



## Effective Health Care

### Evaluation and management of headaches in pregnancy

#### Results of Topic Selection Process & Next Steps

The nominator, ACOG is interested in a new evidence review on Evaluation and management of headaches in pregnancy to develop a new clinical practice guideline.

This topic will go forward for refinement as a new systematic review. The scope of this topic, including populations, interventions, comparators, and outcomes, will be further developed in the refinement phase. When key questions have been drafted, they will be posted on the AHRQ Web site and open for public comment. To sign up for notification when this and other Effective Health Care (EHC) Program topics are posted for public comment, please go to <https://effectivehealthcare.ahrq.gov/email-updates>.

#### Topic Brief

**Topic Number and Name:** #0817, Evaluation and management of headaches in pregnancy

**Nomination Date:** 9/5/2018

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**Conflict of Interest:** None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

## Background

When a pregnant patient presents with a headache, the clinician must first distinguish between a primary headache (when pain is the disease) from a secondary headache (when pain is a symptom of another disease). The primary decisional dilemma is how to make this diagnosis so to begin correct therapy. Primary headache disorders are classified as migraines (acute, chronic), tension headaches or cluster headaches. In pregnant women, secondary headaches may arise from pre-eclampsia/eclampsia or during the postpartum period from anesthesia (post-dural puncture headache) or changes in hormones, hydration, and sleep patterns. In any woman, serious secondary causes can include neurologic emergencies such as intracranial hemorrhage, cerebral venous thrombosis, and pituitary apoplexy.

Headaches are common in pregnancy. In US and international studies, 12-29% of pregnant women met migraine diagnostic criteria, and another 10-16% reported non-migraine headaches.<sup>1,2</sup> While these headaches are benign, they take a toll on quality of life. Migraine headaches have been associated with some poor outcomes in pregnancy. Post-dural puncture headaches (PDPH) are also common: one third of women in the US have a cesarean section, and most of these are receive spinal anesthesia. Up to 30% of these develop PDPH, which is the third most common reason for obstetric claims against anesthesiologists.<sup>3</sup> Even without cesarean section, most women have some type of epidural anesthesia during labor. Although the incidence of accidental dural puncture is less than 1% after epidural anesthesia, more than half of those women develop PDPH.<sup>4</sup> PDPH is notoriously unresponsive to pain medications, and can interfere with maternal-newborn bonding and increase the length of hospitalization. The standard treatment has been a second procedure (epidural blood patch).<sup>5</sup>

Although most headaches during pregnancy are benign, they can also be an indication that a woman is suffering from a dangerous etiology that requires emergent intervention. For example, 2-10% of pregnant women develop preeclampsia, which requires careful management to avoid harm to the mother and child. Headaches can be a symptom that predicts preeclampsia. Cerebral venous thrombosis is another rare but serious outcome that can cause headaches.<sup>6</sup>

There are two significant clinical decisional dilemmas: first, clinicians need guidance on how to quickly and accurately diagnose whether a headache is due to a serious etiology, while weighing the risks and benefits of available imaging and diagnostic tests in pregnancy and guidance is lacking. Secondly, clinicians need guidance on the relative benefits and harms of treatment options for primary headaches to improve the quality of life for pregnant women, but guidance is lacking.

ACOG has not written any guidelines, committee opinions or practice bulletins for any headache topics. The AAP/ACOG "Guidelines for perinatal Care. 2017" mentions headache as a complication of infection, pre-eclampsia, and neuroaxial anesthesia, but does not mention diagnosis, prevention or treatment.<sup>7</sup> The American Headache Society has not published any guidance for pregnant women. Their three recent guidelines based on their own reviews do not mention pregnant women: migraine prophylaxis in 2015<sup>8</sup>, pharmacologic treatment of acute migraine in the emergency department in 2016<sup>9</sup>, and treatment of cluster headache.<sup>10</sup>

## Nominator and Stakeholder Engagement

The nominator (ACOG) is responsive and engaged, and has agreed to the proposed scope.

## Key Questions and PICOTs

The key questions for this nomination are:

1. In pregnant women, what is the diagnostic accuracy of instruments or imaging used to identify [rule out] serious underlying secondary causes of headache?
2. What are the harms, effectiveness, and comparative effectiveness and harms of treatments for headache in pregnancy?
  - a. By headache type:
    - i. migraines (acute, chronic)
    - ii. tension headaches
    - iii. cluster headaches
    - iv. postpartum headaches
    - v. pre-eclampsia headaches
    - vi. suspected medication overuse or withdrawal (analgesics)
  - b. Within each subtype, does effectiveness differ for new onset vs. pre-existing headaches?
3. What are the harms, effectiveness, and comparative effectiveness of interventions to prevent headache in pregnancy?
  - a. By headache type:
    - i. migraines (acute, chronic)
    - ii. tension headaches
    - iii. cluster headaches
    - iv. postpartum headaches
  - b. Within each subtype, does effectiveness differ for new onset vs. pre-existing headaches?

The contextual question is: how should diagnostic tests or treatment algorithms be modified in the pregnant woman?

To define the inclusion criteria for the key questions, we specify the population, interventions, comparators, outcomes, timing, and setting (PICOTS) of interest (Table 1).

**Table 1. Key Questions and PICOTS**

<b>Key Questions</b>	<b>KQ1: diagnosis of serious etiology</b>	<b>KQ2: treatment</b>	<b>KQ3: prevention</b>
<b>Population</b>	Pregnant and postpartum women with new and existing headaches	Pregnant and postpartum women with: <ul style="list-style-type: none"> <li>• Migraine</li> <li>• Tension</li> <li>• Cluster</li> <li>• Postpartum</li> <li>• With preeclampsia and headache</li> <li>• Analgesic medication overuse or withdrawal</li> </ul>	Pregnant and postpartum women with: <ul style="list-style-type: none"> <li>• Migraine</li> <li>• Tension</li> <li>• Cluster</li> <li>• Postpartum</li> <li>• With preeclampsia and headache</li> </ul>
<b>Interventions</b>	Diagnostic tests/instruments, Assessment plus imaging (CT, MRI, MRV, MRA)	Pharmacologic <ul style="list-style-type: none"> <li>• acetaminophen, anti-emetics, antihistamines, caffeine, magnesium, NSAIDs, OTC analgesic,</li> <li>• triptans, narcotics, bupropion</li> </ul> Non-pharmacologic ( <i>hydration, physiotherapy, others</i> )	Pharmacologic <ul style="list-style-type: none"> <li>• verapamil, prednisolone</li> </ul> Non-pharmacologic ( <i>hydration, physiotherapy, others</i> )
<b>Comparators</b>	Other test, no test, Assessment without imaging, usual care?	Other treatment, Placebo, No intervention	Other treatment, Placebo, No intervention
<b>Outcomes</b>	Urgent etiology <ul style="list-style-type: none"> <li>• Intracranial hemorrhage</li> <li>• Increased intracerebral pressure</li> <li>• Cerebral venous thrombosis</li> <li>• Pituitary apoplexy (Sheehan's)</li> <li>• Pre-rupture, expanding cerebral aneurysm</li> <li>• Seizure</li> </ul>	Symptom severity, Resolution	Occurrence rate/frequency, Symptom severity
<b>Timing</b>	Any	Any	Any
<b>Setting</b>	Any	Any	Any

## Methods

We assessed nomination #0817, Evaluation and management of headaches in pregnancy, for priority for a systematic review or other AHRQ EHC report with a hierarchical process using established selection criteria. Assessment of each criterion determined the need to evaluate the next one. See Appendix A for detailed description of the criteria.

1. Determine the *appropriateness* of the nominated topic for inclusion in the EHC program.
2. Establish the overall *importance* of a potential topic as representing a health or healthcare issue in the United States.
3. Determine the *desirability of new evidence review* by examining whether a new systematic review or other AHRQ product would be duplicative.
4. Assess the *potential impact* a new systematic review or other AHRQ product.
5. Assess whether the *current state of the evidence* allows for a systematic review or other AHRQ product (feasibility).
6. Determine the *potential value* of a new systematic review or other AHRQ product.

### Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

### Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years on the key questions of the nomination. See Appendix B for sources searched.

### Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

### Feasibility of New Evidence Review

We conducted a literature search in PubMed from December 2013 to December 2018. Because of the low return, the librarian validated the search strategy, using a list of the citations from two of the most recent reviews. The search found all of them so for a feasibility search strategy it is robust. We then supplemented the librarian search strategy by with the simplified search strategy recommended by Rice et al.<sup>11</sup> We searched PubMed for “similar articles” using the four SR and five trials identified by the librarian search. We reviewed all identified titles and abstracts for inclusion and classified identified studies by key question and study design to assess the size and scope of a potential evidence review. See Appendix C for the PubMed search strategy, validation citations, and simplified search strategy strings, as well as the ClinicalTrials.gov search.

### Value

We assessed the nomination for value. We considered whether or not the clinical, consumer, or policymaking context had the potential to respond with evidence-based change; and if a partner organization would use this evidence review to influence practice.

## Results

See Appendix A for detailed assessments of all EPC selection criteria.

### Appropriateness and Importance

This is an appropriate and important topic. Headaches in pregnancy are common. Women need safe and effective treatment of primary headaches to improve quality of life. Women need prompt diagnosis of rare but serious etiologies to avoid serious consequences.

### Desirability of New Review/Duplication

A new evidence review would not be duplicative of an existing evidence review. We found no up-to-date systematic reviews for the key questions. We found several non-systematic reviews as background.<sup>12-15</sup> See Table 2, Duplication column.

For KQ1 (diagnosis) we found only one SR on the diagnosis of cerebral venous thrombosis during pregnancy.<sup>6</sup> This review is of uncertain quality, as it included case series and case reports, with a total of only 66 patients for metaanalysis. The literature search date ended September 2016.

For KQ2 (treatment), we found four SRs, each with limitations and outdated literature searches:<sup>16-18</sup>

- Carstairs et al (2016) addressed effects of ondansetron (an anti-emetic) on birth defects. However, the search end date was November 2015, and HA indication was not mentioned. Ondansetron is used in non-pregnant women for nausea associated with migraine.<sup>16</sup>
- Basurto et al (2015) published a good quality Cochrane review of pharmacotherapy to treat PDPH, and included a subset of pregnant women. However, the search ended July 2014.<sup>17</sup>
- Alavero et al (2016) was a good quality Cochrane review of posture and fluids for PDPH, however, the review included only one study with obstetric participants (n=80), and the search ended February 2015.<sup>19</sup>
- Marchenko et al (2015) reviewed the reproductive safety of triptans for migraine, and included a meta-analysis. However, the search ended in “2014.”<sup>18</sup>

For KQ3 (prevention), we found 2 reviews, both on post-dural puncture headache (PDPH).<sup>20, 21</sup> Park et al (2018) compared the effect of bedrest to early ambulation on incidence of PDPH, but it was unclear if they included pregnant women in their strategy. Despite the recent publication, the literature search ended in “2014”.<sup>20</sup> Lee et al (2018) compared the type of spinal needle used in women undergoing cesarean section with no initial limitation on dates; however, the end of the search date was not specified. The authors were contacted.<sup>21</sup>

We found no review protocols in the PROSPERO database.

### Impact of a New Evidence Review

A new systematic review may have moderate level of impact. There is a lack of current guidance. Practice patterns are difficult to determine.

ACOG has not written any guidelines, committee opinions or practice bulletins for any headache topics. The AAP/ACOG “Guidelines for perinatal Care. 2017” mentions headache as a complication of infection, pre-eclampsia, and neuroaxial anesthesia, but does not mention diagnosis, prevention or treatment.<sup>7</sup> The American Headache Society has not published any guidance for pregnant women. Their three recent guidelines based on their own reviews do not

mention pregnant women: migraine prophylaxis in 2015<sup>8</sup>, pharmacologic treatment of acute migraine in the emergency department in 2016<sup>9</sup>, and treatment of cluster headache.<sup>10</sup>

### Feasibility of a New Evidence Review

A new evidence review may be feasible for KQ2 if the outcome of interest focuses on harms, especially for migraine treatment, and for KQ3 if the intervention of interest is prevention of PDPH.

#### KQ1: not feasible

We found no observational or randomized studies on KQ1 (diagnosis) in the last 5 years. The yield might be higher if dates were expanded, however, it is unlikely that any diagnostic studies that focus on pregnant women will be discovered. Several non-systematic reviews suggest that this evidence is limited and expert opinion will continue.<sup>22-24</sup> We found no protocols in progress in PROSPERO, and no trials registered at [clinicaltrials.gov](http://clinicaltrials.gov).

#### KQ2: harms may be feasible for migraine only; effectiveness is not feasible

For KQ2, the librarian search limited to randomized or pragmatic trial designs identified 121 citations, of which 2 (2%) were relevant.<sup>25, 26</sup> The “similar articles” search in PubMed produced an additional 69 citations with relevant titles, from which we identified 18 citations. All of these were observational treatment studies that focused on three medication classes: triptans (9)<sup>26-34</sup>, NSAIDS (6)<sup>25, 30, 35-38</sup>, a single anti-emetic (ondansetron (2))<sup>39, 40</sup>. None of these reported on effectiveness, all outcomes were maternal and fetal safety and harms. We found no protocols in progress in PROSPERO, and a single completed registry (for triptans) in [clinicaltrials.gov](http://clinicaltrials.gov).

The yield will be higher for KQ2 if the dates are expanded, if each drug name is included in the search string, if observational trial designs are included, and if additional databases are used. We found no mention of cluster, tension, postpartum, or medication use headaches in these results, which suggests that this topic could be further restricted to migraine therapy.

#### KQ3: prevention is only feasible for post-dural puncture headache.

The librarian search yielded three citations (one observational and two RTC)<sup>41-43</sup>. The simplified search strategy identified an additional four RCTs<sup>3, 44-46</sup> and two more observational studies<sup>47, 48</sup>. All of these focused on prevention of PDPH. We found no studies on prevention of migraine, no protocols in progress in PROSPERO, and no trials registered at [clinicaltrials.gov](http://clinicaltrials.gov).

Not surprisingly, there was a similar low yield for clinical trials. The search of [clinicaltrials.gov](http://clinicaltrials.gov) yielded 102 citations, but after title and abstract review, only six pertained to pregnancy and headache. Four are reported as complete, with no results listed on the website.

See Table 2, Feasibility column.

