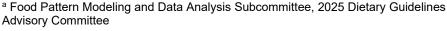


Should foods and beverages with lower nutrient density (i.e., those with added sugars, saturated fat, and sodium) contribute to item clusters, representative foods, and therefore the nutrient profiles for each food group and subgroup used in modeling the USDA Dietary Patterns?:

Food Pattern Modeling Protocol

Christopher A. Taylor, PhD, RDN, LD, FAND, a,b Steven A. Abrams, MD,a,c Sarah L. Booth, PhD,a,d Carol Byrd-Bredbenner, PhD, RD, FAND,a,e Heather A. Eicher-Miller, PhD,a,f Teresa Fung, ScD, RD,a,g Valarie Blue Bird Jernigan, DrPH, MPH,a,b Sameera Talegawkar, PhD,a,i Deirdre Tobias, ScD,a,j Meghan Adler, MS, RDN,k Colleen M. Cruz, MPH, RDN,k Janet de Jesus, MS, RD, Dana DeSilva, PhD, RD,m Laural Kelly English, PhD,n Stephenie Fu,o Hazel Hiza, PhD,k Kevin Kuczynski, MS, RD,k Emily Madan, PhD,p Verena McClain, MSc,p TusaRebecca Pannucci, PhD, MPH, RD,q Ramkripa Raghavan, DrPH, MPH, MSc,n Joe Rorabaugh-Irwin, MS, RD,m Kelley Scanlon, PhD, RD,r Eve Stoody, PhDs



^b The Ohio State University, Subcommittee Chair, Food Pattern Modeling

^c University of Texas at Austin

d Tufts University, Committee Chair

e Rutgers, The State University of New Jersey

^f Purdue University, Subcommittee Chair, Data Analysis

^g Simmons University

h Oklahoma State University

¹ The George Washington University

j Harvard University

^k Food Pattern Modeling Analyst; Nutrition Guidance and Analysis Division (NGAD), Center for Nutrition Policy and Promotion (CNPP), Food and Nutrition Service (FNS), U.S. Department of Agriculture (USDA)

Designated Federal Officer and Nutrition Advisor, Office of Disease Prevention and Health Promotion (ODPHP); Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS)

^m Food Pattern Modeling Analyst, ODPHP; OASH, HHS

ⁿ Systematic Review Analyst, Nutrition Evidence Systematic Review (NESR) Branch; NGAD, CNPP, FNS, USDA

[°] Senior Policy Advisor; Deputy Administrator's Office; CNPP, FNS, USDA

P Food Pattern Modeling Analyst, Panum Telecom, under contract with FNS, USDA

^q Branch Chief, Nutrition and Economic Analysis Branch (NEAB); NGAD, CNPP, FNS, USDA

^r Senior Analytical Advisor; CNPP, FNS, USDA

s Director, NGAD; CNPP, FNS, USDA

Suggested citation: Taylor CA, Abrams SA, Booth S, Byrd-Bredbenner C, Eicher-Miller HA, Fung T, Jernigan VB, Talegawkar S, Tobias D, Adler M, Cruz CM, de Jesus J, DeSilva D, English LK, Fu S, Hiza H, Kuczynski K, Madan E, McClain V, Pannucci T, Raghavan R, Rorabaugh-Irwin J, Scanlon K, Stoody E. Should foods and beverages with lower nutrient density (i.e., those with added sugars, saturated fat, and sodium) contribute to item clusters, representative foods, and therefore the nutrient profiles for each food group and subgroup used in modeling the USDA Dietary Patterns? Food Pattern Modeling Protocol. May 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Guidance and Analysis Division. Available at: https://www.dietaryguidelines.gov/

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Table of contents

Table of contents	3
Rationale	4
Introduction	
Historical perspectives	
Current perspectives	
Methods	
Develop a protocol	
Develop an analytic framework	
Develop an analytic plan	
Conduct analyses	
Synthesize analyses	
Develop conclusion	
Recommend future research	
Protocol amendments	
References	
Acknowledgments and funding	
Figure 1. Calculation of a weighted average nutrient profile for the Red and Orange Vegetables subgroup	6
Table 1. Age-sex groups for which nutritional goals are examined in analyses	12
Table 2. Nutritional goals for analyses	12
Table 3. Protocol amendments	15

