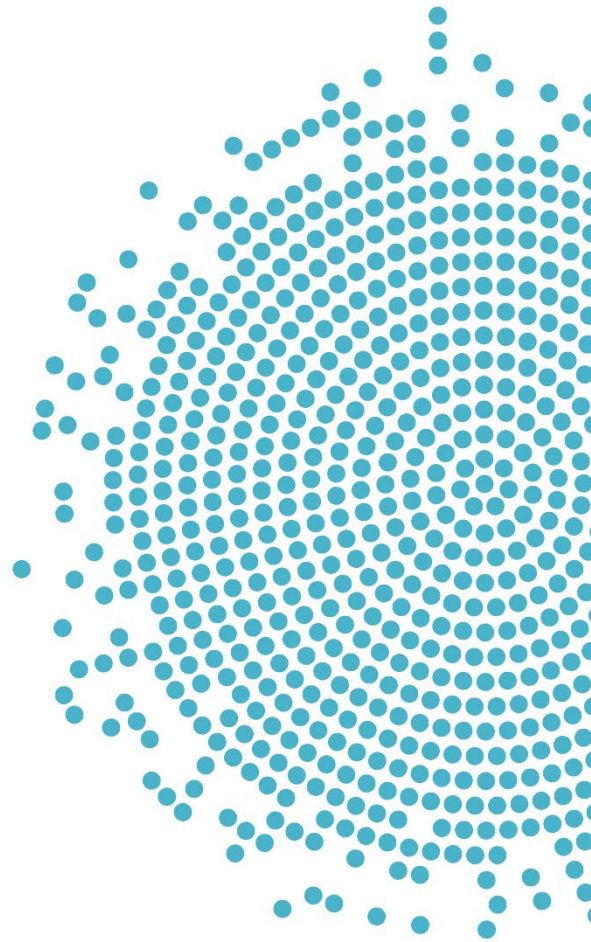




Dietary Patterns and Risk of Type 2 Diabetes: A Systematic Review Protocol

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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 and risk of type 2 diabetes? 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 the systematic review conducted by the Dietary Patterns Technical Expert Collaborative (TEC) (Table 1).

Table 1. Review history

Date	Description	Citation
August 2014	Original systematic review conducted by the Dietary Patterns Technical Expert Collaborative published in 2014	Dietary Patterns Technical Expert Collaborative and NESR Staff. A Series of Systematic Reviews on the Relationship Between Dietary Patterns and Health Outcomes. March 2014. 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/sites/default/files/2019-06/DietaryPatternsReport-FullFinal2.pdf
July 2020	Updated systematic review protocol applied by the 2020 Dietary Guidelines Advisory Committee published as an updated systematic review for children and adolescents, and as an evidence scan for adults and older adults	Boushey C, Ard J, Bazzano L, Heymsfield S, Mayer-Davis E, Sabaté J, Snetselaar L, Van Horn L, Schneeman B, English LK, Bates M, Callahan E, Butera G, Terry N, Obbagy J. Dietary Patterns and Risk of Type 2 Diabetes: A Systematic Review. July 2020. 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.DGAC2020.SR0103
May 2023	Systematic review protocol for the 2025 Dietary Guidelines Advisory Committee published online	Hoelscher DM, Anderson C, Booth S, Deierlein A, Fung T, Gardner C, Giovannucci E, Raynor H, Stanford FC, Talegawkar S, Taylor C, Tobias D, Obbagy J, Callahan EH, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Risk of Type 2 Diabetes: 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: https://nesr.usda.gov/protocols

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

Date	Description	Citation
October 2023	Revisions to the systematic review protocol for the 2025 Dietary Guidelines Advisory Committee published online	Hoelscher DM, Anderson C, Booth S, Deierlein A, Fung T, Gardner C, Giovannucci E, Raynor H, Stanford FC, Talegawkar S, Taylor C, Tobias D, Obbagy J, Callahan EH, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Risk of Type 2 Diabetes: A Systematic Review Protocol. October 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/protocols
June 2024	Revisions to the systematic review protocol for the 2025 Dietary Guidelines Advisory Committee published online	Hoelscher DM, Anderson C, Booth S, Deierlein A, Fung T, Gardner C, Giovannucci E, Raynor H, Stanford FC, Talegawkar S, Taylor C, Tobias D, Obbagy J, Callahan EH, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Risk of Type 2 Diabetes: A Systematic Review Protocol. June 2024. 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/protocols

Methods

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 to by the Committee to answer the systematic review question: What is the relationship between dietary patterns consumed and risk of type 2 diabetes?

This systematic review updates an existing NESR systematic review that examined dietary patterns consumed by children and adolescents that was updated by the 2020 Dietary Guidelines Advisory Committee[†], which included evidence published from January 2013 to October 2019. Eligible studies published since August 2013 will be synthesized, and the new evidence will be assessed as it relates to the existing evidence, according to the methods described below.

This systematic review updates an existing NESR systematic review that examined dietary patterns consumed by adults and older adults that was completed as part of the Dietary Patterns Systematic Reviews Project by the Dietary Patterns Technical Expert Collaborative[‡], which included evidence published from January 1980 to August 2013; Eligible studies published since August 2013 conducted in adults and older adults will be synthesized, and the new evidence will be assessed as it relates to the existing evidence, according to the methods described below.

^{*} 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>

[†] Boushey C, Ard J, Bazzano L, Heymsfield S, Mayer-Davis E, Sabaté J, Snetselaar L, Van Horn L, Schneeman B, English LK, Bates M, Callahan E, Butera G, Terry N, Obbagy J. Dietary Patterns and Risk of Type 2 Diabetes: A Systematic Review. July 2020. 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.DGAC2020.SR0103>

[‡] Dietary Patterns Technical Expert Collaborative and NESR Staff. A Series of Systematic Reviews on the Relationship Between Dietary Patterns and Health Outcomes. March 2014. 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/sites/default/files/2019-06/DietaryPatternsReport-FullFinal2.pdf>

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 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**.

Table 2. Protocol revisions

Date	Protocol change	Description
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.
July 2023	<p>The inclusion and exclusion criteria for the intervention/exposure and comparator were revised to clarify that:</p> <ul style="list-style-type: none"> • a study must provide a description of the foods and beverages in both the intervention/exposure and comparator groups to be included. • 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. 	These revisions were made before evidence synthesis to clarify the intent of the intervention/exposure and comparator criteria, but do not represent a change in how the criteria were applied.
March 2024	<p>The inclusion and exclusion criteria for the outcomes were revised to:</p> <p>All included study designs in children (birth to 19 years) and interventions only in adults (19 years and older):</p> <ul style="list-style-type: none"> • Fasting blood glucose • Fasting insulin • Glucose tolerance/insulin resistance • Hemoglobin A1C • Prediabetes <p>All included study designs in all included age groups:</p> <ul style="list-style-type: none"> • Type 2 diabetes 	This revision was made to align with protocols from questions with T2D outcomes to allow the inclusion of intervention studies in adults and older adults that only measure intermediate outcomes. 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 by infants, toddlers, children, adolescents, adults, and older adults. The comparators are different dietary patterns or different levels of adherence to/consumption of the same dietary pattern. The outcomes include blood glucose, insulin, and glucose tolerance/insulin resistance (in infants, toddlers, children, adolescents from all included study designs; and in adults and older adults from interventions only), hemoglobin A1C (HbA1C), prediabetes and risk of type 2 diabetes (in all populations). The key confounders may impact the relationships of interest and are sex, age, physical activity, anthropometry, socioeconomic position, race and/or ethnicity, and family history of diabetes in all populations, and alcohol intake and smoking in adults and older adults. Dietary patterns are defined as 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.

Figure 1. Analytic framework for the systematic review question: What is the relationship between dietary patterns consumed and risk of type 2 diabetes?

<i>Population</i>	<i>Intervention/ exposure</i>	<i>Comparator</i>	<i>Outcome</i>	<i>Key confounders</i>
Infants and toddlers (birth up to 24 months)	Consumption of a dietary pattern	Different dietary pattern(s) Different adherence or consumption levels to the same dietary pattern	All included study designs in children (birth to 19 years) and interventions only in adults (19 years and older): <ul style="list-style-type: none"> • Fasting blood glucose • Fasting insulin • Glucose tolerance/insulin resistance • Hemoglobin A1C • Prediabetes 	<ul style="list-style-type: none"> • Sex • Age • Physical activity • Anthropometry • Socioeconomic position • Race and/or ethnicity • Family history of diabetes • Smoking (adults, older adults) • Alcohol intake (adults, older adults)
Children and adolescents (2 up to 19 years)				
Adults and older adults (19 years and older)				

Synthesis organization:

- I. **Population:** Infants and toddlers; Children and adolescents; Adults; Older adults
 - a. **Outcome:** Blood glucose; Insulin; Glucose tolerance/insulin resistance; HbA1C; Prediabetes; Type 2 diabetes

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"> • Randomized controlled trials • Non-randomized controlled trials* • Prospective cohort studies • Retrospective cohort studies • Nested case-control studies 	<ul style="list-style-type: none"> • Uncontrolled trials[†] • Case-control studies • Cross-sectional studies • Ecological studies • Narrative reviews • Systematic reviews • Meta-analyses • Modeling and simulation studies
Publication date	<ul style="list-style-type: none"> • January 1980 – May 2023[‡] 	<ul style="list-style-type: none"> • Before January 1980
Population: Study participants	<ul style="list-style-type: none"> • Human 	<ul style="list-style-type: none"> • Non-human
Population: Life stage	<p>At intervention or exposure and outcome:</p> <ul style="list-style-type: none"> • Infants and toddlers (birth up to 24 months) • Children and adolescents (2 up to 19 years) • Adults and older adults (19 years and older) <p>At intervention or exposure:</p> <ul style="list-style-type: none"> • Individuals during pregnancy 	<p>At intervention or exposure:</p> <ul style="list-style-type: none"> • N/A <p>At outcome:</p> <ul style="list-style-type: none"> • Individuals during pregnancy

* 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 1980 to 2013

Category	Inclusion Criteria	Exclusion Criteria
Population: Health status	<ul style="list-style-type: none"> • Studies that <u>exclusively</u> enroll participants not diagnosed with a disease* • Studies that enroll <u>some</u> participants: <ul style="list-style-type: none"> ○ diagnosed with a disease; ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting; ○ born preterm,[†] with low birth weight,[‡] and/or small for gestational age; ○ and/or with the outcome of interest ○ who became pregnant using Assisted Reproductive Technologies; ○ with multiple gestation pregnancies; ○ pre- or post-bariatric surgery; ○ and/or receiving pharmacotherapy to treat obesity 	<ul style="list-style-type: none"> • Studies that <u>exclusively</u> enroll participants: <ul style="list-style-type: none"> ○ diagnosed with a disease;[§] ○ hospitalized for an illness, injury, or surgery;^{**} ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting; ○ born preterm,[†] with low birth weight,[‡] and/or small for gestational age ○ pre- or post-bariatric surgery; ○ and/or receiving pharmacotherapy to treat obesity
Intervention/ exposure	<ul style="list-style-type: none"> • 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"> ○ 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 • Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is provided or can be determined 	<ul style="list-style-type: none"> • 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) • 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)

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

† Gestational age <37 weeks and 0/7 days

‡ Birth weight <2500g

§ Studies that exclusively enroll participants with obesity will be included

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

Category	Inclusion Criteria	Exclusion Criteria
Comparator	<ul style="list-style-type: none"> Consumption of and/or adherence to a different dietary pattern Different levels of consumption of and/or adherence to a dietary pattern 	<ul style="list-style-type: none"> Consumption of and/or adherence to a similar dietary pattern of which only a specific component or food source s differs between groups
Outcome(s)	<p>All included study designs in children (birth to 19 years) and interventions only in adults (19 years and older):</p> <ul style="list-style-type: none"> Fasting blood glucose Fasting insulin Glucose tolerance/insulin resistance Hemoglobin A1C Prediabetes <p>All included study designs in ages 2 years and older:</p> <ul style="list-style-type: none"> Type 2 diabetes 	<ul style="list-style-type: none"> Urinary measures of glucose Non-fasting blood glucose Non-fasting insulin
Confounders	<ul style="list-style-type: none"> Studies that control for at least one of the key confounders listed in the analytic framework 	<ul style="list-style-type: none"> Studies that do not control for any of the key confounders listed in the analytic framework
Study duration	<ul style="list-style-type: none"> Intervention length ≥ 12 weeks 	<ul style="list-style-type: none"> Intervention length < 12 weeks
Size of study groups	<ul style="list-style-type: none"> For intervention studies: <ul style="list-style-type: none"> ≥ 30 participants per study group for between-subject analyses, or a power calculation indicating that the study is appropriately powered for the outcome(s) of interest For observational studies: <ul style="list-style-type: none"> Analytic sample size of ≥ 1000 participants (for adults and older adults) 	<ul style="list-style-type: none"> For intervention studies: <ul style="list-style-type: none"> < 30 participants per study group for between-subject analyses, and no power calculation indicating that the study is appropriately powered for the outcome(s) of interest For observational studies: <ul style="list-style-type: none"> Analytic sample size $n < 1000$ (for adults and older adults)
Publication status	<ul style="list-style-type: none"> Peer-reviewed articles published in research journals 	<ul style="list-style-type: none"> Non-peer reviewed articles, unpublished data or manuscripts, pre-prints, reports, and conference abstracts or proceedings
Language	<ul style="list-style-type: none"> Published in English 	<ul style="list-style-type: none"> Not published in English

Category	Inclusion Criteria	Exclusion Criteria
Country*	<ul style="list-style-type: none"> Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected 	<ul style="list-style-type: none"> Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected

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. 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. Two NESR analysts independently extract and review 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.^{†‡§}

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 first level of synthesis organization will be by population (children and adolescents, adults, and older adults). Then, within each of the population groups, the evidence will be organized by similarity in outcome. Depending on the available

* 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. 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>)

† 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:l4898.doi:10.1136/bmj.l4898

‡ 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>

evidence, the synthesis may be organized by participant characteristics such as race/ethnicity, socioeconomic position, and health status.

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

After the Committee synthesizes the body of evidence, they will draft a conclusion statement or conclusion statements. 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.

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

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 (Jean Altman, MS; Kara Beckman, PhD; Dana DeSilva, PhD, RD; Kevin Kuczynski, MS, RD; TusaRebecca Pannucci, PhD, MPH, RD; Julia Quam, MSPH, RND; Elizabeth Rahavi, RD) and Project Leadership (HHS: Janet de Jesus, MS, RD; USDA: Eve Stody, 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; Verena McClain, MSc).

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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 and risk of type 2 diabetes?

[†] Boushey C, Ard J, Bazzano L, Heymsfield S, Mayer-Davis E, Sabaté J, Snetelaar L, Van Horn L, Schneeman B, English LK, Bates M, Callahan E, Butera G, Terry N, Obbagy J. Dietary Patterns and Risk of Type 2 Diabetes: A Systematic Review. July 2020. 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.DGAC2020.SR0103>

[‡] Dietary Patterns Technical Expert Collaborative and NESR Staff. A Series of Systematic Reviews on the Relationship Between Dietary Patterns and Health Outcomes. March 2014. 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/sites/default/files/2019-06/DietaryPatternsReport-FullFinal2.pdf>

Category	Existing Review	Updated Review	Change and Rationale
Study design	<p><u>Included:</u></p> <ul style="list-style-type: none"> Randomized controlled trials Non-randomized controlled trials (including quasi-experimental and controlled before and after studies) Quasi-experimental studies (i.e., prospective cohort studies) <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Nested case-control studies Case-control studies Uncontrolled trials Case-control studies Cross-sectional studies Uncontrolled before-and-after studies Narrative reviews Systematic reviews Meta-analyses 	<p><u>Included:</u></p> <ul style="list-style-type: none"> Randomized controlled trials Non-randomized controlled trials* Prospective cohort studies Retrospective cohort studies Nested case-control studies <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Uncontrolled trials† Case-control studies Cross-sectional studies Ecological studies Narrative reviews Systematic reviews Meta-analyses Modeling and simulation studies Mendelian randomization studies 	Study design criteria were modified to enable focus on the strongest body of evidence
Publication date	<p><u>Included:</u></p> <ul style="list-style-type: none"> January 1980 – August 2013 <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Before January 1980, after August 2013 	<p><u>Included:</u></p> <ul style="list-style-type: none"> August 2013 – May 2023‡ <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Before August 2013, after May 2023 	Dates were modified to enable focus on the most recent evidence.
Population: Study participants	<p><u>Included:</u></p> <ul style="list-style-type: none"> Human 	<p><u>Included:</u></p> <ul style="list-style-type: none"> Human 	No change

* 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 August 2013

Category	Existing Review	Updated Review	Change and Rationale
	<p><u>Excluded:</u></p> <ul style="list-style-type: none"> • Non-human 	<p><u>Excluded:</u></p> <ul style="list-style-type: none"> • Non-human 	
Population: Life stage	<p><u>Included:</u></p> <ul style="list-style-type: none"> • At intervention/exposure and outcome: <ul style="list-style-type: none"> ○ Children, adolescents, adults, and older adults aged 2 years and older <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • At intervention/exposure and outcome: <ul style="list-style-type: none"> ○ Infants and toddlers (birth up to 24 months) 	<p><u>Included:</u></p> <ul style="list-style-type: none"> • At intervention/exposure: <ul style="list-style-type: none"> ○ Infants and toddlers (birth up to 24 months) ○ Children and adolescents (2 up to 19 years) ○ Adults and older adults (19 years and older) ○ Individuals during pregnancy ○ Individuals during postpartum <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • At outcome: <ul style="list-style-type: none"> ○ Infants and toddlers (birth up to 24 months) ○ Individuals during pregnancy ○ Individuals during postpartum 	No change other than formatting
Population: Health Status	<p><u>Included:</u></p> <ul style="list-style-type: none"> • Subjects who were healthy or at elevated chronic disease risk <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • Low-calorie intervention (defined as <1,600 kcal/day for women and <2,000 kcal/day for men) • Subjects who were hospitalized, diagnosed with disease, and/or receiving medical treatment 	<p><u>Included:</u></p> <ul style="list-style-type: none"> • Studies that <u>exclusively</u> enroll participants not diagnosed with a disease* • Studies that enroll <u>some</u> participants: <ul style="list-style-type: none"> ○ diagnosed with a disease; ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting; ○ born preterm,[†] with low birth weight,[‡] and/or small for gestational age; ○ and/or with the outcome of interest ○ who became pregnant using Assisted Reproductive Technologies; ○ with multiple gestation pregnancies; ○ pre- or post-bariatric surgery; 	No change other than to clarify intent

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

† Gestational age <37 weeks and 0/7 days

‡ Birth weight <2500g

Category	Existing Review	Updated Review	Change and Rationale
		<p>and/or receiving pharmacotherapy to treat obesity</p> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • Studies that <u>exclusively</u> enroll participants: <ul style="list-style-type: none"> ○ diagnosed with a disease;* ○ hospitalized for an illness, injury, or surgery;† ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting; ○ born preterm,† with low birth weight,‡ and/or small for gestational age ○ who became pregnant using Assisted Reproductive Technologies; ○ with multiple gestation pregnancies; ○ pre- or post-bariatric surgery; ○ and/or receiving pharmacotherapy to treat obesity 	
Intervention/exposure	<p><u>Included:</u></p> <ul style="list-style-type: none"> • A description of the dietary pattern(s) consumed by subjects (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) • 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. <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • 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 	<p><u>Included:</u></p> <ul style="list-style-type: none"> • 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 • 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 • Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is provided or can be determined <p><u>Excluded:</u></p>	No change other than formatting to clarify intent of the criteria.

* Studies that exclusively enroll participants with obesity will be included

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

Category	Existing Review	Updated Review	Change and Rationale
	<p>labeled dietary pattern, but do not describe the foods and beverages consumed).</p>	<ul style="list-style-type: none"> 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) 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) 	
Comparator	<p><u>Included:</u></p> <ul style="list-style-type: none"> Adherence to a different dietary pattern Different levels of adherence to a dietary pattern <p><u>Excluded:</u></p> <ul style="list-style-type: none"> N/A 	<p><u>Included:</u></p> <ul style="list-style-type: none"> Consumption of and/or adherence to a different dietary pattern Different levels of consumption of and/or adherence to a dietary pattern <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Consumption of and/or adherence to a similar dietary pattern of which only a specific component or food source s differs between groups 	No change other than formatting
Outcome(s)	<p><u>Included:</u></p> <ul style="list-style-type: none"> Glucose tolerance Insulin resistance Incidence of Type 2 Diabetes <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Urinary measures of glucose 	<p><u>Included:</u></p> <p>All included study designs in children (birth to 19 years) and interventions only in adults (19 years and older):</p> <ul style="list-style-type: none"> Fasting blood glucose Fasting insulin Glucose tolerance/insulin resistance Hemoglobin A1C Prediabetes <p>All included study designs in all included age groups:</p> <ul style="list-style-type: none"> Type 2 diabetes <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Gestational diabetes mellitus Urinary measures of glucose 	Outcome criteria were modified to enable focus on the strongest body of evidence

Category	Existing Review	Updated Review	Change and Rationale
		<ul style="list-style-type: none"> Non-fasting blood glucose or insulin 	
Confounders	<p><u>Included</u></p> <ul style="list-style-type: none"> n/a <p><u>Excluded</u></p> <ul style="list-style-type: none"> n/a 	<p><u>Included</u></p> <ul style="list-style-type: none"> Studies that control for at least one of the key confounders listed in the analytic framework <p><u>Excluded</u></p> <ul style="list-style-type: none"> Studies that control for at least one of the key confounders listed in the analytic framework 	Criteria were added to enable focus on a stronger body of evidence
Study duration	<p><u>Included</u></p> <ul style="list-style-type: none"> n/a <p><u>Excluded</u></p> <ul style="list-style-type: none"> n/a 	<p><u>Included</u></p> <ul style="list-style-type: none"> Intervention length ≥ 12 weeks <p><u>Excluded</u></p> <ul style="list-style-type: none"> Intervention length < 12 weeks 	Study duration criteria were modified to enable focus on the strongest body of evidence
Size of study groups	<p><u>Included</u></p> <ul style="list-style-type: none"> Randomized or nonrandomized controlled trial with at least 30 subjects per study arm and a follow-up rate of at least 80 percent, or a prospective cohort study <p><u>Excluded</u></p> <ul style="list-style-type: none"> Studies with less than 30 subjects per study arm or a follow-up rate of less than 80 percent 	<p><u>Included</u></p> <ul style="list-style-type: none"> For intervention studies: <ul style="list-style-type: none"> ≥ 30 participants per study group for between-subject analyses, or a power calculation indicating that the study is appropriately powered for the outcome(s) of interest For observational studies: <ul style="list-style-type: none"> Analytic sample size of ≥ 1000 participants (only for adults and older adults) <p><u>Excluded</u></p> <ul style="list-style-type: none"> For intervention studies: <ul style="list-style-type: none"> < 30 participants per study group for between-subject analyses, and no power calculation indicating that the study is appropriately powered for the outcome(s) of interest For observational studies: <ul style="list-style-type: none"> An analytic sample size of $< 1,000$ participants (only for adults and older adults) 	Size of study groups criteria were modified to enable focus on the strongest body of evidence
Publication status	<u>Included</u>	<u>Included</u>	No change

Category	Existing Review	Updated Review	Change and Rationale
	<ul style="list-style-type: none"> Peer-reviewed articles published in research journals <p><u>Excluded</u></p> <ul style="list-style-type: none"> Non-peer reviewed articles, unpublished data or manuscripts, pre-prints, reports, and conference abstracts or proceedings 	<ul style="list-style-type: none"> Peer-reviewed articles published in research journals <p><u>Excluded</u></p> <ul style="list-style-type: none"> Non-peer reviewed articles, unpublished data or manuscripts, pre-prints, reports, and conference abstracts or proceedings 	
Language	<p><u>Included</u></p> <ul style="list-style-type: none"> Published in English <p><u>Excluded</u></p> <ul style="list-style-type: none"> Not published in English 	<p><u>Included</u></p> <ul style="list-style-type: none"> Published in English <p><u>Excluded</u></p> <ul style="list-style-type: none"> Not published in English 	No change
Country*	<p><u>Included</u></p> <ul style="list-style-type: none"> Subject populations from countries with high or very high human development, according to the 2011 Human Development Index <p><u>Excluded</u></p> <ul style="list-style-type: none"> Studies conducted in countries classified as medium or low on the 2011 Human Development Index. 	<p><u>Included</u></p> <ul style="list-style-type: none"> Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected <p><u>Excluded</u></p> <ul style="list-style-type: none"> Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected 	NESR now applies the Human Development Index classification from the year in which the intervention/exposure data were collected.

* 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>)