**Table 2.** Key Questions and Results for Duplication and Feasibility

Key Question	Duplication (12/2015-12/2018)	Feasibility (12/2013-12/2018)
KQ 1: Diagnosis	Total number of identified systematic reviews: 1 Diagnosis of CVT <sup>6</sup>	<u>Size/scope of review</u> Relevant Studies Identified: 0 <u>Clinicaltrials.gov</u> <ul style="list-style-type: none"> <li>• Recruiting: 0</li> <li>• Active: 0</li> <li>• Complete: 0</li> </ul>

Key Question	Duplication (12/2015-12/2018)	Feasibility (12/2013-12/2018)
KQ 2: Treatment	Total number of identified systematic reviews: 4 (outdated) Medication (PDPH) <sup>17</sup> Posture/fluid (PDPH) <sup>19</sup> Triptans (migraine) <sup>18</sup> Ondansetron (antiemetic) <sup>16</sup>	<u>Size/scope of review</u> Relevant Studies Identified: # <ul style="list-style-type: none"> <li>• RCT: 0</li> <li>• Observational: 20 <sup>25-40, 49-52</sup></li> </ul> <u>Clinicaltrials.gov</u> <ul style="list-style-type: none"> <li>• Recruiting: 1</li> <li>• Active: 0</li> <li>• Complete: 1</li> </ul>
KQ 3: Prevention	Total number of identified systematic reviews: 2 (unsure dates) Prevention of PDPH <sup>20, 21</sup>	<u>Size/scope of review</u> Relevant Studies Identified: # <ul style="list-style-type: none"> <li>• RCT (PDPH): 6 <sup>3, 42-46</sup></li> <li>• Observational: 3 <sup>41, 47, 48</sup></li> </ul> <u>Clinicaltrials.gov</u> <ul style="list-style-type: none"> <li>• Recruiting: 0</li> <li>• Active: 1</li> <li>• Complete: 3</li> </ul>

*Abbreviations:* AHRQ=Agency for Healthcare Research and Quality; KQ=Key Question, PDPH=post-dural puncture headache, RCT=randomized controlled trial; CVT=cerebral venous thrombosis

### Value

The potential for value is moderate as the nominator (ACOG) is planning to write a guideline. The organization is well respected with high potential to influence practice. However, current practice patterns are unknown.

### Summary of Findings

- Appropriateness and importance: The topic is both appropriate and important, as headaches are common, and medication side effects are worrisome to patients and providers.
- Duplication: A new review would not be duplicative of an existing product. We found no recent existing systematic reviews for any key question.
- Impact: A new systematic review has moderate impact potential.
- Feasibility: A new review may be feasible if the KQs were modified. KQ1 is not feasible. KQ2 (Harms of migraine therapy) is feasible; effectiveness is not feasible. For KQ3, prevention of PDPH is feasible. The evidence base is likely small to medium.
- Value: The potential for value is moderate as the nominator is planning to write a guideline that could influence practice.

## References

## Appendix A. Selection Criteria Assessment

Selection Criteria	Assessment
<b>1. Appropriateness</b>	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes
1b. Is the nomination a request for a systematic review?	Yes
1c. Is the focus on effectiveness or comparative effectiveness?	Yes
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes
<b>2. Importance</b>	
2a. Represents a significant disease burden; large proportion of the population	12-29% of pregnant women have migraine, and another 10-16% reported non-migraine headaches; up to one third of women develop PDPH after obstetric anesthesia. These headaches impact quality of life. Medications in pregnancy may cause fetal and infant harms.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes
2c. Represents important uncertainty for decision makers	Yes
2d. Incorporates issues around both clinical benefits and potential clinical harms	Yes
2e. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	No/ Not assessed
<b>3. Desirability of a New Evidence Review/Duplication</b>	
3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others)	No recent published systematic reviews cover any of the KQ
<b>4. Impact of a New Evidence Review</b>	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Current guidelines are based on expert opinion.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Unknown
<b>5. Primary Research</b>	
5. Effectively utilizes existing research and knowledge by considering:- Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	The literature base is likely to be small, and based on observational study designs. The exception is that some RCTs exist for prevention and treatment of PDPH.
<b>6. Value</b>	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Yes
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Yes. The nominator (ACOG) intends to use the SR to develop a guideline, with high potential to influence practice.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; KQ=Key Question

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37. Nezvalova-Henriksen K, Spigset O, Nordeng H. Effects of ibuprofen, diclofenac, naproxen, and piroxicam on the course of pregnancy and pregnancy outcome: a prospective cohort study. *BJOG*. 2013 Jul;120(8):948-59. doi: 10.1111/1471-0528.12192. PMID: 23489333.
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39. Fejzo MS, MacGibbon KW, Mullin PM. Ondansetron in pregnancy and risk of adverse fetal outcomes in the United States. *Reprod Toxicol*. 2016 Jul;62:87-91. doi: 10.1016/j.reprotox.2016.04.027. PMID: 27151373.
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the Norwegian Mother and Child Cohort Study. *BMJ Open*. 2016 Sep 13;6(9):e011971. doi: 10.1136/bmjopen-2016-011971. PMID: 27625061.

**50.** Harris GE, Wood M, Eberhard-Gran M, et al. Patterns and predictors of analgesic use in pregnancy: a longitudinal drug utilization study with special focus on women with migraine. *BMC Pregnancy Childbirth*. 2017 Jul 14;17(1):224. doi: 10.1186/s12884-017-1399-0. PMID: 28705177.

**51.** Rana K, Jenkins S, Rana M. Insertion of an intrathecal catheter following a recognised accidental dural puncture reduces the need for an epidural blood patch in parturients: an Australian retrospective study. *Int J Obstet Anesth*. 2018 Nov;36:11-6. doi: 10.1016/j.ijoa.2018.08.005. PMID: 30245259.

**52.** Verstraete S, Walters MA, Devroe S, et al. Lower incidence of post-dural puncture headache with spinal catheterization after accidental dural puncture in obstetric patients. *Acta Anaesthesiol Scand*. 2014 Nov;58(10):1233-9. doi: 10.1111/aas.12394. PMID: 25307708.

## Appendix B. Search for Evidence Reviews (Duplication)

Listed below are the sources searched, hierarchically

Primary Search	Results
AHRQ: Evidence reports and technology assessments <a href="https://effectivehealthcare.ahrq.gov/">https://effectivehealthcare.ahrq.gov/</a> ; <a href="https://www.ahrq.gov/research/findings/ta/index.html">https://www.ahrq.gov/research/findings/ta/index.html</a> ; <a href="https://www.ahrq.gov/research/findings/evidence-based-reports/search.html">https://www.ahrq.gov/research/findings/evidence-based-reports/search.html</a>	0
VA Products: PBM, and HSR&D (ESP) publications, and VA/DoD EBCPG Program <a href="https://www.hsrd.research.va.gov/publications/esp/">https://www.hsrd.research.va.gov/publications/esp/</a>	0
Cochrane Systematic Reviews <a href="http://www.cochranelibrary.com/">http://www.cochranelibrary.com/</a>	2 17, 19
HTA (CRD database): Health Technology Assessments <a href="http://www.crd.york.ac.uk/crdweb/">http://www.crd.york.ac.uk/crdweb/</a>	0 (one outdated) <sup>53</sup>
Secondary Search	
Cochrane Protocols <a href="http://www.cochranelibrary.com/">http://www.cochranelibrary.com/</a>	0
PROSPERO Database (international prospective register of systematic reviews and protocols) <a href="http://www.crd.york.ac.uk/prospéro/">http://www.crd.york.ac.uk/prospéro/</a>	0
Tertiary Search	
PubMed <a href="https://www.ncbi.nlm.nih.gov/pubmed/">https://www.ncbi.nlm.nih.gov/pubmed/</a>	5 <sup>6, 16, 18, 20, 21</sup>

- 6.** Kashkoush AI, Ma H, Agarwal N, et al. Cerebral venous sinus thrombosis in pregnancy and puerperium: A pooled, systematic review. *Journal of Clinical Neuroscience*. 2017;39:9-15. PMID: 28274514.
- 16.** Carstairs SD. Ondansetron Use in Pregnancy and Birth Defects: A Systematic Review. *Obstet Gynecol*. 2016 May;127(5):878-83. doi: 10.1097/AOG.0000000000001388. PMID: 27054939.
- 17.** Basurto Ona X, Osorio D, Bonfill Cosp X. Drug therapy for treating post-dural puncture headache. *Cochrane Database of Systematic Reviews*. 2015(7):CD007887. PMID: 26176166.
- 18.** Marchenko A, Etwel F, Olutunfese O, et al. Pregnancy outcome following prenatal exposure to triptan medications: a meta-analysis. *Headache*. 2015 Apr;55(4):490-501. doi: 10.1111/head.12500. PMID: 25644494.
- 19.** Arevalo-Rodriguez I, Ciapponi A, Roque i Figuls M, et al. Posture and fluids for preventing post-dural puncture headache. *Cochrane Database Syst Rev*. 2016 Mar 7;3:CD009199. doi: 10.1002/14651858.CD009199.pub3. PMID: 26950232.
- 20.** Park S, Kim K, Park M, et al. Effect of 24-Hour Bed Rest versus Early Ambulation on Headache after Spinal Anesthesia: Systematic Review and Meta-analysis. *Pain Manag Nurs*. 2018 Jun;19(3):267-76. doi: 10.1016/j.pmn.2017.10.012. PMID: 29269181.
- 21.** Lee SI, Sandhu S, Djulbegovic B, et al. Impact of spinal needle type on postdural puncture headache among women undergoing Cesarean section surgery under spinal anesthesia: A meta-analysis. *J Evid Based Med*. 2018 Aug;11(3):136-44. doi: 10.1111/jebm.12311. PMID: 30070060.
- 53.** Bradbury CL, Singh SI, Badder SR, et al. Prevention of post-dural puncture headache in parturients: a systematic review and meta-analysis. *Acta Anaesthesiol Scand*. 2013 Apr;57(4):417-30. doi: 10.1111/aas.12047. PMID: 23278515.

## Appendix C. Search Strategy & Results (Feasibility)

### Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to December 14, 2018

Date Searched: December 17, 2018

Searched by: Robin Paynter, MLIS

#	Searches	Results
1	Pregnancy/ or Pregnancy Complications/ or Pregnancy Complications, Cardiovascular/ or Hypertension, Pregnancy-Induced/ or Pregnancy, High-Risk/ or Pregnant Women/ or Postpartum Period/ or Pregnancy Trimesters/ or Pregnancy Trimester, First/ or Pregnancy Trimester, Second/ or Pregnancy Trimester, Third/ or Pre-Eclampsia/	838652
2	(pregnancy or pregnancies or pregnant or eclamps* or gestation* or postpartum or postpartum or preeclamps* or pre-eclamps* or puerper* or ((gestat* or pregnan* or postpartum or post-partum or puerper*) adj10 hypertens*)).ti,ab,hw,kf.	1021452
3	or/1-2	1021452
4	headache/ or headache disorders/ or headache disorders, primary/ or migraine disorders/ or migraine with aura/ or migraine without aura/ or tension-type headache/ or cluster headache/ or *headache disorders, secondary/	53489
5	(headache* or migraine*).ti,ab,hw,kf.	105294
6	or/4-5	105294
7	and/3,6	4418
8	limit 7 to english language	3691
9	Diagnosis/ or early diagnosis/ or delayed diagnosis/ or (di or dg).fs. or (assess* or CT or diagnos* or imaging or instrument* or MRI or MRIs or MRV or MRVs or MRA or MRAs or test or tests or testing).ti,ab,kf.	8072726
10	and/8-9	1955
11	limit 10 to (adaptive clinical trial or clinical trial, all or clinical trial or controlled clinical trial or equivalence trial or pragmatic clinical trial or randomized controlled trial)	150
12	limit 11 to yr="2013 -Current"	35
13	limit 10 to (meta analysis or systematic reviews)	87
14	limit 13 to yr="2015 -Current"	29
15	Primary Prevention/ or Secondary Prevention/ or pc.fs. or (prevent* or verapamil or prednisolone or hydrat* or physiotherap*).ti,ab,kf.	2268250
16	and/7,15	787

17	limit 16 to (adaptive clinical trial or clinical trial, all or clinical trial or controlled clinical trial or equivalence trial or pragmatic clinical trial or randomized controlled trial)	82
18	limit 17 to yr="2013 -Current"	18
19	limit 16 to (meta analysis or systematic reviews)	48
20	limit 19 to yr="2015 -Current"	16
21	exp therapeutics/ or exp drug therapy/ or Acetaminophen/ or exp Antiemetics/ or exp Anti-Inflammatory Agents, Non-Steroidal/ or Caffeine/ or exp Histamine Antagonists/ or Magnesium Sulfate/ or exp Narcotics/ or exp Nonprescription Drugs/ or exp Tryptamines/ or (dt or th or tu).fs.	6869852
22	(treat* or therap* or acetaminophen or antiemetic* or anti-emetic* or antihistamine* or anti-histamine* or bultalbitol or caffeine or drug or drugs or hydrat* or magnesium or medication* or narcotic* or nonpharmacolog* or non-pharmacolog* or nonprescription or non-prescription or NSAIDor or NSAIDS or "non-steroidal anti-inflammatory" or ((OTC or "over-the-counter") adj4 analges*) or physiotherap* or pharmacolog* or triptans).ti,ab,kf.	7363213
23	or/21-22	10603862
24	and/8,23	2643
25	limit 24 to (adaptive clinical trial or clinical trial, all or clinical trial or controlled clinical trial or equivalence trial or pragmatic clinical trial or randomized controlled trial)	298
26	limit 25 to yr="2013 -Current"	39
27	limit 24 to (meta analysis or systematic reviews)	111
28	limit 27 to yr="2015 -Current"	37

### ClinicalTrials.gov

Date searched: December 17, 2018

( pregnant OR pregnancy OR pregnancies OR gestation OR post-partum OR postpartum OR pre-eclampsia OR puerper\* OR perinatal OR peri-natal ) AND ( headache OR headaches OR migraine OR migraines ) AND INFLECT EXACT ( "Active, not recruiting" OR "Completed" ) [OVERALL-STATUS] = 102 studies

### **Citations used to test/validate the search strategy (citations culled from the included studies lists in the Negro review (#1 below) and Wabnitz review (#3 below)):**

1. Negro A, Delaruelle Z, Ivanova TA, Khan S, Ornello R, Raffaelli B, Terrin A, Reuter U, Mitsikostas DD, European Headache Federation School of Advanced Studies (EHF-SAS). *Headache and pregnancy: a systematic review*. J HEADACHE PAIN. 2017;18(1):106.

2. Spierings EL, Sabin TD. *De Novo Headache During Pregnancy and Puerperium*. Neurolog. 2016;21(1):1-7.
3. Wabnitz A, Bushnell C. *Migraine, cardiovascular disease, and stroke during pregnancy: systematic review of the literature*. Cephalalgia. 2015;35(2):132-9.
4. Czerwinski S, Gollero J, Qiu C, Sorensen TK, Williams MA. *Migraine-asthma comorbidity and risk of hypertensive disorders of pregnancy*. J Pregnancy. 2012;2012858097.
5. Scott CA, Bewley S, Rudd A, Spark P, Kurinczuk JJ, Brocklehurst P, Knight M. *Incidence, risk factors, management, and outcomes of stroke in pregnancy*. Obstet Gynecol. 2012;120(2 Pt 1):318-24.
6. Williams MA, Peterlin BL, Gelaye B, Enquobahrie DA, Miller RS, Aurora SK. *Trimester-specific blood pressure levels and hypertensive disorders among pregnant migraineurs*. Headache. 2011;51(10):1468-82.
7. Cripe SM, Frederick IO, Qiu C, Williams MA. *Risk of preterm delivery and hypertensive disorders of pregnancy in relation to maternal co-morbid mood and migraine disorders during pregnancy*. Paediatr Perinat Epidemiol. 2011;25(2):116-23.
8. Simbar M, Karimian Z, Afrakhteh M, Akbarzadeh A, Kouchaki E. *Increased risk of preeclampsia (PE) among women with the history of migraine*. Clin Exp Hypertens. 2010;32(3):159-65.
9. Chen HM, Chen SF, Chen YH, Lin HC. *Increased risk of adverse pregnancy outcomes for women with migraines: a nationwide population-based study*. Cephalalgia. 2010;30(4):433-8.
10. Bushnell CD, Jamison M, James AH. *Migraines during pregnancy linked to stroke and vascular diseases: US population based case-control study*. BMJ. 2009;338b664.
11. Facchinetti F, Allais G, Nappi RE, D'Amico R, Marozio L, Bertozzi L, Ornati A, Benedetto C. *Migraine is a risk factor for hypertensive disorders in pregnancy: a prospective cohort study*. Cephalalgia. 2009;29(3):286-92.
12. Sanchez SE, Qiu C, Williams MA, Lam N, Sorensen TK. *Headaches and migraines are associated with an increased risk of preeclampsia in Peruvian women*. Am J Hypertens. 2008;21(3):360-4.
13. Melhado EM, Maciel JA Jr, Guerreiro CA. *Headache during gestation: evaluation of 1101 women*. Can J Neurol Sci. 2007;34(2):187-92.
14. van Vliet JA, Favier I, Helmerhorst FM, Haan J, Ferrari MD. *Cluster headache in women: relation with menstruation, use of oral contraceptives, pregnancy, and menopause*. J Neurol Neurosurg Psychiatry. 2006;77(5):690-2.
15. Adeney KL, Williams MA, Miller RS, Frederick IO, Sorensen TK, Luthy DA. *Risk of preeclampsia in relation to maternal history of migraine headaches*. J Matern Fetal Neonatal Med. 2005;18(3):167-72.
16. James AH, Bushnell CD, Jamison MG, Myers ER. *Incidence and risk factors for stroke in pregnancy and the puerperium*. Obstet Gynecol. 2005;106(3):509-16.
17. Ertresvag JM, Zwart JA, Helde G, Johnsen HJ, Bovim G. *Headache and transient focal neurological symptoms during pregnancy, a prospective cohort*. Acta Neurol Scand. 2005;111(4):233-7.
18. Kelman L. *Women's issues of migraine in tertiary care*. Headache. 2004 [cited 2004 Jan];44(1):2-7.
19. Mattsson P. *Hormonal factors in migraine: a population-based study of women aged 40 to 74 years*. Headache. 2003;43(1):27-35.
20. Sances G, Granella F, Nappi RE, Fignon A, Ghiotto N, Polatti F, Nappi G. *Course of migraine during pregnancy and postpartum: a prospective study*. Cephalalgia. 2003;23(3):197-205.
21. Granella F, Sances G, Pucci E, Nappi RE, Ghiotto N, Napp G. *Migraine with aura and reproductive life events: a case control study*. Cephalalgia. 2000;20(8):701-7.

22. Marcus DA, Scharff L, Turk D. *Longitudinal prospective study of headache during pregnancy and postpartum*. *Headache*. 1999;39(9):625-32.
23. Maggioni F, Alessi C, Maggino T, Zanchin G. *Headache during pregnancy*. *Cephalalgia*. 1997;17(7):765-9.
24. Scharff L, Marcus DA, Turk DC. *Headache during pregnancy and in the postpartum: a prospective study*. *Headache*. 1997;37(4):203-10.
25. Granella F, Sances G, Zanferrari C, Costa A, Martignoni E, Manzoni GC. *Migraine without aura and reproductive life events: a clinical epidemiological study in 1300 women*. *Headache*. 1993;33(7):385-9.
26. Marcoux S, Berube S, Brisson J, Fabia J. *History of migraine and risk of pregnancy-induced hypertension*. *Epidemiology*. 1992;3(1):53-6.

**Similar article search strategy:** <sup>11</sup>

Limit results to English language, pregnant and published after 2013

Search	Query
#28	Similar articles for PubMed (Select 25812804)
#26	Similar articles for PubMed (Select 23903901)
#25	Similar articles for PubMed (Select 23489333)
#23	Search (#22) AND pregnan* Filters: English
#22	Similar articles for PubMed (Select 24805878)
	Search (#20) AND pregnan* Filters: English Sort by:
#21	PublicationDate
#20	Similar articles for PubMed (Select 26176166)
#19	Similar articles for PubMed (Select 25644494)
	Search (#17) AND pregnan* Filters: English Sort by:
#18	PublicationDate
#17	Similar articles for PubMed (Select 26939384)
#15	Search (#14) AND pregnan* Filters: English
#14	Similar articles for PubMed (Select 28274514)
#13	Search #10 Filters: English Sort by: PublicationDate
#10	Similar articles for PubMed (Select 28678882)

**11.** Rice M, Ali MU, Fitzpatrick-Lewis D, et al. Testing the effectiveness of simplified search strategies for updating systematic reviews. *J Clin Epidemiol*. 2017 Aug;88:148-53. doi: 10.1016/j.jclinepi.2017.06.005. PMID: 28625563.

## Original nomination

A topic nomination was submitted on the EHC website:

Submitted on Wednesday, September 5, 2018 - 09:52

==Topic Suggestion==

1. Describe your topic: Our topic nomination is Headaches in Pregnancy. The following is a list of clinical questions practitioners consider when managing such cases:

- a. Which headache symptoms require prompt/urgent evaluation?
- b. When is imaging indicated for headaches during pregnancy?
- c. What are the treatment options for migraine during pregnancy (include both acute and preventative treatment)?
- d. What are the treatment options for tension or cluster headaches during pregnancy?
- e. How is medication overuse headache diagnosed and treated?
- f. How should headache associated with preeclampsia be evaluated and treated?
- g. How should postpartum headache be evaluated and treated?
- h. When is screening for depression warranted in the workup of headaches?

The population of interest includes pregnant patients with headaches (general, tension, cluster) or migraines. The interventions we would like to know more about include prophylactic drug intervention (verapamil, prednisolone) for cluster headaches, physiotherapy or OTC analgesics for tension headaches, MRI or CT imaging for general headaches, and preventive measures (hydration, avoidance of precipitants) or acute treatment options (paracetamol, anti-emetics, NSAIDs) for migraines. The outcomes include recurrence, rate or severity of headaches or migraines.

==Importance of Suggested Topic==

2. Describe why this topic is important: This is an important topic for review because although headaches during pregnancy can be benign, they can also be an indication that a woman is suffering from a more dangerous condition such as a stroke, hemorrhage, eclampsia, or cerebral venous thrombosis. Clinicians need guidance on how to quickly, accurately identify whether a woman is suffering from one of these more serious issues. Additionally, pregnant women more commonly suffer from migraines and tension headaches which can be unpleasant to manage while pregnant. Guidance on treatment options for these conditions is needed to improve the quality of life for pregnant women.

3. Tell us why you are suggesting this topic: We are nominating the topic of headaches in pregnancy because evidence based guidance on diagnosis and treatment options for migraines, tension headaches, and cluster headaches are needed to ensure clinicians are appropriately prepared to care for pregnant women with these conditions.

Target date:

==Impact of a New Evidence Report==

4. Describe what you are doing currently and what you are hoping will change because of a new evidence report.: ACOG is currently working on new clinical guidance in the form of a Practice Bulletin on Headaches in Pregnancy. We hope that a new evidence report will provide more definitive information on treatment options for the different types of headaches pregnant women may experience, to improve their overall health and wellbeing.

5. How will you or your group use the information from a new evidence report? A new evidence report on headaches in pregnancy will be used to develop future clinical guidance in the form of Practice

Bulletins or Committee Opinions on this topic. Clinicians will then be better qualified to identify, make appropriate treatment decisions, and improve health outcomes for pregnant women with headaches.

6. How would you or your group plan to disseminate information from the report? Who would you plan to disseminate it to? ACOG will share the information in this report with its 57,000 members through our website, and will update our clinical guidance to be reflective of the findings from this report.

==Other Stakeholders Who Could Use a New Evidence Report==

7. Do you know of organizations that could use an evidence report to change clinical practice? Are you a part of, or have you been in contact with, any organizations that might implement the research findings of an evidence report? International Headache Society, American Headache Society, American College of Physicians, Society for Maternal-Fetal Medicine, Society for Academic Specialists in General Obstetrics and Gynecology

8. Would you be willing to partner with another organization to develop policy, program, guidelines, or dissemination and implementation materials? This information is for internal discussion only and will not be displayed on the EHC Program Web site.: Yes

==Supporting Document==

Upload Document:

Title or short description:

Comments or notes about this file:

==Information About You==

Provide a description of your role or perspective: Professional society

If you are you making a suggestion on behalf of an organization, please state the name of the organization: The American College of Obstetricians and Gynecologists

Please tell us how you heard about the Effective Health Care Program: AHRQ Alert/Correspondence

First name: Virginia

Last name: Andrews

Title: Program Assistant

Email address: [vandrews@acog.org](mailto:vandrews@acog.org)

May we contact you if we have questions about your nomination? Yes

The results of this submission may be viewed at:

<https://effectivehealthcare.ahrq.gov/node/16119/submission/5979>