2020 DIETARY GUIDELINES ADVISORY COMMITTEE

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PUBLIC MEETING

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WEDNESDAY
JULY 10, 2019
DAY 1 OF 2

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The Dietary Guidelines Advisory Committee met in the Jefferson Auditorium, at the headquarters of the U.S. Department of Agriculture, 1400 Independence Avenue, S.W., Washington, D.C., at 9:00 a.m., Barbara Schneeman, Chair, presiding. The meeting allowed for public viewing, both in-person and by Web.

MEMBERS PRESENT

DR. BARBARA SCHNEEMAN, PhD, Chair
DR. RONALD KLEINMAN, MD, Vice Chair
DR. JAMY ARD, MD, Member
DR. REGAN BAILEY, PhD, MPH, RD, Member
DR. LYDIA BAZZANO, MD, PhD, Member
DR. CAROL BOUSHEY, PhD, MPH, RDN, Member
DR. SHARON DONOVAN, PhD, RD, Member
DR. HEATHER LEIDY, PhD, Member
DR. RICHARD MATTES, PhD, MPH, RD, Member
DR. TIMOTHY NAIMI, MD, MPH, Member
DR. RACHEL NOVOTNY, PhD, RDN, LD, Member
DR. JOAN SABATE, MD, DrPH, Member
DR. LINDA SNETSELAAR, PhD, RD, Member
DR. ELSIE TAVERAS, MD, MPH, Member
DR. LINDA VAN HORN, PhD, RDN, LD, Member

C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

(9:01 a.m.)

DR. STOODY: Good morning. I'm Eve Stoody. I'm lead nutritionist of Nutrition Guidance at USDA Center for Nutrition Policy and Promotion and Designated Federal Officer to the 2020 Dietary Guidelines Advisory Committee.

I want to welcome everyone to the second meeting of the Advisory Committee. We have over 1,000 people who have registered for this meeting with around 300 registered to attend in-person and over 700 online. Thank you for your interest in the dietary guidelines.

The meeting will be today from 9:00 to 4:30 and tomorrow from 8:30 to 12:30 and Dr. Schneeman will do an overview of the agenda in just a moment.

Now a few housekeeping items. For those of you here in-person, you will notice that each of us has a badge and you will need this badge or a USDA badge in order to access the halls of the building. So please keep your badge

visible at all times, and it designates to Security that you are part of this group. You'll also notice that some of the badges say staff. And if you have any questions, please see a member of the staff. If you'd like any refreshments or lunch, the USDA cafeteria is -- We're in Wing 5, take a right and it's at Wing 3.

This is a meeting of the committee and all meetings of the full committee are open to the public. Fifteen of our 20 members are here with us today. I do want to welcome in-person, Drs. Donovan and Naimi who were not able to join us for the first public meeting. Drs. Davis, Dewey, Heymsfield, Mayer-Davis, and Stang were not able to join us today, but we do have a quorum of members for today's deliberations. Throughout your deliberations, we ask the members to state your name prior to speaking so that everyone can follow the conversation.

As a quick reminder, the 2020 Dietary Guidelines Advisory Committee has been established to conduct an independent review of

current research on nutrition and health to be considered by the Departments of Agriculture and Health and Human Services in the development of the next addition of the Dietary Guidelines. Specifically, the charge of the committee as outlined in its charter is to examine the evidence on specific topics and questions identified by the Departments. And these topics and questions will be discussed throughout today's presentations.

The topics and questions were identified by USDA and HHS following a process of federal and public input and prioritized based on four criteria; relevance and importance to developing public health guidance, potential federal impact and avoiding duplication. Following its review, the Committee will develop a report that outlines its science-based review and recommendations to the Departments. And then they will submit its report to the Secretaries of Agriculture and Health and Human Services for consideration as the Departments develop the next

addition of the Dietary Guidelines.

The Committee has the very important role of describing the state of current nutrition science. Each addition of the Dietary Guidelines that USDA and HHS develop, in our partnership, builds upon the previous addition with scientific justification for changes informed by the Committee's scientific report, along with input from the public and federal agencies.

To give you a sense for where we are in the process, this is the second of five meetings of the Advisory Committee. The last Committee meeting will be in March of next year. And the Departments request the Committee's report by May of 2020. And this is so that USDA and HHS can meet our mandate to release the next addition of the Dietary Guidelines within five years, which means we need to release it by December of 2020.

As you can see on this slide, there are multiple opportunities for public input in this process, including comments on the topics

and questions the committee is addressing. A public call for nominations for committee membership, public comments throughout the committee's deliberations, which is ongoing now. And in spring of 2020, a call for comments on the Committee's final scientific report once they submit it to the Secretaries of USDA and HHS.

If you haven't done so already, please save the dates for the remaining public meetings. During this meeting -- actually tomorrow and during Meeting 4, there will be opportunity for oral comments to the Committee from the public. Meeting 4 will be held outside of Washington D.C. in Houston, Texas. And registration for each meeting will be announced about one month prior to the meeting date at DietaryGuidelines.gov and through our Listserv. So please do sign up for our Listserv updates at DietaryGuidelines.gov if you haven't already done so.

More information on the Committee, including the protocols they will be discussing today can be found at DietaryGuidelines.gov under

Work Under Way. And we encourage you to follow along.

So with that, I'm now going to turn the meeting over to the Committee, which is chaired by Dr. Barbara Schneeman. Dr. Schneeman.

CHAIR SCHNEEMAN: Great. Thank you, Eve. So my understanding is they will adjust the microphones to make sure it's heard. So let me know if there's a problem.

So first of all, let me add my welcome to that from USDA and HHS to the committee members. It's great to see you all in-person again. And also to the public who are either here at USDA in the auditorium or watching online.

My remarks -- this brief opening is intended to review the agenda for today and tomorrow so that we can focus -- I can focus then on what we hope to achieve in this second public meeting. And part of our goal then is to share within the Committee, the tremendous amount of work that has been done by the subcommittee since

our first meeting. Most of today's meeting will be reports of the work done by the subcommittees and then discussion by the full Committee.

So in the next several slides, I'll provide you an orientation to the subcommittee presentations, defining key terms and elements of the protocols, and describing the standard NESR criteria that apply across the various protocols.

So since Meeting 1, the subcommittees have met by teleconference frequently. I think you were all promised a significant amount of work at the first meeting and I think we've followed through on that and it won't change.

And so each Committee then has discussed the specific questions that it will address. They've received some additional training on the approaches to examine the evidence. And they've identified the order in which they will develop their protocols for the specific topics. And then they've actually drafted protocols for some or all of its questions. And those are the ones that will be

brought to the full committee for discussion today.

So these are the subcommittee topic areas. And I realize you probably can't read that very well. But just to remind you, the topic areas for the subcommittees are: dietary patterns, pregnancy and lactation, birth to 24 months, beverages and added sugars, dietary fats and seafood, and frequency of eating. And then there's one cross-cutting working group on the data analysis and food pattern modeling. And that cuts across all of them.

So this gives you the subcommittee members, but you'll get more details on that with each subcommittee presentation. And also there will be information on the USDA and HHS staff that has supported the work of the Committee and really helped the subcommittees make a tremendous amount of progress since our first meeting.

So just as another reminder of the way that the committee -- the Advisory Committee is structuring its work. It's using one of three

approaches to examine the evidence; data analysis, food pattern modeling, and the NESR systematic reviews. And those reviews are either original reviews conducted by the Committee or using and/or updating existing NESR systematic reviews. And again, for everything, there's always additional information at DietaryGuidelines.gov.

So for each approach that's used, there's a protocol that details how the methodology is being applied to a specific question. So the protocols then are a plan for how one of the scientific approaches will be used and there's a protocol for each question. And those protocols are created before the Committee looks at the evidence. Again, to be objective in how we approach each of the scientific questions. Those protocols are posted online for the public to view and better understand the approach that the Committee is using. At this point, for this meeting, we have 40 protocols that have been drafted by the subcommittees for discussion

across the full committee today.

So to look at the components then of the protocols, this just reminds you of the various pieces of the protocol. There's an analytic framework, inclusion/exclusion criteria, the search strategy, and then the flow chart for the literature search and screening. The included articles/excluded articles with their rationale.

So in our discussion of the subcommittees today, we're really going to be looking at the analytical framework and the inclusion and exclusion criteria. With the goal that we're trying to finalize these protocols so that they can be implemented. And as they are implemented, the protocols on-line will be updated with the additional information.

So just then to look at those components, the analytical framework defines the core elements of the diet and health relationship that's being examined. And it then serves as the foundation for the rest of the systematic review

process. It informs the inclusion/exclusion criteria and the literature search. It directs the data extraction and risk of bias assessment. And guides the strategy for synthesizing the evidence that the Committee will do in grading the conclusion.

So this next slide gives a template that the committee members should be quite familiar with by now. And you will see many more of them today. And just you'll see this template over and over again. And it gives the key components of the analytical framework. The intervention or exposure and the comparator that's being used. And the population of interest for the specific question that's being examined. And it then has either and/or intermediate outcomes or health outcomes, depending on the nature of the question. And it also then includes key factors that could impact the relationship; co-founders and other covariates or other moderators.

These analytical frameworks will also

include any key terms that need to be defined for the specific question. And the subcommittees have really worked to try to make sure we have some consistent terminology where appropriate. But then of course each analytical framework has been tailored. And so I'm trying to cover the general pieces so that the subcommittees can then focus on how they've tailored the analytical framework for their work.

So looking then at the inclusion and exclusion criteria, these again are established up-front so that they can be objective, consistent, and transparent in identifying the articles that will be included in each review. They're also looked at to make sure that they're relevant for U.S. Federal policy, and standard criteria for the inclusion and exclusion criteria are applied wherever possible.

However, some criteria do need to be tailored to the specific review. And this just gives some examples. Diet-related intervention, exposures of interest, health outcome, endpoints

and/or intermediate outcomes, the dates of publication, size of the study groups, study duration, age of the study participants. Those are examples of things that might need to be tailored to a specific protocol.

So then this slide is a reminder that these are generally items that can be standardized across the protocol. So in terms of the study design, the kinds of studies that have been included in the -- will be included in the systematic reviews and the types of studies that will be excluded from the systematic reviews.

The focus is on peer-reviewed publications, publications that are published in English. And in terms of countries, we're looking at very high or high human development. So it's comparable to the U.S. population. And obviously we're focused on studies that have been conducted in humans. So the types of things that dictate what studies get included.

Now where there might be more tailoring within a particular protocol, looks at

the health status of study participants. And part of this is guided by the overall purpose of the Dietary Guidelines, which is to provide recommendations about reducing risk for chronic disease and promoting health in the general population. And we recognize that sometimes that means including individuals who are at risk, but these are not about management of disease or treatment of disease.

So included are participants who are healthy, but it may include some subjects who are at risk or might have been diagnosed with a particular outcome. But it would exclude any studies where the exclusive focus of the study was treatment or management of individuals who've already been diagnosed or who have already been designated as having the outcome of interest. And we'll see that applied as appropriate across the various protocols.

Likewise with infants, the focus is on full-term. But it can include some infants who are low birth weight, small for gestational age.

But it would exclude studies where that was the exclusive focus of the particular study. And again, we'll hear more detail on that as we go into individual protocols.

So of the protocols that we're going to talk about today, 35 out of the 40 will be focused on the systematic review protocols. So that's the bulk of what we'll be hearing. But we have five questions that will use the data analysis framework. And again, just like with the systematic reviews, the data analysis also develops a protocol for each of its questions.

And so the framework describes the overall scope of the question, the plan details the data, and the subsequent analyses that are included, and the analytical results. And so today, our focus will be on the framework and on the plan for those five questions. And again, as the protocols are implemented, they will be updated on the website.

So in today's agenda then, we'll be going through the subcommittee presentations.

And we've allocated 45 minutes for each of the subcommittees with the idea that we'll have a presentation from the subcommittee chair. But then also have time for discussion amongst the Committee to raise comments and ask questions. And the order of the presentations will be the Data Analysis and Food Pattern Modeling, the Dietary Patterns Subcommittee, the Frequency of Eating, Pregnancy and Lactation, Birth to 24 Months, Beverages and Added Sugars, Dietary Fats and Seafood. And this is the order that we've projected. We've given you a tentative agenda. However, the specific times may vary and be subject to change based on the nature of the work and the discussion that we need to go through.

Oh and I should comment as well that the Committee has the protocols in their notebook, so you have the reference material in front of you. But all of the protocols are available online. So if anyone needs further information, you can get that online.

So each subcommittee will review its

work. It's going to describe the order its developing its protocols. Which questions it's dealing with now. Which questions it's left for future. It will review the protocols themselves and how they've been tailored to address the question and address the topic that's been given to it. And outline its next steps. And we're asking that you keep the remarks at a high level, so that there is time for discussion within the committee for the protocols. And again, you all have them in your binders.

So just to remind you then for tomorrow's agenda, the focus will be on comments from the public to the Advisory Committee. At this point, since March, we've received 7,000 comments. And the public may have comments specific to the 40 protocols that we are discussing today. And we would encourage you to submit those comments by Wednesday, July 24th. Because part of the goal is to be able to start implementing these protocols, so that the committee can complete its work in the time frame

allocated.

But as a general observation, the public comment period is open throughout the Committee's work. So specific to the protocols, it's helpful to get them sooner, rather than later. But it's always open for comment.

So with that, let me just ask the Committee, does anyone have a question or you want to make another observation? Anything I missed about where we need to go? Okay, they're ready. Yes, so our first report then will be Dr. Regan Bailey who is reporting for the cross-cutting working group, the Data Analysis and Food Pattern Modeling.

MEMBER BAILEY: Good morning, everyone. So I'm here representing Working Group 7, which is comprised of the Jamie's; Dr. Jamy Ard and Jamie Stang, Dr. Teresa Davis, Dr. Tim Naimi, Dr. Schneeman, and supported by Dr. Pannucci at the USDA.

Today we'll be describing the first five questions that we will be tackling in order

of protocol development. And I'm not going to read them here at this point because we'll have a slide devoted to each question. The remaining questions that we have to address include beverages, added sugars, frequency of eating, and how those relate to achieving nutrient and food group intake recommendations.

We also have questions to answer regarding food pattern modeling. So are changes to the food patterns needed based on the relationships identified in your committee work and the systematic reviews? Can food patterns for those under two years of age be established? And finally, food pattern modeling questions related to nutrient adequacy, the use of dietary supplements and fortified foods, as well as added sugars.

Before we begin, just a few key definitions. We'll be using the phrase, stage of life. And for data analysis and food pattern modeling, this can mean different things. The age groups for the definition of a stage of life

can differ based on the NHANES sampling weights or by the dietary reference intakes. So the age groups are not perfectly aligned in all cases.

The term, socioeconomic status is a broad term that we use to include income in dollars, poverty to income ratio, food security, federal food assistance programs, and level of education.

And finally, a RACC. This is the reference amount customarily consumed in one occasion as determined by the FDA. And this is represented on the nutrition facts label.

So our analytic framework, our population is the U.S. population. So we'll be working with nationally representative survey data. You'll see here in the blue boxes what we'll be talking about today as the B24 protocols and analytic frameworks are still under discussion. Broadly, children and adolescents are defined 2 to 19. Adults 20 to 64. Older adults 65 and older. And pregnant and lactating women.

I'll use the term demographic subgroups quite a bit to represent that we will have the data stratified by sex, by race, ethnicity, socioeconomic status, and food security status.

The data sources that we have available are What We Eat in America survey component of the NHANES. This data can be analyzed to get nutrient data on foods and beverages with the FNDDS. As Dr. Pannucci described at our first meeting, we also have what's called the FPED. This gives us data on food groups and subgroups. As well as we have the What We Eat in America food categories. So these are foods as they are consumed, as well as information on nutrient intakes from dietary supplements, inclusive of antacids containing calcium or magnesium.

So the first question is to describe and evaluate current intakes of food groups and nutrients. We'll be doing this looking at the mean intakes of foods and subgroups, the usual

intake distributions, food category sources, food group intakes compared to existing recommendations and changes over time. And I'll be a little bit more granular on the upcoming slides.

In terms of looking at nutrient intakes, we are first looking at nutrients from foods and beverages alone. The most recent iteration of the NHANES data, right now the dietary supplement data is not available. And so we're starting with foods and beverages alone to assess mean and usual intake distributions. We will compare those usual intake distributions to the dietary reference intakes. And we'll talk about that a little bit more in detail in Question 3. Food category sources of these nutrients. And then changes that occur over time.

Very similar for food groups. We're looking at population averages. This is from NHANES 2015/16. And in general, when we look at the average or the mean intakes, we'll be looking

at 2015/'16. When we're looking at the population distribution, we have four years of data from 2013 to 2016. So again, as I mentioned, the percent meeting food group recommendations and changes over time. And so for food group intakes, you'll see that here with the What We Eat in America food group categories.

Similarly for nutrient intakes, we'll have the population average. We'll have the usual intake distributions inclusive of foods and beverages and total with dietary supplements. Changes in intake of nutrients over time comparing 2009/'10 to '15/'16. And then food category sources of those nutrients.

The second question is to describe and evaluate the prevalence of nutrition-related chronic health conditions. Right now, these are the nutrition-related chronic health conditions under consideration. And I will not read these as I again, will go through each of these in a little bit more detail in upcoming slides.

The data sources that we have

available. Again, we have the NHANES data that includes the dietary data, laboratory, physical exam data. We also have the National Health Interview Survey or NHIS. This is from 2017. We have data from the National Vital Statistics System in 2017. We have the PRAMS data, the Pregnancy Risk Assessment Monitoring System. As well as the SEER data, which is a wonderful repository of information on cancer registry statistics in the U.S. And this is from 2016.

In terms of the B to 24 group, we'll be looking at the prevalence of low and high weight for length, length for age, and weight for age. This will come from the NHANES data. We'll also be characterizing the prevalence of low birth weight among U.S. infants by race, ethnicity, and the age of the mothers using the National Vital Statistics. We have data available from NHIS on children birth to four years of age on the prevalence of food allergy.

Looking at children 2 to 19, we're interested in characterizing the prevalence of

underweight, overweight, obesity, and severe obesity using the most recent NHANES data. As well as differences in the obesity prevalence by those demographic characteristics that I mentioned earlier; those four components. And the degree of urbanization. We'll also be looking at changes in obesity and severe obesity between 2007/'08 and 2015/'16.

For cardiovascular intermediate outcomes among children, we have the prevalence of hypertension, high LDL, and low HDL by the demographic subgroups, as well as by BMI status from 2013 to 2016. For children, we have data on leukemia from SEER. And from NHANES, we have data on pre-diabetes and type 2 diabetes from the most recent survey cycles of NHANES.

For adults similar to children, we're interested in characterizing the prevalence of underweight, overweight, obesity, and severe obesity from NHANES. As well as waist circumference and waist circumference risk. And then examining obesity by the demographic

characteristics and level of urbanization.

In adults, we have data from NHANES on high triglycerides, high total cholesterol, low LDL, high LDL, and the prevalence of hypertension. So all of that data comes from the physical exam in NHANES. From the National Health Interview Survey, we also have the age-adjusted prevalence of hypertension, coronary heart disease, and prevalence of stroke.

For the Type 2 diabetes and pre-diabetes, we will be able to have this information from 2013 through 2016 for adults. We'll also have the prevalence of metabolic syndrome. So we have the prevalence of each of the five individual risk factors for metabolic syndrome. But we will also have the characteristic of metabolic syndrome based on those five risk factors.

We have data on chronic liver disease outcomes from NHIS 2017. We have age-adjusted chronic liver disease and cirrhosis from the National Vital Statistics System. As well as

high ALT and AST from NHANES 2013 to 2016.

We've talked as a committee about how to use the ALT and AST with regards to data on alcohol consumption. So we're exploring options about characterizing high liver enzymes relative to alcohol intake. So that's a little bit more that we'll have to discuss with what data are available and sample sizes.

These ten cancers are available to the committee through the SEER 2016 data. And we'll have information that is age-adjusted and sex specific, both incidence and mortality.

For pregnant women, we'll have the prevalence of gestational diabetes from the Vital Statistics System, as well as the PRAMS data. We will have information on pregnancy-induced hypertension.

For older adults, we have information on low bone mass and osteoporosis. This is at the femoral neck and lumbar spine. As well as the prevalence of reduced muscle strength. And you'll see that all of these years don't

perfectly overlap. That's because NHANES doesn't collect the same information every year on every topic. So there's exceptions noted in the years throughout.

The third question is to describe and evaluate the nutrients of public health concern. There are no set definitions of what a nutrient of public health concern is. In the National Academy of Science's report and this working group members agree that we should take what is being called a three pronged approach.

So we'll look at the prevalence of inadequate and excessive nutrient intakes comparing current distributions to the dietary reference intakes. When available, we'll consider biological endpoints or validated surrogate endpoints such as biochemical indices of a nutrient status with validated cut-points, in addition to the dietary intake of nutrients. And finally, we would consider the scientific evidence on the relationship between nutrient inadequacy and excess on clinical health

consequences.

A few more definitions. The dietary reference intakes as I'm sure you all know, represent a set of reference values that are established by the National Academies. We have an acceptable -- I am so used to using the acronym, so it's hard for me to actually say these words. So it will be a little bit of an alphabet soup. The AMDR, this is a recommended percent energy intake for macronutrients. And so we'll look below that and above that recommended range, so AMDR.

The estimated average requirement or EAR is what we use to estimate at the population level, the risk of dietary inadequacy. When we don't have scientific data that is compelling enough to establish an EAR, we have what is called an adequate intake or an AI. And this is the level that is assumed to ensure nutritional adequacy. So in the absence of nutrients with an EAR, we have only an adequate intake. And then we have the other end of the spectrum or the UL.

So this is the maximum daily amount that is unlikely to cause adverse health consequences.

With the release of the new report on sodium and potassium, we have another term to include in the DRIs. This is called the Chronic Disease Risk Reduction. This is the lowest level of intake for which sufficient strength of evidence exists to characterize a chronic disease risk reduction. So right now, the CDRR is only available for sodium. That's just the most recently updated sodium and potassium nutrients.

And then finally the term, nutrients of public health concern. As I mentioned, this has been a phrase that is used throughout the guidelines to represent a nutrient that is either under-consumed or over-consumed relative to the DRI and linked in the literature with adverse health outcomes in a general population or in a population subgroup.

Here is the framework. Very similar to some of the previous questions. We'll have nutrient intakes from total and from foods and

beverages alone. For nutrients with an EAR, we'll use the cut-point method. There are some assumptions to the cut-point method that the distributions of requirements are symmetrical. That assumption is violated for menstruating women for the nutrient of iron. So the full probability approach will be used for iron.

Again, comparing nutrients without an EAR, we will look at those relative to the adequate intake. We will examine prevalence of the population that exceeds the UL or the CDRR, as well as people who are the prevalence inside or outside the AMDR. For added sugars and saturated fat, we will use the 2015/2020 guidelines recommendations for less than 10 percent of total energy intake.

In terms of the data sources for the other parameters, we have -- and I'll explain in the next couple of slides -- laboratory data and exam data from NHANES, the nutrient intakes as I described from What We Eat in America, and clinical health consequences that will be either

evidence from the systematic reviews that you are all working on, as well as results from nutrition-related chronic health conditions.

So the analytic plan for ages 1 and older, again looking at the usual intake distribution from foods and beverages and from total inclusive of dietary supplements. In terms of the biomarkers of nutrient status in children, we would prefer to use the most recent survey years. But you'll see here there are exceptions noted, both in what years that the samples are collected and in what survey waves.

So we have ferritin and transferrin. We have low red blood cell folate, low serum folate, low serum copper, low serum zinc, and low 25 hydroxy Vitamin D. You'll see the survey years associated unless otherwise noted. For children 6 to 19 years from 2003 through 2006, we have Vitamin A and carotenoids, Vitamin C, Vitamin E, B12, and B6.

Very similar in adults, we have data on transferrin and ferritin. This is in women

who are to 20 to 49. We have low folate, both in terms of serum and red blood cell. We have data on unmetabolized folic acid in adults, copper, zinc, Vitamin D. In addition to serum, B12, we have elevated methylmalonic acid in 2013/'14. And among pregnant women, we have the medium urinary iodine concentration. Again, at the bottom of this slide are the data on Vitamin A, carotenoid CE, and B6.

So in terms of the next question which is to describe and evaluate the current dietary patterns on beverage consumption, this is really going to be limited to data on the Healthy Eating Index, both means and the component scores, as well as food category contributions to total intake. And this is a noted limitation. So we don't have data on self-selected dietary patterns. For example, are you a vegetarian? Do you follow a specific dietary pattern? We really have the Healthy Eating Index 2015 as how we will evaluate dietary patterns based on the availability of data.

In terms of beverage consumption, we'll look at the types of beverages being consumed, the percent consuming on a given day, the volume variations in beverage consumption. And then how those beverage types contribute to energy, macronutrients, micronutrients, as well as added sugar.

So a beverage pattern here can be defined as the quantities, proportions, varieties, and combinations of different beverages in the diet. The definitions that are being used are discrete beverage categories. So that has been described to us as doing something on purpose. Right? So these definitions are in your binder. They're on the website. So I'm not going to read those. But they include milk, 100 percent fruit juice, coffee, tea, diet beverages.

So diet beverages, this is where that RACC definition comes into play. So a diet beverages contains 40 calories or less per RACC. So sweetened beverages on the other hand contain more than 40 calories per RACC. And include

things like soft drinks, fruit drinks, and sports and energy drinks. Water in any type; tap, bottled, carbonated, enhanced, as long as it has less than 5 kcal per RACC, it is considered by definition to be water. And then alcoholic beverages inclusive of beer, wine, liquor, et cetera.

In terms of dietary patterns, as I mentioned, we'll have the average HEI scores. We'll have the distribution of HEI scores. We'll be able to look at the population average change in scores between 2003 and '04 and 2015/'16 and the food category sources that contribute to total energy intakes.

For beverages for two and older, we have the percent who consumed. We have data on sweetened beverage consumption, mean daily beverage intake, and the percent mean energy of selected nutrients. So the Federal Data Analysis team has prepared data already, specifically on carbohydrates, added sugars, protein, Vitamin C and D, calcium, potassium, magnesium, phosphorus,

and caffeine. And once we identify the nutrients of public health concern, we will also add those to this list.

And then finally, the percent of daily beverage calories consumed by those discrete types.

And I think this is our last question. The question is how does dietary intake, particularly dietary patterns track across life changes from the introduction of foods, into childhood through older adulthood. And it should be noted that because we have the NHANES data to address this question, it's not longitudinal. So we don't have information on the same people and how they're individual patterns change over time. We can just look at life stages in certain years. So that's a little bit of a limitation to specifically address this question. The introduction of foods is defined here. Any foods that are complementary foods and beverages other than human milk or infant formula.

On this slide, we have the analytical framework. So we'll look at differences in food

category sources of nutrients across the different life stages. Differences in mean food group intake. So for two and older, the percent of each age group who meets the existing food recommendations. And then differences in beverage categories and how they contribute to energy and nutrient intakes across different life stages.

Differences in food category contributions to energy intake across different life stages. So for infants and toddlers receiving human milk, energy intake will be limited to those complementary foods, not inclusive of human milk or infant formula. And for two and older, food category contributions to energy intake will also be assessed. We'll also be able to compare differences in HEI 2015 for those two and older. So you'll recall that before this committee's work, there were no dietary guidelines for B to 24. So we don't have a Healthy Eating Index to compare them to at present.

Here's the analytic plan. Very similar to the things that I mentioned before. We have the food category sources. We have population average intakes of food groups and food subgroups. The percent of the population that are meeting these recommendations, as well as daily energy and nutrient intakes from beverages across different life stages with the same nutrients listed here as on the previous slide. We also have the food category sources to energy across different life stages. As well as population average and component scores across life stages.

So our next steps after we discuss these five protocols will be to really have some cross-cutting discussion with the B24 subgroup so that we are all aligned on how the data and food pattern modeling can best support the work of your committee. We'll have cross-cutting discussions with Beverages and Added Sugars on the protocols specifically related to those topics. We'll draft protocols for the frequency

of eating of course in conjunction with that subgroup. And the plan is to have the information on nutrient intakes from dietary supplements this fall so that we can compare how foods and beverages relate to total intakes. And so how much is being contributed by dietary supplements to answer some of those questions. So our plan right now is to review the data analysis results and then draft conclusion statements.

So here are the members again of the committee, as well as the support staff. And a special thanks to the federal family that are the Data Analysis Team who has already prepared a lot of data for us. And will continue to develop the data as we are requesting them. So thank you very much.

Questions? I know that was a lot. That was a lot for me and I'm a talker.

VICE CHAIR KLEINMAN: So Regan, one of the questions that you brought up are the age groupings because those are certainly going to

affect a lot of what the other committees are talking about on many of the outcomes very, very, very dramatically between different age categories. And some of them require a much finer categorization of age then let's say NHANES. DRI is much more specific than NHANES. So can you just elaborate a little bit more for other members of the committee on how you're thinking about that?

MEMBER BAILEY: So some of the analysis has already been conducted. So we have some that does have larger age groups; sometimes two to 18 for example. We have the ability to request data on smaller subgroups. And there are a lot of federal reports that already exist with smaller subgroups. So I think we'll try to cobble together some of what we have and what we need, to get at what you're talking about. But I think especially in terms of a B to 24 subgroup, the changes that occur in eating are so dynamic at that time that we'll have to probably have smaller age groupings than maybe even the DRI.

VICE CHAIR KLEINMAN: But even thinking about age 20 to age 60 -- so 65 and older, okay?

MEMBER BAILEY: Yes.

VICE CHAIR KLEINMAN: But there's a lot of difference there too.

MEMBER BAILEY: Yes.

VICE CHAIR KLEINMAN: I mean I think we're just going to end up with a hell of a lot of data and a lot of analyses -- specific analyses. But I guess there's no other way to think about it.

MEMBER BAILEY: Yes, I think so. And I think that's something that we can put in our recommendations that the federal government try to align in terms of life stages. But in terms of the work of the committee, I think we kind of have our hands tied as to what's available and what we can request. Even the term older adult, is it 60? Is it 65? Is it 71+? A very hard question to grapple with.

We won't comment on our specific ages,

but yes I --

VICE CHAIR KLEINMAN: It's like my definition of a -- I'm a pediatrician. My definition of a pediatric patient is anybody who's younger or shorter than I am.

MEMBER BAILEY: Yes. Well even including 18 year olds and 19 year olds and using the term children is something that I think we all agree, a 2-year-old is very different than a 19-year-old. Although they both have a lot of emotional needs and issues. In terms of their nutrition, yes, very different.

CHAIR SCHNEEMAN: And just be sure and say your name for the transcript.

MEMBER TAVERAS: Elsie Taveras. I have two questions. One, in the analytic plan for adults 20 years and older, there's an examination of chronic liver disease outcomes. Particularly I was thinking of prevalence of high ALT and AST. So is that not available for populations under 20? I'm wondering why that's not an outcome in the pediatric --

MEMBER BAILEY: Yes, I don't think we considered it. It's certainly something that we can look into. And that's why we have these discussions. Because we were thinking about fatty liver in terms of adults. But I think that's a very salient point that if the data are available in children, we should examine those as well.

MEMBER TAVERAS: Yes. No, having seen even 8 year olds with very high ALT and AST, I would recommend that we try if the data's available --

(Simultaneous speaking.)

MEMBER BAILEY: Yes, if it's available, we'll certainly add that.

MEMBER TAVERAS: -- to populations under 20. And then the other question I had was about the data sources. So do we not have any data available from PedNSS or WIC, the supplemental nutrition program for Women, Infants, and Children? Because there's surveillance data that they have on prevalence of

overweight and obesity among women -- among pregnant lactating women and infants under five, I think.

MEMBER BAILEY: Okay, we can look into that for sure. We've kind of thought mainly right now about the data that we've described to you. But there are other federal resources that can be utilized.

MEMBER TAVERAS: And my last question, sweetened beverages, are we including flavored milk in that definition? I see soft drinks, fruit drinks and sport drinks. But I just want to make sure that --

MEMBER BAILEY: I'm going to punt that one to Dr. Pannucci. But I think that the way that the discrete beverage categories are currently consumed is that it's milk as the base. And that is not part of the sweetened beverage category. But I would --

CHAIR SCHNEEMAN: I'm just looking at the slide on Page 19.

MEMBER BAILEY: Yes, I don't have the

slide in front of me.

CHAIR SCHNEEMAN: And milk says plain and flavored milk, other milk dairy drinks, and milk substitutes.

Yes please, Rachel.

MEMBER NOVOTNY: Rachel Novotny. I am interested -- and this is perhaps a B24 question. I know you said you're going to work with them. But on the analytic plan for one and above, the usual intake distributions that exclude infants receiving human milk -- I guess I'm --

MEMBER BAILEY: It's not excluding the infants. It's excluding the data -- the contributions from the infant formula or from human milk. So it's not excluding the children. It's just excluding those as a source of nutrients.

MEMBER NOVOTNY: Yes, I guess -- but that effectively excludes them. Correct? But infants who would be receiving human milk-- I guess what I'm getting at is I realize it's difficult to estimate the volume in the milk.

You'd have to make an estimate. But I think the converse is that we end up with an assumption that the diet pattern of one and above excludes human milk.

MEMBER BAILEY: Yes and I think that's something that we'll have to discuss as we develop the B24 protocol. This is just kind of a first pass at what we're thinking. I know that the databases that are available to analyze human breast milk is an active area of investigation. And you know, that the nutrient composition in terms of fat and nutrients changes quite dramatically. And so I think it's hard to capture that with real accuracy. But I think that's something that the B24 group -- that we'll need to come together with the Data Analysis working group to decide how to handle that specifically.

MEMBER NOVOTNY: I would hope maybe we could find a -- I think an estimate would be better than assuming that.

MALE PARTICIPANT: You'll have to talk

up.

MEMBER NOVOTNY: Sorry, I'm thinking that an estimate might be a better norm to set.

AUDIENCE MEMBER 1: Louder! We can't hear in the back at all.

AUDIENCE MEMBER 2: We can't hear in the middle either.

MEMBER NOVOTNY: Okay.

AUDIENCE MEMBER 3: You guys are whispering to yourselves. This is supposed to be a public meeting.

MEMBER NOVOTNY: Okay, sorry. Okay. So my suggestion is that we see if we can find an estimate so that we can include a pattern of infants who are breast fed in 1+ age group. And it not reflect only those who are not breast-fed.

MEMBER BAILEY: And I just said that is an active discussion that the working group on Data Analysis and Food Pattern Modeling would have with the B24 Committee to figure out how we can best estimate nutrient intakes in this rapidly growing population changing, not growing.

Well they are growing too.

We apologize for the microphones. We can hear each other up here, but we didn't realize that we couldn't hear you. So it wasn't intentional by any means.

CHAIR SCHNEEMAN: Okay, so we have Rick Mattes and Sharon. Were you going to say something also? Rick and then Sharon.

MEMBER MATTES: I'm Rick Mattes. So I'm struck by the overlap or common goals for what you're describing in both the Frequency of Eating and the Beverages and Added Sugars committees. And please take this -- it's intended to be very constructive, rather than --

So if we in the end -- your modeling is going to be based on the large surveys, the epidemiology and so on. The subcommittees -- the other two subcommittees will be looking at randomized control trials and so on. It won't surprise me that in the end there is some disparity between those -- the outcomes from the two sources of data. How are we going to deal

with that? Are we going to say -- we came up with different answers based on the data set? Or do we say there is a hierarchy of science here and the stronger science -- this is what we're going to base on our recommendations on? If the latter, maybe there's so much redundancy here, we should be thinking about do we really need to do the bazillion analyses you've got proposed there.

MEMBER BAILEY: I think what you will identify in your systematic reviews will be complementary to what we're doing. We will identify for example added sugars. You might come to a consensus statement on a recommendation on added sugars. And then we would provide data on the prevalence of intake of sugar-sweetened beverages for example. We wouldn't say that, that necessarily is -- you know, trumps what you found. The data are what the data are. And that's this working group kind of just telling you, these are the facts. Not ma'am, but mister.

And so I don't think that it's a lot of overlap. You're identifying relationships

with health outcomes. And we are providing information on where Americans are at relative to those recommendations. So I think it's kind of more of a dovetail than overlap. But I'd love to hear other people's opinions.

MEMBER BOUSHEY: This is Carol Boushey. It's real short. I wanted to reinforce that. Because this really does help inform or find out what might work well when we're looking at these randomized trials. But you'll give us the gauge as to where we can start from; either up or down.

MEMBER DONOVAN: Sharon Donovan. So I guess I just want to reiterate what Rachel and Elsie have said in terms of the B24 being a new charter. That if we don't consider, you know, human milk and infant formula and also the B24 Committee is talking about some of these follow-on formulas that are actually fed to toddlers. And we anticipate, particularly like iron and other nutrient intakes will be quite different compared to one year olds who move to cow's milk.

So you know, whether it's trying to get access to other data sets -- Because otherwise, we're not going to be able to make any sort of recommendations if we're just considering non --. And you know, not many women -- not a high percentage of women breast feed for longer than a year, but it is recommended. So our committees can work on that. But I think that we really need to do the due diligence about collecting that data and discussing -- because with DRIs, we use average intakes and average consumption to at least extrapolate requirements.

CHAIR SCHNEEMAN: One thing that I would like to hear some discussion from the committee members, you've presented a way of looking at the nutrients of public health concern. You had a diagram for that looking at three components of nutrients of public health concern. And I'm interested in whether other committee members find that a useful approach for going forward or had some questions or comments about how we might define nutrients of public

health concern. It's on Page 13, if you're looking at the slides.

MEMBER BAILEY: So just a reminder, it's looking at those three prongs. One being dietary intakes. Two being biochemical. And three being clinical health consequences. Are there any other ways that we can think about collectively to identify what are nutrients of public health concern?

CHAIR SCHNEEMAN: Dr. Ard, you look like you were posed to say something.

MEMBER ARD: (No audible comment.)

CHAIR SCHNEEMAN: Well I take that to indicate support for the approach that you've proposed. So let me turn the question around. Does anyone see a problem with taking that approach?

MEMBER VAN HORN: Linda Van Horn. The only thing I think, hearkening back to the discussion of the last round of the guidelines related to dietary cholesterol. There was a statement related to dietary cholesterol and that

no longer being a nutrient of concern. And there was a tremendous amount of confusion in the public as to what that meant. Everything from woohoo, let's eat eggs to maybe we should, you know, re-think what the role of dietary cholesterol is.

So my only point is that while I think the definition and the criteria are good, if for whatever reason this group should come up with another decision of that sort, I think we have to be very explicit as to what that means and why that was decided upon. So that we can establish, you know, quite universally what is meant by that decision.

CHAIR SCHNEEMAN: It sounds like you're making sure we recognize all three components. That it's not just one or the other, but all three components. Great, thank you. That's helpful.

MEMBER BOUSHEY: Linda, your comment made me realize, the reality is every nutrient is a public health concern. So we really need to be

careful when we actually label them that way and how we write this up. Because we don't want anyone to think that there isn't any nutrient that isn't important.

MEMBER MATTES: Rick Mattes. So it specifically says nutrients of concern, but there are food constituents that are commonly consumed with health implications. Do we want to talk about phytochemicals and so on?

MEMBER BAILEY: I think the reason that it is labeled a nutrient is because one of the -- we need to have a DRI for it in order to compare it to a reference standard. And we need to have a validated biomarker. And so for a lot of the phytonutrients and things like that, while we recognize they exhibit a health effect. We don't necessarily have that type of data that are available to make the statement is my thinking there.

CHAIR SCHNEEMAN: Yes, please.

MEMBER BAZZANO: Lydia Bazzano. I just wanted to point out that the clinical health

consequences there are really the most -- I would say, you know, those are the things that we have to weigh most heavily. Because where we may not have data -- where we do have data, that's what needs to weigh the most heavily. And I understand that there may not be data for everything.

CHAIR SCHNEEMAN: I'm being reminded to encourage everyone to be sure you speak up so it's amplified well. Other questions or comments about the presentation on the data analysis?

MEMBER NOVOTNY: Rachel Novotny. I will speak as loudly as I can. Just raising the question about the nutrients of public health concern makes me wonder whether as we go forward or not for now because I think we have our agenda, but whether we actually do want to think about foods or food groups or food patterning of public health concern in the future.

MEMBER SABATE: Joan Sabate. That's also my concern. I think going back to these nutrients of intake, biological endpoints, or

clinical health outcomes, if we do not have guidelines as far as some of the food constituencies, such as phytochemicals and so on and so forth, that means that what you're giving priority to some food constituencies called nutrients versus others that are not. Because ultimately all of them come from foods.

So when we make in the hierarchy of making decisions, are we going to just based on the nutrients for which we have guidelines and not for the ones that we don't even though they have influence on health?

And finally, I mean this committee is trying to define nutrients of intake or is trying to guide the general public as far as what foods to consume -- I mean what different proportions.

MEMBER NOVOTNY: Rachel Novotny. Just to elaborate that again, I think also as we communicate with the public about these things, my feeling is that talking in nutrients has contributed to turning to supplements rather than foods. So again, just to reiterate, I think as

we look for language for these things, I think as a food-based group, the more we can talk in foods, the better.

CHAIR SCHNEEMAN: So Regan, I know you pointed to the fact that when it comes to looking at data for dietary patterns, knowing what kind of pattern are you following, we're limited in terms of the type of data there. And it might help to amplify how this relates to the discussion that we're currently having.

MEMBER BAILEY: Yes, so right now what we're limited to is the healthy -- Sorry, Regan Bailey. So to address that, we have data on the Healthy Eating Index only. And the data that Dr. Pannucci presented at the first meeting indicates that most Americans or a high proportion of Americans aren't doing that. We don't have data on what they are doing. And that is something that I think really needs to be addressed for -- I don't think can be addressed for this committee, but certainly for future committees. We have to know the current dietary patterns that

are being consumed, in addition to how they relate to the Healthy Eating Index.

So I think -- I really hear what you're saying and I appreciate it. But at this current point, we're a little bit limited with the data that we do have available to us unfortunately. Don't shoot the messenger.

VICE CHAIR KLEINMAN: The messenger is doing great.

CHAIR SCHNEEMAN: That may be the perfect introduction to our next subcommittee report. So thank you very much, Regan. I think that was very helpful. And I appreciate the comments from the committee. It's been a tremendous amount of work.

So our next subcommittee is to focus on dietary patterns. And Carol Boushey, the chair of that subcommittee will give the report. Carol?

MEMBER BOUSHEY: Thank you. So I was introduced as Carol Boushey. I can confirm that I am. And I represent the Dietary Patterns

Subcommittee. And good, there are the slides. And you can see the other members of the subcommittee up on the slides also. Okay, am I hitting the wrong button? I was holding it upside down. It does not work that way. So for the next people, remember that.

The topic areas that the subcommittee was tasked with are listed on this slide. The first six have asterisks indicating that those will be presented today.

As noted, we're the Dietary Patterns Subcommittee. So the key definition that we are using for dietary patterns in all the 2020 Advisory Committee reviews are the quantities, proportions, variety, or combination of different foods, drinks, and nutrients where available and diets and the frequency with which they are habitually consumed.

This definition was applied to all analytical frameworks for the subcommittee, which will be presented shortly and for the ones that are not yet done. And this is an aspirational

definition that was developed by a panel of international experts for the existing NESR systematic reviews. And all information provided by studies about the dietary patterns tested or examined, including both foods and beverages, macro and micro-nutrients will be extracted from included articles.

So the two questions listed on this slide, what is the relationship between dietary patterns consumed in all-cause mortality? And what is the relationship between dietary patterns consumed and sarcopenia will be answered by conducting original NESR systematic reviews. So these have never been done before.

The four questions listed on this slide with outcomes of neurocognitive health; growth size, body composition, and risk of overweight and obesity; cardiovascular disease; and Type 2 diabetes will be answered by updating existing NESR systematic reviews.

The analytical framework that was brought up earlier is shown on this slide. And

illustrates the systematic review question examining the relationship between dietary patterns and all-cause mortality. Do you think we ran out of batteries already?

DR. STOODY: So it looks like the computer is shutting down, which is nice. So we'll just pause for one second and have IT come set it back up. So if you'll just hold, so we don't continue the discussion without the visual. So one second.

(Long pause.)

MEMBER BOUSHEY: Thank you so much. We'll get rocking and rolling here again.

So I'm going to start at the beginning of this slide. So you'll have heard this sentence before. But just to make sure that we're on the same page.

This is the analytical framework shown on this slide. It illustrates the systematic review question examining the relationship between dietary patterns consumed and all-cause mortality. The analytical framework provides a

foundation for the systematic review and helps to inform the development of the inclusion and the exclusion criteria.

The subcommittee defines all-cause mortality as the total number of deaths from all causes during a specific time-period. This is the first analytical framework presented. The others that you've seen today have been purely demonstration frameworks. So for this presentation, we will add animation to point out all the parts and pieces of the analytical framework.

The intervention or exposure of interest is consumption and/or adherence to a dietary pattern. The comparators are consumption of and/or adherence to a different dietary pattern and different levels of consumption and/or adherence to a dietary pattern. The outcome of interest in this particular case is all-cause, total mortality.

The population of interest for this particular case; intervention, exposure and

outcomes is -- the population of interest for interventions and outcomes are children through older adults, who are healthy and/or at risk for chronic disease. For the question, the subcommittee decided that infants and toddlers from birth to 24 months were out of the scope.

Key confounders, which are factors that may impact the relationship of interest in this systematic review are shown on this slide. And include sex, age, race, ethnicity, socioeconomic status, physical activity, anthropometry, energy intake, and smoking. From this point forward, the analytical frameworks will look like this and not have animation. But they liked it so much, they did it twice.

Okay, the next framework should be sarcopenia. It's coming. Yes, okay. The next topical area is sarcopenia. This is the systematic review framework examining dietary patterns consumed and sarcopenia. The subcommittee discussed and applied a definition of sarcopenia based on the review of the

foundation for the National Institutes of Health Biomarkers, Consortium Sarcopenia project. As well as the consensus of three European working groups that converge to operationally define sarcopenia.

The definitions those groups presented generally aligned on parameters of low skeletal muscle or lean mass, low strength or weakness and/or low muscle performance. That is mobility impairment, walking, speed, or function. Therefore, the definition for sarcopenia applied to this systematic review is progressive and generalized loss of skeletal muscle mass alone or in conjunction with either or both low muscle strength and low muscle performance.

In this particular case, we have intermediate outcomes, which include low muscle mass, strength, and performance. And sarcopenia or severe sarcopenia as endpoint outcomes. The population of interest for the intervention exposure of dietary patterns includes adolescents, adults, and older adults who are

healthy and/or at risk for chronic disease. For this question, the subcommittee decided that infants and toddlers from birth to 24 months were out of scope.

The population of interest for the outcomes of sarcopenia includes adults and older adults who are healthy and/or at risk of chronic disease. The confounders are sex, age, socioeconomic status, anthropometry, total energy intake, dietary protein intake, physical activity, and physical disability.

The next analytical framework is dietary patterns and neurocognitive health. The analytical framework here illustrates the question examining the relationship between dietary patterns consumed and neurocognitive health. The outcomes include developmental domains as specified on the right, academic performance, attention deficit hyperactivity disorder, autism spectrum disorder, cognitive decline, and cognitive impairment and dementia, Alzheimer's disease, anxiety, and depression.

The population of interest includes children through older adults who are healthy and/or who are at risk for chronic disease.

For this question, the subcommittee excluded infants and toddlers because the Birth to 24 Month Subcommittee will be completing this review. The key confounders; sex, age, race, ethnicity, socioeconomic status, anthropometry, total energy intake, alcohol intake, smoking, physical activity, and family history of neurocognitive disorders.

The next analytical framework focuses on dietary patterns consumed and growth, size, body composition, and risk of overweight and obesity. The outcomes include weight and various forms of weight, BMI, body composition and distribution, percent fat mass, fat-free mass, and incidents and prevalence of underweight, failure to thrive, stunting, wasting, healthy weight, overweight, and obesity.

The population of interest for the intervention exposure and outcomes include

children through older adults who are healthy and/or are at risk for chronic disease. For this question, again, the committee excludes infants and toddlers and the Birth to 24 Months Subcommittee will be handling this. Key confounders are sex, age, total energy intake, physical activity, anthropometry at baseline, and smoking.

Cardiovascular disease is shown on this slide. The analytical framework here illustrates the review of dietary patterns consumed and cardiovascular disease. The intermediate outcomes include total cholesterol, low density lipoprotein, high density lipoprotein, triglycerides, and blood pressure. The endpoint outcomes include cardiovascular disease and specifications listed, stroke, venous thrombosis, cardiovascular disease-related mortality. The population of interest here includes children through older adults who are healthy and/or are at risk for chronic disease. The key confounders are sex, age, energy intake,

physical activity, anthropometry, and smoking.

The Type 2 diabetes, that's the last analytical framework that we finished before this meeting. And this illustrates the systematic review for Type 2 diabetes and dietary patterns consumed. The intermediate outcomes include hemoglobin A1c, glucose, insulin, and pre-diabetes. The endpoint outcome is Type 2 diabetes. The population of interest for the intervention exposure and outcomes includes children through older adults who are healthy and/or are at risk for chronic disease.

Key confounders as shown is sex, age, total energy intake, physical activity, anthropometry, and smoking. The inclusion and exclusion here, these criteria were outlined in Dr. Schneeman's presentation. And so we will apply all of the ones that she outlined clearly in her presentation. And then inclusion and exclusion criteria unique to the various analyses that we are doing -- are starting here.

And so for the 2020 Advisory Committee

systematic reviews, examining dietary patterns consumed, we'll apply all of the inclusion, exclusion criteria here for the intervention exposure to operationalize the definition of dietary patterns presented in this presentation. And studies that examine -- So these will be studies that examine consumption and/or adherence to dietary patterns such as, as an example, the dietary approaches to stop hypertension, DASH. A vegetarian or a vegan dietary pattern, a low carbohydrate dietary pattern and high fat dietary pattern will be considered. They'll be measured or derived using a variety of approaches as specified in this inclusion criteria.

Studies must describe the dietary pattern being tested or examined at a minimum providing the foods and beverages consumed in the pattern for inclusion. Studies that examine low carbohydrate or high fat diets will be included as long as they meet the percent specified as -- and this is in the second row, as being the criteria which is less than 45 percent of energy

from carbohydrate, for low carb, and are greater than 35 percent energy from fat, which is high fat. And these are based on the AMDR.

And the exclusion criteria are studies that do not provide a description of the dietary pattern or that they label the dietary pattern, but they do not describe the foods and beverages or the base pattern is solely on nutrients. So this is a very food-oriented group. And studies that do not provide a description of the macronutrient proportion examined or do not examine the percentages specified for low carbohydrate or high fat, if that is the pattern that's being suggested. And then there are corresponding inclusions for the active comparators.

So for some specifics for each of the outcomes that we're going to be looking at, for all cause mortality, it's studies that are reporting all-cause mortality. And then we'll exclude studies that report only one mortality or two because we're looking at mortality from all

causes. And then the inclusions for sarcopenia were covered on the sarcopenia slide. We don't have any exclusion criteria for the neurocognitive health or for the growth size or body composition, overweight and obesity. And these inclusions were shown in the analytical framework slides.

There are exclusions for CVD. And that will exclude hypertensive disorders during pregnancy and/or lactation. And for Type 2 diabetes, we'll exclude gestational diabetes during pregnancy and/or lactation and Type 1 diabetes.

The dates of publications that we'll be using are -- the reason they vary so much -- so we have actually three different date ranges has to do if it's a new -- you know, if it's a brand new systematic review or an update of NESR. So the date range of the publication for the new systematic reviews will be January 2000 to May 2019.

The date range of publications to

update existing systematic reviews for the neurocognitive health outcomes will be August 2014 to July 2019. And this is in addition to the included articles published from 1980 to 2014. And an additional search will be done to capture outcomes that were not considered in the existing review. The neurological health outcomes have had many changes in the labels. And we want to catch all those changes in the labels that have occurred in current times.

The date range of the publication to update the systematic reviews for growth and size and body composition in CVD and Type 2 diabetes will be August 2013 to July 2019. And this is in addition to the included articles from the previous systematic review of 1980 to 2014.

So our next steps as we move forward, we will develop next the protocols for the questions of what is the relationship between dietary patterns consumed and certain types of cancer? And then, the next question will be what is the relationship between dietary patterns

consumed and bone health? Then in addition, what we'll be doing as our next steps is implementing the protocols for all of the questions that were just presented. One, two, three, four, five, six of them.

So many thanks to the DGAC subcommittee members for enthusiastically participating in weekly meetings. And appropriately the support people are displayed in the bottom box. And the reason I say that's appropriate is because they represent the foundation of this enterprise. They're tireless in supporting all the activities or putting together these efforts and really are contributing to the success of the process.

So this slide represents the end and being open for questions.

CHAIR SCHNEEMAN: Please.

MEMBER MATTES: Rick Mattes, one quick question. For the key confounders for the cardiovascular outcomes, did the committee consider sodium in there as something to

contemplate? I know it's a can of worms.

MEMBER BOUSHEY: We did. We did talk about it. It's just it's so poorly measured. What are your thoughts? Do you think we should put it in?

MEMBER MATTES: I agree rarely is there an adequate measurement of it. But it does seem to be an issue that's very much on a lot of the populations mind. And we have an opportunity to evaluate the science and make a statement here. I don't know.

MEMBER BOUSHEY: Yes, so we have different -- and the other thing, because of being hard to assess, it may not be present in the paper. So we could put it in the confounders that won't kill the paper.

MEMBER MATTES: Yes.

MEMBER BOUSHEY: Yes, okay. I'll make a note of that.

CHAIR SCHNEEMAN: Yes, so that becomes a good measure and something where you want the data -- you want to know if sodium has been a

part of the study and reporting.

MEMBER NAIMI: Tim Naimi. Thanks for that nice presentation. So you listed in terms of the patterns, that we'd be considering the DASH and vegetarian, vegan, low carb, high fat. Are there other patterns that are going to be included or is that the list or is that still up for debate?

MEMBER BOUSHEY: Those are e.g's. It shouldn't be i.e. They're e.g's, they're examples. So really the number of patterns available are very wide. And the most important conditions is that we can identify what the foods that comprise the pattern. But it doesn't even have to have a name to make it in as a pattern. And we will take both theoretically derived patterns, as well as hypothetically derived patterns. And I realize that was on this slide, but I didn't say it out loud.

MEMBER LEIDY: Heather Leidy. Two quick questions. One is a follow up to that. And I know these are now examples. But I thought

I'd just bring it back up. In terms of a low carbohydrate diet, will there be ability to separate those out in terms of the other macro-nutrients? So there can be low carb high fat or low carb high protein? It sounds like all patterns are fair game.

But I guess my point is at the end of the day, will they be grouped according to certain dietary patterns that are listed like low carbohydrate diets? And that might actually be very different, depending on the macro-nutrient content.

Do you understand what I'm saying? So there's a pattern that's low carbohydrate, but they're very different. There can be studies that define that. But then within that, they can have very different macro-nutrient compositions. And just maybe a point to consider that some things maybe shouldn't be grouped in terms of a generalized pattern.

MEMBER BOUSHEY: You know, that's an interesting point because we really are looking

at dietary patterns and they would all be together. But that doesn't rule out that we might not look at them, you know, by different types. And I haven't -- others here have been involved in this process before. And so I don't know when we start doing the analysis -- Linda, Linda -- I've been waiting for an opportunity to say that, you know this. So is that something that once we get to the analytical part, that we can pull in parts and pieces and say what happens if we take this one out?

MEMBER VAN HORN: Linda Van Horn. I'll let the other Linda speak for herself. But yes, I think this is definitely a topic that was discussed in some of our calls, including the sodium question, which of course is very much on the hot button list at the moment. But I think in some ways, this is reminiscent of the discussion we just had earlier about nutrients of concern.

MEMBER BOUSHEY: Yes.

MEMBER VAN HORN: I think we're in an

interesting point now in the fact that everyone recognizes that eating patterns are more descriptive of someone's totality of intake. But I don't think there's any way you can separate an eating pattern discussion from nutrients of concern. And I think what we're experiencing even as we're speaking is the fact that in many ways, the discussion about eating patterns really has to incorporate, the concept at least of nutrients, especially macro-nutrients, but even micro-nutrients.

I was thinking as you were speaking about carbohydrates, one of the nutrients of concern in this country is low fiber intake. You know, the U.S. public eats less than half of the recommended amount of dietary fiber, which we all know is derived in complex carbohydrates.

So my only point is here, I don't think we can eliminate from our consideration as we think about dietary patterns, the macro-nutrient or other distinguishing characteristics that really differentiates across these different

eating patterns.

MEMBER BOUSHEY: And I appreciate that completely. Where I'm coming from actually is we're creating now -- we're putting together the structure for these reviews, right, these systematic reviews. And in order to not be biased then, we really would have to make these decisions a priori. That's why I'm asking the question. Is that you know, right now we're lumping these all together. But what you're saying and I am really open to it, is then we -- a priori would need to somehow desegregate some of these to capture what you were talking about because that may be of importance. Because if we put them all in and do it afterwards, that's not following the rules. So that's why I was asking, in the past, has this been done of desegregating these exposures that you -- these studies that you have found. That they met your criteria, but now you're going to split them again.

MEMBER LEIDY: This is Heather again. This is a follow up. I'm just thinking in terms

of the NESR search terms. It's hard to keep it broad because if you're not having -- you know, for example in this case, our discussion has been about everything but protein. So as an example, if you don't search by high protein diets and you just go low carbohydrate diet, there's an opportunity to actually miss some of those within the NESR search criteria, which is something I didn't think about. I guess maybe the search terms will come later on down the road. I mean we're already really establishing that. So there's examples that are listed, but I'm just not sure if that actually translates into all encompassing search terms that will be able to pick up all these different dietary patterns.

MEMBER BOUSHEY: And that's actually an interesting one to check on.

CHAIR SCHNEEMAN: I think it might be worthwhile if the staff could perhaps -- I know you're sitting over there, but I can't see you. Particularly this question on the search terms, I think it would be helpful.

DR. ENGLISH: Yes, this is Laural English. So to the first point earlier, I did just want to touch on the fact that we will extract all data that are reported to speak to your concern about the other nutrients. So if it's a low carbohydrate diet and they report the nutrients -- the other macros, micros, we will extract all information that is reported by the article. And then we can group accordingly to your earlier point in the evidence synthesis with Mediterranean diets, low carbohydrate diet, et cetera. So we can do that and plan to do that.

For the next question on the search terms, we do develop a comprehensive search strategy and there are MeSH terms in the PubMED database. For example, ketogenetic diet, low carbohydrate diet, we also add in key words. So we have developed a comprehensive search and it is peer reviewed by a second librarian. And then we also have test papers that confirm that our search is appropriate. So we believe it is comprehensive to that.

MEMBER LEIDY: Another real quick question. This is on -- I don't think you need to go there, but on Slide 15, it's the Type 2 diabetes. And for me, just more of a clarification. The endpoint outcome is Type 2 diabetes. And I wrestled with this in the frequency of eating and so I thought I'd bring it up.

I'm wondering what the outcome is. So when you look at the cardiovascular disease, there's parentheses with qualifiers in terms of what that endpoint is. With Type 2 diabetes, I understand what Type 2 diabetes is, but it's generally identified as a certain HbA1c. And HbA1c is actually an intermediate outcome. So I'm just wondering what the Type 2 diabetes endpoint outcome will be. Except that if somebody has Type 2 diabetes, but is that the only criteria? Or is it really based on somebody's HbA1c and the changes of that?

It's a moot point, but it's an intermediate right now. And it seems odd why it

isn't in the endpoint outcome. And I'm not a medical doctor, but generally people are diagnosed with their HbA1c levels. And so that's what I'm just trying to figure out why that's not an endpoint instead of an intermediate.

MEMBER BOUSHEY: Well that's a good question. Yeah, that's a good question. Jamy?

VICE CHAIR KLEINMAN: I mean I would think it's both actually. And I think when they're searching, they're searching for the health outcome Type 2 diabetes. But when looking at studies, they'll include studies that have HbA1c's that are below the threshold for Type 2 diabetes. So one can follow that over time to a diagnosis of Type 2 diabetes. I mean I'd ask the staff, is that a correct interpretation? Yes, I see head's bobbing yes.

DR. ENGLISH: Yes, this is Laural English again. And yes, so to that point, it would be diagnosed Type 2 diabetes. So if they were looking at dietary patterns consumed in those who were diagnosed with diabetes versus

those who did not, that's really to get at that.

But to your point, hemoglobin A1c, the other intermediate outcomes, we would be extracting the data that are reported for those continuous measures or the particular levels. So it would be included pretty much as Dr. Kleinman mentioned.

CHAIR SCHNEEMAN: So Dr. Ard? I think we had Dr. Ard and then Dr. Donovan.

MEMBER ARD: So I was just going to -- Jamy Ard, I was going to follow up on Heather's question and point. And the answer that Laurel gave around the macro-nutrient distributions and the dietary patterns associated with that.

I think it will be important for us to think about the categorization of those specific types of dietary patterns. Because as we've said, there's a wide range of what people define as lower carbohydrate or lower fats. And sometimes, I think it's probably just as important to understand what was reduced in the dietary intake, as well as what replaced it.

So in thinking about a lower carbohydrate intake, I want to also know what replaced the carbohydrate. Was that replaced by fat intake or was that replaced by protein intake and maybe even further. You could, you know, see a branching of you know, well was that protein mostly -- vegetable protein or animal protein? Was that fat mostly saturated fat or unsaturated fat?

So I think it will be important for us in describing the results to, as best we can, clarify what we mean when we say this is the particular macro-nutrient dietary pattern. So that we do avoid this sort of general lumping of, well, it's just this. As we wouldn't necessarily say, well, all vegetarian patterns are the same, because there are different forms of vegetarian patterns. And we would be specific to describe well this is vegan or this is lacto-ovo, et cetera.

So I think that will be important for us to at least have a general working framework

of how we might want to categorize that. And then put the studies in those relevant boxes, to some extent. And it may not be at the level of, well, this has to be less than 20 percent carbohydrate or this has to be less than 100 grams per day of carbohydrate or to that extent. But at least some general framework of understanding not just what the reduced macro-nutrient was, but what replaced it.

MEMBER BOUSHEY: Yeah.

MEMBER SNETSELAAR: I just wanted to piggyback on that just a bit. I think too and we've discussed in our committee, the idea that the Mediterranean diet has many different variations. And so this probably will be true of all of the types of dietary patterns that we're looking at. I just wanted to add that.

MEMBER BOUSHEY: Yes, that's absolutely right. But Jamy, we've got -- I really appreciate what you said. Because we've been really sensitive to the complexity of this. And I'm glad that this came up so that really

gives us additional guidance in moving forward. I think we'll be able to find all the papers, but it will be really somehow harmonizing them across the spectrum in some way that makes sense with regard to -- I mean really, what's available now is far more than what we had previously, I do believe.

MEMBER DONOVAN: So Sharon Donovan, this is more just a general comment. Because I noticed that your publication dates; one is May, one is June, one is July. And it seems to me as a committee we should decide what is the latest date that we want all the systematic reviews to go to. We've talked about this because there's a bunch of new -- from the pregnancy B 24 that were just published, but they only went to January of 2017. So while I understand we'll be ruling these, it seems like we should be consistent -- or unless we can really justify why one should be May, one should be June, and one should be July.

CHAIR SCHNEEMAN: Right. And actually I have a feeling that when you're looking at the

date, that's the furthest out date, the closest to now, the intent is to gather whatever is currently available. And perhaps the staff could comment on that. So May or June, I don't think there was an intent to make a difference there. It was probably when the protocol went into the box.

DR. ENGLISH: Yes. This is Laural again. Yes, that's correct. And we wanted to get started as soon as possible after those two first new -- the new questions were approved and those protocols were approved. We did also develop the search strategy and shared the search strategy. And then conducted the search so that the staff could get going on literature search and screening.

CHAIR SCHNEEMAN: But we will be consistent in terms of we're trying to gather the most current data.

DR. ENGLISH: Yes, and if there was anything published after May, between May and July for instance, we could do a secondary search

to make sure that there were no additional publications that were missed between that time period.

MEMBER BOUSHEY: So is that something we should adopt across the board then? Because I'm sure that's happening in every subcommittee.

CHAIR SCHNEEMAN: Oh absolutely. Yes, absolutely.

MEMBER BOUSHEY: Right, right.

VICE CHAIR KLEINMAN: Okay, we have one more report before we take a break at 11:45 for lunch. And -- Oh, I'm sorry.

MEMBER MATTES: Rick Mattes, and I'm thinking about this issue of the patterning and macronutrients and so on a little further just in case it helps your thinking as you go forward. You could couch it in different ways. You could talk about absolute level of each of those nutrients. You could talk about proportion of energy contributed by each of those nutrients. You could talk about the amount relative to recommendations of each of those nutrients. And

I don't know the right answer to that, but they could well give you different answers. And so you may want to think that through to make your decision.

CHAIR SCHNEEMAN: Thank you. So Dr. Sabate had a comment as well.

MEMBER SABATE: Joan Sabate. I have two comments to make. One is in line of what was discussed before as far as what replaces carbohydrates, so foods coming from mainly carbohydrates. And again since this is mainly a committee that has to deal with foods. I think besides whether it is protein or fat that is replacing, I mean I think we at least have to capture -- I mean if the foods that are high in protein and fats are coming from vegetables or from animal intake. Because I mean there are -- from the viewpoint, there are two ways, I mean to accomplish a low carbohydrate diet.

The second point relates to a slide that is Number 13 that we discussed because I am a member of this committee in which we relate the

dietary patterns with anthropometrics, particular overweight and obesity. And total energy intake is listed as a key confounder. I think listing as a key confounder may decrease the ability to connect, I mean dietary patterns and overweight and obesity.

I think before trying to use as a key confounder, we have to analyze as a mediator because some of the dietary patterns may relate to the overweight and obesity mediating through the total energy intake. Especially when we look in descriptive epidemiology and how people, I mean, consume these dietary patterns. So I think that besides using as a key confounder, it has to be studied as a mediator between dietary patterns and anthropometrics. Because it could be that the connection is mainly through total dietary intake.

MEMBER NAIMI: Tim Naimi. Just I wanted to, in terms of consistency, you were controlled for smoking as a confounder for all these. And you controlled for alcohol

consumption for the neurocognitive health, but not for overweight and obesity and cardiovascular disease and diabetes. And so I thought you should probably be consistent one way or the other. But I think it's an important potential source of calories and other possible effects.

MEMBER BOUSHEY: That's a good suggestion.

VICE CHAIR KLEINMAN: All right. I'm so eager for lunch, I jumped to this last one. So we are now at the third presentation. And we will take a break for lunch at 11:45, so we have plenty of time. And Dr. Heather Leidy's going to present for the Frequency of Eating Subcommittee.

MEMBER LEIDY: I'm okay. I'm going to try to use my slides.

CHAIR SCHNEEMAN: So Heather, you have to really work at making sure you're heard. Okay?

MEMBER LEIDY: Okay, sorry about that. We have really short mics. And so I'm short, but not that short. So I'll just -- I'm sorry if you

couldn't hear my comments earlier. I usually have a big mouth.

So I will be presenting on behalf of Steve Heymsfield who isn't able to be here today. He is the chair of this committee. And then also wanted to acknowledge Carol Boushey and then Rick Mattes, as well as Ron Kleinman who were a part of this committee as well.

And so it was pretty exciting to be a part of this subcommittee. These are new areas of questioning that we were able to tackle. And you'll quickly find we spent a substantial amount of time in the earlier weeks defining the topic and working out the framework on the front end. And so as we go through the slides, if you have clarifying questions, feel free to ask. And the rest of the committee, happy to chime in with you all too. I'm going to try to add some rationale behind some of the things that we've selected because they may seem a little -- not off, but just different. And so I'll try to add some context to that.

And so our topics areas that we had were the frequency of eating. And as you can see the remainder, and Carol had already addressed these with the previous topic. But just so everybody's on the same page. You're really looking at eating frequency and all-cause mortality, growth, size, body composition, overweight, and obesity, gestational weight gain, postpartum weight loss, cardiovascular disease, and Type 2 diabetes. And we are covering all of the protocols today. And that's why they're in an asterisk.

And so we really wanted to start with identifying the key definitions. And so if you have questions, feel free to raise them now because it will help drive some of the rest of the conversation.

And so eating frequency, we defined in two manners. One is the number of daily eating occasions. And then the second one is the timing of daily eating occasions. And underneath that then we have the timing of weekly eating

occasions, really identifying week day versus weekend. Meal skipping and then also fasting from a time restricted eating paradigm.

And so obviously now we have other things to define. And so an eating occasion is any ingestive event. And thinking in terms of, you know, what we know from the lay audience and the U.S. American diet, as well as how studies are designed. That includes preload, so that is really anything before another eating occasion. So preloads, meals, and snacks. Within this eating occasion, that includes all foods and/or beverages. And then also whether they're caloric or non-caloric.

Fasting was defined as an absence of an eating event greater than eight hours during a waking period in a 24-hour period. Again, we're really trying to be sensitive to some of the more recent research with time-restricted eating or intermittent fasting, those types of concepts. And so time-restricted eating, were really set patterns of eating occasions throughout the day.

And so that's how that was defined.

And then lastly, meals were dependent on timing throughout the day. So we're really trying to get at, you know, what you typically see as you know breakfast, lunch, dinner/supper. And that's really around the morning, midday, and evening eating occasions. Not that it's an elephant in the room, but you know, obviously snacking is another component. Due to the fact that there really is no standard definition for snacks, we felt the need not to include that as a definition because it's just very variable. I mean some base it on timing or energy or caloric intake. And so we felt that because there's just no standardization, those eating occasions will be included as eating occasions. But we just felt that we shouldn't really define snacks.

The next piece then is well what frequency of eating is not? Because that really came in the discussion. And so two points here. The first is that we are not addressing the frequency of intake of single foods, beverages,

or categories of foods or beverages. This is really about when to eat, not what to eat.

But even in a call yesterday or the day before, it came up that, you know, there will be times that we can address other components -- nutrients, micronutrient content, whatever. But the primary question within a study has to be the frequency of eating. And then within that, we can then look at different types of the foods that were included within that. But this is not really specifically looking at single foods, like the frequency of milk consumption or frequency of seafood consumption, something like that.

And then the second point are studies that do not have eating occasions across the day. And this really came about from this idea of meal skipping and breakfast skipping or dinner or whatever is in the research right now. But you'll find that a lot of studies don't address subsequent eating throughout the day. That it is generally maybe if it's breakfast skipping, it's they assess lunch and that's it. And we really

wanted to encompass with these outcomes, that I'll share here in a minute, that these studies really need to have eating occasions across the entire day to increase the quality of the study or to really adequately answer the question. And so those are the two points to keep in mind. Yes, for sure.

MEMBER ARD: So this is Jamy. So can you help me sort of figure -- or talk through how -- what's the difference between meal skipping and time-restricted eating as you're conceptualizing it? So if you're saying time-restricted eating is a set pattern of eating occasions, and I skip breakfast every day, which one is that? Is that meal skipping or is that just I don't start eating until noon?

MEMBER LEIDY: Sure. And feel free for the rest of the committee to chime in. But that really is encompassing both of those aspects. Because there are studies that just focus on breakfast skipping, which isn't really time-restricted eating. But some time-restricted

eating components have a breakfast skipping component. Or they just -- maybe they also have breakfast and lunch skipping. So I think what we're trying to do is really include that all together. So you know, it depends on how the NESR folks or how we compile the findings at the end. But they can be separate, but they can also be combined, depending on the study design.

MEMBER MATTES: Yes, I think the goal here was to come up with terms that would be captured in a literature search. And it may actually be very similar, but to make sure we captured all the papers, we used both terms.

MEMBER LEIDY: Anybody else?

VICE CHAIR KLEINMAN: I think also we talked on the last call about intermittent fasting for let's say religious reason or some other purpose. And as long as that's not the sole purpose of that study, then we would capture those. So if for example, someone has a usual consistent eating pattern, but fasts periodically throughout the year, those will be captured. But

if they're fasting for four days, that's not the kind of the study that we'll capture.

MEMBER LEIDY: Yes. And again, we really had the mindset on the front end is you know, intermittent fasting has changed to the definition of time-restricted eating. But there are still a number of studies that have never been examined looking at every other day. And so you know, when we look at that, we'll be able to capture that. But to your point, you know, it's not a prolonged fasting period that we're trying to capture.

MEMBER NOVOTNY: Rachel Novotny. I'm wondering about water, especially with the frequency of consuming water throughout the day. We may not find a lot of studies on that, but just, what are your thoughts for handling water?

MEMBER LEIDY: Yes, so we had that included in our definition that it's any eating occasion, caloric or non-caloric. So even those that are water and non-caloric will be included in the analyses. Although as we all know, it's

very difficult -- many studies don't actually assess water intake unless that's the only thing that they're changing. But that would be included in our -- that would be captured in the search terms in terms of -- because we're searching for any eating or drinking occasion. And that would be included.

MEMBER NOVOTNY: So fasting with water is not fasting in your definition. It's drinking water.

MEMBER LEIDY: In our definition, it would not be considered fasting because that would be an ingestive event. But we also have the caloric and non-caloric component to that. Is that in agreement? Okay.

In terms of the inclusion and exclusion criteria, these were the standard NESR criteria used. So I won't go over this slide. And we'll get to some of the things that are a little bit different with these research questions. So I'll just go ahead and move on.

And so again, this is the analytical

framework. It's nice, we've only had one of these so far. But in the afternoon, we're going to see quite a few, I would imagine. The first part is the intervention and exposure, which is really the definitions that I just touched on. So I'm going to kind of go past that because the inclusion/exclusion criteria are there.

In terms of the age of the study participants, you can see here that it's children to older adults. And we are not focusing on infants under the age of two. And that's in our infants and toddlers. And so that's in the excluded criteria. And then in terms of the date of publication, the committee also felt that going from January of 2000 to the present was also appropriate. But we did this for two specific reasons and we thought long and hard about this.

The first one is the methodology using that we have is quite different now than it was 50 years ago in terms of some of the outcomes and the methods of capturing eating frequency. And

so we felt to be consistent, 2000 and beyond would be the best consistent data with that.

And then the second piece too is -- you know, it's interesting much like probably dietary patterns. But eating frequency has a tendency to go through waves of research. And so I remember, I went back and looked last night to make sure, you know, some of the first big studies that came out were like in the 1950s. And there were a cohort that came out. And you didn't see it again until the '70s and then the '90s. And so the challenge that we found is, you know, this is the first time we've asked these research questions. And so it would be nice to go back and look at the totality of the data.

The problem is as we know, eating patterns and eating frequency has changed over the past 50 years. Whereas, you know, 50 years ago, three meals was the staple with very little snacking. And so the control group there would be far different than the control group from like 2000s on where there's -- you know, there's a lot

of meal skipping now and more eating occasions. And so that's why we felt it best to go from 2000 to the present. Because that's the most consistency that we have with dietary patterns and our control comparators would be more consistent with that. So that's why we chose to go with 2000 and beyond.

In terms of the health status of the study participants, again the NESR standard criteria were included. Although, you know, this is more of an interesting thing, you know. Based on looking at the other presentations, I think we're the only ones that included this. But we actually excluded subjects who had post-bariatric surgery. And our thinking on this was, you know, when individuals go through post-bariatric surgery, they would be healthy. Maybe overweight or still obese, but you'd have a cohort of healthy individuals so they should theoretically be included.

But as you know with post-bariatric surgery, they are recommended or prescribed

smaller meals with more increased eating frequency. And we felt that wasn't generalizable to the rest of the population. And so we chose to include those in our exclusion criteria for that reason. It seems a little weird that we just added that on. But it really is because they change their eating patterns.

In terms of dietary data collection, this was also something I think that's unique to our committee. We wanted to have the highest quality data that we could capture given that this is the first time this question has been asked. And so we -- I feel like this is probably a little bit stricter than what you would think. But we chose a minimum of three days of dietary data collection on at least two occasions. And the intent of that was really to capture habitual eating frequency or eating habits. That it wasn't just a single day.

And the other thing too with eating frequency, as an example with meal skipping, a lot of times you'll see that there's one eating

occasion, and then the data in these studies are only captured at that next eating occasion. And so you don't get the rest of the entire day. And it's really difficult to make recommendations when you're not capturing, you know, over a 24-hour period, as well as over the days to look at habitual intake. And so that's why we chose the three days of dietary data.

But as a note, because the question that came up is the food frequency questionnaires because they're done one time. But if you -- you know, a lot of the ones that are validated are over the last week or months or years. And so the food frequency questionnaires would be included within this data. This would be acceptable because they are capturing over a three day period. But we do want with the food frequency questionnaires, there would be two separate time points for those to be included. Does that make sense so far?

And then in terms of the size of the group, we chose 15 participants for studies using

a within subject analyses and then 30 participants for studies using between subject analyses or at least including a power calculation. It wasn't and, it's or. And so if somebody -- if a group or research publication has less than those, but have a power calculation that adequately is powered based on a lower sample size, we felt that was appropriate. Again, our intent is really to increase the quality and to have enough power within a study to detect the differences in the outcomes that they are proposing.

Okay, so now we can get into the actual questions. And all of these questions, we're using the NESR system review to answer those questions.

So the first one is what is the relationship between frequency of eating and all-cause mortality? And what we've done here is you'll see very similar framework. Some of the ones that are in black in terms of the key confounders, potential confounders, and potential

covariates are consistently used with other subcommittees. And then some of the ones are specifically for us. And then as we go along with each of the research questions, if something has changed, they're highlighted in red. So we'll kind of just work through this now.

And so the top piece, we've already covered; the intervention exposure versus the comparator. And the population is included there. In terms of the key confounders, again, we have sex, age, race/ethnicity. Total energy intake is in italics, which is really difficult to see. So I'm going to address that now. And so this was an interesting one that came up. And it's also to your point, Dr. Sabate.

Total energy intake is actually -- if you look at that, it's a key confounder, but it's also a potential covariate. Because we're trying to see whether it's a confounder or mediator. And so we felt that it was appropriate for these research questions with the frequency of eating to include it both ways. And so the only way

that a study would be dinged is if they're not using it in one or the other manner. So that's why we went with it from that aspect.

We did include habitual eating frequency, which I think is probably unique to our research questions. And again, there's a lot of studies out there that will do eating frequency studies. But baseline assessments are not included. And we felt that it was critical to know when somebody's habitually fallen from an eating pattern to know whether it's the change in their habitual eating patterns versus just the eating pattern itself. And so that's why we wanted to include that as a key confounder.

And then we have smoking, anthropometrics and menopausal status. In terms of the potential confounders, we are I believe, the only group that has socioeconomic status as a potential confounder, not a key confounder. And just given the research question, we felt that we did not want that in the risk of bias as a key confounder. So it is included, but it's included

as a potential confounder.

We also have physical activity, cultural practices, eating environment. So in essence, who you eat with, where it is, whether it's work, school, or you know, around an exercise schedule. Thinking in terms of holiday eating or seasonal eating. Sleep schedules, trying to get shift work, dentition, hydration status, pregnancy status, and pubertal status. And so all of these potential key confounders, we felt were important for the frequency of eating, but not served as a key confounder.

And then lastly, the potential covariates would be related to different aspects of energy. And so we have diet energy density, as well as the energy state of the diet. In terms of energy, we were trying to think of it two ways -- one with the diet and one from a physiological energy. And so the first part we wanted to use as a covariate is as I said, the energy balance of total energy intake --

I'm sorry, let me go back. Energy

state of the diet. So whether it's an energy restriction diet or an energy surplus or an overfeed study. But then as well as thinking in terms of energy from an energy balance, whether somebody's in an energy-restricted state or an energy surplus state, thinking in energy intake and energy expenditure. And then we also included portion size macronutrient content, location of eating occasion, habitual eating frequency, and biochemical changes.

And again, you'll see again, some of these are listed both ways. So as a key confounder, as well as potential covariate to see whether they are truly a confounder versus a mediator. And so that's why we have it as such. And I don't think we've actually defined all-cause mortality, but that is the total number of deaths from all causes during a specific time period.

The next question that we had is what is the relationship between the frequency of eating and growth, size, body composition, and

risk of overweight and obesity? And I'll only highlight the changes that we had within this versus the others. And so if you look at obviously the endpoint outcomes were very similar to what Dr. Boushey had presented with the dietary patterns. So I'm not going to go into that because they are identical.

Our key confounders here, the only thing that we added as a key confounder was physical activity. And that's really driven by when you're thinking in terms of some of these outcomes related to obesity. A lot of these studies that have eating frequency also have a physical activity or exercise component. And so we felt that even if they didn't have an exercise component for these types of outcomes, it was critical to have an assessment of their physical activity or energy expenditure status. And so that's why that is a key confounder.

Potential confounders, same as the previous one. Although we did add medication and substance use. And this is related to any types

of substances or medications that would affect body composition or obesity status, those aspects. So we felt it was important for this question to include those.

And then the potential covariates, the only thing that we added was a specialized diet including all liquids diets. There are studies that look at eating frequency and have diets that are just all beverages. And so we felt that was important because that's not very representative of the population of who are consuming those.

Whoops. The next question that we had is what is the relationship between frequency of eating during pregnancy and gestational weight gain. Whoops, sorry about that. There we go. So it's pregnancy and gestational weight gain.

In terms of our intervention/exposure versus comparator. The population was changed obviously to women during pregnancy. Gestational weight gain, I think this might be -- I don't know if we've -- I guess we haven't heard it at this point. So it's change in maternal body

weight from baseline before and during pregnancy to a later time point during pregnancy and/or right before delivery. As well as weight gain in relationship to weight gain recommendations based on pre-pregnancy BMI. And as I said, the population is women during pregnancy.

The key confounders here, we did add pre-pregnancy anthropometrics within that. The potential confounders very similar to previous, except we added the history of gestational diabetes and history of gestational hypertension. And just to make sure we're defining gestational weight gain. That's a weight a woman gains during pregnancy. And no changes to our potential covariates within this model.

The next one is what is the relationship between the frequency of eating during lactation and postpartum weight loss? Within this, this is women during lactation, is the population. And just a side note is that women who are not lactating would not be included within this. We're really focusing on women

during lactation.

Postpartum, the endpoint is changes in weight from baseline postpartum to a later time point during the postpartum period. And postpartum weight retention if gestational weight gain is controlled for. We're defining postpartum weight retention as the amount of weight that remains during the postpartum period minus the woman's pre-pregnancy weight.

And we've added some key confounders, a little bit different than the previous ones. And that being pre-pregnancy anthropometrics and gestational weight gain. But no differences in potential confounders. And given a potential covariate, we included the lactation duration thinking that is a critical point in terms of how long an individual woman has been lactating.

The next question is what is the relationship between the frequency of eating and cardiovascular disease? And within this model, we have same things on the intervention/exposure versus the comparator. In terms of the endpoint

outcomes, we have cardiovascular disease. And you can see those that are listed within that, as well as stroke, venous thrombosis, cardiovascular disease-related mortality. And then we also have the intermediate outcomes listed here, which is very similar to the other subcommittees that have used that.

Key confounders and potential confounders were similar to the previous ones. In terms of potential covariates, those that are highlighted in red were ones that we added for this specific outcome of -- these outcomes of interest. And that being dietary sodium and potassium, as well as dietary fat composition.

And then the last research question is what is the relationship between the frequency of eating and the risk of Type 2 diabetes? Again, very similar as what were previously discussed. Endpoint is Type 2 diabetes. And we can see that our intermediate outcomes here again are you know, glucose, insulin, hemoglobin A1c, and pre-diabetes. Our key confounders, potential

confounders, and potential covariates are the same as the ones that are used previously. So I'm not going to list all those.

I'm quickly realizing though with our group, we have a lot more of these than the dietary patterns. So I'm not sure if we're maybe being more specific or all encompassing. I'm not sure how that works. But we do have quite a bit that we're targeting. The nice part is these don't eliminate studies in terms of the potential covariates or potential confounders. It's just something that we're trying to keep an eye on as we go forward. And I think this is probably driven by the fact that this is the first time these questions are being asked.

In terms of next steps, we will begin screening search results, extract data, and conduct risk of bias assessments, prepare the evidence synthesis, develop graded conclusion statements, and then document limitations and research recommendations.

And so with that, I just wanted to

acknowledge the members and the support staff. It's been a really great opportunity working within this group, especially this support staff have been overly helpful. When questions get raised, it's great -- they come back with examples and things for us to consider. And so it's been a great opportunity. So with that, I'll field any more questions if you all have them.

MEMBER DONOVAN: Thanks, that was great. The only thing I would add, on the frequency of eating and postpartum weight loss, you have lactation duration, but you might also want to consider exclusivity. So if a women is exclusively breast-feeding versus mixed feeding -- so if that's reported.

MEMBER NOVOTNY: I actually got thinking about --Rachel Novotny -- whether you might want to include monthly in frequency of eating. I mean it would need further elaboration. What I'm thinking about is lower income who change your eating patterns at the end

of the month. And eat less, start skipping meals. I'm not quite sure how you get at that. But it would be -- you would probably want socioeconomic status or food security status with that question.

MEMBER LEIDY: That's a really good point. And you know, the same was true with some of our terms that we were still -- as of yesterday, still battling back and -- not battling, discussing back and forth. You know, we have it within a 24-hour period. But in essence, if you're doing intermittent fasting and it's every other day, it actually needs to be extended to about 48 hours or if it's across the week.

So we're not limiting studies based on that. We're just trying to capture eating patterns. And if it's longer than -- you know, I think our minimum would be a 24-hour period. But it would be great if we could extend that. And you're exactly right. I mean eating patterns across a month given SES status would be

critical, if those studies exist and if they actually have that.

MEMBER TAVERAS: Elsie Taveras. Heather, I wonder if -- I saw sleep schedule. But I wonder if sleep duration should also be included and frequency of eating and body composition, gestational weight gain, and postpartum weight loss. Duration as opposed to just schedule. Right? Because you're thinking of -- I'm thinking of duration separate from maybe circadian misaligned eating. So that was one suggestion.

And then I also wondered -- I didn't see any mention as key confounders or potential confounders of screen use. So frequency of eating, especially if that eating is in front of a screen and exposed to advertising. I just wondered if the committee thought of how screens, television viewing played into any of these relationships.

MEMBER LEIDY: To answer your point about the sleep, I think that's a critical

component. We put that in thinking of shift workers. But then, you know, especially with breakfast skipping, there is some correlational data that suggested that's related to sleep or the sleep duration or the quality of sleep is potentially driving some of the meal responses. And so something for us to think about to include.

In terms of the screen use, to my recollection, we didn't include that specifically. But we did talk about where or when or who the eating occasion is with. So if it is at home versus out at a restaurant or something like that, that's included. But just because they're eating at home doesn't mean that they're eating as a family unit. Or that they don't have something else in terms of screen time. So I think that's something that we should probably think about capturing. We do have some components of that, but not a specific statement about screen time. That's a really good point.

MEMBER DONOVAN: Sharon Donovan. I

guess the comments about end of the month, it also made me think that you have habitual eating patterns for both pregnancy and lactation. And I think that women change their eating behaviors and frequency during these periods of time. So I think it's okay to look within these time periods, differences in eating frequency. But I'm not sure you want habitual in as a key confounder.

MEMBER LEIDY: I think our intent was to capture -- Feel free to chime in. But it was to capture what they were habitually consuming before. So this would be pre-pregnancy. So it depends on what we're qualifying as baseline. But if they, you know, became pregnant, their eating frequency may change. And then postpartum, it may change as well.

And so we were trying to figure out just to capture that habitual period of time. Because if their eating patterns are most likely changing, but nobody has really quantified how they're changing. And so that's why we felt that

it was important. Again, not that it's going to exclude a study. But that the quality of the study will be evaluated a bit differently if they've captured that versus if they haven't.

Rick, I don't know if you want to --

MEMBER BAILEY: This is Regan Bailey. Short mic here too. My question was surrounding the diet assessment. I'm not sure that most of the food frequency questionnaires capture that rich contextual detail of timing and screens and with whom you're eating, the way that a 24-hour recall can. So are there any validated questionnaires that assess purposeful versus nonpurposeful skipping of meals or time-restricted feeding that could be considered?

MEMBER LEIDY: There are.

MEMBER BAILEY: Okay.

MEMBER LEIDY: But that's a good point. Again, we're thinking in terms of -- I think we went in thinking highest or best quality of research or data. And so thinking, you know, three dietary recalls would capture that more

effectively than food frequency questionnaires. They're still included, but the rating may be a little less. But there are questionnaires. We've actually used them that look at screen time and different components of that. So I think, you know, food frequency questionnaires can also capture time duration. They're just different questions.

So maybe we just need to think about whether -- you know, right now, we just have food frequency questionnaires included. But you're suggesting that we, you know, maybe call them something a little bit different if it's an eating occasion questionnaire or something like that. I know breakfast skipping questionnaires -- I guess we would need to define what a food frequency questionnaire is. And so we have that generally, but what we think, I think as nutritionists or dietitians, a food frequency questionnaire might be different than some of these other ones and they're just eating questionnaires. And so I think maybe we need to

include that as well.

MEMBER BAILEY: Okay, thanks for that clarity. The way that I understood it originally was that a food frequency questionnaire would be better than the recalls at getting habitual intakes. So that really is helpful in terms of --

MEMBER LEIDY: I'm sorry, yes. The only reason I brought that up is because our first thought is well they wouldn't be included because it's not three days. And then it's well no, food frequency questionnaires, the ones that are generally validated are longer term. But you know, I think if we're rating them, most of us -- the reason we included the three day minimum was thinking of dietary recall assessments as the first. But that we didn't want to exclude any studies that have food frequency questionnaires because some of them do get eating occasions.

MEMBER BAILEY: Okay.

MEMBER LEIDY: So yes, that's the tier that we were thinking of.

MEMBER BAILEY: Great. And then just a followup on that same slide. So a study that has fewer than 15 people but a power calculation that they are adequately powered would be included.

MEMBER LEIDY: Correct.

MEMBER BAILEY: Okay, thank you.

MEMBER SABATE: Joan Sabate. I just would like clarification on the number of daily eating occasions. Because this is the exposure for most of the outcomes that you are relating to, and I put that as an example. Based on your definitions, if somebody has a caloric intake of 1, 2, or 3 times a day, plus drinks water seven times a day is the total number of eating occasions of ten. Will this number of ten, will be different than somebody that has just ten small meals -- caloric meals a day? And will both be the same number and will be related to the outcomes by this numerical way?

MEMBER LEIDY: Go ahead.

MEMBER MATTES: Yes, we actually

thought about that some. So eating frequency can affect total energy intake multiple ways. One is energy actually contributed by the eating event. The other is by just changing the physiology -- the behavior of the individual so that it alters subsequent intake. And so frequent consumption of water may actually have an impact on the energy value in foods selected when there is an energy yielding consumption pattern event. So I think we want to count total in just the frequencies to be able to capture both of those ways frequency impacts intake.

MEMBER LEIDY: But I think, you know -- so that's our search strategy. And then once the findings come in, I think we would comment on whether those eating occasions had calories or didn't or even the food form or those aspects. So I don't think -- much like the dietary patterns, I don't think we're going to -- you know, once we see the studies in their totality, you know, we may be able to pair some together. But if there are very specific differences like

caloric content, then I think they need to be treated separately.

MEMBER SABATE: But I think this should be stated from the beginning. Because one thing is to have the number of frequent occasions. And another one is to -- besides having the number, I mean to compute which ones contribute calories versus which ones do not contribute with calories, which is mainly water. Because it's a completely different approach, especially in the context of intermittent fasting and things of this sort. I'm not saying that what you are saying isn't relevant, but it may get the confusion between the two approaches that I'm proposing.

MEMBER MATTES: So let me ask a question. Would it change your interpretation if multiple ingestive events were primarily water versus a low calorie beverage?

MEMBER SABATE: I think so -- definitely so.

MEMBER MATTES: So you think water is

a unique source of input? I mean what we're trying to capture is something about frequency, not source of nutrients, energy, or whatever. It's a behavior of how often something is ingested.

MEMBER SABATE: I think this is an important question. I'm not saying what you're proposing is irrelevant. But I'm just saying that there is a big definition between a dietary pattern that includes two or three caloric eating frequencies -- sorry, eating occasions versus having ten occasions in which they are caloric derived. I mean the one that is three plus water, I mean many people -- I mean this is one pattern versus -- I will say we have to separate the specific number whether it brings calories into the frequent occasion or not is very relevant.

MEMBER LEIDY: Except that our fundamental research -- the fundamental question of interest is really -- and that's why I put it back up -- it's the number of eating occasions

and the timing. The caloric content isn't -- it's not answering that question. We've gone around about with that, it really is a separate question because we're really just seeing about timing, not so much the content within those. We will have that and we'll be able to document that and look at you know, macronutrient content or energy within each of those occasions. But that first global definition is really about when to eat -- when or the number to eat versus the caloric content within those.

It's a really good point and we've talked about that. But I think we felt that, that was the truest definition of eating frequency was just based on number and timing.

MEMBER MATTES: Yes, and water, we tend to think of it as essential but inert in some ways. And it really isn't. I mean it alters gastric emptying, GI transit time. It may acutely influence appetitive sensations. It has real physiological implications too. And so I think it's artificial to draw a line with that

kind of an event.

MEMBER LEIDY: But that's a really good point. And that's something that we didn't use as a key confounder. In that, there's a lot of studies that don't capture or quantify water. And there are others that do. So we need to probably go back and be sensitive of that because there are a number of studies that will be ad libitum water consumption throughout the day or that's not even stated in their strategy. And I don't think we actually have that as a key Covariate. And we might want to think about putting that in. Because those studies that focus on water will have it documented. Those that don't, don't. And we're not really -- we're not listing that as something of a point of concern.

MEMBER VAN HORN: Linda Van Horn. Just an important point to this discussion relates to children. And we're probably all familiar with the fact that, you know, appetite regulation in children is something that's a

great interest in prevention of obesity. And the type, as well as the amount of calories is important evidently. Especially for children whose -- from the literature I've read and I'm sure most of you have -- their ability when they're drinking a sugary beverage, for example, to regulate their caloric intake in subsequent meals is not the same as when they're consuming either water or some other type of food. But the sugar, you know, liquid candy so to speak has a -- doesn't seem to have the same impact in terms of energy intake in subsequent meals, that it does with other foods.

So my only point is to recognize that children may have a different, you know, response than adults. And it would be valuable to be able to separate that, if the data exists.

MEMBER LEIDY: Well and that's an interesting point too because Rick and I are both also on the Beverage Subcommittee. And so I think that question will also -- that will be more specifically addressed there with beverages.

Just a point that there's a lot of cross-talk with some of these. And I guess fortunately, we're on both.

VICE CHAIR KLEINMAN: Yes, and I was going to add that food patterns as well -- so beverage food patterns and food frequency all have to integrate the information that's being analyzed. And so I think that gets to the points that you're making, Linda, and others have made. Lydia?

MEMBER BAZZANO: Hi, Lydia Bazzano. I just wanted to ask about -- the difference between fasting and meal skipping is really the intentionality. So you're capturing that in the confounding or covariates more.

MEMBER LEIDY: Yes. And again, that point was really just looking at our search terms and what you typically see fasting not -- overnight fasting. It's fasting across the day, trying to target that intermittent fasting. And then there's this other concept of meal skipping. And I think Jamy brought that up. A lot of those

can be synonymous, but we want to just separate them basically for the search strategy.

VICE CHAIR KLEINMAN: Well if there are no other -- Oh Tim?

MEMBER MATTES: Can I just follow up on Rachel's initial comment because I think it was an interesting one about -- about the possibility of a say a monthly cycle and eating frequency. We talked about SES as a covariate. What about something like food insecurity -- Would that be better?

VICE CHAIR KLEINMAN: We talked about that.

MEMBER NOVOTNY: Yes, I know. I was trying to think about how it would be modeled to whether that would be -- you know, I think we're talking about a population -- the population, which I think it is most relevant probably is a food insecure one. But whether we would want to in some way stratify by socioeconomic status too. So I guess to be -- I would be inclusive in the pole. So maybe include as possible confounders,

but consider possibly using a covariate -- one of them as a covariate -- probably the food security one.

VICE CHAIR KLEINMAN: I think we think of those as an effect modifier potentially and so it would be a covariate. And I think it's a very good idea to include it.

MEMBER LEIDY: Yes, it's a good thing to add as well.

VICE CHAIR KLEINMAN: Tim?

MEMBER NAIMI: I just wanted to return to this theme one more time -- this issue about mediators versus confounders. And this very important issue about whether we consider total energy intake as a mediator or confounder or both. And my hope is that you present both. So you have for example, total energy intake and anthropometry as mostly kind of pitched as confounders. And I understand that if you want to isolate out the effects of frequency, then that's appropriate.

But I would say for the public -- and

I think this is where we should consider what the public -- if God forbid I was interested in losing weight, I would want to know does fasting help me lose weight? And then to me, it would be a secondary question as to whether it's because of reduced overall caloric intake because you have fewer eating occasions or because of its impact on metabolism.

So I think it would be nice to report both of those things. But to consider like what would the public find potentially most interesting?

And then my other quick question was again, to come back to alcohol. Is it part of total energy intake? And even if it is, you might want to control for patterning, which has, you know, bodily impacts on cardiovascular disease or diabetes. So that's not listed as a confounder or potential confounder anywhere. So just something to consider.

VICE CHAIR KLEINMAN: All right, are there other questions or comments? Then I think

it may be getting close to time for an ingestive event. So we will adjourn until 1 o'clock. And that's it. Thank you all. Wonderful presentations.

(Whereupon, the above-entitled matter went off the record at 11:40 a.m. and resumed at 1:02 p.m.)

CHAIR SCHNEEMAN: So, I think we'll get started again. Hopefully, everyone had an enjoyable lunch. And we're going to continue with our subcommittee reports. I'm going to turn it back over to Dr. Kleinman.

VICE CHAIR KLEINMAN: Terrific. So, our next report comes from the Pregnancy and Lactation -- wait? Oh, yeah.

CHAIR SCHNEEMAN: I forgot one public service announcement. Please be sure you speak into the microphone, speak loudly, and say your name before you start your comments. So, just to help to make sure that we keep everything open. Great. Sorry.

VICE CHAIR KLEINMAN: So, Ron

Kleinman. And the next report is going to come from the Pregnancy and Lactation Subcommittee. And Dr. Sharon Donovan is going to give us that report.

MEMBER DONOVAN: Thank you, and good afternoon. And I'm Sharon Donovan and I'm presenting on behalf of the committee members that you can see on this slide. Oh, I need the advancer.

Okay, so the Pregnancy and Lactation Subcommittee has three main topic areas. And the first we're going to discuss is dietary patterns during pregnancy and lactation.

And within this topic area, we will be conducting five new systematic reviews, which are shown on the left side of the screen. And the two that are in blue will be the ones that we're going to be discussing today.

We also have four existing reviews that were done as part of the Pregnancy and Birth to 24 Months project that many of you may have seen. They were just recently published in AJCN.

For those who will be updating them, because the last date that they were searched was January 2017, so we'll be updating those searches.

So, we began by focusing on the new reviews. And then, as I mentioned today, we'll do gestational weight gain and postpartum weight loss.

So, the second two areas, two questions, are second dietary supplements and fortified foods, which, you can see the dietary -- the nutrients that we'll be focusing on, are folic acid, iron, B12, omega-3 fatty acids, Vitamin D, and iodine.

And the committee decided to start with folic acid and iron. So, those are the ones we'll be presenting today.

For each of these nutrients there are five health outcomes, which you can see on the right side.

So, basically, these are up to 30 systematic reviews that we'll look at the effects

of supplements and fortified foods.

The final question relates to maternal diet and food allergies, and atopic, allergic diseases. And we have not started on that one yet.

So, jumping right into dietary patterns, so the two questions that we have is, What is the relationship between dietary patterns consumed during pregnancy and gestational weight gain, and dietary patterns during lactation and postpartum weight loss? And so we'll be conducting new systematic reviews.

So, just to remind you, we're using the standard definition of dietary patterns that was presented earlier.

So, this is our first analytical framework. So, I'll set this up for you. So, this is looking at dietary patterns during pregnancy and gestational weight gain.

So, the intervention and exposures and the comparators, again, are consistent with how Dietary Patterns subcommittee defines dietary

patterns.

So, we're looking at -- the key confounders are shown below. And for all of the ones that are in black, these are going to be consistent for all of the dietary pattern questions. And the ones that we've shown in blue are specific to the outcome that we're investigating.

So, as you can see, for this one, which was related to pregnancy and gestational weight gain, we have age, race, ethnicity, socioeconomic status, physical activities, smoking, parity, and anthropometry, which, in this case, is pre-pregnancy BMI.

So then, the one specific for this are history and diagnosis of gestational diabetes, and gestational hypertension. So, from now on I'm not going to repeat the ones that are in black.

So, I think it was mentioned earlier, the main outcomes for gestational weight gain will be that change in maternal body weight from

baseline, either pre-pregnancy or early in gestation, we'll be keeping track of that, and either right at delivery or near delivery.

And then we'll be comparing that weight gain in relation to recommendations based on pre-pregnancy BMI.

So, again, our population, as women during pregnancy, they're healthy, or at risk for chronic disease.

So, the second analytical framework, looking at dietary patterns consumed during lactation, and postpartum weight loss.

Again, what's different about this one is we will be focusing in just on women during lactation. So, if women aren't lactating, then their dietary patterns will be evaluated by the Dietary Patterns Subcommittee.

So, we're looking now at change in weight from baseline postpartum, so close to delivery, we'll be recording that, and then whatever the later time point postpartum.

So, again, we understand the papers to

be quite variable, but we'll be keeping track of that.

And then we'll look at postpartum weight retention if gestational weight gain has been accounted for.

So, again, the only new confounder for this will be breastfeeding. And what we mean by breastfeeding is not only whether or not -- well, obviously, this is lactation, so they will be breastfeeding.

But we'll be looking at are they exclusively breastfeeding, or are they mixed feeding. So, combining breast milk and infant formula. Okay.

So, our standard inclusion and exclusion criteria are, we're using the standard NESR criteria. And then, in terms of dietary patterns, we're using the ones that have been established for dietary patterns.

So, inclusion and exclusion criteria -- again, either women during pregnancy or women during lactation, only human studies.

And for temporality, we're looking studies that assess outcome -- exposure prior to outcome, and excluding those that assess outcome prior to exposure. So, that's to control for reverse causality.

Also, I should point out -- and this is something that we're doing in a number -- is that we're excluding studies in the case of pregnancy, where they might have singleton and multiple births, but they've combined that data.

So, they can have singleton or multiple, but they have to have presented that separately.

The same thing for postpartum. If they have combined data for lactating and non-lactating women together, then we're going to be excluding those.

If there's a paper that has both and they're reported separately, we'll include it, but it's only the pooled data that will be excluded.

Okay, so this is exclusion for health

status. And again, we've talked quite a bit about this, so we will include studies that enroll some or all mothers classified as underweight or obese during pregnancy. That's the only thing that sort of different there. We will enroll, again, studies for some mothers maybe diagnosed with a disease which could include obesity.

So, we will exclude studies that exclusively enroll women who give birth pre-term, or they exclusively enroll women diagnosed with either severe undernutrition or hospitalized with an illness or injury.

So, we're really looking at healthy populations, or those at risk for chronic disease.

Okay, so now, switching to the next set of questions, which is the relationship between nutrients from supplements and/or fortified foods consumed before, during pregnancy and lactation, and a specific health outcome.

So, we're really focusing again on

these nutrients, not necessarily in the foods, but unless they're fortified foods or supplements. And again, the first two nutrients we chose to focus on were folic acid and iron.

So, in terms of key definitions, this is the definition for dietary supplements. It is basically the definition from the Office of Dietary Supplements.

But you can see that this does include not only nutrients, but potentially other dietary ingredients. But again, we will be focusing on the key nutrients, the six key nutrients that we were assigned.

And then, in terms of fortification, again, we're using the FDA definition of fortification, which was also used in the 2015 Dietary Guidelines, so again, trying to use standardized, accepted definitions for supplementation and fortification.

So, starting with our first question, so this is the relationship between folic acid from supplements and fortified foods. And in

this case we're looking at before, during pregnancy and lactation, and all five outcomes.

So, again, I'll just set up this analytical framework. Again, we're looking at exposure to folic acid from dietary supplements, which can be a single supplement or multiple, and fortified foods, or a combination of supplements and fortified foods. And then we'll be -- we have comparators basically focusing on different levels of folate.

So, in this case, we're looking at -- we've just decided for the before-pregnancy exposure. In all cases, we're looking at six months pre-pregnancy. So, we've set that as our time frame, and then during pregnancy and/or lactation.

So, in terms of the markers of folate status, we have folate, Vitamin B12, hemoglobin, mean corpuscular volume, and red blood cell distribution width.

We chose not to include homocysteine, because it's not a specific bio-marker for folate

status.

So, the key confounders are shown at the bottom, and these will be used for all the folic acid questions, with the addition of some additional ones for certain outcomes.

So, this is looking at folic acid before and during pregnancy on gestational diabetes. Again, the intervention and comparators are the same.

For the key confounders, we have added in blue family history of diabetes or pre-diabetes.

We have the intermediate outcomes. This was discussed previously, so I guess based on what we're deciding with diabetes in terms of hemoglobin, A1C, or whether that will be considered an intermediate, as well as an outcome. So, we need to be consistent there.

But really, what we've tried to do for our specific pregnancy and lactation outcomes is mirror the criteria that are being used in other outcomes, so that we're trying to be as

consistent as possible.

So, the next is basically looking at folic acid from supplements and fortified foods on hypertensive disorders of pregnancy. So, same intervention comparator.

Our intermediate outcomes are blood pressure and proteinuria, and the health outcomes, these hypertensive disorders of pregnancy, were used in the criteria established by the American College of Obstetrics and Gynecology, which were recently updated in 2019. So, we're looking at eclampsia, pre-eclampsia, and gestational hypertension.

The key confounders. The only addition here is diagnosis of gestational diabetes, because there's some reports that -- between gestational diabetes and hypertensive disorders during pregnancy.

The next is looking at human milk composition. And the original question was human milk composition and quantity.

And basically, the committee felt as

we discussed this, that there isn't really good evidence for any of these micronutrients impacting the quantity of human milk, so we're basically focusing on human milk composition.

So, very simple outcome, we're basically just looking at folate in human milk. And basically the same intervention comparators, and no new key confounders for this outcome.

And then our last outcome for folic acid is basically looking at developmental milestones, including neurocognitive development. So, this is a little bit different because we're actually not focusing as much on the mother. We're focusing on the child.

And basically our -- I'm sorry. It helps to advance the slide.

The developmental outcomes are similar to what had been previously reported. We don't have things like Alzheimer's, or some of the longer-term outcomes. But we do include anxiety, depression, autism, ADHD.

And because we know if we stayed

within the B-24, that there would be very few of these measures that would be valid, other than developmental milestones.

We've actually considered both infants and toddlers, and even children and adolescents. So, we will be trying to expand that to be able to capture more of these neurocognitive, neurodevelopmental outcomes.

So, in terms of key confounders, we have added child sex, gestational age at delivery, and breastfeeding.

So, in this case, whether or not the child was breastfeeding, and also the duration exclusivity. So really, we're kind of calling this breastfeeding practices.

Okay, so overall, exclusion and inclusion criteria, we're basically using the standard criteria that Dr. Schneeman presented this morning.

The types of studies. Again, we had some discussion about this. Due in large part to the fortification of the food supply with folate,

so we wanted to extend the searches back farther, back to 1980, rather than 2000.

And we also decided to include some cross-sectional studies, and then controlled before and after, so these could be studies that perhaps looked at human milk folate before the fortification of the food supply and after, but also, we felt in this case there would be very few longitudinal studies on human milk composition.

So, we feel that cross-sectional studies in folate intake are appropriate. So, those are the only two differences there.

So, again, inclusion criteria, human participants only. There really isn't anything that's that different in terms of the inclusion criterial.

We will use studies, we will include mothers with obesity, being at risk of chronic disease, and we'll include studies where some of the children or the mothers may have gestational diabetes, hypertension, but exclude ones where

they're only diagnosed with those, and also excluding pre-term infants.

Okay, so I feel like I'm moving through this pretty quickly.

So, the next nutrient that we looked at was iron. And so this, again, will be very similar to folic acid, in terms of the intervention and exposure.

And we had a long discussion about this, but we actually decided to include only iron from supplements, and not from fortified foods.

And the thinking is that in high and very high-income countries, iron is more likely to come from supplements, rather than fortified foods.

So, if you have comments, you can make comments on that. But that was -- Kay Dewey was one of the proponents of that.

Also, in terms of iron, we decided not to look at human milk composition because all of the minerals are tightly regulated at the level

of the mammary gland and there's a lot of evidence that shows that iron supplementation has no impact on human milk iron content.

So, for iron we only have four outcomes and we're not including a systematic review on iron from supplements and fortified foods and milk iron.

So, again, these are going to be very similar to the folate. This is looking at iron consumed before and during pregnancy and lactation, and micronutrient status.

So, basically, same intervention and exposures. It's just in this case we're looking at iron only from supplements.

The outcomes will be iron status, which will basically encompass however that was reported in the manuscripts, so we didn't want to list all of the options. They had diagnoses of iron deficiency, iron deficiency anemia, and anemia.

The population -- again, women during pregnancy and lactation -- and we will be looking

at iron supplementation up to six months prior to conception.

So, for all of the iron outcomes, the only new key confounder that's consistent for all of them is now baseline hemoglobin.

So, we then -- the next analytical framework is iron on gestational diabetes. So, again, the intermediate outcomes and endpoint outcomes will be the same as folic acid in gestational diabetes. The only new key confounders that we've added here is now family history of diabetes and pre-diabetes, as well as baseline hemoglobin.

So, the next is, again, iron and hypertensive disorders during pregnancy. Again, same intermediate outcomes and health outcomes. And the new key confounder in this case is diagnosis of gestational diabetes. And then the last one for this is looking at neurocognitive development and the outcome.

So, again, very similar to folate in terms of the outcomes, expanding the population

up to 18 years of age in the offspring, and now, in addition to hemoglobin, bringing in child sex, gestational age of delivery, and breastfeeding.

So, for the iron and dietary supplements, again, the standard criteria are used for the overall NESR, as well as for folic acid and health outcomes.

So, basically, the next steps, after incorporating any additional comments we receive at this meeting, is to go to our next set of dietary patterns questions.

So, we've done the two on gestational weight gain and postpartum weight retention. The next are human milk composition and quantity, developmental milestones, and micronutrient status. And then we will start on the next set of analytical frameworks for dietary supplements and fortified foods.

So, we haven't necessarily decided yet on the order, but the next are B12, omega-3 fatty acids, Vitamin D, and iodine. And then, for each of those four, we will likely be looking at

all five outcomes.

So, it's another 20 potential systematic reviews. So, we have a lot of work ahead of us.

So, I just would like to acknowledge our committee members and our support staff, and I would like everyone else to really say how wonderful the support staff is and how hard they're working.

And we have our weekly phone calls and they're always prepared and very helpful when we have questions. So, that's all we have.

VICE CHAIR KLEINMAN: Thank you very much. We're open for questions or comments. Linda?

MEMBER VAN HORN: Linda Van Horn. First of all, I just want to congratulate your group. That was a tremendous amount of work just to get it organized. This is a topic area that is so in need of this kind of scrutiny, and I think you made a terrific start, as far as going ahead with it.

Three things -- bear with me -- stuck out to me as you were going through your list, and I can see at the end you included one of them, which was unsaturated fatty acids, and three especially, related to neurocognitive development, and possibly other aspects related to even gestational diabetes, or things of that sort.

CHAIR SCHNEEMAN: Linda?

MEMBER VAN HORN: Oh, sorry. Still having trouble? Sorry. Okay.

And so, but two other things seem important to me. One, the idea of only focusing on supplemental iron to me, even in the developed countries, seems potentially problematic.

Why? Because we have many women who are attempting, at least, to become vegetarians or semi-vegetarians, or what have you. And not only that, we also have women who forego the supplement, the dietary supplement, that's recommended, because, frankly, they don't want to be constipated.

And so, you know, at least in the work that we've been doing over the last six years, we've noticed that this is a trend, at least in an industrialized country, with people who are educated, but just basically don't take those factors into consideration, in terms of a recommended supplement.

So -- and especially since our food supply now is so heavily fortified with iron in various foods, it would just seem to me unfortunate not to be able to really look at, with or without supplemental iron, the impact on your outcome.

So, I know that's a lot more work maybe. But if it's possible, it would seem relevant to be able to incorporate that if it is possible.

And then the third thing -- sorry, one more last thing, and that relates to gestational hypertension and the concerns that, of course, we have with preeclampsia and eclampsia, and gestational diabetes, as well as hypertension,

the topic we raised earlier about sodium, and also calcium.

If you think about it, the DASH diet -- I mean, wouldn't we want all pregnant women to follow something like a DASH diet to reduce their risk for hypertension, as well as obesity or excessive gestational weight gain.

So, as this set of guidelines will be the launch for recommendations related to diet in pregnancy, as well as those first two years, I just think if it's possible to be able to look at some of those factors that could in fact be influencing the common problems with pregnancy related to gestational hypertension and diabetes, wouldn't we want to have a better sense of the diet, the dietary pattern, that could help reduce those risks. So -- sorry, that was my --

MEMBER DONOVAN: No. I mean, those were all --

MEMBER VAN HORN: And others may disagree.

MEMBER DONOVAN: No, they were good

points. And I think in terms of the supplemental iron and fortified -- iron from fortified foods, that was one of the original questions that we got.

So, I think we could consider changing the search terms so we could get both of those, and then be able to compare that.

The omega-3s. Again, with the omega-3s, we will be looking at all five outcomes with that.

The last one I think is interesting, because we don't have a question related to dietary patterns in gestational -- well, but actually, let me correct that.

So, that was one of the previous -- let me see. Let me make sure I'm right. Because there were some of those systematic reviews that were done as part of the pregnancy -- so yes, part of the pregnancy and birth.

We have gestational diabetes, hypertensive disorders during pregnancy, from

gestational age at birth and birth weight related to dietary patterns. So, that's not one of our new ones, but we will update that, so we will get that.

VICE CHAIR KLEINMAN: Any other comments or questions?

MEMBER BOUSHEY: Okay, I concur. I just want to say, I concur --

VICE CHAIR KLEINMAN: Say your name.

MEMBER BOUSHEY: Carol Boushey -- concurs with Linda's comments -- thank you very much -- so that -- because you said, I don't know if others do. So, I'm letting you know, I do.

CHAIR SCHNEEMAN: I wanted to come back on this point of iron and fortified foods. And I'm not sure I fully understood the rationale behind why you might do it, because I think iron is part of the enrichment, so just like folic acid is part of the enrichment. That's why it's in fortified foods. It seems like the same logic would hold for iron.

MEMBER DONOVAN: So, any other people

on the committee? Because I think I was not on that call where this was discussed. And I actually came back and asked. So, do you remember some of the --

(Off-mic comment.)

MEMBER DONOVAN: I think it's also perhaps just because during pregnancy in particular, I mean, the iron supplement level is so high.

But again, I don't think it's a big deal to just include that in the search terms. It's not a new question. Right?

It was part of the original question that we decided as a committee. But I will bring it back and make that decision with the staff.

VICE CHAIR KLEINMAN: All right. Either the post-ingested event coma is settling in, or the questions have been asked. Anyway, thank you very much, Sharon. That was a great presentation.

So, we'll move on now to birth to 24 months. And Dr. Elsie Taveras is going to

present that. And she needs the clicker.

MEMBER TAVERAS: It's going to do much for the post-prandial. So, bear with me, please.

I'm Elsie Taveras. I am presenting for the Birth to 24 Months Subcommittee. Our Chair, Kay Dewey, was not able to be here today, but we have a number of our subcommittee participants, including Sharon and Ron and Lydia.

So, I'm going to get started by telling you a little bit about the protocols that we are going to discuss today.

We have eight protocols that we've completed, and five additional protocols that are yet to be completed.

This slide shows the five topic areas that we're presenting today that relate to feeding human milk and infant formula.

So, you'll see that we're looking at duration, frequency and volume of human milk or infant formula, with growth, size and body composition, with micronutrient status, with developmental milestones, with food allergy,

atopic allergic diseases, and with long-term health outcomes.

And this slide shows the three topic areas that relate to specific nutrients from supplements and fortified foods. We'll be covering four specific nutrients: iron, Vitamin D, Vitamin B12 and omega-3 fatty acids, with three separate outcomes: nutrient status, growth, size and body composition, and bone health.

And the five topic areas still to be completed all relate to complementary feeding, with micronutrient status, growth, size and body composition, developmental milestones, food allergy, and bone health.

So, let's begin by looking at the protocols we've developed to examine human milk and infant formula topics. And I'll warn you all in advance that these are very complicated, with a number of different comparators. So, bear with me.

But also, I want to say ahead of time

that all of the protocols are available to the committee, but also to the general audience and on the Web.

So, our three human milk/infant formula questions will be answered with new, original, systematic reviews. And the three questions that we will be asking are, what is the relationship between the duration, frequency and volume of exclusive human milk and/or infant formula consumption, with growth, size and body composition?

What is the relationship between duration, frequency and volume of human milk and/or infant formula consumption and micronutrient status?

And what is the relationship between the duration of exclusive human milk and/or infant formula consumption and developmental milestones, including neurocognitive development?

We have also two human milk/infant formula questions that will be answered with updates to existing systematic reviews similar to

the pregnancy and lactation reviews.

There are existing reviews on the following two questions that we plan to update. And the two questions that will be updated through updating of existing systematic reviews are the relationship between the duration of exclusive human milk and/or infant formula consumption, and food allergies and atopic allergic diseases, and what is the relationship between the duration of exclusive human milk or infant formula consumption, and long-term health outcomes?

We'll start, as we have with the other frameworks, with some key definitions.

We defined human milk as mother's own milk provided at the breast, or expressed and fed fresh or after refrigeration or freezing, and we will not be examining donor milk.

Infant formula is commercially-prepared infant formula, meeting FDA or international food standards.

And complementary foods and beverages

are foods and/or beverages other than human milk or infant formula, provided to an infant or young child, to provide nutrients and energy.

We also have definitions for feeding methods, which you'll see throughout our analytic frameworks.

The first is human milk feeding, which is feeding human milk alone, or in combination with infant formula and/or complementary foods or beverages, such as cow's milk.

Exclusive human milk feeding, which is feeding human milk alone, and not in combination with infant formula and/or complementary foods or beverages, such as cow's milk. This definition is inclusive of the World Health Organization definitions of exclusive and predominant breastfeeding, which permit limited quantities of drops or syrups containing vitamins, minerals, or medicines, water and water-based drinks, such as sweetened water and teas, fruit juice, oral rehydration salt solutions, and ritual fluids.

Our definition for mixed feeding is

feeding human milk and infant formula, but not complementary foods and beverages. And our definition for topping up is feeding infant formula after human milk during a single feeding session.

So, I'm going to pause a bit. And similar to Carol, I have some animation, because of the complexity of this analytic framework.

So, this is our analytic framework for a new systematic review on the relationship of the duration, frequency and volume of human milk and/or infant formula consumption, with growth, size and body composition.

In the box on the left, you can see our comparators of interest are divided into two groups -- I think I have several clickers -- the top group being which is in red here, shows three specific comparisons we want to use to examine duration of human milk and/or infant formula consumption.

These comparisons align with the first feeding decisions that caregivers have to make.

A caregiver's first decision is whether or not to feed human milk, so we will examine comparisons of infants who ever consume human milk -- that is, any amount of human milk -- with infants who never consume human milk -- that is, completely or entirely formula-fed infants.

Among infants who are fed human milk, subsequent decisions caregivers have to make are how long to feed human milk at all, and how long to feed it exclusively.

And therefore, the second comparison that we are going to make is the comparison of different durations of any human milk consumption among infants who are human milk-fed, and consumption and comparison of different durations of exclusive human milk consumption prior to the introduction of infant formula. That's a mouthful.

But essentially, our top group looks at duration. And our bottom grouping then looks at three specific exposures and comparators, examining frequency and volume of human milk

and/or infant formula consumption.

So here, we want to examine comparisons. First, comparisons of different intensities or proportions or amounts of human milk consumed by mixed-fed infants.

Next, we want to examine comparisons of different intensities or proportions or amounts of human milk consumed at the breast versus by bottle in infants fed human milk as their only source of milk.

And third, we want to examine comparisons of consuming human milk or infant formula, with consuming both human milk and infant formula, during a single feeding session. For example, topping up a human milk feeding with infant formula.

We will examine all of these comparisons in healthy infants and toddlers. Our outcomes, as I mentioned earlier, is growth, size and body composition outcomes that relate to human milk and infant formula comparisons, and they represent a range of outcomes that we will

look at and examine throughout the life span.

And finally, on this slide, very tiny at the bottom there are key confounders that we've identified, and some of these are similar throughout all of our slides: race/ethnicity, socioeconomic status, types and amounts of complementary foods and beverages and infant formula, childhood diet, birth weight, fetal growth, smoking, mode of delivery, and maternal body mass index.

Our next analytic framework is similar in the examination of our interventions and exposures, duration, frequency and volume, but looks at outcomes of micronutrient status.

Here, you'll observe that our comparisons of interest are divided into the same two groups as I showed in the previous slide for growth, size and body composition.

The bottom grouping is a little bit smaller than it was on the previous slide. We retained the comparison of different intensities or proportions or amounts of human milk consumed

by mixed-fed infants.

However, we decided that the breast versus bottle and the topping up comparisons, are less relevant to examine in relation to the micronutrient status outcomes you see on the current slide.

In this case, our outcomes will include micronutrient status in infants and toddlers, specifically, iron, zinc, iodine, Vitamins D and B12, and fatty acids.

This next analytic framework is for the new systematic review on the relationship between the duration of exclusive human milk or infant formula consumption, and developmental milestones, including neurocognitive development.

Here are comparators and -- sorry, our intervention and exposures and comparators all relate to duration of consumption.

Frequency and volume are not part of this question. And therefore, the comparisons of interest here include only the comparisons of ever versus never consuming human milk and/or

different durations of any and exclusive human milk feeding.

In this slide, you will also notice our outcomes of interest are developmental milestones, including cognitive, language/communication, movement/physical and social-emotional developmental outcomes, as well as a range of other outcomes, including academic performance, attention deficit disorder, anxiety, depression, and autism spectrum disorder.

You'll notice also that these outcomes will be examined in infants through adolescence. That's our population for this analytic framework.

The next framework examines human milk or infant formula consumption with food allergies and atopic allergic diseases.

Similar to the previous slide, frequency and volume are not part of this question, and therefore, the comparisons of interest are identical to the previous slide.

The outcomes of interest here are food

allergies, allergic rhinitis, and atopic dermatitis, throughout the life span, and asthma, starting at two years of age.

And that was intentionally done so that we are really capturing asthma, and not transient, recurrent wheeze that happens prior to the age of two.

Finally, this framework is to update an existing systematic review on the relationship between the duration of exclusive human milk and/or infant formula consumption, and long-term health outcomes.

Again, you'll observe that frequency and volume are not part of this question. And again, the comparisons of interest are identical to the previous two slides.

The outcomes of interest here include a number of intermediate outcomes, including intermediate cardiovascular disease outcomes and intermediate diabetes outcomes, and a number of endpoint health outcomes in both of those categories.

Both of these endpoint health outcomes will be examined among children through older adults.

For inclusion and exclusion criteria, for of the questions related to human milk or infant formula consumption, we propose using the standard inclusion and exclusion criteria that were described by our committee chair for publication status, language of publication, study participants, and health status of participants.

But we have number of ways that we are tailoring the inclusion and exclusion criteria for a few of the categories.

First, we propose including literature published from 1980 to the present. This will align with the existing systematic reviews that have already been conducted, with examined the literature back to 1980.

Additionally, 1980 was the year that the US Congress passed the Infant Formula Act, which established nutrient requirements for

commercial infant formulas in the US, and thus, health effects associated with formula consumption before 1980 might be different.

So, that was the reason that we tailored a bit the date of publication.

Second, we propose including studies with at least 30 participants per group, or a power analysis indicating that the study was appropriately powered for the outcome of interest, and excluding studies with fewer than 30 participants per group with no power analysis.

You may have noticed that our age of study participants varies across our analytic frameworks. And we wanted to acknowledge and justify the variability in age and outcome across the reviews.

We want to look at studies that examine human milk or infant formula consumption in relation to growth, size, body composition, atopic diseases, and long-term health outcomes, throughout the life span.

So, you'll see that for those outcomes

we are including -- the age of participants is throughout the life course. However, for asthma, for cardiovascular disease and diabetes outcomes, the age of study participants begins at age two years.

That's consistent with the existing systematic reviews on human milk and infant formula. These decisions were also made, as I already mentioned, because an asthma diagnosis under age two may actually represent transient, recurrent wheeze, rather than asthma.

In addition, there is some uncertainty regarding whether and how intermediate outcomes, such as blood lipids in infants and toddlers, may relate to subsequent cardio-metabolic risk.

We thought it was most important to address whether and how human milk or infant formula consumption may impact child development. And thus, we did not go beyond adolescence.

And finally, we thought it was most important to examine nutrient status during the period of infancy and toddlerhood, when human

milk and infant formula are being consumed.

Finally, we proposed tailoring the standard criterion for country. Our inclusion criteria for our analytic frameworks on infant formula or human milk consumption will include studies conducted in countries ranked as high or very high in human development, and we will exclude studies conducted in countries ranked as medium or lower human development.

So, with that I want to switch our focus to look at the protocols we've developed to examine topics related to specific nutrients from supplements and fortified foods.

The approach to answer this next set of questions that examines specific nutrients from supplements or fortified foods consumed during -- between birth to 24 months, and multiple health outcomes, will be original, systematic reviews.

As noted on this slide, there are four public health nutrients of interest for these questions, which are iron, Vitamin D, Vitamin B12

and omega-3 fatty acids.

So, four nutrients of interest, three outcomes of interest, which are nutrient status, growth, size and body composition, and bone health, resulting in 12 analytic frameworks.

Again, some key definitions. And I won't read these word-for-word. These -- I know, sorry, Gene. I know you really wanted me to read these.

These are the key definitions discussed by our subcommittee, that are provided on each analytic framework with this set of questions.

The definition for dietary supplements is from the 1994 Dietary Supplement Health and Education Act, is provided here on the slide. And the definition for fortification is as defined by the US Food and Drug Administration, and is also available online.

So, we'll start with our first analytic framework examining nutrients, nutrient status. This next set of systematic review

questions examine the relationship between a specific nutrient -- in this case, iron -- from supplements and/or fortified foods, again, consumed during infancy and toddlerhood, birth through 24 months, and the specific nutrient status outcomes.

The intervention or exposure of interest in this next set of slides that you will see, is consumption of a specific nutrient -- again, here I'm showing iron -- from supplements and/or fortified foods or beverages.

The comparators for consumption of the nutrient from supplements are, consumption of the specific nutrient at a different dosage or frequency, from supplements, and/or consumption of the nutrient from fortified foods.

The population of interest for the intervention/exposure, comparator and outcomes include infants and toddlers, birth to 24 months, who are healthy and/or at risk for chronic diseases.

The outcomes discussed by our

subcommittee as most relevant for iron consumption include iron status, including iron deficiency and anemia, zinc status and copper status.

And here, the key confounders are similar to ones I have shown before, but in this case include feeding practices, anthropometry at birth or baseline, gestational age, prenatal vitamin supplement use, and baseline nutrient status.

So, similar to the previous slide, this analytic framework is also examining supplements -- sorry, a nutrient -- in this case, Vitamin D, from supplements and/or fortified foods consumed from birth to 24 months, and in this case, Vitamin D nutrient status as the outcome.

Again, our intervention or exposure of interest and comparator is the specific nutrient of interest, which here is Vitamin D.

The outcome of interest for this framework is Vitamin D status and anemia. And

the same key confounders as the previous slide are shown here, with the exception of the addition of sun exposure for Vitamin D.

Similar to the previous two slides of iron and Vitamin D, this slide shows the analytic framework for Vitamin B12 and nutrient status.

And again, similar to the previous two slides, the intervention or exposure of interest and comparator relates here to the nutrient of Vitamin B12, the same population of interest as presented on the previous slides.

The outcomes for nutrient status include Vitamin B12 and folate status. And the key confounders are all, similar to the previous slides, with the addition here of -- as a key confounder, of maternal vegan diet.

And finally, this question examines omega-3 fatty acids from supplements and/or fortified foods, from birth to 24 months, with the exposure or intervention of interest and comparator being omega-3 fatty acids.

We are examining the same population

of interest as the previous slides. And here, the outcome of interest is fatty acid status.

So, next we are -- this is the analytic framework. And this is good. The next series of slides are going to look very similar as the previous four, with the specific nutrient, so iron, Vitamin D, Vitamin B12, and omega-3 fatty acids.

But the next series of slides look at growth, size and body composition. Again, the slide I'm showing here shows iron and intake of iron from supplements and/or fortified foods. That's the intervention or exposure and comparator.

The outcomes here are growth, size and body composition outcomes. And these will be the same for the next series of slides looking at growth, size and body composition as the outcomes.

The same population of interest for both intervention exposure and outcome in this slide is similar for the previous sets of

questions.

And our key confounders here include key confounders that are similar in the previous slides: sex, race/ethnicity, socioeconomic status, parental education, feeding practices, anthropometry at birth or baseline, and gestational age.

I'll go fairly quickly through these next slides, because really the only difference in the next three slides is the nutrient of interest.

In this case, it's Vitamin D. In the next analytic framework it's Vitamin B12, and in the next framework it's omega-3 fatty acids. In all of those slides, the outcome is the same -- growth, size and body composition.

And finally, the next four slides, all similar to the previous eight, look at a specific nutrient, but now shifting the outcome to bone health.

And I'll pause for a minute to define our outcomes -- our bone health outcomes. Here,

the outcomes include bone mass, bone mineral density, bone mineral content, biomarkers of bone metabolism, rickets and fractures.

And so, what you'll see in the next series of slides, this one shows the specific nutrient of interest is iron. And the next series of slides will show the specific nutrient with the same bone health outcomes and the same key confounders.

So, for example, this next slide shows Vitamin D as the specific nutrient of interest from supplements and/or fortified foods, and the outcome, again, in this slide, is bone health.

In this slide, the specific nutrient of interest is Vitamin D, and the outcomes are the same. Sorry, that was supposed to be Vitamin B12. And the outcomes are the same, the bone health outcomes.

And finally, the specific nutrient of interest in this final slide is omega-3 fatty acids, with the same bone health outcomes as the previous slides.

Our inclusion and exclusion criteria that we propose will be the standard criteria for the criteria, or for the categories shown here on this slide. But in the upcoming slides, I'll illustrate, again, where we are tailoring the inclusion and exclusion criteria for this set of questions.

So, first, the criteria shown here for the intervention/exposures correspond to what was illustrated on all of the analytic frameworks. Specifically, for inclusion criteria, we will include studies that specify the dosage amount and fortification level received of each of the specific nutrients.

We'll also include studies that examine animal products that contained added nutrients as a result of feeding the animal a specialized diet.

Follow-up formula will be considered as a fortified food or beverage. The subcommittee discussed the interest in examining evidence of follow-up formula, but recognized the

lack of an accepted definition, and potential overlap with infant formula.

There are no name or claim requirements for toddler milks, and there's a wide variation and statement of identity for what a follow-on formula is.

For exclusion criteria, studies that do not specify the dosage amount or fortification level received or the specific nutrient, will be excluded, as well as studies that vary nutrients other than the nutrient of interest, without controlling for that variation.

We also propose tailoring, similar to the previous set of analytic frameworks, the age of study participants, for bone health outcomes the age will include only children and adolescents ages two to 12 years.

We also are proposing to tailor the sources of foods, beverages or nutrients. For the sources of these we -- given the age of intervention and exposure, and that it is birth to 24 months, we will consider studies in which

infant formula is examined, as long as it meets the FDA or international standards.

Our next steps are to implement the protocols that we discussed today, eight in total, followed by developing the remaining protocols, which all relate to complementary feeding.

We also plan to meet with the Data Analysis and Food Pattern Modeling, Cross-cutting Working Group, to discuss assessing food group and nutrient intakes among children birth to 24 months.

I want to acknowledge our subcommittee members and the overwhelming amount of work and support that we get from the USDA staff. It's been an incredible amount of work, as Sharon mentioned, developing these protocols, and many more to come.

And it wouldn't be possible without all the help that we get from the staff, so thank you.

VICE CHAIR KLEINMAN: Thank you very

much, Elsie. We're open for questions and comments. This is a new topic and a lot of work has been done by the Birth to 24 Committee working on it before we got to it. But a lot of work continues. Questions? Comments? Rachel?

MEMBER NOVOTNY: Thank you. That was really great to see how much you've broken down the human milk piece. I appreciate that.

I have a question and it's part relating back to our earlier conversations. And I think I understand at least somewhat your rationale for the definitions of complementary feeding and exclusive breastfeeding. But I'm thinking specifically again about water.

And I know that typically we have thought of complementary feeding as beginning to add new foods and often around complexity of nutrients. But also, different types of ways of eating.

And so, I'm thinking again about the definition of complementary foods is to provide nutrients and energy. So, presumably, water is

not a complementary food. And then, the predominant feeding would include water in your definition of exclusive breastfeeding.

So, I guess I would like to be able to pull away the predominant feeding from the exclusive breastfeeding, not necessarily for all analyses, but perhaps for some that have to do with eating patterns around when things besides the breast have been introduced, or the human milk have been introduced.

And then, similarly on the complementary foods, I wonder if we want water as a pattern, or as a food, to be able to be identified.

So, I'm not positive of the answer, but I think it's an inconsistency that will evolve with our other approaches. And I think this first has to hang together as a B24 question.

But I think even as a B24 question, there might be some reasons to be able to pull those things out to keep it together or apart.

MEMBER TAVERAS: But you're right, Rachel, that the definition of complementary foods and beverages does not include water.

And that also is consistent with the World Health Organization definition, that allows water in the definition of predominant breastfeeding and exclusive breast milk feeding.

But is your question about whether -- I don't think your question is whether water should be. It's how water is --

MEMBER NOVOTNY: Whether it could be identified --

MEMBER TAVERAS: It could be identified.

MEMBER NOVOTNY: -- in that setting, so that it could be pulled out. And I think there was a time when we were more strict with exclusive breastfeeding.

And for some of our questions about habits around food and drink, it might be -- useful to be able to pull it apart and similarly with the complementary.

MEMBER TAVERAS: It's a good point I will - it will depend on how much it's being reported. I think it was a good point even in the adult studies, about the lack of studies actually saying how much water is consumed.

And I suspect that we might run into the same issue in the Birth to 24 Month group.

VICE CHAIR KLEINMAN: I mean, I think until the WHO did come up with that broader definition of exclusive breastfeeding, water was not included, nor was anything else.

But then, along came a couple of things. One, recommendations to supplement with Vitamin D and iron in the exclusively breastfed infant, and a struggle to help families understand how you call something exclusive, but yet you supplement.

And then, I think the other consideration is hydration at that age and how you ensure adequate hydration, which can, by and large, be assured through exclusive breastfeeding, but occasionally requires water,

particularly during the first few weeks postpartum, when bilirubin metabolism is an issue.

So, there's nothing very clean about this, and it does pose some challenges to us. And I suppose we -- I mean, we can ask the question whether water intake can be identified. But I don't think we're going to get a clean set of outcomes based on information about water intake.

Juice and other things, that -- and teas, I think that's where you get into predominant. And that makes it even more challenging for us. And I suspect many of us would just as soon consider that complementary feeding.

But in an effort to be consistent with worldwide recommendations and common practices, that's why it's lumped together.

So, I don't think I'm shedding any light on this, but I'm just trying to say why it's more --

MEMBER NOVOTNY: But maybe we can just code whether it's exclusive or predominant if it's identified. And that would give the potential to do an exclusive analysis.

VICE CHAIR KLEINMAN: Yeah. Thank you.

CHAIR SCHNEEMAN: This is Barbara Schneeman. I'm wondering if we also want to ask the staff about pulling out that kind of information.

It sounds like you're coming to the fact that it needs to be data that's collected if it's available --

MEMBER TAVERAS: If it's available.

CHAIR SCHNEEMAN: Yeah. And so, I don't know if the staff wants to comment on that.

MS. GUNGOR: Sure. This is Darcy Gungor. And this definition came about actually during the Pregnancy and Birth to 24 Months project and sort of has been carried over into this one.

And I think there was just an

acknowledgment among experts of that team, and now of this team, that there are sometimes not great definitions and great parameters and descriptions of what is fed to infants.

And so, I think the intention was to sort of capture the spectrum of full breastfeeding, both exclusive and predominant, but we absolutely extract as much data and as many definitions as are provided in every research article, in terms of the feeding exposures.

And so, if there are clear definitions of predominant versus exclusivity in what's fed and when, all of those data are pulled, and we can certainly present it in that way.

CHAIR SCHNEEMAN: And, Darcy, including water? Because I think that was the --

MS. GUNGOR: If it's presented, it would be available for you to look at. Yeah.

(Off-mic comment.)

MEMBER BOUSHEY: Hi. This is Carol Boushey, and that was really -- that was

fantastic. There was so much to go through.

Looking at weeds here, and it really is, in that first grouping, I guess I had thought that there would be something on parent education.

In the second group, parent education is listed in your key confounders, but it isn't in the first group. And so I was curious as to what made these two concepts so different that parent education wouldn't be listed as a confounder?

MEMBER TAVERAS: That's a very good question. I don't --

MEMBER BOUSHEY: Oh, okay. Well good. Take it back to the group.

MEMBER TAVERAS: I'll look to the staff. Was that an omission, maybe?

MS. GUNGOR: Is the question whether there is parent education on the framework for growth, size and body composition?

MEMBER TAVERAS: As a key confounder.

MS. GUNGOR: Yeah, I think that would

be picked up as a part of socioeconomic status, perhaps? I think we tended to --

MEMBER BOUSHEY: Socioeconomic status is in the other group also. That's why it kind of jumped out at me.

MS. GUNGOR: Yeah, that's a great point.

MEMBER BOUSHEY: So --

MS. GUNGOR: I think that the --

MEMBER TAVERAS: Yeah. No, that's a good point.

MS. GUNGOR: -- the distinction, when it was put on sort of down the road for the developmental milestones, I think was to make sure that that specific indicator was there as well. But we can certainly bring that back to the team.

MEMBER BOUSHEY: And then, this is also minor. The race/ethnicity, when that's listed, is that for the parent, or is that for the child?

MEMBER TAVERAS: That's a good

question.

MEMBER BOUSHEY: Because we do -- these are mixed. You know, they're mixed parent and they're mixed child. So, I just wasn't clear.

MS. GUNGOR: It's a good question. I think the intention is to extract it for the infant. But I think if it's presented for the level of the parent, I think we would extract that as well.

MEMBER BOUSHEY: So, I mean, I just -- I mean you can pick what you want. I just want to be clear on that.

MEMBER BAILEY: Elsie, again, great job. Lots of information.

CHAIR SCHNEEMAN: This is Regan Bailey.

MEMBER BAILEY: Sorry, Regan Bailey. Short microphone, tall person. When you have the nutrient status, does that need to be more clear in terms of biomarkers? Are you -- what is status?

MEMBER TAVERAS: So, where we expect to have actual biomarkers, we made note of it. So, I can pull them up, but in several of them, particularly for the bone health outcomes, we included biomarkers.

But I don't think we -- if there were biomarkers for every single outcome. Is that what you're asking, Regan?

MEMBER BAILEY: Yeah, I was just asking for like Vitamin D status. Is that serum 25 hydroxy D? Is that dietary intakes?

MEMBER TAVERAS: Yeah. So here we didn't include the exact biomarker. But yes, where available, we plan to include biomarker status as well, as our for-short status, essentially.

CHAIR SCHNEEMAN: I guess just to follow up on that question, because I was curious about the same thing, because there's a difference in looking at intake versus looking at status from a clinical biomarker.

So, is the aim to look at a

biochemical or clinical status marker?

MEMBER TAVERAS: Yes, if it's available.

CHAIR SCHNEEMAN: Oh, okay. And then, I know you also had fatty acid status. And so, I was interested in knowing what do you think would be included in that?

MEMBER TAVERAS: So, that's a good question, because we didn't have a list for the fatty acid outcomes there.

MS. ENGLISH: Yeah. This is --

MEMBER TAVERAS: And biomarkers.

MS. ENGLISH: Yeah. This is Laurel English. I just wanted to add on there that we do have some more specific examples included in the inclusion/exclusion criteria that's posted online in the protocols.

But as a typical standard approach, we extract anything that is reported. So, for the example of fatty acid status, we would certainly extract omega-3s, omega-6, omega-9. I think the subcommittee discussed red blood cell membrane.

So, if it's reported, we will certainly extract it and it would be available for the evidence that this is.

MEMBER DONOVAN: Yeah, this is Sharon Donovan. I recall the same conversation, because these are all so zero to two years of age. So, a lot of the standard markers that we might expect in adults may not be available.

So, I think the idea was whatever in the paper that they're reporting as their iron status marker, and then we'll basically pull it all. And then, in the analysis phase we'll need to go through that.

But it also talks about like some of the bone markers may not necessarily be validated in this age. So, you know, we -- the issue with this whole area is that the amount of evidence may not be very deep.

So, we're trying to cast the net widely, at least at this point, in terms of -- but this is really -- status, we were thinking primarily biomarkers, because we're going to be

collecting the intake, and then we're looking at the effect on whatever the health outcome is.

MEMBER NOVOTNY: Can I just ask a question. And I feel kind of stupid because I'm on the committee, but I can't remember the conversation around when we looked at specific, like omega-3 fatty acids in growth, size and body composition, when we looked at human milk feeding, we looked longer than just B24.

But for all of the specific nutrients on growth, size and body composition, we were only talking about birth to 24 months. For bone, we're going farther.

But I'm just thinking that some of the aspects on growth may not play out yet in the first two years. So, I think the committee should maybe reconsider for just mainly for those -- the bone and the growth for growing longer.

MEMBER TAVERAS: No, I agree. For bone and growth for sure.

MEMBER DONOVAN: For bone it's already

through 18. But for some reason, for the -- it's there for the human milk but not for the specific nutrients on growth and size and body composition.

VICE CHAIR KLEINMAN: Linda.

MEMBER VAN HORN: Just quickly. First of all, adding my compliments and accolades to the work that's been done, two quick things. One relates to, I'm so happy to see inclusion of mode of delivery.

I think as we're looking at a rapidly escalating interest in the microbiome and understanding the differences, in terms of C-section versus vaginal delivery as it affects the microbiome, it's of interest to consider that aspect, not only -- I think I saw it in one slide, but I didn't see it in the others.

And of course, only if it's available. And it may be or may not. So, that was one comment. The other, in the interest of both Vitamin D and also bone health, I was surprised that there was no mention of dietary calcium or

sources of calcium.

And my concern is related to the large number of moms who really don't understand the difference between dairy milk and plant-based milks, and how different those can be in terms of source and bioavailability of dietary calcium.

So, I just, again, it may not be available. But again, with the end in mind, it would be --

MEMBER TAVERAS: Right, good to include it.

MEMBER VAN HORN: -- good to consider it. Yeah.

MEMBER TAVERAS: No, that's a good point.

VICE CHAIR KLEINMAN: Rachel?

MEMBER NOVOTNY: Rachel Novotny. Just wondered about the rationale for the very high development countries. I assume it's more and longer human milk feeding. But wonder if you had anything more to say?

