Topic Brief: Protocols for Pre-Existing or Gestational Diabetes in Pregnant and Postpartum Women

Date: 7/03/2021
Nomination Number: 0953

Purpose: This document summarizes information addressing a nomination submitted on July 3, 2021, through the Effective Health Care (EHC) Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions on whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue:

Several existing clinical practice guidelines address the management of pre-existing and gestational diabetes during pregnancy. However, the clinical approach to maternal and neonatal glycemic control during the intrapartum and postpartum periods remains variable. Additionally, none of the existing guidelines directly address how optimizing glycemic control in the intrapartum and early postpartum periods may improve initiation and continuation of breast-feeding.

Program Decision

The scope of this topic met all EHC Program selection criteria and was considered for a systematic review, however it was not selected.

Key Findings

- We found one systematic review (which included only two relevant studies) and six primary studies for KQ1, evaluating the effectiveness and comparative effectiveness of standardized protocols for glycemic control in women with pre-existing and gestational diabetes in the intrapartum period.
- We found no systematic reviews and only one RCT for KQ2, comparing the effectiveness of different methodologies for glycemic control in women with pre-existing or gestational diabetes during the early postpartum period.
- We did not identify any systematic reviews or primary studies addressing KQ3, pertaining to the effect of optimized glycemic control on the initiation and continuation of breast-feeding.

Background

Diabetes affects approximately 6-9% of pregnancies, with gestational diabetes accounting for over 90% of cases. Both pre-gestational and gestational diabetes is associated with significant risks due to maternal hyperglycemia, which increases the risk of several pregnancy specific adverse events, and hypoglycemia which poses the risk to the mother. Good glycemic control is particularly important intrapartum because maternal hyperglycemia during labor increases the risk for fetal acidemia and neonatal hypoglycemia, the leading cause of admission to the neonatal

intensive care unit[1]. In the postpartum, as maternal insulin needs decrease due to rapid hormonal changes following placental delivery, avoidance of maternal hyperglycemia becomes less critical and the focus of glycemic management shifts towards preventing maternal hypoglycemia[2].

Numerous professional societies, including the American Association of Clinical Endocrinologists[3], the American College of Obstetrics and Gynecology[4] and the American Diabetes Association[5] issued clinical guidelines for diabetes management during pregnancy and in the intrapartum and early postpartum periods. Despite the existing guidance, currently there is a lack of consistent, standardized approach to glycemic control during labor and delivery and during postpartum. We also found limited published literature examining the association between optimized maternal glycemic control and breast-feeding.

Nomination Summary

The Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN) is seeking to update their 2016 clinical practice guideline[6] to incorporate evidence-based recommendations for glycemic management in women with pre-existing and gestational diabetes during the intrapartum and early postpartum periods. The AWHONN is particularly interested in developing clinical practice recommendations regarding the use of standardized protocols for maternal and neonatal glycemic control based on available evidence-based assessments of the effectiveness and comparative effectiveness of these protocols[7].

Scope

Key Questions:

1. What is the effectiveness and comparative effectiveness of different standardized protocols for glycemic control in women with pre-existing and gestational diabetes during the intrapartum period?
2. What is the effectiveness and comparative effectiveness of different standardized protocols for glycemic control in women with pre-existing and gestational diabetes during the early postpartum period?
3. What is the effect of using standardized protocols for glycemic control in women with pre-existing and gestational diabetes who want to breastfeed on initiation and continuation of breastfeeding during the intrapartum and early postpartum periods?