Rationale

Food Pattern Modeling (FPM) is a methodology used to a) illustrate how hypothetical changes to the amounts or types of foods and beverages in a dietary pattern might affect meeting nutrient needs, and b) assist in defining quantitative dietary patterns that reflect the evidence for health-promoting diets synthesized from systematic reviews, while meeting energy and nutrient needs. Each food group and subgroup within the USDA Dietary Patterns has a defined nutrient profile that serves as the foundation of any FPM analysis. The nutrient profiles are calculated as the average of nutrient-dense forms of foods and beverages assigned to each food group or subgroup, weighted according to the proportions of reported consumption (by gram weight consumed) in the U.S. population. Historically, nutrient profile calculations included the proportional contribution of intake relative to all foods and beverages in a food group or subgroup reported in What We Eat in America, National Health and Nutrition Examination Survey (WWEIA, NHANES). Although nutrient profiles of food groups and subgroups included foods and beverages regardless of their nutrient density in the composite to calculate the proportions of reported consumption (in grams), only nutrient-dense representative foods are used to estimate energy and nutrients for each food group or subgroup in calculating the nutrient profiles. This protocol describes an approach to exclude some foods and beverages that are lower in nutrient density from the calculation of nutrient profiles, thus using revised proportions of consumption and the energy and nutrients from nutrient-dense representative foods. By creating a revised nutrient profile, foods and beverages included in the patterns may increase the contribution of nutrients while limiting saturated fat, added sugars, and sodium. This revision could, in turn, provide greater flexibilities for including less-nutrient dense options of food and beverage choices across food groups in the Healthy U.S.-Style (HUSS) Dietary Pattern while still staying within calorie recommendations.

The following FPM analyses will derive new nutrient profiles for each food group and subgroup from which foods and beverages lower in nutrient density (i.e., those with added sugars, saturated fat, and sodium) are removed from these calculations. Of note, the revised approach is not suggesting that foods and beverages lower in nutrient density no longer contribute to a given food group or subgroup as defined in the USDA Food Patterns Equivalents Database.² Additional analyses will examine scenarios where foods and beverages with lower nutrient density may be added to an overall health promoting dietary pattern that includes recommended limits for energy, added sugars, saturated fats, and sodium.

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 impact to federal programs, and avoiding duplication, which were posted for public comment.^{1,3} The Departments appointed the 2025 Dietary Guidelines Advisory Committee (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*. These questions were refined and prioritized by the Committee for consideration in their review of the evidence.

The Committee will be asked to answer the following question using FPM analyses:

Considering each life stage, should changes be made to the USDA Dietary Patterns (Healthy U.S.-Style, Healthy Mediterranean-Style, and/or Healthy Vegetarian); should additional Dietary Patterns be developed/proposed based on:

Findings from systematic reviews, data analysis, and/or FPM analyses; and

Population norms (e.g., starchy vegetables are often consumed interchangeably with grains), preferences (e.g., emphasis on one staple grain versus another), or needs (e.g., lactose intolerance) of the diverse communities and cultural foodways within the U.S. population?

Changes to USDA Dietary Patterns may include modification to the amounts of food groups/subgroups and/or recategorization of food groups/subgroups, as well as subsequent changes to energy available for other uses, including for added sugars.

As part of that process and to address the overarching FPM question, the following question for analysis has been identified:

Should foods and beverages with lower nutrient density (i.e., those with added sugars, saturated fat, and sodium) contribute to item clusters, representative foods, and therefore the nutrient profiles for each food group and subgroup used in modeling the USDA Dietary Patterns?

The Committee will use FPM analyses to address this question, with support from USDA's FPM methods team. This protocol will establish methods used to develop and compare revised nutrient profiles to nutrient profiles developed using existing methods for each food group (i.e., Vegetables; Fruits; Grains; Dairy and Fortified Soy Alternatives; and Protein Foods) and subgroup (i.e., Dark-Green Vegetables; Red and Orange Vegetables; Beans, Peas, and Lentils; Starchy Vegetables; Other Vegetables; Whole Grains; Refined Grains; Meats, Poultry, and Eggs; Seafood; Nuts, Seeds, and Soy Products).

Historical perspectives

Historically, all foods and beverages reported in WWEIA, NHANES that contribute to a food group and/or subgroup are used in the development of nutrient profiles. The existing steps used to calculate a weighted average nutrient profile are described in detail below and visualized in Figure 1. An approach to revise these steps follows the description of existing approaches.

- 1. First, all foods and beverages, including combination foods and mixed dishes, reported in WWEIA. NHANES are disaggregated into ingredients and categorized into ~400 item clusters.⁴ An item cluster is a group of similar foods or beverages (e.g., all sources of cooked carrots grouped together). Each food group and subgroup nutrient profile is comprised of a collection of item clusters, each representing the various types and sources of foods and beverages comprising a food group or subgroup, such as the Red and Orange Vegetables subgroup.
- 2. Second, each item cluster is assigned a single, nutrient-dense representative food to exemplify the energy and nutrient values that represent the item cluster in FPM. The Dietary Guidelines for Americans, 2020-2025 defines nutrient-dense foods and beverages as those which provide vitamins, minerals, and other health-promoting components and have no or limited added sugars, saturated fat, and sodium. For FPM, a nutrient-dense representative food is chosen by selecting a single food or beverage within the item cluster with the least amounts of added sugars, saturated fats, and/or sodium (e.g., cooked carrots with no added sugars, fat, or salt to represent all sources of cooked carrots). In some cases, if there is no nutrient-dense food within an item cluster (e.g., flavored milk item clusters), then a nutrient-dense form of a food from a similar item cluster (e.g., unflavored skim milk) is selected as the representative food.
- 3. Third, dietary recall data from WWEIA, NHANES is used to calculate the proportion of consumption that each item cluster contributes to the entire food group or subgroup. The result is a composite for each food group or subgroup (i.e., the proportional contribution of each item cluster within each food group or subgroup). While the energy and nutrients assigned to each item cluster are represented by a nutrient dense food, the proportion of consumption of that item cluster to the entire food group or subgroup considers all food or beverage sources, regardless of nutrient density (e.g., consumption of all cooked

- carrots regardless of if they contain added sugars, salt, and/or fat or are used as an ingredient in a food (i.e., carrots in carrot cake) to calculate the proportional contribution of the item cluster, "Carrots, cooked" to the subgroup "Red and Orange Vegetables").
- 4. Fourth, a weighted average nutrient profile is calculated to develop the nutrient profile for each food group and subgroup. The calculation of each nutrient profile considers the proportional contribution from multiple item clusters. The percent contribution of each item cluster within a food group or subgroup is multiplied by the energy and nutrients in their assigned nutrient-dense representative foods. The results are summed to determine the overall nutrient profile for each food group and subgroup. The following formula is used to calculate each nutrient profile:

(% contribution of each item cluster x nutrients in the representative food)

The 2020 Dietary Guidelines Advisory Committee used FPM to explore the development of dietary patterns for individuals less than 2 years of age. 5 The nutrient profiles for this age group were developed using the same steps, but with a few distinctions. The foods and beverages were limited to those reported (by proxy reporting) for this age group (i.e., < 2 years of age) and the proportion of consumption of each item cluster was specific to proportions of consumption in this age group. Differences in the representative foods used, compared to those used for nutrient profiles in FPM for ages 2 and older, were the following:

- Whole milk was used instead of fat-free milk
- Reduced-fat plain yogurt was used instead of fat-free yogurts (plain or flavored with noncaloric sweeteners)
- Reduced-fat cheeses were used as representative foods for all cheese item clusters instead of using skim or fat-free cheese options when available

Tomato juice Red peppers, cooked Tomatoes, cooked and raw Pumpkin Winter squash Sweet potatoes, vams Nutrient profile = % contribution of each item cluster to Red chili peppers Σ (% contribution of each item cluster X the red/orange vegetable subgroup* nutrients in the representative food) Carrots, raw Carrots, cooked **Carrot juice** Other red/orange Tomatoes, raw

Figure 1. Calculation of a weighted average nutrient profile for the Red and Orange Vegetables subgroup

^{*2020} FPM Report 2+: https://www.dietaryguidelines.gov/sites/default/files/2020-07/FoodPatternModeling Report 2YearsandOlder.pdf

Each nutrient profile includes energy, the macronutrients, 12 vitamins, and 8 minerals. For example, the nutrient profile for the Red and Orange Vegetables subgroup includes ~45 kcal, ~2.4 g of fiber, and ~43 mg of vitamin C, which reflects the weighted average contribution of the nutrients in the nutrient-dense representative foods that represent each item cluster that make up Red and Orange Vegetables subgroup.

Current perspectives

This protocol describes a multi-phased approach to identify foods and beverages that are lower in nutrient density and determine which, if any, should be omitted from the development of a revised nutrient profile. The same general steps for constructing nutrient profiles remain, and the revised approach does not mean that foods and beverages lower in nutrient density no longer contribute to a given food group or subgroup as defined in the USDA Food Patterns Equivalents Database. The development of revised nutrient profiles allows the Committee to estimate the anticipated nutrient composition for each food group and subgroup that could be obtained by eating a variety of foods from each group in nutrient-dense forms, while avoiding foods and beverages that are notably higher in saturated fat, added sugars, and sodium. The resulting nutrient profiles are used in subsequent analyses to assess nutrient adequacy of dietary patterns for various individuals. The Committee will consider if the existing approach or a revised approach to calculating nutrient profiles will be used for subsequent FPM analyses.

Methods

This section presents an overview of the methods, or the process, that will be used by the Committee to answer the question:

Should foods and beverages with lower nutrient density (i.e., those with added sugars, saturated fat, and sodium) contribute to item clusters, representative foods, and therefore the nutrient profiles for each food group and subgroup used in modeling the USDA Dietary Patterns?

Develop a protocol

A FPM protocol is the plan for how USDA's FPM methodology will be used to conduct specific FPM analyses. The protocol is established by the Committee before the analysis is conducted. The protocol describes the components of the FPM process, including the analytic framework, analytic plan, analysis synthesis, conclusion development, and future research recommendations. It is developed through Committee discussion of the strengths and limitations for various analysis types and exercises to identify the most appropriate and relevant methods to answer each FPM question. FPM is an iterative process; thus, results from initial analyses may inform refinement of this protocol or subsequent protocols.

When reviewing questions or topics addressed by prior Committees, the Committee uses the previous analytic framework, plan, and protocol to inform and refine their current approaches. Any changes to this protocol from its first publication will be described in Table 3. Protocol amendments.

Develop an analytic framework

An analytic framework represents the overall scope of the FPM analyses, including the population, type of analyses, and data sources identified to answer the question. It also includes the definitions of key terms.

Question:

Should foods and beverages with lower nutrient density (i.e., those with added sugars, saturated fat, and sodium) contribute to item clusters, representative foods, and therefore the nutrient profiles for

each food group and subgroup used in modeling the USDA Dietary Patterns?

Population:

The nutrient profiles modeled in these FPM analyses are based on dietary intake data among the U.S. population ages 12 months and older. The contribution of complimentary foods and beverages consumed by infants less than 12 months will not be included in the calculation of nutrient profiles.

The nutrient profiles tested modeled in these FPM analyses will be applied to the 2020 <u>HUSS Dietary Pattern</u> published for ages 12 through 23 months, who are no longer consuming human milk or infant formula, and for ages 2 years and older.¹ Around 12 months a dietary pattern that no longer includes infant formula or human milk may be established; however, consumption of human milk in the second year of life is common.

Types of analyses:

The overall FPM methodology used to develop and update the USDA Dietary Patterns includes six steps: (1) identifying appropriate energy levels for the patterns; (2) identifying nutritional goals for the patterns; (3) establishing food groupings and food group amounts; (4) determining the amounts of energy and nutrients that would be provided by consuming various foods within each food group or subgroup; and (5) evaluating nutrient levels in each pattern against nutritional goals; and (6) multiple iteration and re-evaluation of revised nutrient profiles may be required to examine differences in the exclusions of foods and beverages that are lower in nutrient density from being used to calculate nutrient profiles.

This question will focus on step 4, determining the amounts of energy and nutrients that would be obtained by consuming various foods within each food group and step 5, evaluating nutrient levels in each pattern against nutritional goals.

FPM analyses for answering these questions will involve:

- Calculate a nutrient profile for each food group and subgroup using existing methods that does not exclude the contribution of identified less nutrient-dense foods and beverages.
- Identify foods and beverages that are lower in nutrient density and that currently contribute to item clusters, representative foods, and, therefore, nutrient profiles for each food group and subgroup used in modeling the HUSS Dietary Pattern.
- Calculate a revised nutrient profile for each food group and subgroup that excludes the contribution of identified foods and beverages that are lower in nutrient density.
- Compare food group and subgroup nutrient profiles that exclude the contribution of foods and beverages
 that are lower in nutrient density to nutrient profiles calculated using existing methods that do not exclude
 less nutrient-dense foods and beverages.
 - Evaluate proportional contribution of item clusters (i.e., each item cluster's percent contribution)
 to the total composite of each food group and subgroup.
- Compare total energy and nutrients provided in the HUSS Dietary Pattern, as defined in the *Dietary Guidelines for Americans*, 2020-2025 for ages 12 through 23 months and for ages 2 years and older, when nutrient profiles are calculated using the revised methods to the total energy and nutrients provided when nutrient profiles are calculated using existing methods.¹
 - o Identify the age-sex groups and life stages for whom nutrient needs are met or not met at each calorie level.
- FPM is an iterative process (i.e., repeated analyses), thus results from initial analyses may inform refinement of this protocol. Any changes to this protocol will be described in **Table 3. Protocol amendments**.
- Determine if existing or revised nutrient profiles will be used for subsequent FPM analyses.

Data Sources:

- What We Eat in America, NHANES 2017-2018, individuals 1 years and over, days 1 and 2, weighted to produce nationally representative estimates. Available: ars.usda.gov/nea/bhnrc/fsrg
- FNDDS 2017-2018: U.S. Department of Agriculture, Agricultural Research Service. 2020. *USDA Food and Nutrient Database for Dietary Studies 2017-2018*. Available: ars.usda.gov/nea/bhnrc/fsrg
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Key definitions:

Key definitions in this protocol include existing definitions used by the 2020 Dietary Guidelines Advisory Committee and/or published in the *Dietary Guidelines for Americans, 2020-2025*, such as definitions operationalized in the HUSS Patterns. The 2025 Dietary Guidelines Advisory Committee will continue to consider terminology and implications of terms related to health equity and/or communication to the public. Future revisions to existing definitions will be noted.

Food groups and subgroups in the 2020 HUSS Dietary Pattern: USDA's HUSS Dietary Pattern for ages 2 years and older provides amounts of five major <u>food groups</u> and <u>subgroups</u> including:

- F<u>ruits</u>
- Vegetables:
 - Dark-Green; Red and Orange; Beans, Peas, and Lentils a; Starchy; and Other
- Dairy and Fortified Soy Alternatives
- Grains:
 - Whole Grains; Refined Grains
- Protein Foods:
 - Meats, Poultry, and Eggs; Seafood; Nuts, Seeds, and Soy Products; Beans, Peas, and Lentils a
 - a. Beans, Peas, and Lentils are typically modeled as Vegetables in the HUSS Pattern but can also be counted toward the Protein Foods group. For the analyses in this protocol using the HUSS Dietary Pattern, Beans, Peas, and Lentils will only be modeled in the Vegetables food group.
 - b. For the HUSS Dietary Pattern for ages 12 through 23 months, there are separate subgroups for 1) Meats and Poultry and 2) Eggs.

Oils: Oils are sources of essential fatty acids and include canola, corn, olive, peanut, safflower, soybean, and sunflower oils. Oils also are naturally present in nuts, seeds, seafood, olives, and avocados. The fat in some tropical plants, such as coconut oil, palm kernel oil, and palm oil, are not included in the oils category because they contain a higher percentage of saturated fat than do other oils.

Added sugars: Added sugars are either added during the processing of foods or are packaged as sweeteners (e.g., a bag of table sugar). Added sugars include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetables juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. Added sugars, such as those in fruit or milk, are not defined as added sugars. Specific examples of added sugars that can be listed as an ingredient include brown sugar, corn sweetener, corn syrup, dextrose, fructose, glucose, high-fructose corn syrup, honey, invert sugar, lactose, malt syrup, maltose, molasses, raw sugar, sucrose, trehalose, and turbinado sugar.

Limits on calories for other uses (as defined in the HUSS Dietary Pattern)^{1,6}: Foods are assumed to be in nutrient-dense forms, which are lean or low-fat and prepared with minimal added saturated fat, added sugars, refined starches, or sodium. If all food choices to meet food group recommendations are in nutrient-dense forms, a small number of calories remain within the overall limit of the pattern (i.e., limit on calories for other uses). The amount of calories depends on the total calorie level of the pattern and the amounts of food from each food group required to meet nutritional goals. Calories up to the specified limit can be used for added sugars, refined starches, saturated fat, and/or alcohol (for nonpregnant adults of legal drinking age only), or to eat more than the recommended amount of food in a food group.

