

# Dietary Patterns Consumed During Pregnancy and Risk of Gestational Diabetes Mellitus: A Systematic Review Protocol

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**Related citations:** Raghavan R, Dreibelbis C, Kingshipp BJ, Wong, YP, Terry N, Abrams B, Bartholomew A, Bodnar LM, Gernand A, Rasmussen K, Siega-Riz AM, Stang JS, Casavale KO, Spahn JM, Stoody E. Dietary Patterns before and during Pregnancy and Risk of Gestational Diabetes Mellitus: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.PB242018.SR0102>

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# Introduction

To prepare for the development of the *Dietary Guidelines for Americans, 2025-2030*, the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) identified a proposed list of scientific questions to be addressed by the 2025 Dietary Guidelines Advisory Committee (Committee), based on relevance, importance, potential federal impact, and avoiding duplication, which were posted for public comment.\* The Departments appointed the Committee in January 2023 to review evidence on the scientific questions. Their review forms the basis of their independent, science-based advice and recommendations to HHS and USDA, which is considered as the Departments develop the next edition of the *Dietary Guidelines*. As part of that process, the following systematic review question has been identified: What is the relationship between dietary patterns consumed during pregnancy and risk of gestational diabetes mellitus? The Committee will conduct a systematic review to address this question, with support from USDA’s Nutrition Evidence Systematic Review (NESR) team. This question will update an existing systematic review conducted by the Pregnancy Technical Expert Collaborative (**Table 1**).

**Table 1. Review history**

Date	Description	Citation
April 2019	Original systematic review conducted by the Pregnancy Technical Expert Collaborative as part of the Pregnancy and Birth to 24 Months Project published	Raghavan R, Dreibelbis C, Kingshipp BJ, Wong, YP, Terry N, Abrams B, Bartholomew A, Bodnar LM, Gernand A, Rasmussen K, Siega-Riz AM, Stang JS, Casavale KO, Spahn JM, Stoody E. Dietary Patterns before and during Pregnancy and Risk of Gestational Diabetes Mellitus: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <a href="https://doi.org/10.52570/NESR.PB242018.SR0102">https://doi.org/10.52570/NESR.PB242018.SR0102</a>
May 2023	Systematic review protocol for the 2025 Dietary Guidelines Advisory Committee published online	Fisher JO, Abrams S, Andres A, Byrd-Bredbenner C, Deierlein A, Eicher-Miller H, Odoms-Young A, Palacios C, Obbagy J, Nevins J, Raghavan R, Scinto-Madonich S, Higgins M, Butera G, Terry N. Dietary Patterns Consumed During Pregnancy and Risk of Gestational Diabetes Mellitus: A Systematic Review Protocol. May 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <a href="https://nesr.usda.gov/protocols">https://nesr.usda.gov/protocols</a>
October 2023	Revisions to the systematic review protocol for the 2025 Dietary Guidelines Advisory Committee published online	Fisher JO, Abrams S, Andres A, Byrd-Bredbenner C, Deierlein A, Eicher-Miller H, Odoms-Young A, Palacios C, Obbagy J, Nevins J, Raghavan R, Scinto-Madonich S, Higgins M, Butera G, Terry N. Dietary Patterns Consumed During Pregnancy and Risk of Gestational Diabetes Mellitus: A Systematic Review Protocol. May 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <a href="https://nesr.usda.gov/protocols">https://nesr.usda.gov/protocols</a>

\* Dietary Guidelines for Americans: Learn About the Process. 2022. Available at: <https://www.dietaryguidelines.gov/work-under-way/learn-about-process>

## Methods

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The NESR methodology manual\* has a detailed description of the NESR methodology as it will be applied in the systematic reviews for the Dietary Guidelines for Americans, 2025-2030 Project. This section presents an overview of the specific methods that will be used by the Committee to answer the systematic review question: What is the relationship between dietary patterns consumed during pregnancy and risk of gestational diabetes mellitus? This systematic review updates an existing NESR systematic review completed by the Pregnancy Technical Expert Collaborative as part of the Pregnancy and Birth to 24 Months Project, which included evidence published from January 1980 to January 2017.† This updated systematic review will synthesize the studies from the existing review with eligible studies published since January 2017 as one body of evidence, according to the methods described below.

### Develop a protocol

A systematic review protocol is the plan for how NESR's methodology will be used to conduct a specific systematic review and is established by the Committee, *a priori*, before any evidence is reviewed. The protocol is designed to capture the most appropriate and relevant body of evidence to answer the systematic review question. Development of the protocol involves discussion of the strengths and limitations of various methodological approaches relevant to the question, which then inform subsequent steps of the systematic review process. The protocol describes all of the methods that will be used throughout the systematic review process. Additionally, the protocol includes the following components, which are tailored to each systematic review question: the analytic framework, the inclusion and exclusion criteria, and the synthesis plan. When updating an existing review, the Committee uses the analytic framework and the inclusion and exclusion criteria from the existing review and makes adjustments to the protocol, if necessary. Differences in the inclusion and exclusion criteria between the existing and updated reviews are documented in **Appendix 1**.

The protocol for this systematic review was posted online (<https://nesr.usda.gov/protocols>) in May 2023. Revisions to the systematic review protocol were made during the review process. These revisions are documented in **Table 2**.

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\* USDA Nutrition Evidence Systematic Review Branch. USDA Nutrition Evidence Systematic Review: Methodology Manual. February 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://nesr.usda.gov/methodology-overview>

† Raghavan R, Dreibelbis C, Kingshipp BJ, Wong, YP, Terry N, Abrams B, Bartholomew A, Bodnar LM, Gernand A, Rasmussen K, Siega-Riz AM, Stang JS, Casavale KO, Spahn JM, Stoody E. Dietary Patterns before and during Pregnancy and Risk of Gestational Diabetes Mellitus: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.PB242018.SR0102>

**Table 2. Protocol revisions**

Date	Protocol revision	Description
July 2023	The inclusion and exclusion criteria for the intervention/exposure and comparator were revised to clarify that: <ul style="list-style-type: none"> <li>• a study must provide a description of the foods and beverages in both the intervention/exposure and comparator groups to be included.</li> <li>• studies that examine consumption of and/or adherence to similar dietary patterns of which only a specific component or food source differs between groups are excluded.</li> </ul>	These revisions were made to clarify the inclusion and exclusion criteria for the intervention/exposure and comparator, but do not represent a change in how the criteria were applied. These revisions were made before any evidence was synthesized.
July 2023	Inclusion and exclusion criteria were added for confounders, specifying that studies must control for at least one key confounder listed in the analytic framework to be included.	This revision was made to enable focus on a stronger body of evidence. The revision was made before any evidence was synthesized.

## Develop an analytic framework

An analytic framework visually represents the overall scope of the systematic review question and depicts the contributing elements that will be examined and evaluated. **Figure 1** is the analytic framework for the systematic review and shows that the intervention or exposure of interest is dietary patterns consumed during pregnancy; the comparators are different dietary patterns or different levels of adherence to/consumption of the same dietary pattern; the outcomes are hemoglobin A1C, blood glucose, glucose tolerance/insulin resistance, and gestational diabetes mellitus in individuals during pregnancy; the key confounders are age, physical activity, race and/or ethnicity, socioeconomic position, anthropometry (pre-pregnancy BMI), smoking, parity, and history of GDM. The confounders may impact the relationships of interest.

**Figure 1. Analytic framework for the systematic review question: What is the relationship between dietary patterns consumed during pregnancy and risk of gestational diabetes mellitus?**

<i>Population</i>	<i>Intervention/ exposure</i>	<i>Comparator</i>	<i>Outcome</i>	<i>Key confounders</i>
Individuals during pregnancy	Consumption of a dietary pattern	<ul style="list-style-type: none"> <li>• Different dietary pattern(s)</li> <li>• Different adherence/ consumption levels to the same dietary pattern</li> </ul>	In individuals during pregnancy: <ul style="list-style-type: none"> <li>• Hemoglobin A1C</li> <li>• Fasting blood glucose</li> <li>• Glucose tolerance/insulin resistance</li> <li>• Gestational diabetes mellitus</li> </ul>	<ul style="list-style-type: none"> <li>• Age</li> <li>• Physical activity</li> <li>• Race and/or ethnicity</li> <li>• Socioeconomic position</li> <li>• Anthropometry (pre-pregnancy BMI)</li> <li>• Smoking</li> <li>• Parity</li> <li>• History of gestational diabetes mellitus</li> </ul>

**Synthesis organization:**

- I. **Population:** Individuals during pregnancy
  - a. **Outcome:** Hemoglobin A1C; Fasting blood glucose; Glucose tolerance/insulin resistance; Gestational diabetes mellitus

**Key definitions:**

Dietary patterns: the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed.

## Develop inclusion and exclusion criteria

The inclusion and exclusion criteria provide an objective, consistent, and transparent framework for determining which articles to include in the systematic review (see **Table 3**). These criteria ensure that the most relevant and appropriate body of evidence is identified for the systematic review question, and that the evidence reviewed is:

- Applicable to the U.S. population of interest
- Relevant to Federal public health nutrition policies and programs
- Rigorous from a scientific perspective

**Table 3. Inclusion and exclusion criteria**

Category	Inclusion Criteria	Exclusion Criteria
Study design	<ul style="list-style-type: none"> <li>• Randomized controlled trials</li> <li>• Non-randomized controlled trials*</li> <li>• Prospective cohort studies</li> <li>• Retrospective cohort studies</li> <li>• Nested case-control studies</li> </ul>	<ul style="list-style-type: none"> <li>• Uncontrolled trials†</li> <li>• Case-control studies</li> <li>• Cross-sectional studies</li> <li>• Ecological studies</li> <li>• Narrative reviews</li> <li>• Systematic reviews</li> <li>• Meta-analyses</li> <li>• Modeling and simulation studies</li> </ul>
Publication date	<ul style="list-style-type: none"> <li>• January 1980 – May 2023‡</li> </ul>	<ul style="list-style-type: none"> <li>• Before January 1980, after May 2023</li> </ul>
Population: Study participants	<ul style="list-style-type: none"> <li>• Human</li> </ul>	<ul style="list-style-type: none"> <li>• Non-human</li> </ul>
Population: Life stage	<ul style="list-style-type: none"> <li>• At intervention or exposure and outcome: <ul style="list-style-type: none"> <li>○ Individuals during pregnancy</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• At intervention or exposure and outcome: <ul style="list-style-type: none"> <li>○ Individuals before pregnancy</li> <li>○ Individuals during postpartum</li> </ul> </li> </ul>
Population: Health status	<ul style="list-style-type: none"> <li>• Studies that <u>exclusively</u> enroll participants not diagnosed with a disease§</li> <li>• Studies that enroll <u>some</u> participants: <ul style="list-style-type: none"> <li>○ diagnosed with a disease;</li> <li>○ with the outcome of interest;</li> <li>○ who became pregnant using Assisted Reproductive Technologies;</li> <li>○ with multiple gestation pregnancies;</li> <li>○ pre- or post-bariatric surgery;</li> <li>○ and/or hospitalized for an illness, injury, or surgery</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Studies that <u>exclusively</u> enroll participants: <ul style="list-style-type: none"> <li>○ diagnosed with a disease;**</li> <li>○ with the outcome of interest (i.e., studies that aim to treat participants who have already been diagnosed with the outcome of interest);</li> <li>○ who became pregnant using Assisted Reproductive Technologies;</li> <li>○ with multiple gestation pregnancies;</li> <li>○ pre- or post-bariatric surgery;</li> <li>○ and/or hospitalized for an illness, injury, or surgery††</li> </ul> </li> </ul>
Population: Analytic approach	<ul style="list-style-type: none"> <li>• Studies that enroll both singleton and multiple gestation pregnancies and present uncombined findings</li> </ul>	<ul style="list-style-type: none"> <li>• Studies that enroll both singleton and multiple gestation pregnancies and only present aggregate findings</li> </ul>

\* Including quasi-experimental and controlled before-and-after studies

† Including uncontrolled before-and-after studies

‡ This review update date range encompasses the original systematic review date range, which included articles published from January 1980 to January 2017

§ Studies that enroll participants who are at risk for chronic disease will be included

\*\* Studies that exclusively enroll participants with obesity will be included

†† Studies that exclusively enroll participants post-caesarean section will be included



Category	Inclusion Criteria	Exclusion Criteria
Intervention/ exposure	<ul style="list-style-type: none"> <li>Studies that examine consumption of and/or adherence to a dietary pattern [i.e., the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed], including, at a minimum, a description of the foods and beverages in the pattern of each intervention/exposure and comparator group                             <ul style="list-style-type: none"> <li>Dietary patterns may be measured or derived using a variety of approaches, such as adherence to a priori patterns (indices/scores), data driven patterns (factor or cluster analysis), reduced rank regression, or other methods, including clinical trials</li> </ul> </li> <li>Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is provided or can be determined</li> </ul>	<ul style="list-style-type: none"> <li>Studies that do not provide a description of the dietary pattern, which at minimum, must include the foods and beverages in the pattern (i.e., studies that examine a labeled dietary pattern, but do not describe the foods and beverages consumed in each intervention/exposure and comparator group)</li> <li>Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is not analyzed or cannot be determined (e.g., due to multiple intervention components within groups)</li> </ul>
Comparator	<ul style="list-style-type: none"> <li>Consumption of and/or adherence to a different dietary pattern</li> <li>Different levels of consumption of and/or adherence to a dietary pattern</li> </ul>	<ul style="list-style-type: none"> <li>Consumption of and/or adherence to a similar dietary pattern of which only a specific component or food source is different between groups</li> </ul>
Outcome(s)	<ul style="list-style-type: none"> <li>Hemoglobin A1C</li> <li>Fasting blood glucose</li> <li>Glucose tolerance/insulin resistance</li> <li>Gestational diabetes mellitus</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Confounders	<ul style="list-style-type: none"> <li>Studies that control for at least one of the key confounders listed in the analytic framework</li> </ul>	<ul style="list-style-type: none"> <li>Studies that do not control for any of the key confounders listed in the analytic framework</li> </ul>
Publication status	<ul style="list-style-type: none"> <li>Peer-reviewed articles published in research journals</li> </ul>	<ul style="list-style-type: none"> <li>Non-peer-reviewed articles, unpublished data or manuscripts, pre-prints, reports, editorials, retracted articles, and conference abstracts or proceedings</li> </ul>
Language	<ul style="list-style-type: none"> <li>Published in English</li> </ul>	<ul style="list-style-type: none"> <li>Not published in English</li> </ul>
Country*	<ul style="list-style-type: none"> <li>Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul>	<ul style="list-style-type: none"> <li>Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul>

\* The classification of countries on the Human Development Index (HDI) is based on the UN Development Program Human Development Report Office (<http://hdr.undp.org/en/data>) for the year the study intervention occurred or data were collected. If the study does not report the year(s) in which the intervention/exposure data were collected, the HDI classification for the year of publication is applied. Studies conducted prior to 1990 are classified based on 1990 HDI classifications. If the year is more recent than the available HDI values, then the most recent HDI classifications are used. If a country is not listed in the HDI, then the current country classification from the World Bank is used (The World Bank Country and Lending Groups, available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-country-and-lending-groups>)

## Search for and screen studies

NESR librarians, in collaboration with NESR analysts and the Committee, will use the analytic framework and inclusion and exclusion criteria to develop a comprehensive literature search strategy. The literature search strategy will include selecting and searching the appropriate bibliographic databases, translating search using syntax appropriate for the databases being searched, and employing search refinements, such as search filters. Search strategies from the existing review will be updated, as appropriate, for each database. The full literature search will be available upon request, and will be fully documented in the final review.

The results of all electronic database searches, after removal of duplicates, will be screened independently by two NESR analysts using a step-wise process by reviewing titles, abstracts, and full-texts to determine which articles meet the inclusion criteria. Manual searching will be conducted to find peer-reviewed published articles not identified through the electronic database search. These articles will also be screened independently by two NESR analysts at the abstract and full-text levels.

## Extract data and assess the risk of bias

NESR analysts will extract all essential data from each included article to describe key characteristics of the available evidence, such as the author, publication year, cohort/trial name, study design, population life stage at intervention/exposure and outcome, intervention/exposure and outcome assessment methods, and outcomes. One NESR analyst will extract the data and a second NESR analyst will review the extracted data for accuracy. Each article included in the systematic review will undergo a formal risk of bias assessment, with two NESR analysts independently completing the risk of bias assessment using the tool that is appropriate for the study design.<sup>\*†‡</sup> For the review update, data extraction and risk of bias assessment will be updated, if needed.

## Synthesize the evidence

The Committee will describe, compare, and combine the evidence from all included studies to answer the systematic review question. Synthesis of the body of evidence will involve identifying overarching themes or key concepts from the findings, identifying and explaining similarities and differences between studies, and determining whether certain factors impact the relationships being examined. The synthesis will be organized by population at intervention or exposure, which includes individuals during pregnancy. Then the evidence will be organized by similarity in outcome.

## Develop [a] conclusion statement[s] and grade the evidence

After the Committee considers and synthesizes the existing and updated evidence together, they will draft a conclusion statement or conclusion statements for the full body of evidence. A conclusion statement is one or more summary statements carefully constructed to answer the systematic review question. It reflects the evidence reviewed, as outlined in the analytic framework (e.g., PICO elements) and synthesis plan, and does not take evidence from other sources into consideration. The Committee will review, discuss, and revise the conclusion statement until they reach agreement on wording that accurately reflect the body of evidence.

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\* Sterne JAC, Savovic J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. Aug 28 2019;366:I4898.doi:10.1136/bmj.I4898

† Sterne JA, Hernan MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ*. Oct 12 2016;355:i4919.doi:10.1136/bmj.i4919

‡ ROBINS-E Development Group., Higgins J, Morgan R, et al. Bias In Non-randomized Studies - of Exposure (ROBINS-E). 2022. <https://www.riskofbias.info/welcome/robins-e-tool>

The Committee will then assign a grade to each conclusion statement (i.e., strong, moderate, limited, or grade not assignable). The grade communicates the strength of the evidence supporting a specific conclusion statement to decision makers and stakeholders. NESR has predefined criteria, based on five grading elements that the Committee will use to evaluate and grade the strength of the evidence supporting each conclusion statement. The five grading elements are: consistency, precision, risk of bias, directness and generalizability of the evidence. Study design will also be considered during the grading process.

## Recommend future research

The Committee will identify and document research gaps and methodological limitations throughout the systematic review process. These gaps and limitations will be used to develop research recommendations that describe the research, data, and methodological advances that are needed to strengthen the body of evidence on a particular topic. Rationales for the necessity of additional or stronger research may also be provided with the research recommendations.

## Acknowledgments and funding

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The Committee members are involved in: establishing all aspects of the protocol, which presents the plan for how they are planning to examine the scientific evidence, including the inclusion and exclusion criteria; reviewing all studies that meet the criteria the Committee sets; deliberating on the body of evidence for each question; and writing and grading the conclusion statements. The NESR team, with assistance from Federal staff from HHS and USDA (Dennis Anderson-Villaluz, MBA, RD, LDN, FAND; Hazel Hiza, PhD; Tessa Lasswell, MPH, RDN; TusaRebecca Pannucci, PhD, MPH, RD; Elizabeth Rahavi, RD; Kelley Scanlon, PhD, RD; Colleen Sideck, MPH, RDN) and Project Leadership (HHS: Janet de Jesus, MS, RD; USDA: Eve Stoodly, PhD), supports the Committee by facilitating, executing, and documenting the work necessary to ensure the reviews are completed in accordance with NESR methodology. Contractor support was also provided by Panum Telecom (Emily Madan, PhD).

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## Appendix

### Appendix 1: Inclusion and exclusion criteria comparison between existing\* and updated systematic reviews for the research question: What is the relationship between dietary patterns consumed during pregnancy and risk of gestational diabetes mellitus?

Category	Existing Review	Updated Review	Change and Rationale
Study design	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Randomized controlled trials</li> <li>• Prospective cohort studies</li> <li>• Retrospective cohort studies</li> <li>• Nested case-control studies</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Non-randomized controlled trials</li> <li>• Cross-sectional studies</li> <li>• Case-control studies</li> <li>• Uncontrolled studies</li> <li>• Pre-post studies with a control</li> <li>• Pre-post studies without a control</li> <li>• Narrative reviews</li> <li>• Systematic reviews</li> <li>• Meta-analyses</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Randomized controlled trials</li> <li>• Non-randomized controlled trials<sup>†</sup></li> <li>• Prospective cohort studies</li> <li>• Retrospective cohort studies</li> <li>• Nested case-control studies</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Uncontrolled trials<sup>‡</sup></li> <li>• Case-control studies</li> <li>• Cross-sectional studies</li> <li>• Ecological studies</li> <li>• Narrative reviews</li> <li>• Systematic reviews</li> <li>• Meta-analyses</li> <li>• Modeling and simulation studies</li> </ul>	Non-randomized controlled trials, including quasi-experimental and controlled before-and-after studies, will be included in the updated review to align with current NESR standards.
Publication date	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• January 1980 – January 2017</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Before January 1980, after January 2017</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• January 1980 – May 2023<sup>§</sup></li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Before January 1980, after May 2023</li> </ul>	End of the date range is updated to extend from the end of the search in the existing review to the present.

\* Raghavan R, Dreibelbis C, Kingshipp BJ, Wong, YP, Terry N, Abrams B, Bartholomew A, Bodnar LM, Gernand A, Rasmussen K, Siega-Riz AM, Stang JS, Casavale KO, Spahn JM, Stoody E. Dietary Patterns before and during Pregnancy and Risk of Gestational Diabetes Mellitus: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.PB242018.SR0102>

<sup>†</sup> Including quasi-experimental and controlled before-and-after studies

<sup>‡</sup> Including uncontrolled before-and-after studies

<sup>§</sup> This review update date range encompasses the original systematic review date range, which included articles published from January 1980 to January 2017

Systematic review protocol: Dietary patterns and gestational diabetes mellitus

Category	Existing Review	Updated Review	Change and Rationale
Population: Study participants	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Human subjects</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Animal and in vitro models</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Human</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Non-human</li> </ul>	No changes other than to wording for clarity.
Population: Life stage	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• At intervention or exposure:               <ul style="list-style-type: none"> <li>○ Adolescent girls and women capable of becoming pregnant (15-44 years)</li> <li>○ Pregnant girls and women (15-44 years) – single and multiple pregnancies</li> </ul> </li> <li>• At outcome:               <ul style="list-style-type: none"> <li>○ Pregnant girls and women (15-44 years) – single and multiple pregnancies</li> </ul> </li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• N/A</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• At intervention or exposure and outcome:               <ul style="list-style-type: none"> <li>○ Individuals during pregnancy</li> </ul> </li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• At intervention or exposure and outcome:               <ul style="list-style-type: none"> <li>○ Individuals before pregnancy</li> </ul> </li> <li>• Individuals during postpartum</li> </ul>	Individuals before pregnancy were excluded from the updated review based on 2025 DGAC question prioritization discussions. Minor changes were made to formatting and wording for clarity.

Category	Existing Review	Updated Review	Change and Rationale
Population: Health Status	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Studies conducted in generally healthy women of reproductive age, including women in pre/peri-conception and pregnancy</li> <li>• Studies conducted in samples with elevated chronic disease risk or pregnancy related conditions, or that enroll <i>some</i> subjects with a disease or with health outcome of interest such as:                             <ul style="list-style-type: none"> <li>○ Anemia</li> <li>○ Gestational diabetes</li> <li>○ Hypertension</li> <li>○ Preeclampsia</li> <li>○ Hypermesis Gravidarum</li> <li>○ Previous adverse outcome (e.g., preterm)</li> <li>○ Obesity</li> </ul> </li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Pregnancies conceived ONLY using Assisted Reproductive Technologies</li> <li>• Studies that <i>exclusively</i> enroll subjects with chronic conditions (e.g. hypertension, diabetes) that are not related to the index pregnancy</li> <li>• Studies that <i>exclusively</i> enroll subjects with a disease or with the health outcome of interest (intermediate or endpoint health outcomes)</li> <li>• Studies done in hospitalized or malnourished subjects, if hospitalization is not related to index pregnancy</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Studies that <i>exclusively</i> enroll participants not diagnosed with a disease*</li> <li>• Studies that enroll <i>some</i> participants:                             <ul style="list-style-type: none"> <li>○ diagnosed with a disease;</li> <li>○ with the outcome of interest;</li> <li>○ who became pregnant using Assisted Reproductive Technologies;</li> <li>○ with multiple gestation pregnancies;</li> <li>○ pre- or post-bariatric surgery;</li> <li>○ and/or hospitalized for an illness, injury, or surgery</li> </ul> </li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Studies that <i>exclusively</i> enroll participants:                             <ul style="list-style-type: none"> <li>○ diagnosed with a disease;†</li> <li>○ with the outcome of interest (i.e., studies that aim to treat participants who have already been diagnosed with the outcome of interest);</li> <li>○ who became pregnant using Assisted Reproductive Technologies;</li> <li>○ with multiple gestation pregnancies;</li> <li>○ pre- or post-bariatric surgery;</li> <li>○ and/or hospitalized for an illness, injury, or surgery‡</li> </ul> </li> </ul>	<p>Studies that exclusively enroll participants with obesity are included in the updated review due to its prevalence and relevance as a risk factor for other conditions. All other changes are to formatting and wording for clarity.</p>

\* Studies that enroll participants who are at risk for chronic disease will be included

† Studies that exclusively enroll participants with obesity will be included

‡ Studies that exclusively enroll participants post-cesarean section will be included

Systematic review protocol: Dietary patterns and gestational diabetes mellitus

Category	Existing Review	Updated Review	Change and Rationale
Population: Analytic approach	Not specified	<p data-bbox="974 224 1073 251"><u>Included:</u></p> <ul data-bbox="974 272 1419 358" style="list-style-type: none"> <li data-bbox="974 272 1419 358">• Studies that enroll both singleton and multiple gestation pregnancies and present uncombined findings</li> </ul> <p data-bbox="974 380 1073 407"><u>Excluded:</u></p> <ul data-bbox="974 428 1444 505" style="list-style-type: none"> <li data-bbox="974 428 1444 505">• Studies that enroll both singleton and multiple gestation pregnancies and only present aggregate findings</li> </ul>	<p data-bbox="1503 224 1986 358">Criteria were added to the updated review to clarify that studies enrolling participants with both singleton and multiple gestation pregnancies will only be included if the singleton pregnancy findings can be isolated.</p>

Category	Existing Review	Updated Review	Change and Rationale
Intervention/exposure	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Studies that provide a description of the dietary pattern(s) (i.e., foods and beverages) consumed by subjects and that methodologically use:                             <ul style="list-style-type: none"> <li>○ Indices &amp; scores</li> <li>○ Cluster or factor analysis</li> <li>○ Reduced rank regression</li> <li>○ Other methods</li> </ul> </li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Studies that do not provide a description of the dietary pattern(s) (i.e., foods and beverages) consumed by subjects</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Studies that examine consumption of and/or adherence to a dietary pattern [i.e., the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed], including, at a minimum, a description of the foods and beverages in the pattern of each intervention/exposure and comparator group                             <ul style="list-style-type: none"> <li>○ Dietary patterns may be measured or derived using a variety of approaches, such as adherence to a priori patterns (indices/scores), data driven patterns (factor or cluster analysis), reduced rank regression, or other methods, including clinical trials</li> </ul> </li> <li>• Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is provided or can be determined</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Studies that do not provide a description of the dietary pattern, which at minimum, must include the foods and beverages in the pattern (i.e., studies that examine a labeled dietary pattern, but do not describe the foods and beverages consumed in each intervention/exposure and comparator group)</li> <li>• Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is not analyzed or cannot be determined (e.g., due to multiple intervention components within groups)</li> </ul>	<p>Revisions were made to clarify the intent of the intervention/exposure criteria, but do not represent a change in how the criteria were applied.</p>



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Category	Existing Review	Updated Review	Change and Rationale
Comparator	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Different levels of adherence to a dietary pattern</li> <li>Adherence to a different dietary pattern</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Consumption of and/or adherence to a different dietary pattern</li> <li>Different levels of consumption of and/or adherence to a dietary pattern</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Consumption of and/or adherence to a similar dietary pattern of which only a specific component or food source is different between groups</li> </ul>	Revisions were made to clarify the intent of the comparator criteria, but do not represent a change in how the criteria were applied.
Outcome(s)	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Intermediate outcomes:                             <ul style="list-style-type: none"> <li>Glucose intolerance</li> <li>Insulin resistance</li> <li>HbA1C</li> <li>HOMA-IR</li> <li>Fasting blood glucose</li> <li>Oral glucose tolerance test</li> </ul> </li> <li>Endpoint outcome:                             <ul style="list-style-type: none"> <li>Gestational diabetes mellitus</li> </ul> </li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Hemoglobin A1C</li> <li>Fasting blood glucose</li> <li>Glucose tolerance/insulin resistance</li> <li>Gestational diabetes mellitus</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>	No changes other than to wording and formatting for clarity.
Confounders	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Studies that control for one or more of the key confounders listed in the analytic framework.</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Studies that do not control for any of the key confounders listed in the analytic framework.</li> </ul>	Criteria were added to enable focus on a stronger body of evidence.

\* For example, a study would be excluded from the systematic review if the dietary pattern were labeled “vegetarian” but lacked a description of what foods/beverages were consumed as part of that dietary pattern

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Category	Existing Review	Updated Review	Change and Rationale
Temporality	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Studies when the exposure was assessed prior to the outcome</li> <li>Studies when exposure and outcome assessment occurred during overlapping time periods, as long as the study explicitly states that the exposure was assessed prior to the outcome</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Studies when the outcome was assessed prior to the exposure</li> <li>Studies when exposure and outcome assessment occurred during overlapping time periods and the study does not explicitly state that the exposure was assessed prior to the outcome</li> </ul>	<ul style="list-style-type: none"> <li>Not specified</li> </ul>	Criteria are covered under “Study Design”.
Publication status	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Studies published in peer-reviewed journals</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Grey literature, including unpublished data, manuscripts, reports, abstracts, conference proceedings</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Peer-reviewed articles published in research journals</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Non-peer-reviewed articles, unpublished data or manuscripts, pre-prints, reports, editorials, retracted articles, and conference abstracts or proceedings</li> </ul>	No changes other than to wording for clarity.
Language	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Studies published in English</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Studies published in languages other than English</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Published in English</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Not published in English</li> </ul>	No changes other than to wording for clarity.

Systematic review protocol: Dietary patterns and gestational diabetes mellitus

Category	Existing Review	Updated Review	Change and Rationale
Country*	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Studies conducted in Very High and High Human Development Countries</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Studies conducted in Medium and Low Human Development Countries</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul>	No changes other than to wording for clarity.

\* The classification of countries on the Human Development Index (HDI) is based on the UN Development Program Human Development Report Office (<http://hdr.undp.org/en/data>) for the year the study intervention occurred or data were collected. If the study does not report the year(s) in which the intervention/exposure data were collected, the HDI classification for the year of publication is applied. Studies conducted prior to 1990 are classified based on 1990 HDI classifications. If the year is more recent than the available HDI values, then the most recent HDI classifications are used. If a country is not listed in the HDI, then the current country classification from the World Bank is used (The World Bank. World Bank country and lending groups. Available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-country-and-lending-groups>)