This document describes the protocol to answer the following questions: [For those under 2 years of age] Can USDA Food Patterns be established based on the relationships identified [in the systematic reviews]? If so, how well do USDA Food Pattern variations meet nutrient recommendations for infants and toddlers? If nutrient needs are not met, is there evidence to support supplementation and/or consumption of fortified foods to meet nutrient adequacy?

The 2020 Dietary Guidelines Advisory Committee, Data Analysis and Food Pattern Modeling Cross-Cutting Working Group, answered these questions with support from the federal food pattern modeling specialists of the Data Analysis Team.

Food pattern modeling methodology for answering these questions involved:

- aiming to establish food patterns that incorporate goals for nutrient adequacy for energy, nutrients, and other dietary components to compared to the DRIs and potential recommendations of the 2020 Committee;

- developing nutrient profiles of food groups and subgroups using data on foods consumed by infants and toddlers 6 to less than 24 months of age from NHANES, What We Eat in America 2015-2016 and corresponding food composition data from USDA Food and Nutrient Database for Dietary Studies, USDA National Nutrient Database for Standard Reference, and the USDA Food Patterns Equivalents Database;

- testing modifications of USDA food pattern elements, for example the inclusion of fortified foods, and proportions of intake from human milk and/or infant formula and complementary foods and beverages where appropriate based on developmental age;

- testing nutrient adequacy of healthy eating pattern variations compared to the DRIs and potential recommendations of the 2020 Dietary Guidelines Advisory Committee;

- developing conclusion statements to summarize the answer to each food pattern modeling question; and

- making research recommendations to inform future work on this topic.

This protocol includes details about the methodology, aiming to establish food pattern(s), developing nutrient profiles of food groups and subgroups, and testing nutrient adequacy of drafted pattern(s).

- The analytic framework (p. 2) describes the overall scope of the question and approach used to describe how the food patterns were updated and compared to nutrient recommendations

- The analytic plan (p. 3) details the data and methods included for food pattern modeling

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- The results (p. 7) explains how to access summarized and full documentation of the food pattern modeling analyses described in this protocol.

More information about food pattern modeling methods, which were used in this food pattern modeling protocol is available on the Dietary Guidelines for Americans website: https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling

ANALYTIC FRAMEWORK

The analytic framework describes the overall scope of the food pattern modeling, including the population and type of analyses and data sources identified to answer the question. It also includes the definitions of key terms.

**Question**: [For those under 2 years of age] Can USDA Food Patterns be established based on the relationships identified [in the systematic reviews]? If so, how well do USDA Food Pattern variations meet nutrient recommendations for infants and toddlers? If nutrient needs are not met, is there evidence to support supplementation and/or consumption of fortified foods to meet nutrient adequacy?

The overall food pattern modeling methodology used to develop and update the USDA Food Patterns includes: (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 nutrients that would be obtained by consuming various foods within each group, (5) evaluating nutrient levels in each pattern against nutritional goals, and (6) iteration and re-evaluation of the Patterns to align with current or potential recommendations.

**Population:**

The patterns tested in these food pattern modeling exercises are intended to apply to the U.S. population ages 6 to less than 24 months old.

**Data Sources:**


Key Definitions:

**Food Groups and Subgroups:** USDA Food Patterns provide amounts of five major food groups and subgroups including:

- Fruits
- Vegetables: Dark-green, red/orange, beans and peas, starchy, and other
- Dairy, including calcium fortified soy beverage
- Grains: Whole grains and refined grains
- Protein Foods: Meats, poultry, and eggs; seafood; nuts, seeds, and soy products*

*For the purpose of this protocol beans and peas will only be modeled in the vegetable group

**Nutrient Profiles:** the anticipated nutrient content for each food group and subgroup that could be obtained by eating a variety of foods in each food group in nutrient dense forms. The nutrient profiles are based on a weighted average of nutrient dense forms of foods. The weighted average calculation considers a range of American food choices, but in nutrient dense forms and results in a food pattern that can be adapted to fit an individual’s preferences.

**Nutrient Dense Representative Foods:** for the purpose of USDA’s food pattern modeling, nutrient dense representative foods are those within each item cluster in forms with the least amounts of added sugars, sodium, and solid fats.

**Added sugars:** Added sugars that are either added during the processing of foods, or are packaged as such (e.g., a bag of 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 (FDA, 2016). Naturally occurring sugars, such as those in fruit or milk, are not 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.

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**ANALYTIC PLAN**

Each step used to develop the patterns and test them is described here.

1. **Establish energy levels**

Dietary Reference Intakes (DRI) formulas used to calculate Estimated Energy Requirements
(EER) for infants and toddlers account for energy deposition for the growing child\(^1\). A range of EER for infants and toddlers based on age in months, reference body lengths, and median body weights and sex of the child were used to calculate appropriate energy levels for each age-sex group and determine the appropriate pattern calorie level.

The food patterns included 5 energy levels from 600 to 1000 calories at 100 calorie “step” intervals intended to cover energy needs for the majority of the population ages 6 months to less than 24 months.

2. Establish nutritional goals

Specific nutritional goals for each food intake pattern (i.e., calorie level) were selected based on the age/sex group(s) for which the pattern was targeted. If a food intake pattern at a calorie level aimed to meet the needs for more than one age/sex group, the pattern was evaluated against the nutrient goals for all those groups. Goals for energy, 3 macronutrients, 3 fatty acids, 12 vitamins, and 9 minerals were based on DRI reports released between 1997 and 2018. Other goals included potential recommendations of the 2020 Dietary Guidelines Advisory Committee. Because the Food Patterns were designed as plans for individuals to follow, the goals were the RDA amounts for nutrients having an RDA. The Adequate Intake (AI) was used when an RDA was not published.

The pattern calorie levels that applied to 6 to less than 12 months and those that applied to 12 to less than 24 months were evaluated against nutritional goals specific to those respective age groups.

3. Establish food groupings and food group amounts

Existing food groups and subgroups in the USDA Food Patterns published in the 2015-2020 Dietary Guidelines for Americans informed this exercise\(^{ii}\).

Patterns were tested with the percent of energy for complementary foods and beverages (CFB) calculated as the calorie level minus the energy from human milk. The focus of the proposed FPM exercises was for infants and toddlers receiving human milk, because the proportion of nutrients required from CFB is different for infants receiving fortified infant formula. Energy from human milk included three proportions (below) at each of four ages (6, 9, 12, and 18 mo.). Proportions were the mean percent of calories from human milk\(^{iii}\) and an amount 15% lower and 15% higher than the mean as shown in the table below.


For 6 months, an intake of human milk that is 15% above average would be 95%, very close to 100% of energy from human milk, at which point there is no pattern for CFB to model.

In the initial aim to develop food patterns for under 24 months of age, food group amounts for the 1000 calorie pattern established in the 2015-2020 USDA Food Patterns were used. To develop patterns less than 1000 calories, amounts of each food group were modified to smaller amounts. To reduce introduction of bias when modifying food group amounts, amounts were first decreased such that the food group density (i.e. food group or subgroup amounts per 100 calories) in the pattern remained similar to the food group density of the 1000 calorie pattern. Food group amounts in the draft patterns were compared to mean food group intakes in each age group. As part of the exercises to test the feasibility of patterns for these age groups, amounts recommended from each food group were modified to reach all or most of the specified goals.

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

We used a “composite” system to determine the anticipated nutrient content, or Nutrient Profile, of each food group as described below.

a) To create Nutrient Profiles, all foods reported for individuals 6 to less than 24 months as part of What We Eat in America NHNAES 2015-2016 were disaggregated into their ingredients.

b) Similar ingredients were aggregated into food item clusters (see Figures 1 and 2).

c) A nutrient-dense form of the food specific to the life stage was selected as the representative food for each cluster.

   • Unique considerations for this life stage were identified where relevant.

d) The proportional intake of each item cluster within each food group or subgroup was calculated and used to compute a weighted average of nutrient dense forms of foods representing each food item cluster.

   • The proportional intake was calculated based on intakes of infants and toddlers 6 to less than 24 months.

e) Using the nutrients in each representative food and the item cluster's proportional intake, a nutrient profile was calculated for each food group or subgroup. Nutrient profiles were also calculated for oils and solid fats using food supply data to determine proportional intakes.

The nutrients amounts used for human milk were the mean concentrations of each nutrient published in the respective reports for the development of the DRIs for infants.
5. **Evaluate nutrient level in each pattern against nutritional goals**

Using the updated nutrient profiles that applied to 6 to less than 24 months, the nutrients provided in the patterns were compared to the pattern’s goals, which in most cases aimed to meet at least 90% of the RDA or AI.

6. **Iteration and re-evaluation of the patterns to align with current or potential recommendations**

After any nutrient goals that were not met in the resulting food patterns were identified, approaches to make additional adjustments in the patterns were considered. There were four modifiable elements to the patterns that provided approaches to further iterate the patterns:
food group amounts could be increased or decreased, goals and constraints could be adjusted, food group nutrient profiles could be adjusted through selection of different representative foods or categorization of item clusters, and certain foods could be included or excluded. After the pattern was further iterated, the nutrient adequacy of the pattern was reassessed.

After all iterations were complete, calories from all food groups and oils, termed “essential calories,” were summed and the remaining calories up to the calorie limit for the pattern were calculated and its uses discussed, such as in relation to limits on added sugars.

**RESULTS**

The Advisory Committee’s findings are summarized within Part D, Chapter 7 of the Scientific Report of the 2020 Dietary Guidelines Advisory Committee: https://www.dietaryguidelines.gov/2020-advisory-committee-report

In addition, an online-only supplement was prepared by the food pattern modeling team for the 2020 Dietary Guidelines Advisory Committee to support its review of the scientific evidence: https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling