Billing Code: 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Healthcare Research and Quality
Scientific Information Request on Management of Postpartum Hemorrhage

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of Management of Postpartum Hemorrhage, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:
Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/. Please select the study for which you are submitting information from the list to upload your documents.

E-mail submissions:SIPS@epc-src.org.

Print submissions

Mailing Address:
Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
PO Box 69539
Portland, OR 97239

Shipping Address (FedEx, UPS, etc.):
Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
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Portland, OR 97239

FOR FURTHER INFORMATION CONTACT:

Ryan McKenna,Telephone: 503-220-8262 ext. 58653 or Email: SIPS@epc-src.org.

SUPPLEMENTARY INFORMATION:

AHRQ has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for Management of Postpartum Hemorrhage.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Management of Postpartum Hemorrhage, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1918.

This notice is to notify the public that the EHC program would find the following information on Management of Postpartum Hemorrhage helpful:

· A list of completed studies that your company has sponsored for this indication. In the list, please indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.

· For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

· A list of ongoing studies that your company has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

· Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your company for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EHC Program. Since the contents of all submissions will be made available to the public upon request, materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EHC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC program web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is also available online at: http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1918

The Key Questions (KQ)

KQ1. What is the evidence for the comparative effectiveness of interventions for management of postpartum hemorrhage?

a. What is the comparative effectiveness of interventions intended to treat postpartum hemorrhage likely due to atony?

b. What is the comparative effectiveness of interventions intended to treat postpartum hemorrhage likely due to retained placenta?

c. What is the comparative effectiveness of interventions intended to treat postpartum hemorrhage likely due to genital tract trauma?

d. What is the comparative effectiveness of interventions intended to treat postpartum hemorrhage likely due to uncommon causes (e.g., coagulopathies, uterine inversion, subinvolution)?

KQ2.What is the evidence for choosing one intervention over another and when to proceed to subsequent interventions for management of postpartum hemorrhage?

KQ3. What are the comparative harms, including adverse events, associated with interventions for management of postpartum hemorrhage?

KQ4. What is the comparative effectiveness of interventions to treat acute blood loss anemia after stabilization of postpartum hemorrhage?

KQ5. What systems-level interventions are effective in improving management of postpartum hemorrhage?

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOMES, TIMING, AND SETTING)

Population

- KQ1-3: Women with postpartum hemorrhage (PPH) immediately post-birth to 12 weeks postpartum following pregnancy >24 weeks gestation
- KQ4: Women with stabilized PPH and acute blood loss anemia

- KQ 1-5: All modes of birth

Intervention(s)

- KQ1-3, 5

    - Compression techniques (external uterine massage, bimanual compression, aortic compression)

    - Medications (oxytocin [Pitocin], prostaglandin El [Misoprostol, Cytotec], methylergonovine [Methergine], prostaglandin 15-methyl F2a [Hemabate], prostaglandin E2 [Dinoprostone], recombinant factor Vila [NovoSeven], and tranexamic acid [Cyklokapron])

    - Devices (Bakri postpartum balloon, Foley catheter, Sengstaken-Blakemore tube, Rusch balloon)

    - Procedures (manual removal of placenta, manual evacuation of clot, uterine tamponade, uterine artery embolization, laceration repair)

    - Surgeries (curettage, uterine artery ligation, uterine hemostatic compression suturing, hysterectomy)

    - Blood and fluid products

    - Anti-shock garment

    - Systems-level interventions (e.g., implementation of protocols, training)

- KQ4

    - Interventions for acute blood loss anemia (e.g., iron replacement, erythropoietin)

Comparator

- Different intervention (any intervention compared with any other intervention)

- Placebo

Outcomes

- Intermediate outcomes

    - Blood loss

    - Transfusion

    - ICU admission

    - Anemia

- Length of stay

· Final outcomes

- Mortality
- Uterine preservation
- Future fertility
- Breastfeeding
- Psychological impact
- Harms

Timing

· Immediately post-birth to 12 weeks postpartum

· Primary (< 24 hours postpartum) or secondary (>= 24 hours postpartum)

Setting

All birth settings (hospital, birth center, home)

Dated: July 1, 2014.

Richard Kronick,
AHRQ Director.

[FR Doc. 2014-16667 Filed 07/17/2014 at 8:45 am; Publication Date: 07/18/2014]