Item Clusters: Identified groupings of the same or similar foods or beverages that make up each food group and subgroup. Item clusters are used to calculate the weighted average consumption for use in calculating a nutrient profile for each food group and subgroup used in USDA FPM.

Nutrient-Dense Representative Foods: For the purpose of USDA's FPM, each item cluster is assigned a nutrient-dense representative food which are those foods or beverages that represent the forms with the least amounts of added sugars, sodium, and saturated fats. The nutrient composition of the nutrient-dense representative food is used to represent the nutrient composition of the entire item cluster when calculating the nutrient profile for a food group or subgroup.

Nutrient Profiles: The proportional nutrient composition from the item clusters that represent each food group and subgroup from the variety of foods in each food group in their nutrient-dense forms. The nutrient profiles are based on a weighted average of nutrient-dense forms of foods (i.e., a composite of nutrient-dense forms of foods and beverages within a food group or subgroup). The weighted average calculation considers a range of

food choices in the United States, but in nutrient-dense forms, and results in a food pattern that can be adapted to fit an individual's preferences.

Develop an analytic plan

Establish energy levels:

Dietary Reference Intakes (DRI) formulas are used to calculate Estimated Energy Requirements (EER) for each age-sex group and for three age groups specific to pregnancy and lactation (14-18 years, 19-30 years and 31-50 years).8 (See Table 1.) EER is based on sex, age, height, weight, level of physical activity, and life stage and, during pregnancy, gestational weeks. The EERs for pregnancy account for the energy cost of tissue accretion and deposition based on pre-pregnancy BMI category and IOM recommended rates of gestational weight gain. The EERs for lactation account for the energy cost of human milk production and mobilization of postpartum tissue stores for gradual weight loss.1

Computed weight for a body mass index (BMI) of 22.5 kg/m² for adult males and 21.5 kg/m² for adult females (ages 19+ years) and median height are used to calculate reference energy levels for each age-sex group.¹ The computed weight based on the corresponding BMI is obtained using the following equation.

BMI 22.5 or 21.5 x (median height in m)² = computed weight in kg

These BMIs correspond to the 50th percentile (median) for reference weight among 19-year old males and females based on the 2005 DRI for energy and the 2000 CDC Growth Charts. 9,10 The EER calculations for adults follow the 2020 Committee's approach to base reference weight on a BMI of 18.5 to <25 kg/m² but are enhanced to incorporate median heights for each age-sex group using updated NHANES data instead of using one median height for all adult males and one median height for all adult females.^{5,11} For children and adolescents ages 2-18 years, median height and the 50th percentile BMI-for-age are obtained using NHANES anthropometric data and the CDC Growth Charts. 11,12 For young children ages 12 through 23 months, EERs from the DRI report using NHANES median weight and length are used, as these result in similar calorie levels as WHO Growth Chart data. 8,13 These weight, height/length, and BMI assumptions for estimating energy levels in FPM align with those being used in the Committee's data analysis work. The use of median height/length also aligns with the DRI for energy report.8

A lower energy level (for inactive individuals) rounded to the nearest 200 calorie level and its associated pattern are determined for each age-sex group and used in evaluating the patterns against nutritional goals. (See step 2: Establish nutritional goals.) The 2020 USDA Dietary Patterns for ages 12 through 23 months are established to meet the EER for those ages. For ages 2 years and older, the 2020 Dietary Patterns generally are not age- or sex- specific. However, the 2020 Dietary Patterns at 1,000, 1,200, and 1,400 calorie levels are designed to meet the nutritional needs of children ages 2 through 8 years. Patterns from 1,600 to 3,200 calories are designed to meet the nutritional needs of children 9 years and older and adults. The 1,000 and 1,200 calorie level patterns are not intended for children 9 years and older or adults, and the 1,400-calorie level is not intended for children ages 10 years and older or adults. Individuals may require a calorie level that is higher or lower than the calorie level associated with each population-level age-sex group.

Table 1. Age-sex groups for which nutritional goals are examined in analyses

Children (Male/Female)	Males	Females	Pregnancy (Per 1 st , 2 nd , and 3 rd Trimesters)	Lactation (Per 0-6 and 7-12 months postpartum)
1-3 years				
	4-8 years	4-8 years		
	9-13 years	9-13 years		
	14-18 years	14-18 years	14-18 years	14-18 years
	19-30 years	19-30 years	19-30 years	19-30 years
	31-50 years	31-50 years	31-50 years	31-50 years
	51+ years	51+ years		

Establish nutritional goals:

Specific nutritional goal quantities for a dietary intake pattern are set according to energy intake level and based on the DRI age-sex group(s) for which the pattern is designed. Goals for total energy, fat, protein, carbohydrates, 3 fatty acids, 12 vitamins, 8 minerals, added sugars, and fiber are based on DRI reports released between 1997 and 2023 and on quantitative recommendations in the current *Dietary Guidelines for Americans*, 2020-2025 (DGA).^{1,8,14-17} The macronutrients, fatty acids, vitamins, and minerals that are considered nutritional goals for these analyses are specified in **Table 2**. Because the dietary patterns are designed as a framework for achieving a healthy dietary pattern, the goals are the Recommended Dietary Allowance (RDA) amounts for nutrients having an RDA. The Adequate Intake (AI) is used as the nutrient goal when an RDA is not established.

Table 2. Nutritional goals for analyses

Food Component	Specific Nutrients (and Source of Goal ^a)	
Energy	Energy (EER)	
Macronutrients	Carbohydrate (AMDR/RDA), Protein (AMDR/RDA), Total Fat (AMDR)	
Fatty acids	Saturated Fatty Acids (DGA 2020-2025, <10% of total energy), 18:2 Linoleic Acid (AI), 18:3 Linolenic Acid (AI)	
Vitamins	Vitamin A (RDA), Vitamin C (RDA), Vitamin D (RDA), Vitamin E (RDA), Vitamin K (AI), Thiamin (RDA), Riboflavin (RDA), Niacin (RDA), Vitamin B6 (RDA), Folate (RDA), Vitamin B12 (RDA), Choline (AI)	
Minerals	Calcium (RDA), Copper (RDA), Iron (RDA), Magnesium (RDA), Phosphorus (RDA), Potassium (AI), Sodium (CDRR), Zinc (RDA)	
Added Sugars	Added Sugars (DGA 2020-2025, <10% of total energy)	
Fiber	Total Dietary Fiber (AI, 14g/1,000 calories)	

^a AI = Adequate Intake, AMDR = Acceptable Macronutrient Distribution Range, CDRR = Chronic Disease Risk Reduction Level, DGA 2020-2025 = Dietary Guidelines for Americans, 2020-2025, RDA = Recommended Dietary Allowance

Establish food groupings and amounts:

Existing food groups and subgroups in the USDA HUSS Dietary Pattern for ages 12 through 23 months and ages 2 years and older (published in the Dietary Guidelines for Americans, 2020-2025) will be used in these analyses.1

Determine the amounts of nutrients that would be obtained by consuming various foods within each group:

- A composite system is used to determine the anticipated energy and nutrient content, or nutrient profile, of each food group or subgroup as described below.
 - All foods reported by individuals ages 1 year and older as part of WWEIA, NHANES 2017-2018 are disaggregated into their ingredients.18
 - Existing nutrient profile development approach: all foods and beverages that have a food group or subgroup contribution are included in the set of foods used to calculate nutrient profiles.
 - Revised nutrient profile development approach: some foods and beverages that are lower in nutrient density are excluded from the set of foods used to calculate nutrient profiles.
 - Exclude foods/beverages based on WWEIA Food Categories and companion item clusters
 - Exclude foods/beverages for which less than [defined proportion] of the total ingredients contribute to a food group/subgroup.
 - Exclude item clusters when a nutrient-dense representative food would not be a practical, nutrient-dense alternative for the foods and beverages within an item cluster.
 - Exclude item clusters when the representative food is an outlier compared to other nutrient-dense representative foods based on the amount of added sugars, saturated fat, and/or sodium.
 - Similar ingredients are aggregated into food item clusters.
 - A nutrient-dense form of the food is selected as the representative food for each cluster.
 - The proportional intake of each item cluster within each food group or subgroup is calculated and used to compute a weighted average of nutrient-dense forms of foods representing each food item cluster.
 - The proportional intake is calculated for ages 1 year or older similar to methods from previous updates.1
- Using the nutrients in each representative food and the item cluster's proportional intake using the life stage approach (children less than 2 years and the population 2 years and older), a nutrient profile is calculated for each food group or subgroup. Thus, a nutrient profile specific to each child age 12 through 23 months and to the rest of the population is created and used to estimate the anticipated nutrients in the

patterns. Nutrient profiles are also calculated for oils and solid fats using food supply data to determine proportional intakes.

Evaluate nutrient level in each pattern against nutritional goals:

Using the revised nutrient profiles that apply to young children less than 2 years and the population 2 years and older, the nutrients provided by amounts recommended in the Dietary Guidelines for Americans, 2020-2025 from each food group (and oils) are compared to the age, sex, and life stage-specific goals (usually at least 90% of the RDA or AI).

Iteration and re-evaluation:

After identifying the implications of the defined revised nutrient profiles and their comparison to the nutrient profiles calculated with existing methods, the Committee may use a stepwise, iterative approach to make adjustments. This may result in testing a different set of defined exclusions of foods and beverages and reevaluation of the resulting nutrient profiles. Any changes to this protocol will be described in Table 3. Protocol amendments.

Conduct analyses

The USDA FPM methods team, in collaboration with the Committee, will use the analytic framework and analytic plan as a guide for conducting analyses and preparing tables and reports describing the analytic results for each analysis.

The first level of analysis will be by population, with results described for each age-sex groups and life stage (e.g., pregnancy and lactation). Depending on available data and resources, subsequent analyses may be based on population subgroups, race and/or ethnicity, and/or socioeconomic position.

Synthesize analyses

The Committee will describe, compare, and combine the evidence from all FPM analyses conducted to answer the primary FPM question: Should foods and beverages with lower nutrient density (i.e., those with added sugars, saturated fat, and sodium) contribute to item clusters, representative foods, and therefore the nutrient profiles for each food group and subgroup used in modeling the USDA Dietary Patterns?

Synthesis of the analyses will involve summarizing results with particular emphasis on implications for each life stage: infants, children, adolescents, adults, older adults, and individuals who are pregnant or lactating. Implications for each of the existing USDA Dietary Patterns or rationale for new pattern development, including energy levels, will also be included.

The analyses from each individual protocol, along with the results of simulated diet analyses, related systematic review evidence, and related data analysis findings, will be considered together in answering the primary FPM question.

Develop conclusion

The Committee will review and discuss the synthesis of the analyses to develop conclusion statements for each FPM question. Conclusions from this protocol will be used along with conclusions from all other FPM protocols, the graded conclusion of any related systematic review, and related data analysis findings to collectively inform the Committee's advice on the development or refinement of healthy dietary patterns.

Recommend future research

The Committee will identify and document research gaps and methodological limitations throughout the FPM 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 process to model and develop healthy dietary patterns. Rationales for the necessity of additional or stronger research may also be provided with the research recommendations.

Protocol amendments

The first version of this protocol was published in May 2023. A revised version was published in October 2023. This revised version was published in February 2024. Amendments listing protocol changes are documented below in Table 3.

Table 3. Protocol amendments

Date	Protocol change	Description
October 2023	Protocol name	The header displaying the name of the protocol changed in anticipation of the Committee publishing an additional protocol that will examine a different aspect of nutrient profile development. The previous name in the header was "Nutrient Profile Development". This was updated to "Nutrient Profile Development – Basis". The future protocol will be called "Nutrient Profile Development – Population Subgroups"
October 2023	Rationale	The rationale was expanded to provide clarity around the intention of the planned analyses.
October 2023	Editorial	Editorial changes were included in the protocol to align with other protocols posted in September 2023. These edits are included to provide clarity to the reader.
February 2024	Analytic Plan	The analytic plan was revised to establish energy levels based on the updated Estimated Energy Requirement (EER) equations from the Dietary Reference Intakes for Energy report published by the National Academies of Sciences, Engineering, and Medicine in 2023.8

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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 development of an analytic framework and analytic plan; synthesizing analysis results; and writing conclusion statements. The analytic framework and

plan provide details about the types of analyses that will be conducted, synthesized, and from which conclusions will be drawn to inform subsequent FPM questions and the Committee's advice on the development or refinement of healthy dietary patterns. The FPM Methods Team, with assistance from Federal Liaisons and Project Leadership, supports the Committee by facilitating, executing, and documenting the work necessary.

Funding: United States Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Alexandria, VA; Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Rockville, MD.