MEMBER TAVERAS: The very high what?

Sorry?

MEMBER NOVOTNY: Human development level of inclusion criteria of your population.

MEMBER TAVERAS: So, it's partly to be consistent with the existing reviews. Is that right?

VICE CHAIR KLEINMAN: Yeah, it was meant to be representative of the US population, rather than globally.

MEMBER NOVOTNY: Okay. I thought it went one level down.

VICE CHAIR KLEINMAN: It's very high and high.

MEMBER NOVOTNY: And most of the rest are just high, are they not?

VICE CHAIR KLEINMAN: No, they're both.

MEMBER NOVOTNY: Oh, they're both. Okay.

MEMBER TAVERAS: The very high and high is one of the general standard criteria, and was what was used for the existing reviews.

MEMBER BOUSHEY: I have just one other little small thing. Carol Boushey. And thanks for bringing up calcium. That's where I was going next, but I won't say that now. But what I will share is that having the older ages for the bone is a great idea.

But in the analytical framework, those higher ages aren't included. So, you want to make sure those get in there.

MEMBER TAVERAS: Thank you for pointing that out.

VICE CHAIR KLEINMAN: All right, I think that we've exhausted that topic, for the moment anyway. So, turn it over to you, Barbara.

CHAIR SCHNEEMAN: Right. So, we're actually -- if you advance the slides, we're scheduled to have a break at 2:30 that hopefully no one will object if we give you all ten extra minutes.

We do try to hold to the time schedule as much as possible because we know that people are watching online and various other ways. So,

why don't we break now. And then we'll expect you back at 2:45.

(Whereupon, the above-entitled matter went off the record at 2:21 p.m. and resumed at 2:47 p.m.)

CHAIR SCHNEEMAN: I will, once again, remind the Committee members, please make every effort to say your name and speak as directly into the microphone as you possibly can. So, it helps both with the transcription as well as people hearing who are participating either online or in the room. So, that would be great.

So, we are ready for our next two subcommittee presentations. And so our next one is the beverage -- beverages and added sugars subcommittee and Rick, I believe you are going to do the presentation for that.

MEMBER MATTES: Right. Thank you.

CHAIR SCHNEEMAN: Microphone.

MEMBER MATTES: Okay. Yep, got the mic on. Okay, so here's the list of Committee members and, as you can see, that Beth is

actually the subcommittee chair, but since she is not here I'm sitting in for her.

I think if we were to run this presentation through iThenticate, relative to what's already been done, we would be expelled for plagiarism.

(Laughter.)

MEMBER MATTES: We've already covered much of this, but we will go through it, just so it is on record and clear.

CHAIR SCHNEEMAN: But this is government, so ---

MEMBER MATTES: Right. Right, right. Okay, so, our questions fall into three primary topic areas. And the first is the role of non-alcoholic beverages and consumption on a number of different outcomes, including, anthropometric measures and each of those is assessed across the life span, but also, the role of non-alcoholic beverages during pregnancy and effects on birth weight, standardized for gestational age and sex, as well as gestational weight gain. And then,

the third question under this topic area concerns non-alcoholic beverage consumption during lactation and its effects on postpartum weight loss and still --- still, oh, there we go, sorry about that. And human milk composition and quantity.

So the subcommittee has worked through the first four of these -- they are the ones highlighted with the asterisk. The one that we haven't gotten to yet is human milk composition and quantity.

The second topic area is added sugars and is largely parallel to the way we have handled the beverages question -- some small differences in terms of the general population. We've added questions related to risk for cardiovascular disease and type 2 diabetes and for the analysis concerning pregnancy. We have taken out birth weight but retained gestational weight gain. And then for lactation, the impact on milk composition and quantity is removed, but postpartum weight loss is retained.

Alcohol will be the third main area and again, we haven't gotten there yet and the questions there are defined here, but since we haven't gotten to them, I won't belabor those.

Whoops, sorry about that.

So, the four questions that we will present in a little bit more detail are listed here. The way we will be approaching them is through the NESR systematic reviews.

We do have a couple of definitions that are probably worth specifying. We are using the same definition of beverage pattern, but I do want to, kind of, emphasize the orientation here, because pattern can evoke many different concepts, it can be circadian, infradian, seasonal, cultural, nutrient and so on. And different subcommittees are indeed, picking up on them in different facets, so the frequency of eating group will be looking more at temporal patterns, the dietary pattern group will be looking more at sources.

So our focus here really is primarily

on quantity, on portion size, and as Regan pointed out first thing this morning, we will definitely have to work across subcommittees to integrate all of this as we go forward.

Our definition of gestational weight gain is drawn from the CDC and is pretty straightforward -- women -- the weight women gain during pregnancy and the IOM 2009 definition is used for post-partum weight retention. It is the amount of weight that remains -- interesting choice of words -- during the post-partum period, minus the woman's pre-pregnancy weight.

Okay. We are the beverage group, so it's incumbent on us to define beverages in a bit more detail than some of the other groups have ventured into. And we have defined ten discrete -- no, I shouldn't say that -- we have defined ten categories. They are not as discrete as one might hope, but, so one large cluster is milk or dairy products, and as you can see on the slide, so under milk there are gradations based on fat content, under flavored milks there is flavor

added, but it is also still gradations of fat content. And then there is dairy drinks and substitutes. A lot of these plant-based milk-like beverages, milk shakes and that sort of thing.

And then we get to the non-alcoholic beverage sources and one category there are hundred percent juices and they can either be fruit or vegetable.

For diet beverages, I want to take a little bit of an opportunity -- or a side track here -- it includes low calorie, sweetened. Now it says here, high intensity sweetened. We've talked about thinking of our questions in the context of the population and communicating messages and so on. I would like to put in a statement that we consider -- rather than calling them high intensity sweeteners, we have an opportunity here to try to standardize language in this field. High intensity, I would argue, is really not the right word because nothing is sweeter than nine percent sucrose. These things

aren't sweeter than plain old sugar. It is just you can get to that level of sweetness at a much lower concentration. So it really isn't an appropriate term. They aren't artificial because stevia is not artificial. We could call them high potency but that sort of medical-izes it and I don't think that's desirable. They are not non-caloric because aspartame is caloric.

So, I would argue that we adopt the terminology of low calorie sweetener. It probably conveys most clearly to consumers what the primary goal of their use may be and it's as fitting a description as I think we are going to come up.

So, we do include beverages with low calorie sweeteners in them, but also in that category are beverages that have just been diluted with water.

And then, obviously a very big issue amongst consumers is sweetened beverages. And there we have soft drinks, fruit drinks, sports beverages and then other items that -- specialty

teas and coffees, smoothies and so on.

Nutritional beverages would include meal replacement products, smoothies that have a specific, intentional nutrient content, protein shakes, and then other -- what we are calling functional drinks -- beverages that somebody believes contains something that has some special physiological impact. Right?

And then we have, clearly, coffee and tea that can be either sweetened or unsweetened.

Plain water, which could be subdivided by tap or bottle and then flavor, or enhanced water, so, with gas in it or some flavoring.

Relevant to the discussion we've been having about water -- do we include it, do we not include it -- let me, also, just take this opportunity to just point out that any beverage is almost entirely water. All right. On a weight basis there is no beverage that isn't mostly water. And it is really just a gradation. So if we consider water sort of the vehicle or the most elemental of things that we drink, we

can add a little odor to it, or we can add a little gas to it and I don't know to what degree you think that fundamentally changes it. We can add a low calorie sweetener to it -- to what degree does that change it? We can add an actual sweetener to it, or some fat to it, or some protein to it. We can make it more or less viscous as we go on. It is just a continuum -- and we have to decide where we want to draw the line in that continuum, and it may be this is one of those issues we identify and say, next, dietary guidelines committee -- think about it.

(Laughter.)

MEMBER MATTES: Okay. Then -- so this is our first analytical framework and it has to do with growth, size, body composition, risk of overweight and obesity. And we have taken those ten beverage categories and put them in the first box as our intervention exposure and the comparator will be the consumption of any one of those relative to a different type of beverage, a different amount of that same beverage, compared

to a beverage with different nutrient content, a different sensory property or a different physical form -- so gradation in viscosity, for example. There are quite a few studies out there comparing beverages to a solid food even within the same -- so a juice compared to a whole fruit, or a vegetable compared to a blended vegetable -- and so on.

And I think it is important to have these distinctions because it does, in fact, allow us to compare across categories to see to what degree is it -- is whatever health outcome we are measuring, really due to the fact of delivery system -- it's a beverage -- relative to what property it also conveys. Is it just a delivery system for nutrients -- and is the nutrients, is it the sensory thing -- is it really something special about sweetened beverages that has a health impact, or is it just something about the vehicle that changes how we react to sweetness?

So by having broken this down as

discretely as we have, we can, I think, get much deeper into the question of where the actual impact lies -- where the mechanism lies.

So our outcomes on this one are the same as a number of other groups have identified the anthropometric sorts of indices, which primarily fall into various measures of adiposity. Our key confounders are sex, age, race, ethnicity, sociodemographic status, total energy intake and anthropometric measurements pre-period of time that we are studying so that we can see what effect of a change of beverage consumption may have had.

One thing we don't have in here, and I noticed nobody else, sort of, raised questions about what their subcommittee included or didn't include, but I want to throw it out so that --- it sort of dawned on me that we didn't include customary beverage intake on this one. We do on some others, and again, if we want to look at what effect a change in beverage intake has had we may want to include that so we -- as we talk

about it -- I think we ought to consider that.

The second analytical framework focuses on birth weight. We have the same exposures and comparators. The difference here is in the outcome. So obviously we are looking at birth weight and relative to age, length, gestational age and sex. And in this framework the intervention is on the woman -- on the mother --- and the outcome is on the infant. So it is a distinction here that is different from the other analyses that we have undertaken.

The third analytical framework is gestational weight gain. Again, the same intervention, same comparator, the outcomes, though are gestational weight gain and weight gain in relation to recommendations based on pre-pregnancy and BMI.

The primary population here is the woman -- the pregnant woman -- and the key confounders are maternal age, race, ethnicity, socioeconomic status, pre-pregnancy beverage intake, pre-pregnancy BMI, smoking. And once

again, we have gestational diabetes in several of the other analytical frameworks, but we didn't include it in this one. It seems to me relevant if we are looking at gestational weight gain. So we may want to consider that during the discussion period, as well.

Our final analytical framework is on postpartum weight loss -- same intervention, same comparator. The outcomes here though are change in weight from baseline to some later time point during the postpartum period and post-partum weight retention if gestational weight gain is controlled.

The key confounders are maternal age, race, ethnicity, socioeconomic status, pre-pregnancy beverage intake, pre-pregnancy BMI, gestational weight gain is used here, smoking, and breast feeding status. And the one that we don't have here, again, is gestational diabetes that may be relevant that we can discuss momentarily.

In terms of inclusion and exclusion

criteria, we are using the same standard criteria that have been described multiple times before. For the upper part we have tailored a few of them. We are setting a date going forward for which papers to include of January 2000 and it will go through the end of June 2019.

In terms of study duration, we decided that we should set a minimum of eight weeks. The rationale being that a lot of our outcomes are weight-related and it just takes time to measure a change in body weight that is something other than a transient shift in fluid balance. And even eight weeks is probably truly a minimum, but we were afraid of losing too many papers if we went too much further than that.

In terms of inclusion and exclusion, in terms of study participants, the inclusion criteria, as I mentioned, we will be looking over the lifespan so those categories are defined on this slide. And I think are consistent with some of the other groups, though, I guess not all.

And, by definition the complement is

we will not be looking at beverage consumption in infants and toddlers.

In terms of birth weight we will only be looking at humans, excluding animal trials.

And gestational weight gain we will be looking at females who are pregnant, capable of becoming pregnant, and then their offspring.

And consistent, I think with the exclusion criteria that Sharon outlined for their subcommittee, we will be excluding protocols that don't uniquely identify outcomes for single versus multiple pregnancies. And for women who are in hospitals for reasons other than their pregnancy.

And then for postpartum weight loss we have added postpartum women who are lactating as inclusion criteria and obviously, those that aren't will be excluded.

And finally for inclusion and exclusion, with regard to health status, we will be including studies that enrolled participants who are healthy in the general population, and

people who may have a health condition but aren't targeted because of their health condition, to be included in the trial. We will be excluding studies that exclusively enroll participants who are -- including individuals with obesity as the target group.

In terms of postpartum weight loss, what we are including that is a variation on the theme, are studies that enroll mothers with infants born full term and studies that enroll some mothers with infants who are born full term, but may also have low birth weight, or low -- small for gestational age -- offspring. And for this one we actually will exclude studies that exclusively enroll pre-term infants, but also studies that exclusively enroll mothers with obesity, which is a difference from the other analytical models.

Next steps will be to finish our analysis in the general population focusing on human milk composition and quantity -- whoops, sorry --- so the last question in that category.

Then we will move on to the added sugars category and you can see listed there the different outcomes we'll be focusing on and then finally alcohol.

And we do want to thank the staff's outstanding job in keeping us on track and providing us with the information we needed to give our advice. So, I will stop there.

CHAIR SCHNEEMAN: So, we can --this is Barbara -- we can take some questions or comments or I think you threw out a few things that sounds like you would like input on. And particularly from, I think the B through 24 and the pregnancy and lactation groups.

MEMBER DONOVAN: For the questions that you had about -- this is Sharon Donovan -- the gestational diabetes. I think it might make sense to add that to your confounders. And I understand the question with postpartum weight retention is, you know, what is the impact of beverage intake during lactation and postpartum weight loss? But to me, it would be

interesting, just beverage intake postpartum and I understand it is a different question, but I think that women who aren't breast feeding might choose to start to drink more alcohol, for example, or make different dietary choices.

So, but I understand we were given the questions to address, but you will have studies, I think, that have non-lactating women in them.

MEMBER MATTES: Yes, that is a good point. I wouldn't be surprised if, in some of those papers they are the comparison group. So, we might be able to pick up some of that information.

MEMBER NOVOTNY: Rachel Novotny. Yes, on the gestational diabetes. I think, though, the question may be a bit of harmonization amongst our groups. I think we were taking this -- correct me if I'm wrong -- approach, a very minimalist approach, of things that would exclude studies from, you know, from their ranking. So maybe we need another box for some things that we want to consider in analysis, but that maybe

wouldn't necessarily ding the study. And I am not sure where that is a must-include.

MEMBER MATTES: Actually, could I ask the staff -- because when we were working on these models, there was a third box, for a while and it kind of disappeared. Can you comment on that?

DR. KINGSHIPP: Sure. This is Brittany Kingshipp. So we do have a supplemental document -- it is not part of the formal analytic frameworks that you have shown -- that we have a list of additional Covariates that will be considered. So for instance if a study presents information on -- for instance, gestational diabetes, like you all were talking about --- we would pull that information and present it to you, but it wouldn't be considered in the list of key confounders -- the confounders that actually are considered in the risk of bias when we are assessing these studies. And so, it is just a, just kind of a tier down from those lists that are on the analytic framework, but something that

we would still be considering.

MEMBER ARD: Jamy Ard. So, to continue on that point, I think it might be useful to --when there are similar outcomes or populations, we might want to really sort of compare -- which confounders do we really believe are key? So, for example, like I've looked at parity. Parity is included for pregnancy- and lactation-related outcomes, but not frequency of eating in sugar sweetened beverage when it comes to gestational weight gain. And so, I would want to say, okay, if we are going to say it is key for gestational weight gain in this one particular question, do we have a rationale for not including it in others, or should it be, when it comes to gestational weight gain, parity is something that we are going to consider across all of the particular questions?

So it might be good for us to just have a grid or something that we can share across committees to make sure that we are at least consistent in our rationale. And it's, right

now, it feels sort of haphazard, like, oh yes, I thought about this one. What about it? But we could probably harmonize that a little bit.

CHAIR SCHNEEMAN: Yes, this is Barbara Schneeman. And Jamy, I think that is a good point. Certainly one of the points here is making sure we all know what is going on with each of the subcommittees and looking for exactly those kind of items. So, it is probably a bit of homework to make sure if something is relevant in one area, we're consistent across. It's a very good point. Tim?

MEMBER NAIMI: Tim Naimi. I don't know if it was in our other box, but physical activity is another key covariant in most --- physical activity is a key covariant, key confounder, for a lot of the other groups and I'm not sure if it was in our other box that disappeared or whether it is just an omission. I don't know if anyone remembers.

MEMBER MATTES: I will let Brittany give the real answer, but I'm pretty sure it is

in the other box.

DR. KINGSHIPP: Yes, you are correct.

MEMBER MATTES: We decided that it wouldn't be in a lot of the papers, and so if we put it as a key confounder we would be downgrading a lot of relevant papers. But I think it is ---

DR. KINGSHIPP: That is correct, yes.

MEMBER MATTES: -- yep.

CHAIR SCHNEEMAN: And going forward it's probably important to make sure we have those other boxes visible as part of the protocols, as well. So, Heidi?

MEMBER LEIDY: Same type of thing, but I think the grid will really help. But I was thinking that, you know, with our sugar sweetened -- or the beverages one, we also have the criteria for the eight weeks, for when looking at changes in obesity-related outcomes. But I don't think that we have it in the eating frequency -- and there may not be in the other ones. So I think having a grid like that and then having a

discussions in terms of what we should standardize I think would be great. And that is just another one that came to mind.

CHAIR SCHNEEMAN: So, Eve, I'm going to -- hopefully that is something that we can work with staff to put together going forward. Great. Eve is nodding her head yes, for the record.

MEMBER SABATE: Joan Sabate. As far as the analytical frame -- as far as the analytical framework between the beverages and the growth size, body composition and risk of overweight and obesity, one of the key confounders is total energy intake. This is, I assume, total energy intake for the whole diet. And then, if that is the case, I mean, how are we going to distinguish between the beverages that carry energy versus the ones that they do not? And how are we going to, you know, do this, as far as you want to answer the question, if carrying energy into the beverages versus not, has an impact on the outcomes of interest regardless of the other

components of the diet?

MEMBER MATTES: Yeah, we definitely spent some time talking about this. The issue is I don't think there are a lot of papers that will differentiate the beverage contribution to total daily energy intake. But we're looking at primarily intervention kinds of studies. What we will see is: to what degree did the addition or subtraction of a particular beverage have an impact on the health outcome?

So we want to know what the energy intake was prior to the intervention to be able to determine what impact the change in beverage consumption had. That was the rationale for putting it in there.

If we had data on beverage energy intake prior to the intervention, that would be wonderful. But I don't think it's reported very often.

MEMBER SABATE: Would you be able to answer the question if energy beverages versus beverages that has no calories, I mean, has an

impact on the outcomes of interest?

MEMBER MATTES: If what happens -- if the mechanism of, say, weight gain with beverage consumption is due to lack of compensation for that energy, then it would be essential to know the pre-energy intake to be able to assess that.

MEMBER SABATE: Yes. But what about during the intervention? That's one thing.

And the second thing is: are you going also to consider study designs other than intervention studies?

MEMBER NAIMI: I think they're primarily intervention studies in our bailiwick.

They're actually in your slides, the kinds of studies we're going to.

CHAIR SCHNEEMAN: Right. So yes, the inclusion criteria for the studies is the same as for all of the -- that's the standard protocol. So if you just go back to --

MEMBER SABATE: So once you took the studies, particular studies, how are you going to --

CHAIR SCHNEEMAN: Right, it's just the quality of the evidence varies by the type of --

MEMBER SABATE: Correct.

CHAIR SCHNEEMAN: -- study. So we're not pulling out something as only looking at one type of study here. It's the same inclusion criteria.

MEMBER SABATE: But if the adjustment is just for the total energy intake, then you will not be able to see the difference between one versus the other. Because, I mean, you don't take into consideration the energy that is carried on the beverage.

MEMBER MATTES: If it's an intervention study where the intervention is a manipulation of the beverage, then we need a baseline to be able to determine what that change in beverage -- what impact that change in beverage intake had.

So that -- maybe I'm missing your point, but it seems to me we need that information in order to draw a conclusion about

the role of the beverage.

MEMBER SABATE: Yes. But on an epidemiological study, for instance, I mean if you adjust for the total energy intake, the energy of the beverage is included in the adjustment.

MEMBER NAIMI: Well, I think you're -- are you alluding to the fact that I think you're thinking primarily of intervention studies --

MEMBER SABATE: That's correct.

MEMBER NAIMI: -- in which case you'd like to know the baseline.

But I think you're thinking of something which I was concerned about, which is if you're looking at an epidemiological study, you would actually like to be able to control for the non-beverage calorie intake of the person, you know, over the study period to isolate out the effect of the beverage as opposed to all of the -- so I think it depends on the study design.

MEMBER SABATE: Correct. Yes.

MEMBER MATTES: I think for this

committee, it's drawing primarily from clinical intervention. So I think the point I've been making is relevant, but to the point of epidemiological trials, I actually think that your group is more likely to answer that question.

(Laughter.)

MEMBER BAILEY: Can't put this one on me, Mattes.

So we'll have the nationally representative survey data that we can look at the contribution that beverages make towards total energy intake. But we don't have beverage intake in some sort of exposure controlling for energy intake.

So, we will have prevalence estimates, and means, and distributions, and contributions, but not necessarily controlling for it, the words you're saying, yeah.

MEMBER MATTES: So it's the complement of studies that will give us the answer I think. Yeah.

MEMBER SABATE: No, but one thing is a descriptive of what the American population is doing. Another thing is in a longitudinal study, not an intervention, a short intervention. And to answer the question, the consumption of a non-calorie beverage versus one calorie beverage has an effect on obesity, I mean this is a very valid question that is within I think the scope of this committee.

CHAIR SCHNEEMAN: So Carol, did you want to say something?

So I -- yeah, okay.

MEMBER BAZZANO: This is Lydia Bazzano. I was just going to point out that, you know, in most nutritional epidemiology and with the longitudinal designs, we take into account total energy intake. And it's just that if there is measurement error around that, I don't necessarily know if you could pluck out the part of the beverage specifically in order to get that information.

But you can look at whether the

beverage as a whole seems to contribute to the outcome.

CHAIR SCHNEEMAN: So Dr. Sabate, my understanding is you're -- are you trying to make sure that we account for beverages that have calories and beverages that don't have calories? Is that part of what you want to make sure we want to account for?

MEMBER SABATE: I wasn't aware that the subcommittee was only looking or majorly looking at the interventional studies. I think there is some part of the literature that is trying to also look at these from a longitudinal perspective.

So put in simple terms, if somebody has zero energy coming from the beverages that this person consumed versus another individual has 50 percent of their daily calories coming from beverages, if we adjust for total energy intake while making the two beverages equal, therefore is not going to be any effect, just by mathematical definition.

So what I'm saying is one thing is to adjust for the diet other than beverage, and another thing is to take away the effect of the energy in the beverage that may have on the outcome. I don't know. Probably Timothy can explain it better.

MEMBER MATTES: Well, if you take the example of somebody who took 100 percent of their calories from sugared soda, let's say, and then you control for their total energy intake, you will over-control. You will basically -- so the more that, the more that somebody's total calories come from beverages, and then you control for total energy, or over-controlling and you're basically controlling away the -- you're trying to isolate the effect of a beverage, so you would like to control for energy intake from things other than that beverage, or at least other than beverages to distill out that in a longitudinal or epidemiological study as opposed to a intervention study.

CHAIR SCHNEEMAN: So it sounds like

this is a factor that will come into play when we're looking at the observational data.

MEMBER BOUSHEY: So if you do find some longitudinal studies that address this, then you can or you will only limit it to interventions.

MEMBER MATTES: I understand your point. It's well taken. I'm not sure that we have included longitudinal studies in the array of terms that we are going to be looking at.

So if that's something we should change, that's something we should change.

DR. KINGSHIPP: Rick, can I clarify?

MEMBER MATTES: Yeah, please.

DR. KINGSHIPP: Just from the staff perspective. And so it is correct that the slides that Dr. Schneeman presented earlier, the standard criteria, are being used for these beverage consumption questions. So we will be including any prospective/retrospective cohort trials. So in that case we might have observational longitudinal data.

It is true that we are also including experimental studies, RCTs, that sort of thing. So I mean we haven't got into them yet, so we don't yet know what the proportions and breakdown will be, but both types of study designs will be included.

MEMBER NAIMI: Okay. Good. Thank you.

And just to make a general point, I mean of course intervention studies are good because they can be well, carefully controlled. But they're good for determining short-term effects.

And as you mentioned, Rick, the ability to look at an impact on something like weight, you know, oftentimes a longitudinal study which can go over years or even decades may be more relevant.

So I expect we'll have both kinds of studies to look at, but I don't know. We'll see.

CHAIR SCHNEEMAN: So, I think we have Dr. Sabate's comments about what's needed in terms of the observational data. Okay? Great.

Thank you.

So we have one more subcommittee to go through. So I want to be sure we have time to do that. So that is the Dietary Fats and Seafood, and Dr. Snetselaar.

MEMBER SNETSELAAR: Thank you.

My subcommittee on Dietary Fats and Seafood, I have Regan Bailey, Joan Sabate, and Linda Van Horn. So thank you so much for being a part of the committee. Also Barbara Schneeman was the Advisory Committee chair rep.

So for our particular subcommittee, we have two topics areas: dietary fats, and seafood. And there were three seafood questions, specifically on seafood intake during pregnancy and lactation, and childhood and neurocognitive and cardiovascular outcomes.

And then our second topic on dietary fats included all-cause mortality, cancer, cardiovascular disease, and neurocognitive development and health.

And I am including here some key

acronyms so that just as I'm going through the slides these will be familiar.

You've heard them probably already today: N-3, N-6, PUFAs, MUFAs, EPA, DHA, CVD, and methylmercury.

And these are our seafood questions. I'm not going to read through them in detail because I will be showing you the analytic framework for each one. The systematic review protocols that our subcommittee will develop will answer these three questions on seafood consumption and health.

We began with a definition of seafood that was taken from the 2015-2020 Dietary Guidelines for Americans, definitions for seafood. And that definition includes marine animals and -- okay, one more. There we go.

So seafood is defined as marine animals that live in the sea and in freshwater lakes and rivers. And it includes, for example, salmon, tuna, trout and tilapia. And the shellfish examples would be shrimp, crab, and

oysters.

And then we are also going to be looking at seafood in terms of the characteristics. And as you see here, type, source is very important; the amount and frequency of intake; and then the timing of exposure.

And this is our first analytic framework, our first question. And that is: what is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development of the infant?

And I'm going to be going through separate elements within this analytic framework in the next few minutes.

So this first slide is focusing on the box that includes intervention and exposure versus comparators. And we will be looking at seafood consumption as it was defined earlier. And the seafood consumption will examine studies that look at types, sources, amounts of seafood consumed, or different frequency and timing of

seafood consumption.

And then here highlighted are populations that we are considering. They include looking at infants, toddlers, children, and adolescents, birth to 18 years.

And the measures of neurocognitive development will be very consistent with those addressed by other subcommittees. So, once again we're trying to be very consistent in the work that we're doing with this particular subcommittee so that across the board our subcommittees are focusing on those same characteristics for neurocognitive development.

Okay, moving on to key confounders. We are paying particularly close attention to sources of confounding that will include child age, sex, birth weight, gestational age, maternal age, race, ethnicity, SES, anthropometrics, parity, smoking, dietary patterns.

And components of the maternal diet will include alcohol intake, dietary supplements, particularly n-3 polyunsaturated fatty acids and

iron. And then we'll also be looking at non-fish dietary exposure to n-3 polyunsaturated fat.

We're looking at parental education, family history of neurocognitive disorders. And we will be looking at key confounders that include ADD, ADHD, anxiety, ASD and depression.

And then additionally we will be looking at key covariates. And these are likely to impact the relationship between seafood consumption and health. And they include key nutrients. For example, n-3 PUFAs, selenium, environmental chemicals, mercury, PCBs for example, and then blood or human milk biomarkers of seafood intake, and infant feeding mode.

And then our second question will focus on seafood consumption during childhood and neurocognitive development. And the intervention, exposure, and comparator here is similar to the previous question.

And once again the boxes in red include our population. We are going to be focusing on seafood consumption from birth to 18

years of age, with neurocognitive endpoint outcomes assessed from age 2 years and older throughout adulthood.

And outcomes which reflect both neurocognitive development and neurocognitive health will also be considered, as you see here on this particular slide.

And then, again, key confounders and key covariates are similar to our previous question. However, infant feeding mode will be considered as a potential source of confounding rather than a key covariate.

And then our final seafood question focuses on seafood consumption during childhood and risk of cardiovascular disease. And intervention, exposure, and comparators are the same as in our previous analytic framework. Cardiovascular disease outcomes to be examined near those across the rest of the project.

And once again we have here population. Our focus here will be on seafood consumption during childhood. We'll be assessing

intermediate outcomes in children, adolescents, adults, and older adults, and then endpoint outcomes in adults and older adults as well.

And then key confounders and covariates, we'll consider the relationship between seafood intake during childhood and cardiovascular disease. This is going to be similar to those I identified earlier, but it will include family history of cardiovascular disease.

And then very importantly, we will be looking at inclusion/exclusion criteria. And the inclusion/exclusion criteria for seafood questions are consistent with the standard criteria as you've already seen in terms of the committees' systematic reviews. As you can see, we are including study design, publication status, date of publication, language of publication, country, and health status of participants.

And more specifically here in terms of our subcommittee's role, there will be studies

that measure seafood consumption. Again, it is important to keep in mind that there will be some exclusions. So fish oil or n-3 PUFA, supplement studies, and studies that only examine biomarkers of seafood intake will not be included. And this would include studies that evaluate infant formulas with added DHA and EPA.

And now moving on to our dietary fats questions, this is our second topic. The focus on dietary fat consumption will be at each stage of life. We'll be looking at neurocognitive development and health, and risk of cardiovascular disease, cancer, and all-cause mortality.

Some key definitions. Saturated, monounsaturated, polyunsaturated fat types will be looked at. We'll be looking at omega-3 polyunsaturated fatty acids, EPA and DHA, and then omega-6 polyunsaturated fatty acids and cholesterol.

You might note here that we have not included trans fats. And one of the reasons for

that is that some work was done to look at intake since 2012. And intake was at about 1.5 grams per day. And trans fats are also not included in federal food and nutrient databases, and they've been not used in a lot of studies. So that's one of the reasons you do not see trans fats in that list.

In key definitions, we feel -- and certainly this is borne out in the literature -- that sources of fat are very important as we talk about dietary fats. So dairy, eggs, meat, and plant sources will be important.

We'll be looking at amounts of specific types of fat and proportions where we're looking at ratios. And then replacement, where saturated fat may indeed be replaced with polyunsaturated fat, and then also carbohydrate and protein replacement in terms of saturated fat.

It's important I think here to note that our committee was not tasked with looking at overall amounts of dietary fat. And so we will

rather be focusing specifically on types of fat and certainly amounts of types of fat.

And so the first question that we are looking at is the relationship between types of dietary fat and neurocognitive development and neurocognitive health. And this analytic framework reflects our definition of types of fat that will be used across the dietary fat questions. The neurocognitive endpoint outcomes are consistent with previously presented analytic frameworks on this particular outcome.

And then again, looking at those red squares where we're identifying our population. We will be evaluating studies conducted in infants, toddlers, children, adolescents, adults, and older adults.

Key confounders will include sex, age, race, ethnicity, socioeconomic status, BMI, smoking, outcome. And age-specific key confounders will include neurocognitive development, birth to 18 years, parental education, neurocognitive health, 19-plus years,

education, ADD, ADHD, anxiety, ASD, depression, Alzheimer's, a family history of neurocognitive disorders. And we'll also be looking at mercury in fat that originates from seafoods. And that will be considered as a key covariate for this particular question.

And then all-cause mortality, the relationship of dietary fat to all-cause mortality at each stage of life. The intervention, exposure and comparators are the same as previously described for dietary fat analytic frameworks. And all-cause mortality outcome has already been described with several of the other presentations. And we will be examining studies conducted in subjects 2 years and older.

And then key confounders are similar to those considered previously: total energy and alcohol intake, physical activity and anthropometry, a family history of CVD, cancer, and diabetes.

Covariates will be considered also to

include carbohydrate and protein intake, and other types of dietary fats and BMI.

And then the next question involves cancer. And here, in terms of the analytic framework, we're describing examining the consumption of dietary fats and risk of certain types of cancer. And so you see the different types of cancer on this particular slide. Intervention, exposure, and comparators are basically what we've previously described.

And just important to keep in mind that we did add liver to our list of types of dietary cancer since we have been seeing that in the literature recently.

And then our population. We will be evaluating studies that assess dietary fat in subjects at each stage of life. And outcomes will be assessed in subjects 2 years and older.

And then looking at types of cancer, again one of the things to keep in mind is that we will consider menopausal status as a moderator. And key confounders listed on this

slide are similar to previous analytic frameworks, except that there's the inclusion of family history of cancer outcome, a variety of cancer-specific confounders that include hormonal contraceptive use, the age of menopause for breast and endometrial cancer, IBD for colon and rectal cancer, lung disease and exposure to lung carcinogens for lung cancer, and then viral liver infection for liver cancer.

And then our final analytic framework addresses the relationship between types of dietary fat consumption and risk of cardiovascular disease. The intervention exposure comparators, the target populations and the outcomes are consistent with what I've described previously in terms of our analytic framework.

And then key covariates. They are similar to previous analytic frameworks presented, except for the inclusion of family history of CVD or diabetes, and the exclusion of anthropometry which was considered to be a key

covariate.

And then additional key covariates include carbohydrate and protein intake, other types of dietary fats, baseline CVD risk category which might be high, moderate, and low, and duration of intensity of the intervention, and n-3 polyunsaturated fat supplement use.

And then as you see here, our inclusion/exclusion criteria is consistent with standard criteria across the subcommittees. I think it's important to note here for our specific subcommittee that studies that do not assess the consumption of types of dietary fat, so that might be studies that only include biomarkers or that only assess total fat intake, our overall macronutrient consumption will be excluded.

And then next steps. The literature database searches and screening for seafood and neurocognitive outcome questions are complete, and hand searches and data extraction will begin shortly.

The literature search for seafood and CVD will be conducted this summer. And the subcommittee plans to begin work on the dietary fats questions, starting with all-cause mortality reviews.

And I want to again thank my subcommittee and, also, in particular thank our support staff who have done an incredible job in terms of working with us on every single call. The calls happen once a week and certainly have been an incredible help to all of the work for this particular subcommittee. And are one of the reasons that we have gotten quite far along in terms of the work that we have done so far. Many thanks.

CHAIR SCHNEEMAN: So, I think we can take some questions or discussion on the protocol. Protocols. Yes?

MEMBER MATTES: Sorry if I missed it; can you clarify what is outcome-specific key confounders? Are they for a given outcome you'll pick from that list which you use?

MEMBER SNETSELAAR: Say that again?

MEMBER MATTES: What is the definition of outcome-specific key confounders?

MEMBER SNETSELAAR: They are just specifically related to the work that we are doing for the specific question we're asking.

MEMBER MATTES: So, for example, you might pick ADD for one paper and ADHD for another paper, or you would expect all of these in any paper that you selected?

MEMBER SNETSELAAR: No. I think we would certainly be looking at one at a time.

MEMBER MATTES: Okay. Otherwise, I was going to say, you'd probably ding a lot of papers if you had all of those in at once.

MEMBER SNETSELAAR: Yeah. And it's important to keep in mind that confounders and covariates aren't eliminating papers. So, certainly, our exclusion criteria will do that. But that's something to keep in mind.

MEMBER NOVOTNY: I don't know if you know -- I wasn't aware of -- oh, this is Rachel

Novotny -- of freshwater fish being in the seafood group. Do we know that the freshwater fish have similar levels of mercury and other -- or what is the rationale for including freshwater fish with seafood?

MEMBER SNETSELAAR: I think the idea is that we want to be sure that we are generalizing to other populations. And, in the Midwest, for example, that type of fish are probably the kind of fish that would be consumed. So, that's the reason.

I'm happy to have one of my subcommittee members also maybe talk about that. But we thought that there definitely was a reason for including freshwater fish.

Linda, would you like to respond?

MEMBER VAN HORN: Linda Van Horn. And, yes, as the person who probably glows in the dark from all the Coho salmon we eat out of Lake Michigan, you know, I think there are many sources of freshwater fish across the country that are consumed all the time. Freshwater fish

are potentially contaminated and, therefore, definitely should be included, we think, in the fish and seafood category.

MEMBER SNETSELAAR: I guess the name, I would prefer to call it fish and -- fish and seafood or something, or seafood and fish.

MEMBER BOUSHEY: And to add to that -- this is Carol Boushey -- to add to that, of course, we have fish that live in both, you know, that Coho salmon that you eat.

CHAIR SCHNEEMAN: I think the important point is that it's captured and it's also identified as to whether it's fresh or seafood.

Other questions or comments? Oh, please.

MEMBER VAN HORN: Sorry. This is Linda Van Horn again. And I'm on this subcommittee, but when we were going through our slides and you don't have any chance to put it all in perspective, this is probably a parking lot issue. But it occurred to me, especially

after all of what we've heard today, that, you know, adverse pregnancy outcomes are a risk factor for cardiovascular disease.

And what's of interest as I was looking at all of this, realizing we're talking about the entire population now, if there are dietary factors associated with adverse pregnancy outcomes -- as we were thinking earlier about gestational diabetes, gestational hypertension, et cetera -- and maternal intake of these types of foods, any of them -- I'm thinking fatty acids but it could be any of them -- that relate to the maternal risks, I also wonder if, because of the adverse pregnancy outcomes, the child, the offspring, is at greater risk for depression, anxiety, you know, any other developmental problems that still could stem from initial diet-related relationships maternally. I don't think there's a whole lot of data that anybody's really looked at those connections across the lifespan.

So, again, as I say, I think this is way too much, you know, to try to expect us to do

within this particular environment and all these questions that we're already trying to address. But I think, if it's possible on the basis of any data that do exist that relate these connections, we should recognize those as being potentially important as we go forward. Because if it all starts with maternal nutrition, there's reason to think, you know, we should be more mindful of those relationships.

CHAIR SCHNEEMAN: Yeah, go ahead.

MEMBER ARD: Jamy Ard. So, one question comes to mind related to fish and seafood consumption. In thinking about the definitions and the things that are considered in analysis of type, source, amount, and frequency, timing, one of the other things that comes to mind from some data I can recall is the preparation. So, a high proportion of seafood consumption, especially fresh water fish and seafood, is fried, right?

And so there are data that suggest that there's a different impact of seafood, or

maybe the beneficial impacts are not there when the preparation is taken into consideration.

MEMBER SNETSELAAR: And our committee did definitely talk about that. And I was thinking that it was still listed somewhere. But I will need to look at that again.

I don't know, Joanne, you may remember more about that than I. But we have talked about that, definitely. That's a good point.

MS. SPAHN: The subcommittee did identify preparation. And we had said that that would be an element of seafood we would extract and would present in evidence tables for the committee's evaluation during synthesis.

CHAIR SCHNEEMAN: So it's part of the data extracted.

MEMBER SNETSELAAR: I remember that specifically because it was something that I felt strongly about.

CHAIR SCHNEEMAN: Other questions or comments about getting the analytical framework down?

We do have -- we can move to the committee discussion, just a general discussion. And I think what we did the last time was just go around and allow each of the committee members, if you have comments at this point reflecting on any one particular protocol, or just thinking about the way forward from here, it would be great to have as part of our closing comments from today.

So I'm going to start with you, Elsie, because I know you're going to pop out soon.

MEMBER TAVERAS: None that come to mind at the moment.

MEMBER ARD: So, I'll steal Rick's comment from earlier about sodium. And I wonder if there might be some unifying concepts or ideas or themes that go across the age span and different questions that we might -- may not, you know, sort of have all the data to, or specific questions to address per se, but we might take the opportunity to pose either areas for additional work or at least speak to the idea

that, you know, A, this is what we were tasked to look at, but, B, these are some other things that we might need to consider that would modify the effects that we're reporting out on. And sodium would obviously be one of those that's measured.

CHAIR SCHNEEMAN: Heather?

MEMBER LEIDY: This is Heather Leidy. Just a small comment. I really like the grid idea. So, I think just that will help clear up some of the inconsistencies I think that we have. But something else that I had talked with a few folks about, and that being it seems we're at the stage now where, you know, as we start getting the data, or summaries, there's going to need to be, I think, a lot of crosstalk between a lot of the different committees. And we haven't really done that so much in our subcommittee calls.

And so I think I would just like to see more where some of the chairs are sitting on -- are able to call in on some of our subcommittees, because I think the crosstalk would be really helpful moving forward. So

that's something that came to mind today, that there's a lot of things that I think now we can start being a little bit more integrative.

MEMBER NAIMI: Tim Naimi. Nothing to add at this time.

MEMBER MATTES: Rick Mattes. I was going to make that same point. I think that we have to integrate more to avoid redundancies and to make sure we capture everything, because a couple of new ideas came out.

MEMBER BOUSHEY: This is Carol Boushey. And I have a similar comment to what Jamy said, and Rick and everyone.

I think we sometimes some of the language needs to be harmonized a bit. We're talking about the same thing but we use different words, and I think -- which is fine because those words are there, otherwise we wouldn't have picked them out to use them, but it might be easier for us to actually do comparisons if we're using the same terms.

CHAIR SCHNEEMAN: Sharon.

MEMBER DONOVAN: Pretty much the same. I was surprised, for example, like with the beverages, that there's quite a bit related to pregnancy and lactation. And so, in addition to make sure the covariates are consistent, but also how we're defining gestational weight gain, postpartum weight retention. So I think we need to kind of clean those up before we actually start the systematic reviews.

MEMBER SNETSELAAR: I don't really have a lot to add. I think that being consistent across the subcommittees, which has already been indicated. But one thing, for example, parity was brought up as something that might certainly be a part of many of the different subcommittee questions. So, I could just see that there are a variety of things that we might want to look at, which I'm sure has probably been primed already anyway.

MEMBER SABATE: Okay. Joan Sabate. On the presentations before the break, particularly the one on birth to 24 months, there

was quite a lot of discussion and presentations on the specific nutrients and nutritional status. I think this is quite interesting and very important from the nutritional viewpoint.

But I'm a little bit surprised by this emphasis, and particularly in the context of, if this is the task of this committee, or is the task of the Institute of Medicine, the one that issues the dietary DRIs, you know our outcomes in general is health, not nutritional studies. And going into specific nutrients when they come from different sources, that could be the nutrients in foods, the foods that have been supplemented or also taking independent supplements. See, basically we are just focusing on nutrients independent of the source.

And I don't know to what extent we are going to -- once we get the nutritional status, I mean, if we are going to make food recommendations based on nutritional status or based on health outcomes.

MEMBER NOVOTNY: Rachel Novotny.

Yeah, echoing most of what I heard. In addition, thinking about the analytic frameworks and harmonization in presentation that I think will help our conversations to be more to the points we are trying to make. I think, even analytically, I think there may be some commonalities on, of course, the classic "what to do with energy" that is always going to be there, particularly for some of our overweight outcomes. I think it could be useful to have some analytic crosstalk as well.

MEMBER BAILEY: Regan Bailey. Just echoing the -- and will be of no surprise to the federal staff, who I keep talking about this with -- but harmonization and standardization of the terms that we are using, things like, what is a life stage? And that we're all on the same page about the terms that we're using. What is a covariate versus what is a confounder? How we define nutrients of public health concern versus shortfall nutrients. So, really having some clarify around those terms I think would be

helpful.

I really like, Jamy, your idea of the grid for having consistent confounders and covariates for each outcome. And, Heather, you had some good ideas on that as well. And I think that is mainly what I wanted to say. Thank you.

MEMBER VAN HORN: And, Linda Van Horn. I've been pretty vocal, so I'll try to keep it short. But I, likewise, agree with Jamy on the sodium question for sure. That's got to be something that we address because it's so relevant to everything we're doing.

And also what Regan was just referring to as far as nutrients of concern. In teaching, one of the things that I use continually is the wonderful slide that shows what are the recommendations and what are the current American eating behaviors. And I think that just sends such an important message.

And one thing that was brought up about beverages, I think it was Joan who said, you know, is there a percentage of energy intake

from beverages that should be recognized as being excessive in relation to obesity, weight control, things like that? I don't think we know the answer to that. But I think, you know, I remember an AJCN paper that once demonstrated that those who had higher intake of caloric intake from beverages were more often overweight or obese.

And so, you know, practical questions like that that are relevant to public health, you know, I think beginning with the end in mind, you know, it would be helpful if we could provide some guidance and direction on that as well.

MEMBER BAZZANO: This is Lydia Bazzano. I don't have any additional comments at this time.

CHAIR SCHNEEMAN: Ron, come back to you.

VICE CHAIR KLEINMAN: Yeah, I mean, I think everyone's summarized my thoughts pretty well. I do think that our focus should be on health outcomes, just as Joan said.

And I think, in fact, it is. Where we have focused on specific micronutrients, it's in the context of ultimately understanding the impact of that micronutrient status on health outcome. So I think, in a way, that's an intermediate step to health outcomes where that comes up. But I totally agree that this has to inform the public about how to improve their health through what they eat. And I think that's the goal.

I've been incredibly impressed with the amount of information that is going to be generated from this process. What Carol was saying before, as we were chatting, when I started this I couldn't have imagined the number of questions that each of these topics would generate. I thought they were fairly straightforward. And, you know, 10 minutes, 15 minutes, we could go through at least a couple of these topics. And they continue to expand.

So I would say that we have to keep in mind that it's important to cover what's

important, but to keep in mind that expanding this analytic framework means that we get an extraordinarily expansive evidence base that we'll then have to deal with.

And so, to some degree, I'm quite comfortable with where we are now. I do think sodium is an important consideration and we should bring that in. And I particularly appreciate that comment about a need for longitudinal observations so that we can put diet in context with these isolated aspects of diet.

So, those are two of the more important things, I think, for us. And then we have talked about creating a grid for some time now. And I think that's a must. And that's something that we can talk through as well with the subcommittee chairs on one of those -- on our regular calls. And I know that the staff, I think, is currently working on that. So I think we're on our way towards the next stage of this process. Thank you.

CHAIR SCHNEEMAN: Great.

VICE CHAIR KLEINMAN: And I did want to -- sorry, I did want to say that I really appreciate all the work that those who presented today put into the presentations. I thought they were terrific. I've been sitting in on three subcommittees now, and Barbara's been sitting in on four. And I thought the summaries were outstanding.

And I had some insight into the work that went into putting those together, both by the staff, as well as the members of the committee and those who presented. And it's very impressive, and it made a great difference today. So, thank you all for that.

CHAIR SCHNEEMAN: Great. Thank you for those comments. I think, Ron, you've captured a lot of what has been going through my mind. First of all, just to thank everyone for the work that they've done on the subcommittees and then in the presentations today.

And I hear what you're saying. I think we've made some progress toward harmonizing

terminology, but I agree with everyone, that the discussion today shows that there's more we need to do. And also the more we need to do to facilitate the crosstalk among the subcommittees, because I think that's going to be critical for the work going forward.

I'm going to just do some practical things. I'll remind folks who are interested in making comments, if the public is interested in making comments on the protocol, they will be most useful to the committee if they could be submitted by July 24th. You're welcome to submit them any time, but to be most impactful, July 24th would be great.

And as the committee continues to move forward with its work and it starts to implement these protocols, there will be updates to the web. So we want to be sure and encourage people to stay on the listserv that USDA and HHS have, to visit the website, because that will be an ongoing source of information. I think both departments have really committed themselves to

try and be as transparent as possible. And so getting information out there is a key part of that.

We are prepared to adjourn at this point. I would remind folks that we will reconvene tomorrow morning. And tomorrow morning we start at 8:30. This morning we started at 9:00. So, we'll start a little bit early. And we're looking forward to hearing the public comments for the committee tomorrow.

And we, yes, we'll come right back here. So, again, thank you. Thank you all for attending and being here. And thank you to the committee for all your hard work.

(Whereupon, the above-entitled matter went off the record at 4:13 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: 2020 Dietary Guidelines
Advisory Committee Meeting

Before: USDA

Date: 07-10-19

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter