Hemabate, Carboprost):**
250 micrograms IM (may repeat in q15 minutes, maximum 8 doses); **Avoid with asthma; use with caution with hypertension**

**Misoprostol (Cytotec):**
800-1000 micrograms PR
600 micrograms PO or 800 micrograms SL

**Tone** (i.e., atony)
**Trauma** (i.e., laceration)
**Tissue** (i.e., retained products)
**Thrombin** (i.e., coagulation dysfunction)

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https://www.acog.org/-/media/project/acog/acogorg/files/forms/districts/smi-ob-hemorrhage-bundle-hemorrhage-checklist.pdf

# Response Opportunity: Stage-based PPH Management Plan

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

**INITIAL STEPS:**

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

**MEDICATIONS:**

- ☐ Continue Stage 1 medications; consider TXA

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

**BLOOD BANK:**

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

**ACTION:**

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

**Possible interventions:**

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



https://www.acog.org/-/media/project/acog/acogorg/files/forms/districts/smi-ob-hemorrhage-bundle-hemorrhage-checklist.pdf

# Response Opportunity: Stage-based PPH Management Plan

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

**INITIAL STEPS:**

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

**MEDICATIONS:**

- ☐ Continue Stage 1 medications; consider TXA

**BLOOD BANK:**

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

**ACTION:**

- ☐ Achieve hemostasis, intervention based on etiology
- ☐ Escalate interventions

**Oxytocin (Pitocin):**
10-40 units per 500-1000mL solution

**Methylergonovine (Methergine):**
0.2 milligrams IM (may repeat);
**Avoid with hypertension**

**15-methyl $PGF_2\alpha$ (Hemabate, Carboprost):**
250 micrograms IM
(may repeat in q15 minutes, maximum 8 doses)
**Avoid with asthma;**
**use with caution with hypertension**

**Misoprostol (Cytotec):**
800-1000 micrograms PR
600 micrograms PO or 800 micrograms SL

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

**Possible interventions:**

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

https://www.acog.org/-/media/project/acog/acogorg/files/forms/districts/smi-ob-hemorrhage-bundle-hemorrhage-checklist.pdf

# Response Opportunity:
# Stage-based PPH Management Plan

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

**INITIAL STEP:**

☐ Mobilize additional resources

**MEDICATIONS:**

☐ ACLS

**BLOOD BANK:**

☐ Simultaneous aggressive massive transfusion

**ACTION:**

☐ Immediate surgical intervention to ensure hemostasis (hysterectomy)

**Post-Hemorrhage Management**

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

Revised September 2020

Safe Motherhood Initiative

ACOG The American College of Obstetricians and Gynecologists District II

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# Response Opportunity: *Medical Therapy*

The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

Dan L. Longo, M.D., *Editor*

## Postpartum Hemorrhage

Jessica L. Bienstock, M.D., M.P.H., Ahizechukwu C. Eke, M.D., Ph.D., and Nancy A. Hueppchen, M.D.

POSTPARTUM HEMORRHAGE CONTINUES TO BE THE LEADING PREVENTable cause of maternal illness and death globally.[1,2] Worldwide, postpartum

**Table 1. Medical Therapy for Postpartum Hemorrhage.***

| Medication | Mechanism of Action | Route of Administration and Dose | Concerns and Contraindications | Adverse Effects |
|---|---|---|---|---|
| First-line therapy: oxytocin | Stimulates oxytocin receptors in the uterus | IV route, 10–40 IU/500–1000 ml of lactated Ringer's solution; IM or IMM route, 5–10 IU for up to 4 doses | SIADH, hypotension | Rapid bolus administration may cause hyponatremia, hypotension, tachycardia, and arrhythmia |
| Second-line therapy | | | | |
| Methylergonovine maleate (ergot alkaloid) | Partial agonist or antagonist at serotoninergic, dopaminergic, $\alpha_1$-adrenergic receptors in the uterus | IM or IMM route, 0.2 mg every 2–4 hr, for a maximum of 5 doses; oral route, 0.2 mg every 6–8 hr for 2–7 days | Hypertension, cardiovascular disease (stroke, Renaud's disease) | Elevated blood pressure, nausea, vomiting, myocardial infarction |
| Carboprost tromethamine ($PGF_{2\alpha}$) | $PGF_{2\alpha}$ agonist in uterine myometrium | IM or IMM route, 250 $\mu$g every 15–90 min for a maximum of 8 doses | Asthma, cardiovascular disease, hepatic disease, renal disease | Nausea, vomiting, and diarrhea |
| Adjunctive agents | | | | |
| Tranexamic acid | Diminishes the dissolution of hemostatic fibrin by plasmin, stabilizing clot in uterine vessels | IV route, 1 g (100 mg/ml) over a 10-min period; if bleeding persists after 30 min or stops and restarts within 24 hr after the first dose, a second dose may be administered | Contraindicated if known hypersensitivity to tranexamic acid, thromboembolic event during pregnancy, history of hypercoagulopathy | Headache, musculoskeletal pain, nausea, diarrhea |
| Recombinant factor VIIa | Activates clotting cascade by cleaving factor IX and factor X, which activates these factors and leads to activation of thrombin and fibrin | IV route, 50–100 $\mu$g/kg (single dose) | Severe anemia, severe thrombocytopenia, hyperfibrinogenemia, allergy to mouse, hamster, or bovine proteins | Thromboembolic events, cerebrovascular infarcts, myocardial infarction |
| Treatment of uncertain usefulness: misoprostol | $PGE_1$ agonist in the uterine myometrium | Sublingual, oral, or rectal route (sublingual route preferred), 600–1000 $\mu$g in single dose; repeat doses not recommended | Sepsis, allergy to misoprostol, concurrent anticoagulant therapy, cardiovascular disease; efficacy is disputed | Nausea, vomiting, fever, diarrhea |

* IM denotes intramuscular, IMM intramyometrial, IV intravascular, $PGE_1$ prostaglandin $E_1$, $PGF_{2\alpha}$ 15-methyl prostaglandin $F_{2\alpha}$, and SIADH syndrome of inappropriate antidiuretic hormone secretion.

# Response Opportunity: Tamponade

## OBJECTIVE:

To assess the efficacy, effectiveness, and safety of uterine balloon tamponade (UBT) for treating PPH

## RESULTS:

- Ninety-one studies, including 4729 women, met inclusion criteria (6 randomized trials, 1 cluster randomized trial, 15 nonrandomized studies, and 69 case series)
- Overall pooled UBT success rate was 85.9% (95% CI, 83.9-87.9%)
- Highest success rates: uterine atony (87.1%), placenta previa (86.8%)
- Lowest success rates: placenta accreta spectrum (66.7%), retained products of conception (76.8%)
- UBT success rate was lower with cesarean deliveries (81.7%) than with vaginal deliveries (87.0%)

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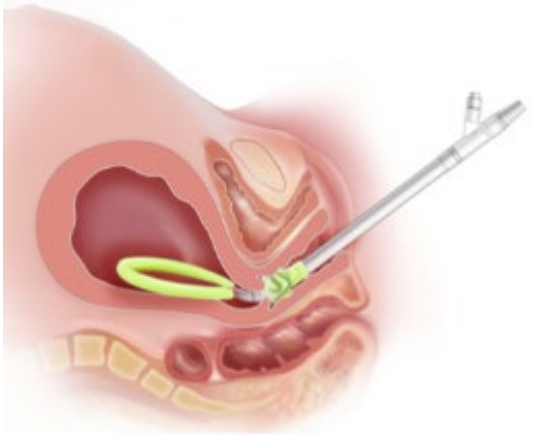
Suarez S, et al. *Am J Obstet Gynecol*. 2020;222:293.e1-e52.

# Response Opportunity: Jada



## OBJECTIVE:

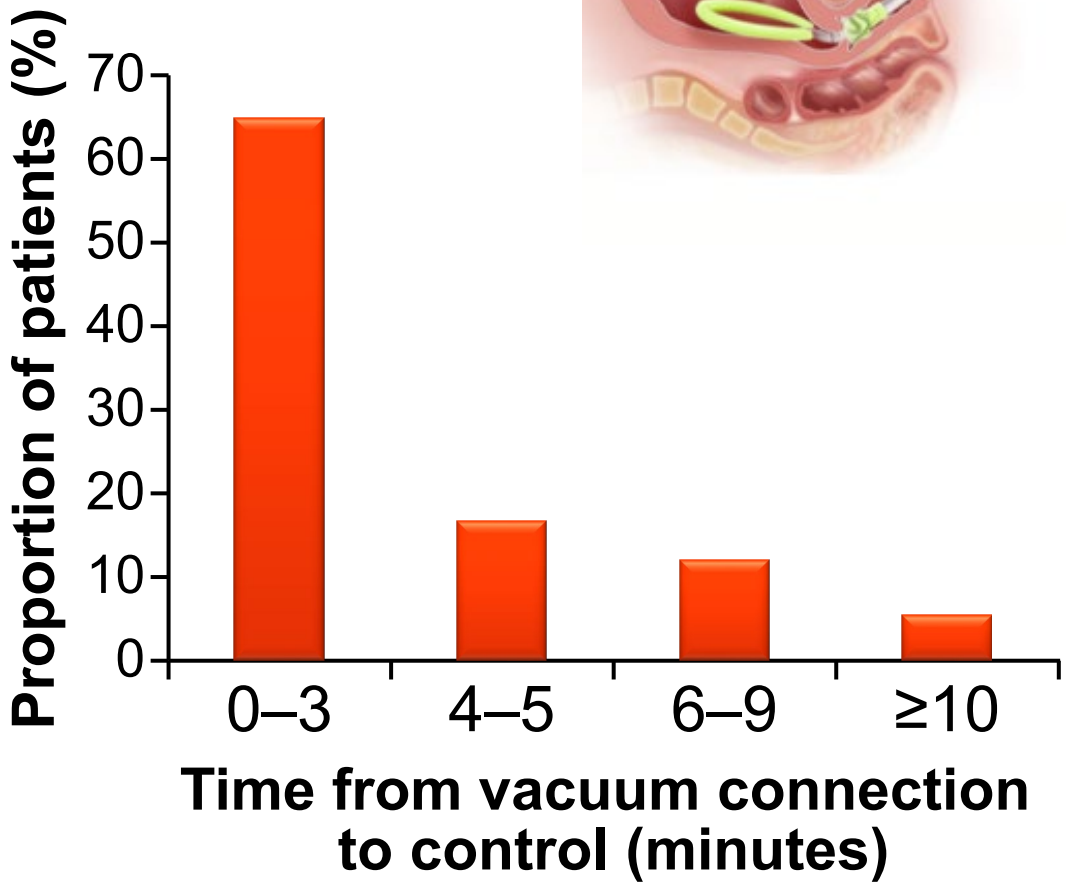
To evaluate effectiveness and safety of an intrauterine vacuum-induced hemorrhage-control device for PPH treatment

## METHODS:

Multicenter, prospective, single-arm treatment study of a novel intrauterine device that uses low-level vacuum to induce uterine myometrial contraction to achieve control of abnormal postpartum uterine bleeding and PPH

## RESULTS:

- 106 received any study treatment with the device connected to vacuum
- Successful treatment was observed in 94% (100/106, 95% CI 88–98%) of participants

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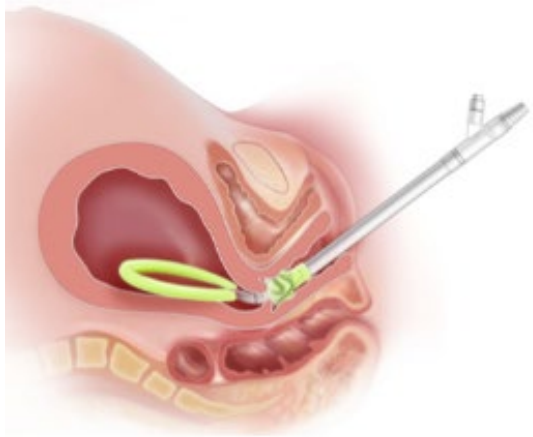
D'Alton ME, et al. *Obstet Gynecol*. 2020 Nov;136(5):882-891

# Response Opportunity: Jada

## SAFETY

- Eight adverse events reported deemed “possibly related” to the procedure
- All events were expected risks and resolved with treatment
- Events included mild endometritis, mild presumed endometritis, mild bacterial vaginosis, mild vaginal candidiasis, mild laceration repair disruption (n=1), and moderate endometritis (n=3)



## OVERALL INVESTIGATOR ASSESSMENT

- 98% reported device did not prohibit normal postpartum activities



Goffman poster [data on file]. D'Alton ME, et al. *Obstet Gynecol*. 2020 Nov;136(5):882-891.

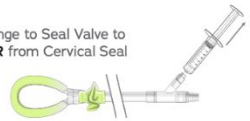
# Jada SYSTEM Quick Reference Guide

## 1. EVALUATE PATIENT & PREPARE JADA

**Evaluate patient** for lacerations, retained products of conception, or other causes of bleeding before using Jada.

**Connect a vacuum** canister and standard vacuum tubing to a regulated vacuum source.

Connect syringe to Seal Valve to **REMOVE AIR** from Cervical Seal before use.

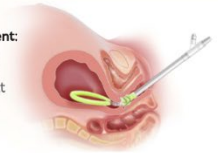


## 2. INSERT JADA

Grasp and compress Intrauterine Loop and **insert transvaginally**.

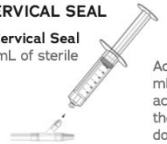
Use gentle traction on the anterior cervical lip to stabilize the cervical opening, if needed.

**Ensure correct placement:** Intrauterine Loop within the uterus and Cervical Seal within the vagina at the external cervical os.



## 3. FILL CERVICAL SEAL

**Fill the Cervical Seal** with 60 mL of sterile fluid.



Add up to another 60 mL of fluid, if needed, to achieve full coverage of the external cervical os; do not exceed 120 mL.

**Do NOT advance** Cervical Seal into the uterus while filling. Confirm Cervical Seal is outside cerfical os.

## 4. TURN ON & SET VACUUM, THEN CONNECT TUBING

**Turn on vacuum** source and set to 80 mm Hg (+/- 10 mm Hg) while occluding the end of the tubing.
Maximum vacuum pressure is 90 mm Hg.

80 mm Hg = 1.5 psi = 10.7 kPa = 3.2 in Hg = 106.7 mbar

**Connect Jada** to vacuum tubing.

## 5. TREATMENT

- **Leave Jada in place** with vacuum applied, using tape to secure the Tube to the patient's inner thigh.
- Blood flow into the vacuum tubing and/or improvement in uterine tone should be noted after initiation of vacuum.
- After initial evacuation of any pooled blood, presentation may vary during treatment: there may be no further blood evacuation, or additional blood moving into the tubing, or accumulation of blood in the canister.
- **Verify bleeding is controlled**.
- **Leave vacuum on for at least one hour** after bleeding is controlled, and verify the uterus is firm and patient is stable before disconnecting vacuum.
- Consider prophylactic antibiotics for prolonged use. **Do not leave the Jada in place for >24 hours.**

## 6. VERIFY

- Ensure Tube remains secured with tape to patient's inner thigh.
- **Disconnect vacuum tubing** from Jada while vacuum is on.
- **Remove all sterile fluid** from Cervical Seal.
- **Wait at least 30 minutes** to verify bleeding is controlled.
- If bleeding recurs, repeat steps 3 – 6, if appropriate.

## 7. REMOVE JADA

- If bleeding remains controlled and the uterus remains firm, **remove the Jada slowly** while supporting the uterine fundus.

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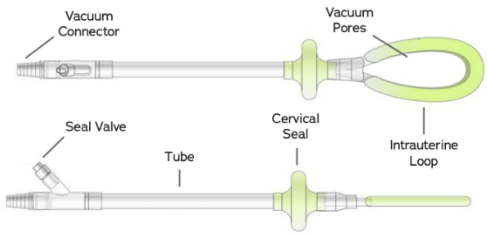
## TROUBLESHOOTING

| SITUATION | RECOMMENDED ACTION |
|---|---|
| Vacuum is not detected at the end of the vacuum tubing. | a) Check connection on all system components:<br>• Confirm vacuum source is functional, including regulator.<br>• Confirm lid of vacuum canister is fully seated and that canister is not cracked.<br>• Confirm vacuum tubing is securely connected at both ends and any connection in between.<br>b) Confirm desired vacuum level is regulated in the appropriate units (i.e. mm Hg vs. cm Hg). |
| Vacuum system is connected and working but uterus does not collapse and/or bleeding does not stop. | a) Increase vacuum pressure to maximum (90 mm Hg).<br>b) Disconnect the vacuum tubing from Jada and occlude the end of the tubing to check vacuum.<br>c) Confirm appropriate Jada placement, with ultrasound if needed:<br>• Confirm proper placement of Intrauterine Loop in uterus (vs. misplacement in posterior vaginal fornix).<br>• Confirm proper placement of Cervical Seal outside of the cervical os (vs. misplacement into uterus).<br>• Ensure Cervical Seal is sufficiently filled with sterile fluid to create adequate seal at the cervix.<br>d) Re-evaluate patient for other sources of bleeding. |

## JADA COMPONENTS




## MATERIALS REQUIRED BUT NOT SUPPLIED

- Regulated Vacuum Source
- Vacuum Canister
- Tape
- Sterile Vacuum Tubing: 10'-12'
- 60 mL Sterile Fluid (Max 120 mL)
- Sterile Luer Tapered Syringe: 60 mL recommended

CAUTION: Please refer to the Jada System Instructions for Use (IFU) for complete information. The Jada System IFU can be found at www.alydiahealth.com/IFU

Federal law (USA) restricts the Jada System to sale by or on the order of a physician.



Alydia HEALTH

**ONGOING EVALUATION OF VITAL SIGNS AND CLINICAL TRIGGERS**

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

i. Perform fundal massage
ii. Record and announce cumulative quantitative blood loss
iii. Record vital signs and oxygen saturation every 5 minutes
iv. Obtain hemorrhage supply cart and bring to patient's bedside
v. Establish IV access with at least 18 gauge, if possible
vi. Insert/Maintain urinary catheter
vii. Increase IV fluid (crystalloid 3:1 ratio without oxytocin)
viii. Increase oxytocin, additional uterotonics (Table 5)
ix. Confirm active type and screen and consider Type & Cross 2 units RBCs
x. Determine and treat etiology by evaluating uterine atony, trauma or laceration, retained placenta, placenta accreta, uterine inversion, uterine rupture, coagulopathy or amniotic fluid embolism.

(Evaluate patient for the 4 T's (tone, trauma, tissue, thrombin).

a) For uterine atony with ongoing bleeding despite fundal massage and appropriate first-line uterotonics, consider vacuum-induced hemorrhage control device (if available). See PPC Guideline, **"Jada Intrauterine Vacuum Hemorrhage Control."**

c. **STAGE 2: Continued bleeding with EBL up to 1500 mL OR requiring ≥ 2 uterotonics with NORMAL vital signs AND lab values (2 or more uterotonics in addition to routine oxytocin administration; or ≥ 2 administrations of the same uterotonic).**

i. Activate rapid, coordinated hemorrhage response team
ii. Establish second IV access with 16 gauge, if possible
iii. Draw and send STAT labs including: CBC, coagulation profile and fibrinogen level
iv. If uterine atony present, consider vacuum-induced hemorrhage control device (if available), intrauterine balloon, embolization or surgical interventions
v. Continue administration of medications from Stage 1 (Table 5), consider TXA (Table 6)
vi. DO NOT WAIT for lab results. Transfuse patient per clinical signs, symptoms and ongoing blood loss
vii. Notify Blood Bank of OB hemorrhage while obtaining 2 units RBCs to bedside and thaw 2 units FFP
viii. Prepare OR. Consider moving patient to operating room for improved exposure and potential D&C



ix. Perform team huddle and move to Stage 3 if continued blood loss and/or abnormal vital signs.

d. **STAGE 3: Continued bleeding with EBL >1500mL OR >2 units RBCs given OR at risk for occult bleeding/coagulopathy OR any patient with ABNORMAL vital signs/labs/oliguria**

# Demonstration Video

- https://www.alydiahealth.com/jada
- https://www.youtube.com/watch?v=9Pnb9GDNppI&feature=youtu.be

# Summary Points

- Obstetric hemorrhage bundles provide a framework for comprehensive review of readiness, recognition, response and reporting

- PPH risk assessment provides an opportunity to consider risk for each patient and to be prepared
  However PPH can occur without obvious risk factors and risk can evolve over time; therefore, it is important to always be ready

- Objective and cumulative assessment of blood loss is critical to promote recognition of PPH and to allow timely intervention

# Summary Points

- Improved recognition promotes early aggressive response
- Effective response requires:
  - Key teamwork behaviors
  - Seamless multidisciplinary communication
  - Effective uterotonic administration
  - TXA
  - Device use
  - Surgical intervention when bleeding not promptly controlled with conservative measures

# Questions?