Table 1a. Questions and PICOTS (population, intervention, comparator, outcome, timing, and setting)

Key Questions	1. What is the effectiveness and comparative effectiveness of different standardized protocols for glycemic control in women with pre-existing and gestational diabetes during the intrapartum period?	2. What is the effectiveness and comparative effectiveness of different standardized protocols for glycemic control in women with pre-existing and gestational diabetes during the early postpartum period?
Population	Women with: (a) pre-existing DM Type I; (b) pre-existing DM Type II; or (c) gestational DM	Women with: (a) pre-existing DM Type I; (b) pre-existing DM Type II, or (c) gestational DM
Interventions	Standardized protocols for glycemic control (e.g., using continuous subcutaneous (via insulin pump) or intravenous insulin infusion combined with periodic blood glucose monitoring)	Standardized protocols for glycemic control (e.g., using oral hypoglycemic agents or subcutaneous or parenteral insulin, combined with periodic blood glucose monitoring)

Comparator	Treatment as usual (without the use of standardized protocols) Other standardized protocol	Treatment as usual (without the use of standardized protocols) Other standardized protocol
Outcomes	Maternal outcomes: • Blood glucose level stability during the intrapartum period (mg/d); • Frequency/severity of hypoglycemia; • Frequency/severity of hyperglycemia; • Any glucose value exceeding upper protocol threshold; • Insulin administered for maternal hypoglycemia; • Total insulin units administered; • Maternal mortality (at 30 days postpartum); • Time to discharge. Neonatal outcomes • First neonatal blood glucose level; • Blood glucose levels in the first 24 hours of life; • Hypoglycemia; • Respiratory distress; • Number of glucose treatments received to treat neonatal hypoglycemia; • Frequency of NICU admissions. • Infant weight gain • Infant length of stay	Maternal outcomes: • Maternal blood glucose levels during the early postpartum period (6 weeks postpartum); • Frequency/severity of hypoglycemia; • Frequency/severity of hyperglycemia; • Maternal mortality (at 30-days postpartum); • Time to discharge; • Diabetes related hospital readmissions
Timing	Intrapartum period	First 6 weeks of the postpartum period
Setting	Inpatient	Inpatient (immediate postpartum period (24-72 hours after delivery)) Outpatient (early – mid postpartum period (up to 6 weeks after delivery))

Abbreviations: DM Type 1 = Diabetes Mellitus Type 1; DM Type 2 = Diabetes Mellitus Type 2; Gestational DM = Gestational Diabetes Mellitus; IV = Intravenous; NICU = Neonatal Intensive Care Unit.

Table 1b. Questions and PICOTS (population, intervention, comparator, outcome, timing, and setting)

Key questions	3. What is the effect of using standardized protocols for glycemic control in women with pre-existing and gestational diabetes who want to breastfeed on initiation and continuation of breastfeeding during the intrapartum and early postpartum periods?
Population	Women with pre-existing DM Type I, pre-existing DM Type II, or gestational DM who want to breast-feed.
Interventions	Standardized glycemic management protocols used during the intrapartum and early postpartum periods.
Comparator	Standard care (i.e. glycemic management without the use of standardized protocols) Other standardized protocol
Outcomes	• Time to initiation of breast-feeding; • Proportion of women successfully breast-feeding at discharge; • Proportion of women successfully breast-feeding at 6 weeks post-delivery
Timing	Intrapartum and first 6 weeks postpartum
Setting	Inpatient and outpatient

Abbreviations: DM Type 1 = Diabetes Mellitus Type 1; DM Type 2 = Diabetes Mellitus Type 2; Gestational DM = Gestational Diabetes Mellitus; IV = Intravenous; NICU = Neonatal Intensive Care Unit.

See Appendix A.

Summary of Literature Findings

After reviewing 720 titles and abstracts (including over 100 systematic reviews and approximately 600 primary studies), we identified a total of eight publications relevant to key questions of the nomination.

For KQ1 pertaining to the effectiveness and comparative effectiveness of standardized protocols for glycemic control in women with pre-existing and gestational diabetes in the intrapartum period, we identified one systematic review[8] and six primary studies[9-14].

The 2018 systematic review[8] evaluated the effectiveness of different protocols for intrapartum insulin administration on maternal and neonatal glycemic control outcomes among women with pre-existing and gestational diabetes, although only two of the 26 studies included in the review directly addressed glycemic control during the intrapartum period.

Since only two studies included in the 2018 review examined protocols for intrapartum glycemic control, we also conducted a primary literature search. Among the six primary studies relevant to KQ1, we identified two retrospective cohorts[9, 10] evaluating the effectiveness of standardized protocols for intrapartum intravenous (IV) insulin infusion in women with pre-existing and gestational diabetes. One prospective cohort[12] that enrolled women with gestational diabetes previously treated with either metformin or subcutaneous insulin, compared glycemic control outcomes between a subgroup that received intrapartum insulin infusion compared to a control subgroup that did not. Two RCTs[11, 13] (including one in-progress trial), compared glycemic control outcomes in women with gestational diabetes randomized to either intrapartum insulin infusion protocols targeting either "tight" or "liberalized" maternal blood glucose goals. The remaining in-progress RCT[14] compared intrapartum glycemic control protocols using rotating IV fluids compared to continuous insulin infusion among women with gestational and pre-existing type 2 diabetes.

We found no systematic reviews and only one RCT[15] addressing KQ2, regarding the effectiveness of standardized protocols for glycemic control during the early postpartum period. The RCT compared the effectiveness of metformin versus subcutaneous insulin monotherapies on glycemic control in women with gestational diabetes during the first six weeks postpartum. We found no systematic reviews or primary studies relevant to KQ3, regarding the association between improved glycemic control during the intrapartum or immediate postpartum periods and initiation and continuation of breast-feeding. Of note, most of the reviews and primary studies identified in our search addressed a related but different question of whether breast-feeding was associated with better postpartum glycemic control in women with diabetes.

Table 2. Literature identified for each Question

Question	Systematic reviews (8/2019-8/2021)	Primary studies (8/2017-8/2021)
KQ1: Effectiveness of standardized protocols in the intrapartum period	Total: 1[8] • Cochrane – 0 • AHRQ – 0 • Other – 1[8]	Total: 6[9-14] Published primary studies: • RCT – 1[11] • Retrospective cohort – 2[9, 10]

Question	Systematic reviews (8/2019-8/2021)	Primary studies (8/2017-8/2021)
		• Prospective cohort – 1[12] Clinicaltrials.gov • Recruiting trials – 2[13, 14]
KQ2: Effectiveness of standardized protocols in the early postpartum period	Total: 0	Total: 1[15] Published primary studies: • RCT – 1[15] Clinicaltrials.gov • Recruiting trials – 0
KQ3. The effect of standardized protocols on breast-feeding	Total: 0	Total: 0 Clinicaltrials.gov • Recruiting – 0

Abbreviations: AHRQ= Agency for Health Care Research and Quality; KQ= Key Question; RCT= Randomized Controlled Trial

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

Summary of Selection Criteria Assessment

This nomination meets all selection criteria for an evidence review to address KQ1. However, KQs 2 and 3 did not meet the feasibility requirement due to a low volume of primary literature addressing these questions.

A new evidence review for KQ1 comparing the effectiveness of existing standardized protocols for intrapartum and early postpartum glycemic control in women with pre-existing and gestational diabetes would be highly impactful and valuable as it would provide the AWHONN with evidence-based findings to inform their guideline update.

Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

Related Resources

We identified several additional resources that may be helpful to the nominator. Specifically, we found six primary studies, including two RCTs[16, 17] (one published and one in-progress), four retrospective cohort studies[18-21] and one narrative article[22] that may be relevant to KQ1. We also found one published RCT[23] that may be applicable to KQ2.

For KQ1, four retrospective cohort studies[18-21] and one in-progress RCT evaluated the effectiveness of different standardized protocols for glycemic control in women with pre-gestational and gestational diabetes hospitalized for antenatal corticosteroid administration in anticipation of preterm delivery. Another published RCT compared the effectiveness of glycemic control protocols for diabetic women requiring hospitalizations between first and third trimesters of pregnancy. Finally, we also found one narrative publication[22] describing one medical center's experience developing and implementing standardized protocols for intrapartum glycemic management in women with gestational diabetes.

For KQ2, we also found one published RCT[23] that compared the effectiveness of metformin alone compared to dual therapy with metformin and liraglutide in women with gestational diabetes at 36 to 84 weeks postpartum.

References

1. Kline G, Edwards A. Antepartum and intra-partum insulin management of type 1 and type 2 diabetic women: Impact on clinically significant neonatal hypoglycemia. Diabetes Res Clin Pract. 2007 Aug;77(2):223-30. doi: https://doi.org/10.1016/j.diabres.2006.10.024. PMID: 17126946

2. Dude A, Niznik C, Peaceman A, et al. Evaluation of an Intrapartum Insulin Regimen for Women With Diabetes. Obstetrics & Gynecology. 2020 08;136(2):411-6. doi: https://doi.org/10.1097/AOG.0000000000003940. PMID: 32649492

3. Blumer I, Hadar, E., Hadden, D., Jovanovič, L., Mestman, J., Murad, M., Yogev, Y. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2013;98(11):4227-49. doi: https://doi.org/10.1210/jc.2013-2465

4. ACOG Practice Bulletin No. 201: Pregestational Diabetes Mellitus. Obstet Gynecol. 2018;132(6):e228-e48. doi: https://doi.org/10.1097/aog.0000000000002960. PMID: 00006250-201812000-00048

5. Association AD. 14. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes—2021. Diabetes Care. 2021;44(Supplement 1):S200-S10. doi: 10.2337/dc21-S014. https://care.diabetesjournals.org/content/diacare/44/Supplement_1/S200.full.pdf

6. Association of Women's Health OaNNA. Clinical Practice Guideline on Nursing Care of the Woman with Diabetes in Pregnancy. 2016. https://my.awhonn.org/productdetails?id=a1B2E000008LOXaUAO

7. Dietz D, Gordon L, Lee McLeroy M, et al. Incorporation of Specialty Standards in the Care of Pregnant Women With Diabetes. Journal of Obstetric, Gynecologic & Neonatal Nursing. 2018;47(3):S23. doi: 10.1016/j.jogn.2018.04.046. https://doi.org/10.1016/j.jogn.2018.04.046

8. Yamamoto JM, Benham J, Mohammad K, et al. Intrapartum glycaemic control and neonatal hypoglycaemia in pregnancies complicated by diabetes: a systematic review. Diabet Med. 2018 02;35(2):173-83. doi: https://dx.doi.org/10.1111/dme.13546. PMID: 29117445

9. Dude AM, Niznik C, Peaceman AM, et al. Evaluation of an Intrapartum Insulin Regimen for Women With Diabetes. Obstet Gynecol. 2020 08;136(2):411-6. doi: https://dx.doi.org/10.1097/AOG.0000000000003940. PMID: 32649492

10. Dinglas C, Muscat J, Adams T, et al. Software-guided insulin dosing improves intrapartum glycemic management in women with diabetes mellitus. Am J Obstet Gynecol. 2018 Aug;219(2):191.e1-.e6. doi: 10.1016/j.ajog.2018.05.003. PMID: 29750952

11. Hamel MS, Kanno LM, Has P, et al. Intrapartum Glucose Management in Women With Gestational Diabetes Mellitus: A Randomized Controlled Trial. Obstet Gynecol. 2019 06;133(6):1171-7. doi: https://dx.doi.org/10.1097/AOG.0000000000003257. PMID: 31135731

12. Farrant MT, Williamson K, Battin M, et al. The use of dextrose/insulin infusions during labour and delivery in women with gestational diabetes mellitus: Is there any point? Australian and New Zealand Journal of Obstetrics and Gynaecology. 2017;57(3):378-80. doi: https://doi.org/10.1111/ajo.12518. https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1111/ajo.12518

13. G. G. Intrapartum Glucose and Insulin Compared to Glucose Alone in Diabetic Women. In-progress clinical trial. 2017. https://clinicaltrials.gov/ct2/show/NCT03273881

14. Paglia M. Intrapartum Glycemic Control With Insulin Infusion Versus Rotating Fluids. In-progress clinical trial. 2019;ClinicalTrials.gov Identifier: NCT03912363. https://www.clinicaltrials.gov/ct2/show/NCT03912363
15. Jahanshahi M SARKEARVS. Effects of metformin and insulin therapy regimens on postpartum oral glucose tolerance test results in pregnant women with gestational diabetes mellitus: a comparative study. Hormone molecular biology and clinical investigation. 2020;41(4). https://pubmed.ncbi.nlm.nih.gov/33581015/
16. Amini FG, Nia AF, Sharbafi MH, et al. Comparison between the effect of regular human insulin and NPH with novo-rapid and levemir insulin in glycemic control in gestational diabetes. Hum Antibodies. 2019;27(4):285-9. doi: https://dx.doi.org/10.3233/HAB-190385. PMID: 31156155
17. Battarbee AN. Glycemic Control After Antenatal Corticosteroids in Women With Pregestational Diabetes. In-progress clinical trial. 2021;ClinicalTrials.gov Identifier: NCT04542148. https://clinicaltrials.gov/ct2/show/NCT04542148
18. Battarbee AN, Anderson SB, Tita ATN, et al. Methods of Glycemic Control and Neonatal Outcomes after Antenatal Corticosteroid Administration among Women with Pregestational Diabetes. Am J Perinatol. 2020 11;37(13):1351-6. doi: https://dx.doi.org/10.1055/s-0039-1693717. PMID: 31365928
19. Kulasa K, Serences B, Nies M, et al. Insulin Infusion Computer Calculator Programmed Directly Into Electronic Health Record Medication Administration Record. J Diabetes Sci Technol. 2021 Mar;15(2):214-21. doi: 10.1177/1932296820966616. PMID: 33118415
20. Rowe CW, Putt E, Brentnall O, et al. An intravenous insulin protocol designed for pregnancy reduces neonatal hypoglycaemia following betamethasone administration in women with gestational diabetes. Diabet Med. 2019 02;36(2):228-36. doi: https://dx.doi.org/10.1111/dme.13864. PMID: 30443983
21. Rowe CW, Watkins B, Brown K, et al. Efficacy and safety of the pregnancy-IVI, an intravenous insulin protocol for pregnancy, following antenatal betamethasone in type 1 and type 2 diabetes. Diabet Med. 2021 Apr;38(4):e14489. doi: https://dx.doi.org/10.1111/dme.14489. PMID: 33277738
22. Dude A, Niznik CM, Szmuilowicz ED, et al. Management of Diabetes in the Intrapartum and Postpartum Patient. Am J Perinatol. 2018 09;35(11):1119-26. doi: https://dx.doi.org/10.1055/s-0038-1629903. PMID: 29534258
23. Elkind-Hirsch KE, Shaler D, Harris R. Postpartum treatment with liraglutide in combination with metformin versus metformin monotherapy to improve metabolic status and reduce body weight in overweight/obese women with recent gestational diabetes: A double-blind, randomized, placebo-controlled study. J Diabetes Complications. 2020 04;34(4):107548. doi: https://dx.doi.org/10.1016/j.jdiacomp.2020.107548. PMID: 32046931
24. Doyle J, Gabel K, Inturrisi M, et al. Clinical Practice Guideline on Nursing Care of the Woman with Diabetes in Pregnancy. 2016. Accessed at http://works.bepress.com/janice-lazear/14/

Authors

Irina Arkhipova-Jenkins, MD
Lisa Winterbottom, MD
Christine Chang, MD
Suchitra Iyer, PhD
Robin Paynter, MLIS

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

Acknowledgements
Charlotte Armstrong, BS

This report was developed by the Scientific Resource Center under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. HHSA 290-2017-00003C). The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. No statement in this article should be construed as an official position of the Agency for Healthcare Research and Quality or of the U.S. Department of Health and Human Services.

Persons using assistive technology may not be able to fully access information in this report. For assistance contact EPC@ahrq.hhs.gov.

Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years from August 17, 2021 on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
  - AHRQ Evidence Reports https://www.ahrq.gov/research/findings/evidence-based-reports/index.html
  - EHC Program https://effectivehealthcare.ahrq.gov/
  - US Preventive Services Task Force https://www.uspreventiveservicestaskforce.org/
  - AHRQ Technology Assessment Program https://www.ahrq.gov/research/findings/ta/index.html
- US Department of Veterans Affairs Products publications
  - Evidence Synthesis Program https://www.hsrd.research.va.gov/publications/esp/
  - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program https://www.healthquality.va.gov/
- Cochrane Systematic Reviews https://www.cochranelibrary.com/
- University of York Centre for Reviews and Dissemination database https://www.crd.york.ac.uk/CRDWeb/
- PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/
- PubMed https://www.ncbi.nlm.nih.gov/pubmed/
- Campbell Collaboration http://www.campbellcollaboration.org/
- McMaster Health System Evidence https://www.healthsystemsevidence.org/
- UBC Centre for Health Services and Policy Research http://chspr.ubc.ca/
- Joanna Briggs Institute http://joannabriggs.org/
- WHO Health Evidence Network http://www.euro.who.int/en/data-and-evidence/evidence-informed-policy-making/health-evidence-network-hen

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 Medline, Cochrane Central Register of Controlled Trials, and ClinicalTrials.gov from August 17, 2017 through August 17, 2021. We reviewed all identified titles and abstracts for inclusion and classified relevant studies by key question and study design to estimate the size and scope of a potential evidence review.

Search Strategy

Ovid MEDLINE ALL 1946 to August 16, 2021

Date searched: August 17, 2021
1 Pregnancy in Diabetics/ or Diabetes, Gestational/ (21900)
2 exp Pregnancy/ and (Diabetes Mellitus/ or exp Diabetes Mellitus, Type 1/ or exp Diabetes Mellitus, Type 2/) (10119
3 (GDM or ((gestational or maternal or partur* or preexisting or pre-existing or pregestational or pregnan*) adj3 (diabetes or diabetic or T1D or T2D or T1DM or T2DM))).ti,ab,kf. (28165)
4 or/1-3 (36805)
5 Cesarean Section/ or exp Delivery, Obstetric/ or exp Labor, Obstetric/ or Parturition/ or Perinatal Care/ or Perioperative Care/ or Perioperative Medicine/ or Perioperative Period/ or Peripartum Period/ or Postnatal Care/ or exp Postpartum Period/ (214584)
6 (antepartum or ante-partum or birth* or caesarean$1 or cesarean$1 or c-section$1 or childbirth* or delivery or deliveries or hospital* or inpatient* or intranatal or intra-natal or intraoperat* or intra-operat* or intrapartum or intra-partum or labor* or labour* or neonat* or newborn$1 or obstet* or parturient* or perinatal or peri-natal or perioperat* or peri-operat* or peripartum or peri-partum or postnatal or post-natal or postpartum or post-partum or preoperat* or pre-operat* or puerper*).ti,ab,kf. (3706192)
7 or/5-6 (3765030)
8 Glycemic Control/ or exp Hypoglycemic Agents/ or Insulin/ or exp Metformin/ or exp Breast Feeding/ or Milk, Human/ or Lactation/ (354821)
9 (((antidiabet* or anti-diabet* or oral) adj (agent$1 or drug$1 or pharmac*)) or hyperglyc* or hypoglyc* or insulin or metformin or ((glyc?emi$1 or glucose or glyburide or insulin or metformin or antidiabet* or anti-diabet* or antihypergly* or antihypogly* or glycem* or glycaem* or glucos*) adj5 (administrat* or closed-loop or continuous* or control* or dose$1 or dosag* or dosing or drip$1 or IV or IVs or IVES or infusion$1 or intravenous* or manage or management or managing or monitor* or oral or orally or parenteral* or regimen$1 or subcutaneous* or syringe$1 or therap* or treat*)) or breastfeeding or breastfed or (breast adj (fed or feed*)) or lactat* or protocol* or standard or tight).ti,kf. or dt.fs. (2740246)
10 or/8-9 (2884682)
11 4 and 7 and 10 (5173)
12 limit 11 to english language (4633)
13 limit 12 to yr="2014 -Current" (2139)
14 13 not ((exp Animals/ not Humans/) or (animal* or canine* or bovine or cat or cats or cow or cows or dog or dogs or feline* or pig or pigs or porcine or rat or rats or rattus).ti.) (2031)
15 14 not (exp Diet Therapy/ or exp Exercise Therapy/ or exp Nutrition Therapy/ or Screening/ or ("assisted reproduction" or blastocyst* or diet$1 or dietary or educat* or embryo* or exercis* or food$1 or fruit$1 or IVF or in-vitro or lifestyle$1 or nutrition* or "omega-3" or (physical adj (fitness or activity)) or prepregnancy or probiotic* or screen* or supplement$1 or supplementation or testing or tranexamic or vegetable$1).ti. or dh.fs.) (1721)
16 (guideline or meta-analysis or systematic review).pt. or (guideline or metaanal* or meta-anal* or protocol or ((scoping or evidence or systematic) adj3 (review or synthesis))).ti,ab,kf. (802479)
17 and/15-16 (243) SRs / MAs
18 (randomized controlled trial or controlled clinical trial or clinical trial).pt. or (control* or placebo* or random* or trial).ti,kf. (1562707)
19 and/15,18 (303) TRIALS

EBM Reviews - Cochrane Central Register of Controlled Trials July 2021

Date searched: August 17, 2021
1 Pregnancy in Diabetics/ or Diabetes, Gestational/ (1107)
2 exp Pregnancy/ and (Diabetes Mellitus/ or exp Diabetes Mellitus, Type 1/ or exp Diabetes Mellitus, Type 2/) (236)

3 (GDM or ((gestational or maternal or partur* or preexisting or pre-existing or pregestational or pregnan*) adj3 (diabetes or diabetic or T1D or T2D or T1DM or T2DM))).ti,ab. (3829)
4 or/1-3 (3953)
5 Cesarean Section/ or exp Delivery, Obstetric/ or exp Labor, Obstetric/ or Parturition/ or Perinatal Care/ or Perioperative Care/ or Perioperative Medicine/ or Perioperative Period/ or Peripartum Period/ or Postnatal Care/ or exp Postpartum Period/ (9769)
6 (antepartum or ante-partum or birth* or caesarean$1 or cesarean$1 or c-section$1 or childbirth* or delivery or deliveries or hospital* or inpatient* or intranatal or intra-natal or intraoperat* or intra-operat* or intrapartum or intra-partum or labor* or labour* or neonat* or newborn$1 or obstet* or parturient* or perinatal or peri-natal or perioperat* or peri-operat* or peripartum or peri-partum or postnatal or post-natal or postpartum or post-partum or preoperat* or pre-operat* or puerper*).ti,ab. (381922)
7 or/5-6 (382599)
8 Glycemic Control/ or exp Hypoglycemic Agents/ or Insulin/ or exp Metformin/ or exp Breast Feeding/ or Milk, Human/ or Lactation/ (23859)
9 (((antidiabet* or anti-diabet* or oral) adj (agent$1 or drug$1 or pharmac*)) or hyperglyc* or hypoglyc* or insulin or metformin or ((glyc?emi$1 or glucose or glyburide or insulin or metformin or antidiabet* or anti-diabet* or antihypergly* or antihypogly* or glycem* or glycaem* or glucos*) adj5 (administrat* or closed-loop or continuous* or control* or dose$1 or dosag* or dosing or drip$1 or IV or IVs or IVES or infusion$1 or intravenous* or manage or management or managing or monitor* or oral or orally or parenteral* or regimen$1 or subcutaneous* or syringe$1 or therap* or treat*)) or breastfeeding or breastfed or (breast adj (fed or feed*)) or lactat* or protocol* or standard or tight).ti. (79100)
10 or/8-9 (89356)
11 4 and 7 and 10 (816)
12 limit 11 to english language (578)
13 limit 12 to yr="2014 -Current" (382)
14 13 not ((exp Animals/ not Humans/) or (animal* or canine* or bovine or cat or cats or cow or cows or dog or dogs or feline* or pig or pigs or porcine or rat or rats or rattus).ti.) (382)
15 14 not (exp Diet Therapy/ or exp Exercise Therapy/ or exp Nutrition Therapy/ or Screening/ or ("assisted reproduction" or blastocyst* or diet$1 or dietary or educat* or embryo* or exercis* or food$1 or fruit$1 or IVF or in-vitro or lifestyle$1 or nutrition* or "omega-3" or (physical adj (fitness or activity)) or prepregnancy or probiotic* or screen* or supplement$1 or supplementation or testing or tranexamic or vegetable$1).ti.) (289) TRIALS

ClinicalTrials.gov

Date searched: August 17, 2021
(EXPERT SEARCH) EXPAND[Concept] "glycemic control" AND (cesarean OR intrapartum OR intra-partum OR peripartum OR peri-partum OR perinatal OR peri-natal OR obstetric OR labor OR breastfeeding) | GDM OR diabetes | First posted from 01/01/2014 to 08/17/2021 (116) TRIALS

Link to Clinical Trials

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.

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
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. The nomination seeks to evaluate the effectiveness and comparative effectiveness of existing standardized protocols for glycemic management in women with pre-gestational and gestational diabetes.
1b. Is the nomination a request for an evidence report?	Yes. The nominator is requesting an evidence review to inform an update of their guideline regarding glycemic control in diabetic women during the intrapartum and early postpartum periods.
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.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Yes. Approximately 14.9 million of American women have diabetes and almost 10% of all pregnancies are affected by pre-gestational and gestational diabetes.
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. The AWHONN requested a systematic review of the comparative effectiveness of standardized protocols for intrapartum and early postpartum glycemic management in women with pre-existing and gestational diabetes to inform an update of their 2016 Nursing Care of the Woman with Diabetes in Pregnancy Guideline[24].
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes.
2d. 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	Yes.
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other evidence review is not available on this topic	Yes
4. Impact of a New Evidence Review	
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)?	Yes. Currently there is a lack of recent evidence-based guidance regarding the effectiveness of standardized protocols for glycemic control in diabetic women during the intrapartum and postpartum periods.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Yes. As above, a new review would address the evidence gap in the intrapartum and postpartum glycemic management in diabetic women.
5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review	We found one systematic review and seven primary studies that partially addressed KQs of this nomination.

- Newly available evidence (particularly for updates or new technologies)	We reviewed the entire search yield of 720 titles and abstracts and identified the following: • For KQ1, we found 6 primary studies[9-14] (3 published or in-progress RCTs, 2 retrospective cohorts and 1 prospective cohort). • For KQ2, we found 1 published RCT[15]. • For KQ3, we did not find any primary studies. The estimated size of a new systematic review addressing only KQ1 is small.
6. Value	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Yes. An updated guideline reviewing the effectiveness of different protocols for intrapartum and postpartum glycemic control would help standardize glycemic management in diabetic women during pregnancy.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Yes. The AWHONN is a professional association dedicated to promoting excellence in nursing practice, and fostering education and research in women's health, obstetric, and neonatal care. The AWHONN intends to use findings from a potential evidence review to update their 2016 guideline[24] on management of diabetes in pregnancy.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; AWHONN= the Association of Women's Health, Obstetric, and Neonatal Nurses; KQ= Key Question; SR= Systematic Review; RCT= Randomized Controlled Trial; U.S.= United States.