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Dietary Patterns and Risk of Cardiovascular Disease: A Systematic Review Protocol

Deanna M Hoelscher, PhD, RDN, LD, CNS, FISBNPA,[a,b] Cheryl A.M. Anderson, PhD, MPH, MS,[a,c] Sarah Booth, PhD,[a,d] Andrea Deierlein, PhD, MPH, MS,[a,e] Teresa Fung, ScD, RD,[a,f] Christopher Gardner, PhD,[a,g] Edward Giovannucci, MD, ScD,[a,h] Hollie Raynor, PhD, RD, LDN,[a,i] Fatima Cody Stanford, MD, MPH, MPA, MBA, FAAP, FACP, FAHA, FAMWA, FTOS,[a,h] Sameera Talegawkar, PhD,[a,j] Chris Taylor, PhD, RDN, LD, FAND,[a,k] Deirdre Tobias, ScD,[a,h] Julie Obbagy, PhD, RD,[l] Emily H. Callahan, MS,[m] Laural Kelly English, PhD,[m] Amanda Fultz, PhD,[m] Ramkripa Raghavan DrPH, MPH, MSc,[m] Nicole Reigh, PhD,[n] Molly Higgins, MLIS,[o] Gisela Butera, MEd, MLIS,[p] Nancy Terry, MLIS[p]

[a] Dietary Patterns and Specific Dietary Pattern Components Across Life Stages Subcommittee, 2025 Dietary Guidelines Advisory Committee

[b] UT Health Houston School of Public Health, Subcommittee Chair

[c] University of California San Diego

[d] Tufts University, Committee Chair

[e] New York University

[f] Simmons University

[g] Stanford University

[h] Harvard University

[i] University of Tennessee Knoxville

[j] The George Washington University

[k] The Ohio State University

[l] Branch Chief, Nutrition Evidence Systematic Review (NESR) Branch; Nutrition Guidance and Analysis Division (NGAD), Center for Nutrition Policy and Promotion (CNPP), Food and Nutrition Service (FNS), U.S. Department of Agriculture (USDA)

[m] Systematic Review Analyst, NESR Branch; NGAD, CNPP, FNS, USDA

[n] Systematic Review Analyst, Panum Telecom, under contract with FNS, USDA

[o] Systematic Review Librarian, NESR Branch; NGAD, CNPP, FNS, USDA

[p] Biomedical Librarian/Informationist, National Institutes of Health Library

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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 based on relevance, importance, potential federal impact, and avoiding duplication, which were posted for public comment.[*] The Departments appointed the 2025 Dietary Guidelines Advisory Committee (Committee) in January 2023 to review evidence on the scientific questions. The proposed scientific questions were refined and prioritized by the Committee for consideration in their review of the evidence. 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 cardiovascular disease?

The Committee will conduct a systematic review to address this question, with support from USDA's Nutrition Evidence Systematic Review (NESR) team. This review will update an existing 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	Evidence scan conducted by the 2020 Dietary Guidelines Advisory Committee published in 2020	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 Cardiovascular Disease: 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.SR0102
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, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Risk of Cardiovascular Disease: 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, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Risk of Cardiovascular Disease: 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
February 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, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Risk of Cardiovascular Disease: 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

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 by the Committee to update the existing systematic review[†] to address the question: What is the relationship between dietary patterns consumed and risk of cardiovascular disease?

This systematic review updates an existing NESR systematic review which included evidence published from January 1980 to August 2013 and completed as part of the Dietary Patterns Project by the Dietary Patterns Technical Expert Collaborative[‡] and subsequently updated as part of the 2020 Dietary Guidelines Project by the Dietary Guidelines Advisory Committee,[§] examining new evidence in children and adolescents through October 2019. This updated systematic review will synthesize the studies conducted in children and adolescents from the existing reviews with eligible studies published since October 2019 as one body of evidence, according to the methods described below. Eligible studies conducted in adults and older adults, 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.

[*] 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 Cardiovascular Disease: 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.SR0102

[‡] 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

[§] 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 Cardiovascular Disease: 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.SR0102

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 the **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 revision	Description
September 2023	The inclusion and exclusion criteria for the intervention/exposure and comparator were revised to clarify that: • 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 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.
September 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 in order 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.
September 2023	Inclusion and exclusion criteria for population were revised to exclude infants and toddlers.	This revision was made because current recommendations for saturated fat intake differ for infants and toddlers compared to other life stages.* These revisions were made before any evidence was synthesized.

*U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at DietaryGuidelines.gov

Date	Protocol revision	Description
September 2023	Inclusion and exclusion criteria for study duration were revised to include studies with a duration of ≥4 weeks	The study duration criteria for intervention studies were revised from ≥12 weeks to ≥4 weeks to acknowledge that, despite the original criteria being selected to capture the exposure of habitual dietary pattern intake, changes in intermediate cardiovascular-related outcomes can occur within 4 weeks. These revisions were made before any evidence was synthesized.
September 2023	Inclusion and exclusion criteria for size of study groups were revised to include all observational studies, irrespective of the size of study groups.	The revision to include observational studies irrespective of the size of the study groups (i.e., not limiting to studies with >1000 participants) was made to include smaller observational studies that may enroll under-represented populations and life stages. These revisions were made before any evidence was synthesized.
September 2023	Inclusion and exclusion criteria for country were revised such that for studies conducted in adults and older adults, only those studies conducted in the U.S. will be included.	The revision to include studies conducted in the U.S. (only for adults and older adults population) was made based on the following considerations: 1) the existing systematic review that the Committee is updating for this question has a conclusion statement of strong for adults; 2) to enable the Committee to focus their update on studies that are most applicable to the U.S. population in terms of dietary intake, risk of cardiovascular disease, and other factors that may impact the relationship being examined.

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 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 cholesterol (HDL, LDL), triglycerides, hyperlipidemia, blood pressure (systolic and diastolic), hypertension, CVD morbidity (e.g., myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease, stroke) or composite CVD morbidity and mortality, and CVD-related mortality. The key confounders that may impact the relationships of interest are sex, age, physical activity, anthropometry, socioeconomic position, and race or ethnic background in all populations, 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 cardiovascular disease (CVD)?

Population	***Intervention/ exposure***	***Comparator***	***Outcome***	***Key confounders***
Children and adolescents (2 up to 19 years) Adults and older adults (19 years and older)	Consumption of a dietary pattern	Different dietary pattern(s) Different adherence/ consumption levels to the same dietary pattern	In children and adolescents, adults and older adults • LDL cholesterol • HDL cholesterol • Triglycerides • Hyperlipidemia • Blood pressure (systolic, diastolic) • Hypertension In adults and older adults • CVD morbidity (e.g., myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease, stroke) or composite CVD morbidity and mortality • CVD-related mortality	• Sex • Age • Physical activity • Anthropometry • Race and/or ethnicity • Socioeconomic position • Smoking (adults, older adults) • Alcohol intake (adults, older adults)

Synthesis organization:

I. ***Population***: Children and adolescents (2 up to 19 years)
   a. ***Outcome:*** Cholesterol (HDL, LDL), triglycerides, hyperlipidemia, blood pressure (systolic, diastolic), hypertension

II. ***Population***: Adults, older adults (19 years and older)
   a. ***Outcome:*** Cholesterol (HDL, LDL), triglycerides, hyperlipidemia, blood pressure (systolic, diastolic), hypertension, CVD morbidity (e.g., myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease, stroke) or composite CVD morbidity and mortality, and CVD-related mortality

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	• Randomized controlled trials • Non-randomized controlled trials[*] • Prospective cohort studies • Retrospective cohort studies • Nested case-control studies	• Uncontrolled trials[†] • Case-control studies • Cross-sectional studies • Ecological studies • Narrative reviews • Systematic reviews • Meta-analyses • Modeling and simulation studies • Mendelian randomization studies
Publication date	• January 1980 – May 2023	• Before January 1980 • After May 2023
Population: Study participants	• Human	• Non-human
Population: Life stage	At intervention or exposure and outcome: • Children and adolescents (2 up to 19 years) • Adults and older adults (19 years and older) At intervention or exposure: • Individuals during pregnancy	At intervention or exposure and outcome: • Infants and toddlers (birth to 24 months) At outcome • Individuals during pregnancy

[*] Including quasi-experimental and controlled before-and-after studies

[†] Including uncontrolled before-and-after studies

Category	Inclusion Criteria	Exclusion Criteria

Population: Health status	• Studies that <u>exclusively</u> enroll participants not diagnosed with a disease[*]
	• Studies that enroll <u>some</u> participants:
	  ○ diagnosed with a disease;
	  ○ and/or hospitalized for an illness, injury, or surgery
	  ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;
	  ○ pre- or post-bariatric surgery;
	  ○ receiving pharmacotherapy to treat obesity;
	  ○ and/or with the outcome of interest
		• Studies that <u>exclusively</u> enroll participants:
		  ○ diagnosed with a disease;[†]
		  ○ hospitalized for an illness, injury, or surgery;[‡]
		  ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;
		  ○ pre- or post-bariatric surgery;
		  ○ and/or receiving pharmacotherapy to treat obesity

Intervention/ exposure	• 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	• 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	• Consumption of and/or adherence to a different dietary pattern • Different levels of consumption of and/or adherence to a dietary pattern	• Consumption of and/or adherence to a similar dietary pattern of which only a specific component or food source is different between groups

[*] 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

Category	Inclusion Criteria	Exclusion Criteria
Outcome(s)	• LDL cholesterol • HDL cholesterol • Triglycerides • Hyperlipidemia • Blood pressure (systolic, diastolic) • Hypertension • CVD morbidity (e.g., myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease, stroke) or composite CVD morbidity and mortality • CVD-related mortality	• N/A
Confounders	• Studies that control for at least one of the key confounders listed in the analytic framework	• Studies that do not control for any of the key confounders listed in the analytic framework
Study duration (not applied to pregnancy and postpartum studies)	• Intervention length ≥4 weeks[*]	• Intervention length <4 weeks
Size of study groups (not applied to pregnancy and postpartum studies)	• For intervention studies: ○ ≥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 intervention studies: ○ <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
Publication status	• Peer-reviewed articles published in research journals	• Non-peer reviewed articles, unpublished data or manuscripts, pre-prints, reports, and conference abstracts or proceedings
Language	• Published in English	• Not published in English

[*] U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research. Assessment of Pressor Effects of Drugs Guidance for Industry. https://www.fda.gov/media/113477/download

Category	Inclusion Criteria	Exclusion Criteria
Country*	For children and adolescents: • Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected For adults and older adults: • Studies conducted in the U.S.	For children and adolescents: • Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected For adults and older adults: • Studies conducted outside of the U.S.

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

* 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

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 including children and adolescents, adults, individuals during pregnancy, individuals during postpartum, and older adults. Then, within each of the population groups, the evidence will be organized by similarity in outcome. Depending on the available evidence, the next level of organization will be by participant characteristics, such as race and/or ethnicity, socioeconomic position, or 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 Stoody, 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 (Verena McClain, MSc).

Funding: United States Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Alexandria, VA

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 cardiovascular disease?

Category	Existing Review	Updated Review	Change and Rationale
Study design	Included: • Randomized controlled trials • Non-randomized controlled trials (including quasi-experimental and controlled before and after studies) • Quasi-experimental studies (i.e., prospective cohort studies) Excluded: • 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	Included: • Randomized controlled trials • Non-randomized controlled trials[‡] • Prospective cohort studies • Retrospective cohort studies • Nested case-control studies Excluded: • 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 and to align with current NESR standards.

[*] 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

[†] 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 Cardiovascular Disease: 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.SR0102

[‡] Including quasi-experimental and controlled before-and-after studies

[§] Including uncontrolled before-and-after studies

Category	Existing Review	Updated Review	Change and Rationale
Publication date	Included: • January 1980 – August 2013 Excluded: • Before January 1980, after August 2013	Included: • August 2013 – October 2019/May 2023* Excluded: • Before August 2013, after May 2023	End of the date range is updated to extend from the end of search in the existing review to present
Population: Study participants	Included: • Human Excluded: • Non-human	Included: • Human Excluded: • Non-human	No change
Population: Life stage	Included: • At intervention/exposure and outcome: ○ Children, adolescents, and adults aged 2 years and older Excluded: • At intervention/exposure and outcome: ○ Infants and toddlers (birth up to 24 months)	Included: • At intervention/exposure and outcome: ○ Children and adolescents (2 up to 19 years) ○ Adults and older adults (19 years and older) • At intervention/exposure: ○ Individuals during pregnancy ○ Individuals during postpartum Excluded: • At intervention/exposure and outcome: ○ Infants and toddlers (birth up to 24 months) • At outcome: ○ Individuals during pregnancy ○ Individuals during postpartum	No change
Population: Health Status	Included: • Subjects who were healthy or at elevated chronic disease risk Excluded:	Included: • Studies that exclusively enroll participants not diagnosed with a disease† • Studies that enroll some participants: ○ diagnosed with a disease; ○ and/or hospitalized for an illness, injury, or surgery ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;	Population health status criteria is modified to exclude those receiving pharmacotherapy to treat obesity.

* This review update date range encompasses the original systematic review date range, which included articles published from January 1980 to August 2013

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

Category	Existing Review	Updated Review	Change and Rationale
	• 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	○ born preterm, with low birth weight, and/or small for gestational age; ○ pre- or post-bariatric surgery; ○ receiving pharmacotherapy to treat obesity; ○ and/or with the outcome of interest Excluded: • Interventions designed to induce weight loss or treat overweight and obesity through energy-restriction/hypocaloric diets for the purposes of treating additional or other medical conditions • Studies that exclusively enroll participants: ○ diagnosed with a disease;* ○ hospitalized for an illness, injury, or surgery;† ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting; ○ pre- or post-bariatric surgery ○ and/or receiving pharmacotherapy to treat obesity	
Intervention/exposure	Included: • 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. Excluded: • Studies that do not provide a description of the dietary pattern, which at minimum, must include	Included: • 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	Revisions were made to clarify the intent of the intervention/exposure and comparator criteria, but do not represent a change in how the criteria were applied.

* 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
	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).	• Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is provided or can be determined. Excluded: • 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	Included: • Adherence to a different dietary pattern • Different levels of adherence to a dietary pattern Excluded: • N/A	Included: • Consumption of and/or adherence to a different dietary pattern • Different levels of consumption of and/or adherence to a dietary pattern Excluded: • Consumption of and/or adherence to a similar dietary pattern of which only a specific component or food source is different between groups	No change other than to clarify the intent.
Outcome(s)	Included: • Total cholesterol • LDL cholesterol • HDL cholesterol, including TC:HDL and LDL:HDL ratios • Triglycerides • Blood pressure	Included: • LDL cholesterol • HDL cholesterol • Triglycerides • Hyperlipidemia • Blood pressure (systolic, diastolic) • Hypertension	Outcome criteria has been modified to include the most relevant outcomes

Category	Existing Review	Updated Review	Change and Rationale
	• Cardiovascular disease (e.g., myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease) • Stroke • Venous thrombosis • Cardiovascular disease-related mortality	• CVD morbidity (e.g., myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease, stroke) or composite CVD morbidity and mortality • CVD-related mortality Excluded: • Total cholesterol • Hypertensive disorders of pregnancy	
Confounders	Included • n/a Excluded • n/a	Included: • Studies that control for one or more of the key confounders listed in the analytic framework. Excluded: • Studies that do not control for any of the key confounders listed in the analytic framework.	Criteria were added to enable focus on a stronger body of evidence.
Study duration	Included • n/a Excluded • n/a	Included • Intervention length ≥4 weeks Excluded • Intervention length <4 weeks	Study duration criteria were modified to enable focus on a stronger body of evidence

Size of study groups	Included
	• 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
	Excluded
	• Studies with less than 30 subjects per study arm or a follow-up rate of less than 80 percent
		Included
		• For intervention studies:
		  ○ ≥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
		Excluded
		• For intervention studies:
		  ○ <30 participants per study group for between-subject analyses,
			Size of study groups criteria were modified to enable focus on a stronger body of evidence

Category	Existing Review	Updated Review	Change and Rationale
		○ and no power calculation indicating that the study is appropriately powered for the outcome(s) of interest	
Publication status	Included • Peer-reviewed articles published in research journals Excluded • Non-peer reviewed articles, unpublished data or manuscripts, pre-prints, reports, and conference abstracts or proceedings	Included • Peer-reviewed articles published in research journals Excluded • Non-peer reviewed articles, unpublished data or manuscripts, pre-prints, reports, and conference abstracts or proceedings	No change
Language	Included • Published in English Excluded • Not published in English	Included • Published in English Excluded • Not published in English	No change
Country*	Included • Subject populations from countries with high or very high human development, according to the 2011 Human Development Index Excluded • Studies conducted in countries classified as medium or low on the 2011 Human Development Index.	Included For children and adolescents: • Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected For adults and older adults: • Studies conducted in the U.S. Excluded For children and adolescents: • Studies conducted in countries classified as medium or low on the Human Development	For children and adolescents, NESR now applies the Human Development Index classification from the year in which the intervention/exposure data were collected. For adults, and older adults, the review will include studies conducted in the U.S. This decision is based on the following considerations: 1) an existing conclusion statement of strong for adults; 2) to enable focus on studies that are most applicable to the U.S. population in terms of dietary intake, risk of

* 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)

Category	Existing Review	Updated Review	Change and Rationale
		Index the year(s) the intervention/exposure data were collected For adults and older adults: • Studies conducted outside of the U.S.	cardiovascular disease, and other factors that may impact the relationship being examined