2020 DIETARY GUIDELINES ADVISORY COMMITTEE

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PUBLIC MEETING

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FRIDAY
OCTOBER 25, 2019

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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, SW, 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, RD, Member
DR. TERESA DAVIS, PhD, Member
DR. KATHRYN DEWEY, PhD, Member
DR. SHARON DONOVAN, PhD, RD, Member
DR. STEVEN HEYMSFIELD, MD, Member
DR. HEATHER LEIDY, PhD, Member
DR. RICHARD MATTES, PhD, MPH, RD, Member
DR. ELIZABETH MAYER-DAVIS, PhD, 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. JAMIE STANG, PhD, MPH, RD, Member

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

9:02 a.m.

MEMBER de JESUS: Good morning. I'm pleased to welcome everyone to the third meeting of the Dietary Guidelines Advisory Committee on day two.

I'm Janet de Jesus, from the Office of Disease Prevention and Health Promotion at the Department of Health and Human Services.

It is my pleasure to welcome our morning speaker, Admiral Brett Giroir. He is the 16th Assistant Secretary for Health at the U.S. Department of Health and Human Services. He serves as the Secretary's principal public health and science advisor, senior advisor for HRSA, CDC, SAMHSA and chief opioid policy advisor.

He also oversees the Office of the Surgeon General and the U.S. Public Health Service Commissioned Corps.

His office leads many critical national initiatives, including a historic new plan to end the HIV epidemic in America, the

Physical Activity Guidelines, the Revised Common Rule, and a cross-agency effort to improve the outcome of patients with sickle cell disease.

Previously, Dr. Giroir served in numerous leadership positions in the federal government and in academic institutions. Most notably, he was the first physician to be appointed as an office director at the Defense Advanced Research Project Agency.

As a pediatric critical care physician, Dr. Giroir cared for critically ill children for 14 years. He continues to bring that hands-on patient-centered perspective to his work as Assistant Secretary for Health, where his primary goal is leading America to healthier lives.

Please join me in welcoming Admiral Giroir.

(Applause.)

DR. GIROIR: Well, good morning everyone, and good morning to everyone who's watching us in the virtual space.

I love introductions like that because the introductions are longer than my remarks are supposed to be.

(Laughter.)

DR. GIROIR: So, and I'm always very jealous about the Department of Agriculture because they really have wonderful architecture and historic buildings, so it's really great to be here.

I am really here because primarily, I want to thank the members of the Committee. I really do. We had such a long period of time going through the process to understand how this Committee would work to receive nominations.

And, I can tell you that when I met with Secretary Azar and Secretary Perdue in his office talking about the Committee, we were floored by the credentials, and the passion, and the commitment that all of you have.

So, I think this is, you know, this is the rock star committee, Advisory Committee, and we really appreciate your work.

I know how much time you have to put into this. I think a lot of people understand the time commitment that's involved, but I don't think people understand the physical stresses of all the travel and work that you need to be through.

But, I think also people don't realize it's a little bit emotionally stressful. And, I felt that when I was on advisory committees. Because, what you do really affects millions of lives over the next few years. And the issues are not easy. They're really rough science engagement, but they're so very important. So, the main reason I am here is to really thank you. So, I do appreciate that.

I also want to thank all the staff who put this together. This is not an easy lift by any chance. So, if you're a staff member either at USDA or at HHS who's worked on putting this together, stand up, please.

(Applause.)

DR. GIROIR: So, my office is

primarily responsible for leading America to healthier lives. We try to provide the road map for being healthy where -- whether that's vaccine policy, whether that's the elimination of viral hepatitis, very recently the Physical Activity Guidelines for Americans. So, we are all about prevention and keeping people healthy.

And, every single time I talk, I talk about the dynamic duo of nutrition and exercise. And, that really is the foundation of all health in my mind.

You look at our expenditures now, $3.6 trillion dollars in the United States. $6 trillion dollars by 2027, almost 19 percent of the GNP, 90 percent of our expenditures on chronic conditions.

I'm a pediatrician as you heard, and of course, I'm extraordinarily thrilled that we're able to move into the newborn to 24-month age group, and also pregnancy and lactation.

But, if you look at some of the estimates, today's two year olds, it is estimated

by the time they're 35, 60 percent of them will be clinically obese.

Our country cannot survive 60 percent of our 35 year olds being clinically obese with the long tail not only of obesity, cardiovascular disease, hypertension and diabetes, but we now know that so many forms of cancer are linked to improper nutrition and obesity. So, our country cannot survive this.

If you look today, three-quarters of our 17 to 24 year olds could not, could not meet the standards for the military if they applied to it. Three-quarters. About a third of that is obesity and physical fitness. About a third of that is education. About a third of that is substance use disorder.

So, again, there is no way our country is going to survive unless we get to some of the root causes.

The promising news though, the promising news is I know that with the appropriate guidelines, it can serve as a basis

for all of us to move forward.

I know that by good nutrition, even the estimates right now, that about half of all cardiovascular mortality can be averted.

We also know that between easy things like vaccination, elimination of smoking and appropriate nutrition, we could prevent 42 percent of all cancers right now. That's what we know about and I bet as things move forward, we'll learn more and more about the prevention that we can get.

I'm very excited about new cell therapies for cancer, but I really want to put the National Cancer Institute out of business. And, I think we can go a long way with that by just doing the kinds of things that, that you recognize.

So, again, I, I do want to thank you for all your work. I want everyone to know that even though the schedule hasn't been right that I've been able to be here on the previous meetings, that we spent a lot of time, a whole

lot of time at the level, at my level and at the level of the secretaries, trying to understand what you're doing, caring about what you're doing, trying to facilitate your work. And, I just want everyone to understand that, you know, as we say, we got your six, right?

We really got your back, we want you to do the best job possible because so many important things depend on the outcome of this Committee.

Nutrition really is the foundation. I'll say the dynamic duo of nutrition and exercise together really has such profound effects.

Oh, I forgot the one I really wanted to talk about, which is my, my, my new latest kick is we're learning more and more as you know, and about every month there's a new great article -- this is not my field -- but the impact of nutrition and exercise on neurodegeneration.

This, perhaps to me, is one of the most exciting areas because I turn 59 next week,

so I'm getting up to the age group where you start worrying about these things. But, if you look at the epidemiology of the aging population and the fact that we don't have, we really don't have a paradigm for neurodegeneration.

But, what we do know is if you don't smoke, if you don't drink excessively, if you have exercise and you have a good, healthy nutritional program with high quality diet, you can reduce your risk by about 60 percent.

If there was a pill that reduced your risk of Alzheimer's by 60 percent, it would sell $10 trillion tomorrow.

So, I look forward as we open the aperture on what nutrition can do for us. Food is medicine, both preventative medicine as well as healing medicine if you're sick.

And, again, I want to thank you so much for your time, your commitment, your passion. And, anything you need, we're there for you.

So, thank you very much. Appreciate

it.

(Applause.)

CHAIR SCHNEEMAN: Thank you very much for those comments. I know the Committee appreciates having the support of both USDA and the HHS as it moves forward with the work, and the importance of the, the work.

So, I'm pleased to welcome you to day two of our, our meeting -- oh great. And, I'm welcoming both the people online as well as those of you in, the, the room. And, loyal Nats fans, who I'm sure would rather be watching the Dietary Guidelines Advisory Committee than the --

(Laughter.)

CHAIR SCHNEEMAN: -- than the World Series.

But, so, just to remind you of the purpose of our public meeting. This meeting three for the Dietary Guidelines Advisory Committee. We are describing the status and providing updates on the work of subcommittees for the full committee discussion and decisions.

The subcommittees have been reviewing evidence and providing advice to this parent committee, and each subcommittee conducts its work together between meetings, but all of the decisions going forward are made by the full committee in its public meetings.

So, the updates to be -- that will be discussed and the presentations that we discussed yesterday will continue today, are any of the substantial updates to the 40 protocols that were discussed at meeting two. So, any of those revisions.

We are doing discussion and deliberation on 19 new protocols that have been developed by the subcommittees and we're able to then review evidence that is available that some of the subcommittees are bringing forward for the, the committee, although most findings are still to come. But we are starting that process of looking at the evidence and developing conclusion statements.

So, again, just to remind you that all

of the information is available on DietaryGuidelines.gov. So, all of the protocols that we will be talking about are being posted on DietaryGuidelines.gov.

So, by going to the website, identifying the questions and, then from those questions that are of interest to you, you can find the, the protocols. And also on that website, you can track the progress of the, the Committee as it, it moves forward with the, the work.

So, in yesterday's discussion, we had a presentation to look at the NESR approach to the synthesis of evidence since that is the phase that the committee is, is moving into as it implements its protocols.

And, we heard the subcommittee updates for the Dietary Patterns Subcommittee, the Dietary Fats and Seafood Subcommittee, Beverages and Added Sugars, and we also moved from today's agenda, the Frequency of Eating Subcommittee report. So, we had that report yesterday.

And, then we had the opportunity for committee discussion and it was a good opportunity for the Committee to start thinking about and discussing the overall format of the, the report as we move forward. And, the notion that we're using a life stages approach as we report our findings to the Departments.

So, for today's agenda, we're almost finished with the opening remarks, and we will continue our subcommittee updates starting with the Birth to 24 Months Subcommittee. And, Birth to 24 has been working with Dietary Patterns. So, we're going to have a bit of a, a joint report.

And, then the Pregnancy and Lactation Subcommittee, and then the Data Analysis and Food Pattern Modeling working committee, followed by committee discussion, closing remarks.

And, just to remind folks, we announced yesterday and I'll note it again now, that we're expecting to do all of the subcommittee reports before having to take the

lunch break. So, we will probably be ending at the, the lunch time today. That's what we are anticipating for, for today's agenda.

And, the agenda doesn't show a break, but we will try to work in a break since it, it can be a long morning.

And, finally, let me remind you that if the public listening to the presentations, if you have comments that are specific to the new protocols that are being presented and discussed today, it's most helpful for our work if they can be submitted by November 7th, so that they can be considered before we start implementing the, the protocols.

However, the comment period remains open throughout the Committee's work ending in 2020. But, for those protocols, November 7 is the important time.

So, those are my remarks for opening. I'll just ask the Committee if you have any questions or comments you want to raise at this point, or, ready to go? Okay, so Dr. Dewey, do

you want to -- oh, okay.

MEMBER DEWEY: Thank you very much, Barbara.

I first want to thank the members of this subcommittee that are very dedicated and hardworking. It's been a real pleasure to have our weekly conference calls, and the staff that has supported us, which are also amazing.

And, in particular, I'd like to thank Elsie Taveras, because I was not able to be here for the July meeting, and she was very good at presenting our protocols at that time.

I'll tell you the punch line here, we don't have any conclusion statements yet, but we have made a lot of progress, and we have been working very hard on both developing and implementing all the protocols.

There are, you know, many protocols available on the web, but I wanted -- I went through and, and looked at well, how many questions or relationships are we actually trying to look at in terms of conclusion statements, and

I think it's at least 50.

So, you can imagine how confusing it can get. And that's just the ones that our subcommittee is looking at this age group as you'll see in a moment. The other subcommittees are also working on issues related to this age group.

And the other aspect even though it is many, many relationships we're looking at, we are really only scratching the surface of the issues around feeding infants and toddlers.

And, for the most part, the questions we're looking at relate to what to feed, and we aren't going to be able to really address the issues of how to feed. For example, issues like responsive feeding. But, that's work for the future.

So, I'd like to start by explaining that the Birth to 24 Months topics are, are being addressed actually by four different subcommittees as shown here.

And, on the next slides I will

describe the B24 topics that are addressed by these different subcommittees. And I'd also like to point out that all this information is available on DietaryGuidelines.gov.

So, in our subcommittee, this is one of the slides that shows the ones that we are working on directly. That includes the recommended duration of exclusive human milk and/or infant formula feeding as it relates to five different categories of outcomes.

And, I won't read through all of them, but just to point out that one of those is micronutrient status, and that actually encompasses six different nutrients. So, there are many questions embedded within that particular topic.

And, then for the frequency and volume of human milk or infant formula feeding, we're looking at how that relates to two of those five outcome areas, micronutrient status and growth size and body composition.

And, then for the third topic shown

here, the overall question is how do dietary supplements from either supplements or fortified foods relate to three different outcome domains: nutrient status, growth size and body composition, and bone health.

And, there are four nutrients as shown here, that we're focused on in terms of supplements or fortified foods.

Now, in terms of complementary feeding, we also have quite a suite a questions we're examining that look at how both the timing of introduction of complementary foods, and the types of complementary foods are related to outcomes in five domains shown here.

And, again for the micronutrient status domain, we actually are, are focused on six different nutrients, so there are multiple questions embedded in that.

Now, in addition to the work that our subcommittee is doing on complementary feeding, the Data Analysis and Food Pattern Modeling Subcommittee is going to be directly tackling

these questions of whether USDA food patterns could be established based on relationships identified, will they meet nutrient recommendations, and is there evidence to support supplementation or fortified foods to meet those nutrient needs?

We haven't really started tackling that yet, I think Regan will mention that a little later.

Then, in terms of beverages, our subcommittee is looking directly at how beverage consumption relates to growth, size and body composition. And, actually, the previous pregnancy and birth to 24 months' work encompassed some of, of this systematic review process because they're included, beverages were included, within the complementary food feeding exposures.

And, again, the Data Analysis and Food Pattern Modeling Subcommittee will be examining other questions related to this. How does beverage consumption by infants and toddlers

relate to achieving nutrient and potential food group recommendations?

Then, in terms of added sugars, the Data Analysis and -- sorry, it says B24 and/or Beverages and Added Sugars Committees at the top there -- will be looking at how added sugars relate to three different types of outcomes.

And the Data Analysis and Food Pattern Modeling Subcommittee is looking at how added sugars may relate to achieving nutrient and food group recommendations, and whether certain amounts of added sugars can be accommodated in the healthy diet while still meeting food group and nutrient needs.

Now the, the top question there, again, is related to the previous work that was done because sugar sweetened beverages were part of the beverages that were looked at. So, that is a, a significant proportion of the added sugars that children in this age group are exposed to.

Then, in terms of types of dietary

fats, the Dietary Fats and Seafood Subcommittee is looking at how dietary fats relate to four different types of outcomes. And, in this age group, the literature on some of those longer term outcomes is probably very scant.

But, in terms of neurocognitive development, that's an area where there's probably a lot more to work with.

Then, in terms of seafood, the lead subcommittee is -- we're still kind of working out who's doing what, but the Dietary Fats and Seafood will probably be taking the lead on how seafood consumption in this age range relates to neurocognitive development and risk of cardiovascular disease. And I think we'll be working closely with that subcommittee on those questions.

Now, what I'd like to do at this point is tell you where we are with the human milk and infant formula protocols, which were presented in July. And those are being implemented.

And these protocols either had no

revisions or very minor revisions that won't result in substantive changes to the reviews. So we won't spend committee time going over those minor changes, but please note that all the protocols are available at DietaryGuidelines.gov.

But one item that we do want to report to the Committee is that we discussed the parameters around how the studies define food allergy.

We decided that it was best to review studies in which food allergies were diagnosed based on fairly rigorous criteria, gold standard being food challenge, but also making room for studies that included both food sensitization, as well as some other evidence such as a history of clinical reaction.

The Pregnancy and Lactation Subcommittee is also discussing the exact wording of that second criterion and so, we're -- we still may have a few wording changes to, to put here, but that's the, the basic principle. And that aligns with the methods that we used in the

existing review from the previous project that we are updating.

So, we would now like to update the committee in our progress in implementing the protocols presented in July. And, the first good news is that the literature search is complete.

We actually used two different literature searches for the human milk and infant formula reviews. And, one was from the Pregnancy and Birth to 24 Months Project, and the other was new for the current 2020 Dietary Guidelines Advisory Committee.

So, you may recall that across the committee, some of the work we will do will involve updating the existing NESR systematic reviews.

And, in our subcommittee, those existing reviews are from the Pregnancy and Birth to 24 Months Project, which was completed just prior to the work of this committee.

So, during that prior project, the search for human milk and infant formula

literature captured over 35 years of research, from January 1980 to March of 2016. And it included human milk and infant formula literature relevant to our current work.

Systematic reviews were completed for food allergies and atopic allergic diseases, cardiovascular disease outcomes, and diabetes outcomes. And, systematic reviews were planned but not completed for growth, size and body composition, micronutrient status and developmental milestones.

And the second literature search which was recently conducted captures literature from January 2016 through last month. And this search allows us to update the existing reviews with evidence from the last three years, as well as examine nearly 40 years of evidence for our new reviews.

Now, two NESR analysts independently screened the literature search results using the inclusion and exclusion criteria that we presented in July, and data are being extracted

from the studies that met our inclusion criteria.

We decided to start with the systematic review examining the relationship between the duration, frequency and volume of human milk and/or infant formula consumption, and micronutrient status. And we think that this will be one of the smaller bodies of evidence.

So, as you can see here, there are currently between zero and ten articles included for the various nutrients of interest, which include iron, zinc, iodine, vitamin D, vitamin B12, and fatty acids.

These numbers may change slightly because the NESR analysts have not yet finished their manual search, which involves using the references of the included articles as an additional source of articles to screen.

However, due to having no articles or a very small number of articles for some of these nutrients, we anticipate that we will probably have insufficient evidence to determine the relationship between duration, frequency and

volume of exclusive milk, human milk, and/or infant formula consumption with some of them, but not all of them.

Our other important set of questions revolves around nutrients from supplements and fortified foods. And again, those protocols were presented in July and, they are in the process of being implemented.

As with our human milk and infant formula protocols, these protocols had either no revisions or minor revisions that won't result in substantive changes to the review, and they are available at DietaryGuidelines.gov.

And just to remind you, the specific nutrients that were focused on here are iron, vitamin D, vitamin B12, and omega-3 fatty acids.

The literature search for the systematic reviews is in the final stages of development and will be run very shortly.

In addition, we have been meeting with the other subcommittees to discuss cross-cutting topics that are relevant to this age group. In

particular with the Data Analysis and Food Pattern Modeling Subcommittee, we've discussed the availability of data for this age group, and actually looking at three sub-age groups: 0 to 6 months, 6 to 12 months, and 12 to 24 months because of the differences in infant feeding recommendations and dietary patterns during those periods.

We've also discussed the minimum sample size that we might need, and the feasibility of stratifying by the main milk source, human milk or infant formula, or both, to examine food group and nutrient intake at 6 to 12 and 12 to 24 months.

We've also tried to grapple with the issues around adequacy of information on human milk nutrient content, as well as discussed the identification of priority nutrients for this age group. And, after I finish, Regan will be presenting more about what that subcommittee has been working on for this group.

With the Dietary Fats and Seafood

Subcommittee, we've discussed the developmental outcomes in the age range of 0 to 2 years, and we are currently working with them on developing the protocols for Birth to 24 Months.

So, our next steps will include continuing to implement the protocols we developed, which are listed here once again, and we will also continue working across the subcommittees to have conversations about the cross-cutting topics relevant to this age group.

Finally, we will develop the remaining protocols which are updates to existing systematic reviews about complementary feeding. As you may remember, those were tackled in the previous Pregnancy through Birth to 24 Months Project.

So we've held off on finishing any further work on those protocols in order to focus on getting the first reviews completed that I've already shown you.

So I'd like to again thank all the members and the really terrific support staff.

There's no way we could have gotten to this point without their very, very hard work.

So, thank you very much.

MEMBER BAILEY: So, I am representing the Data Analysis and Food Pattern Modeling Working Group.

And, we thought that it would be salient to describe the work that we're doing specific to B24 right after Dr. Dewey's presentation so it's fresh in your mind. And, then we'll talk about what we're doing in the two-plus group after Sharon Donovan talks about Pregnancy and Lactation.

So, again, this is the group that I'm representing with the members listed here on this slide. Oh, there we go. I was looking at my own computer, which is confusing.

(Laughter.)

MEMBER BAILEY: As if I'm not confusing enough, right?

So, when we were here in July, we presented the first of five protocols, and we had

an asterisk around all of those protocols that we had ongoing discussions with the B to 24 subgroup.

So, that's what we're going to be talking about in the next couple of slides this morning. So, how we've extended the work, or we're proposing to extend the work, to that age range.

And, so just to be quite clear, we always say the term B24 but it's actually birth to less than 24 months, so that's something that has been changed in the protocols throughout.

We utilize nationally representative data sources for the work that we're doing in this group. The life stages that we're talking about, infants and birth to less than 24 months, with exceptions that are noted on certain slides.

We, as Dr. Dewey mentioned, are interested in looking at infants together, and then stratified by primary milk source. So, when I use the word stratified, that is simply to reflect that we're looking at these two groups.

We will look at them together, and then as two separate groups by the primary source of milk. And in ages groups listed here. In the 12 to 24 months we'll also look at those children who are not receiving formula or human milk as a separate group.

Again, we've discussed at length that we will be utilizing the NHANES data for most of the work we're doing. Given the small sample sizes of birth to less than 24 months historically collected in NHANES, we need to combine five survey cycles.

So, we will be representing ten years of data for this age group, and we have data that's available through all of the databases that are listed here.

So, we will have energy and nutrients, we will have food groups, food subgroups and foods as they are consumed by What We Eat in America, food categories. And, dietary supplements with the database that's available.

Breastfeeding initiation and duration

will be collected, or is collected, and will be analyzed through the national immunization survey, and that's representative of 2017 to 2018.

These are some of the key definitions that we're working with and we have aligned with the B24 group to make sure that we're working with the same kind of definitions. So, you will see throughout the next couple of slides CFB, that is used to represent complementary foods and beverages.

Our definitions of infant formula are presented here, so meeting the FDA standards, as well as Codex Alimentarius.

Mixed feeding is a term that is defined as having both human milk and infant formula, but not complementary foods and beverages. And, then exclusive human milk feeding, which Dr. Mayer-Davis described yesterday. And, so our definition is inclusive of the WHO definitions of exclusive, or predominant.

So, let's jump right in and talk about the food groups and nutrients.

First, we're going to look at the prevalence of initiation and duration rates for breastfeeding. We will look at the prevalence of food group intake, mean intakes of food groups and subgroups, as well as food category sources of food group intakes, when that information is available.

So, we thought that the clearest way to explain what we're hoping to do is with this table. And, you'll see that this -- that the columns in this table represent ages and months.

So, for less than 4 months, we will be looking at the prevalence of complementary foods and beverages, as well as 4 to less than 6 months.

In those 6 to 12 months of age, again, we're going to look at the whole group of infants, as well as stratified by primary milk source for prevalence of food groups, and mean intakes of food groups. And, for food category

sources, we'll look at infants combined by primary milk source.

And, then for those 12 months to less than 24 months, we will look at that primarily as one group.

In terms of our analytical framework, will have the mean intakes of nutrients from foods, beverages, and dietary supplements, usual intake distributions adjusted for within person variation from foods alone, and from foods inclusive of dietary supplements.

And, the exceptions to the life -- the age groupings are listed here because for the dietary reference intakes, one year olds are in the 1 to 3 group. So, when we're comparing it to the dietary reference intakes, that will be the framework which we are using as the benchmark. And, then of course, food category sources of nutrient intakes.

When we're trying to describe the nutrients of public health concern, again we will be looking at these usual intake distributions

inclusive and exclusive of dietary supplements compared to the DRI, stratified by infant milk source as previously mentioned.

When we are trying to evaluate the current dietary patterns and beverage consumption patterns, we will be looking at food group and subgroup intake, and there's an asterisk there because not all subgroups are consumed in sufficient -- with sufficient sample size to make stable estimates.

So, when available, we will have subgroup data but if sample size does not permit, we will have the very high level food group intakes.

We are proposing at this point that we will standardize that based on 100 calories. So, with two years and older, we have the Healthy Eating Index, which is expressed as per 1,000 calories. Given the much lower calorie intake of this age range, we're at least initially talking about standardizing that to 100 calories.

In terms of beverage consumption, the

percent of infants and young children consuming given beverage type, the amount that is consumed in ounces, as well as the nutrient and food component contributions, from these beverages.

In terms of next steps, right now what we have is information from foods and beverages. We will move on to be inclusive of dietary supplements as that data is available. We'll summarize the findings after we finalize the discussions around the table today, and hopefully have some draft conclusions available for you soon.

And then the final piece of all of this is the Food Pattern Modeling.

So, I'd like to thank the support staff, Dr. Pannucci, Casavale, Emily Callahan, Cheyenne, and Eve Stoody, as well as the federal data analysis team who's been providing data to us throughout this process.

So, I think both Kay and I are happy to have questions about either of the presentations here today.

MEMBER MATTES: So, I understand you're, you're addressing the issue of food allergies.

How are you going to interpret the evolving literature on early exposure and risk for allergy, and how are you going, how are you going to evaluate the, the different levels of intake relevant to that since it's kind of a new science?

MEMBER DEWEY: Yes, so the previous Pregnancy to Birth 24 Months Project tackled that already, and the paper has been published that looked at how complementary feeding relates to those -- well, the human milk and formula as well as complementary feeding, but the question that you posed as more to do with the foods, the complementary foods.

And, the, there were two experts on that tech that had training and background in that area and did a terrific job with the staff of looking, you know, food by food. So, peanuts, fish, milk, et cetera, were all looked at

separately.

And, at the time the paper was written, there was enough evidence for peanut to be quite definitive about that issue, particularly the need to introduce that in the first year of life.

And, there's emerging evidence for all of those categories and Ron may want to speak to that. So, I think what we'll be looking at when we get to updating the complementary feeding protocols and doing the searches, is what has emerged since the end date for the searches that went into that previous publication.

And, there might be quite a few for some of those food categories, so we'll have to work at looking at whether there's more evidence and the grade might change. But, we have been looking carefully both at the, the timing and the type of food.

Quantity, I, I think is probably less of an issue in terms of the data that are available for the relationship. But, just having

it in the diet is, is part of that issue.

You want to add anything?

VICE CHAIR KLEINMAN: No, I think you've described it really well from the fish and, and nuts and the others that are probably furthest along at this point. But I don't think there's really any definitive evidence that anyone is willing to put into a guideline at this point.

So, I think it's, you know, we'll have to see how that evolves over the next six months. I think the further question is about feeding during -- mothers' intake of these food during pregnancy. And, so, I guess we'll get to that during that discussion.

But, that, that is something that has changed dramatically since the previous guidelines.

Are there other questions?

MEMBER MATTES: Ask one more for Regan.

So, you'll be looking at, at other

beverages. Have you defined which ones -- so we, the beverage gang, we have this table and I think there's 28 possible beverages. If you did all pair-wise comparisons, there would be 378 to look at, which is clearly not manageable.

MEMBER BAILEY: Yes, I --

MEMBER MATTES: So, we're going to have to prioritize some of these. Have you thought about that?

MEMBER BAILEY: And, in the next presentation I think we have the discrete categories of beverages.

But you're right, we're not going, especially in these young age groups, we'll focus a lot on milk and milk substitutes, 100 percent fruit juices, what are the sources of added sugars?

But it will be a limited number. We won't have sample size sufficient to look through all of the different categories.

Interesting to know you guys are a gang.

(Laughter.)

MEMBER BAILEY: We'll talk about that offline.

(Laughter.)

VICE CHAIR KLEINMAN: Are there other comments? Yes.

MEMBER SNETSELAAR: Just one more quick question, this is Linda Snetselaar.

I was wondering, and, and I think you alluded to this at the beginning of your comments, but I was wondering what you might be doing in terms of looking at food allergies and the ways in which foods are introduced to children eating fresh foods. Will you be looking at that at all?

For example, how to identify an allergy in a child? I think that's changed over time. And, just wondered if you might be looking at that concept.

MEMBER DEWEY: I'm not sure I completely understand the question. We have been trying to define the criteria for the search by

means of either a food challenge for defining food allergy, or a combination of both food sensitization and some sort of clinical reaction.

Is that what you mean?

MEMBER SNETSELAAR: Yes, exactly. Thank you.

MEMBER DEWEY: Okay. And while I have the microphone, I wanted to add one more comment about the, the types of data that we're going to try to be compiling for this age group. And it had to do with the prevalence of introduction of complementary food and beverages at 4 months, or before 4 months, or at 4 to 6 months.

We met just the other day so some of the things that we discussed didn't make it into the slides, but I think it is probably worthwhile to stratify by human milk or formula as predominant milk even for that outcome, because there's some evidence that the age of introduction of other foods and beverages is probably a bit earlier in formula fed infants.

MEMBER BAILEY: That's a good point.

We saw that in the FITS 2016 data so I think we could also examine that similarly with the NHANES data.

VICE CHAIR KLEINMAN: Any other comments or questions? You've got a lot to analyze.

All right, is -- Regan, are you going to continue, or we're going to go to Pregnancy and Lactation?

(Off-microphone comments.)

VICE CHAIR KLEINMAN: Great. Sharon?

MEMBER DONOVAN: Okay, so good morning. My name is Sharon Donovan, and I'm presenting on behalf of the Pregnancy and Lactation Subcommittee shown on this slide.

And, like everyone else, I'd like to thank this committee for their hard work, as well as the support staff. And I think we've made quite a bit of progress since the meeting in July.

So, today I'll be presenting new protocols, as well as the implementation of some,

some of the protocols that we presented in July. And, we actually have some draft evidence synthesis, grading, conclusion statements for two outcomes related to folic acid.

So, as a reminder, the, the committee is addressing three broad topics: dietary patterns, dietary supplements and fortified foods, and maternal diet.

And, these are the new protocols to be discussed today, so the effect of dietary patterns on human milk, micronutrient status of the mother, and infant developmental milestones.

In terms of dietary supplements, we have new protocols for B12, omega-3 fatty acids, and vitamin D, and as was just discussed, new protocols on the impact of maternal diet on food allergies.

So, these are the protocols that were presented in July that we're currently implementing.

So, in addition to the three on the previous slide for dietary patterns, we're

investigating gestational weight gain and postpartum weight loss.

And, as Kay alluded to, this gets very complicated because we have a number of nutrients of which have multiple outcomes. So, I think counted we're doing 40 systematic reviews in, in Pregnancy and Lactation alone.

Okay. So, these, these are still to come. These are protocols and development that won't be presented today. So, hopefully at our next meeting.

So, these are updates to the protocols that were presented in July. So, in terms of dietary patterns and gestational weight gain and postpartum weight loss, we modified the inclusion and exclusion criteria for the intervention and exposure to clarify that basically what was discussed yesterday in terms of the, the dietary patterns, that specific macronutrient proportion diets will be included when they fall outside of the acceptable AMDR, and only studies that describe all macronutrients.

Then, in terms of dietary supplements and fortified foods, we had proposed in July to only cover the supplements. And, based on feedback from the public, we have amended that protocol for iron to include both supplements and fortified foods.

So, now I'll move on to the developing the plan, so the new protocols. And, I have a lot of analytical frameworks to present so you'll see that in terms of like, exposures and comparators, there's a lot of repetition. So, I'm going to primarily point out the uniqueness of, of each one so we can get through this a little bit more quickly.

So, these are protocols related to dietary patterns. So, just to remind you of the, the definition of the dietary patterns that were -- was discussed yesterday.

So, first, what is the relationship between dietary patterns consumed during lactation and human milk composition and quantity?

So, I'll walk through this one in a little bit more detail, but the analytical -- so, the intervention exposure is consumption of and/or dietary adherence to a dietary pattern compared to consumption of a different dietary pattern, or different levels of consumption.

So, the population in this case is human milk composition and human milk quantity. So, basically for composition we're including women during lactation, healthy and/or at risk for chronic disease. But for quantity, we're focusing only on those mothers that are exclusively or predominantly breastfeeding, so that we can get more accurate assessments of intake. And, they will be healthy or at risk for chronic disease.

So, we have a, a number of outcomes in this. So this, and we, and this was mentioned yesterday, but we will be looking at milk collected after 14 days postpartum.

So, this is more representative of mature milk as opposed to colostrum. So, some of

the standard macronutrients: water soluble vitamins, fat soluble vitamins, minerals.

One of the aspects of human milk minerals is that they, they're quite invariable. They're tightly regulated at the mammary gland with the exception of iodine and selenium. So, we're focusing on those two.

We're also including some bioactive proteins where there's, where there's data. And again, this was mentioned before.

So, in terms of -- these are -- as you will see as we go through, these are a lot of our standard key confounders that we are carrying through so I'll predominantly mention when we have additions to that.

So, again, there's -- we're using the standard NESR criteria that was described by Dr. Schneeman, and we also are using the criteria for these sets of questions related to dietary patterns that are consistent with the Dietary Patterns Subcommittee.

You'll see that for a lot of our

searches we are going back to 1980 because this has not been previously included in the Dietary Guidelines so we're trying to capture a broader database. But again, for this, we're only going to 2000 because as was mentioned yesterday, this, this is more of a relatively new type of analysis.

So, these are the, the types of studies. Again, kind of following the standard NESR inclusion and exclusion criteria with the exception that for studies related to human milk composition and quantity, we are -- decided to include some cross-sectional studies because we felt there might be insufficient longitudinal studies to address these questions.

Okay, so the next analytical framework is dietary patterns on infant developmental milestones, including neurocognitive development.

So again, same intervention and exposure. You can see the developmental milestones. And, we're looking at this related to a couple different outcomes, and they're

consistent with what Linda Snetselaar reported yesterday in terms of looking at cognitive, language, communication, movement, motor and motor development, social, emotional, academic performance, ADD, ADHD, anxiety, depression and ASD.

And, we're looking at infants and toddlers, birth -- B24, but also in this case, looking at longer terms outcomes because a lot of these, particularly language development and academic performance, we'll need to look at, at later ages.

So, a lot of the, the same key confounders, we're also including aspects that have been known to impact infant cognitive outcomes, which include where they -- so, family history and diagnosis of neurocognitive disorders, maternal substance abuse. We also have in here things related to parity, child sex, breastfeeding practices, so duration and exclusivity. Again, standard NESR criteria and 2000 to to be determined.

So, the next framework is again, dietary patterns during pregnancy and maternal micronutrient status. Same interventions and comparators.

The micronutrient status that we're looking at in the mothers is iron folate, B12, vitamin D, iodine and omega-3 fatty acids. Our population is women during pregnancy, healthy or at risk for chronic disease.

In terms of key confounders, we are -- we've added as a factor to be considered not as a key confounder, gestational diabetes because there is some evidence that the metabolism of some of these micronutrients can be different in women with gestational diabetes. Again, standard criteria here.

So, those were the, the dietary, the new dietary patterns analytical frameworks. So, now, moving on to the relationship between nutrients from supplements and/or fortified foods consumed before and during pregnancy, and lactation.

So, we have five nutrients altogether. I'll talk about iron and folate later. We presented those in July and were now implementing those.

But, these are the new frameworks: B12, omega-3, and vitamin D. And, for each of these nutrients, we're investigating all five of, of these outcomes, so you can do the math.

Just a reminder of again, using standard definitions of dietary supplements from ODS and fortification from the FDA.

We also had to define some of the criteria. So, because this is including before pregnancy, we considered the time of up to six months prior to pregnancy as being the before pregnancy time frame.

Pre-pregnancy BMI is being defined based on health records for up to one year before to up to and including the first trimester, because we oftentimes don't have those measurements from -- in health records.

Gestational weight gain defined

according to the CDC. And, again, gestational diabetes. Again, diabetes occurring during pregnancy in women not previously diagnosed, and this is consistent with what was used in the pregnancy, or B24 Project.

Okay, so now we'll talk about B12 first. So again, we have five outcomes, so I will explain the first one in a little bit more detail, and then just highlight the differences.

So, this one is on B12 and from supplements and/or fortified foods consumed before and during pregnancy and lactation on micronutrient status. So, we're looking at exposure to B12 either from supplements, fortified foods, or the combination, compared to those who were not exposed, or exposed to a different level of intake.

So, women before and during pregnancy and/or lactation, healthy or at risk for chronic disease.

For our B12 markers, we're considering B12, methylmalonic acid, homocysteine, and

holotranscobalamin in, in the maternal circulation. We're also looking at folate, hemoglobin, mean corpuscular volume and red blood cell distribution width. And, our population is women during pregnancy and/or lactation.

So, the, the standard key confounders for other factors to be considered, we're including substance abuse, alcohol or drug intake, and gestational age.

We also I can point out, we're as a key confounder, we have vegan or vegetarian diets in here as well for B12.

So, but this is the relationship between B12 and risk of gestational diabetes. So, these are the same. So, in this case we have intermediate outcomes, which could be reported -- we're not using these as diagnostic. Basically, the end point for diagnosis is gestational diabetes.

We have added a couple additional confounders in a family history of diabetes or prediabetes, and under other factors to consider,

we have prior history of a large for gestational age infant, or enrollment in an intervention/prevention trial.

So, these data will be extracted. They're not considered a key confounder, but we are asking the staff to collect data on this.

This is the framework for B12 on the risk of hypertensive disorders during pregnancy. So, again, we have some intermediate outcomes. Blood pressure and proteinuria. And, then the health outcomes are eclampsia, preeclampsia, and gestational hypertension.

In terms of the, the key confounders, we added here diagnosis of gestational diabetes because sometimes these co-occur quite commonly. Smoking, history or diagnosis of hypertension or cardiovascular disease. Under other factors we've added also physical activity to be extracted.

This is B12 and human milk composition. It's a little bit more simple. The only outcome here is B12 concentration in human

milk. And we didn't have any additional confounders or other factors.

Okay, this is on, on B12 on infant developmental milestones, including neurocognitive development.

So, again, these are the same outcomes that I reported previously for looking at the developmental -- or I'm sorry, dietary patterns and infant neurocognitive outcome. And again, the, the outcomes and confounders are very similar to the dietary patterns except now the vegan and vegetarian diets.

So, we've, you know, done our best to try to be as consistent not only internally, but also as we work with other committees.

Okay, so for all of the B12 analytical frameworks, again, the standard inclusion/exclusion criteria.

So, again, the same types of studies and continuing to include cross-sectional studies only for human milk composition, and going back to 1980 for these, these outcomes.

So, now we have the analytical frameworks for omega-3 fatty acids. So, these basically looking at relationship between the intake and the same five outcomes that I just described. So, I again, I'll try to go through this pretty concisely.

So, we have exposure to omega-3 fatty acids through supplements, fortified foods, or the combination compared to a different level of exposure. For our nutrient status we're looking at fatty acid status in red blood cells and plasma of the omega-3 fatty acids, and omega-6 fatty acids.

So, alpha linolenic acid, docosahexaenoic acid, and EPA. And then linoleic acid and arachidonic acid.

So, in terms of the key confounders, we're including fish and other seafood consumption, and obesity status. Again, there's some, some indication of differences based on maternal BMI and, and those were the additions for the omega-3 fatty acids.

So, these again, omega-3 fatty acids and risk of gestational diabetes very much the same. Same intermediate outcomes for the, the previous nutrients and the endpoint of gestational diabetes. And again, including fish and seafood.

Here, other factors could be included in an intervention/prevention trial and the large prior infant as well. And, family history of diabetes/prediabetes. So, again, consistent with the other nutrients looking at these outcomes.

Again, the same. The omega-3s and the hypertensive disorders. And omega-3s and human milk composition and we're going to basically look at fatty acid composition. So, not only obviously the omega-3s, but the, the whole fatty acid composition in the milk where available.

And this is the infant -- so this is relationship between again, maternal consumption from supplements and fortified foods before and during pregnancy, and infant developmental milestones.

So, while the B24 is going to be looking more directly at the intake of the infant, this would be potentially effects mediated for maternal diet through milk.

So, again, the same, same outcomes including again, breastfeeding practices, intensity and duration. So, hopefully, being able to pull out exclusive from partial breastfeeding. Again, same inclusion/exclusion.

So, now we're going to do vitamin D again, with the five outcomes.

So, for vitamin D status, I just want to point out that the way we're, we're looking at vitamin D status is 25 hydroxy vitamin D. In terms of for all of the vitamin D outcomes, we've added basically as another factor to be considered, is sunlight exposure and use of sunscreen.

So, we know that not all papers will provide that, so we didn't want to include it as a key confounder, but we do want to collect that data when, when possible.

So, again, very, very similar in terms of now vitamin D and gestational diabetes, vitamin D and risk of hypertensive disorders, and vitamin D and human milk composition.

And in this case, we're trying to capture all of -- any or all of the vitamin D forms that could be reported in, in the human milk. And, you know, lastly, the vitamin D and neurocognitive development. So, same inclusion/exclusion criteria.

Just again, these are as Kay had mentioned, available on DietaryGuidelines.gov, so if you want more detail you can certainly visit those.

So, the last new protocol I wanted to discuss is: What is the relationship maternal diet during pregnancy and lactation, and risk of infant and child food allergies and atopic diseases?

So, this is just one outcome and we're looking at again: What is the effect of maternal diets on this?

So, this is very broad. Dietary intake of foods and food groups, either not consuming that food or a different amount of that food. So, this is going to be a very broad search.

Our outcomes, we have food allergies, allergic rhinitis and atopic dermatitis. Dermatitis and rhinitis are often times on the atopic march prior to diagnosis of food allergies, but we, as Kay mentioned, had some discussions about including food sensitization on its own because sensitization alone does not indicate that that child will actually manifest an allergic reaction.

So, in terms of outcomes, we have timing of introduction of our key confounders -- I'm sorry, timing of introduction of complementary foods and beverages, types of complementary foods and beverages, family history of atopic disease and if reported, urban/rural environment, exposure to animals, pets and farms, because all of those have been implicated in affecting allergy.

And again, other factors to be considered could be indoor/outdoor environments if that's reported.

But, we're trying to make this a very broad search because as Rick mentioned, this is a rapidly developing area and so we'd like to try to determine the impact of maternal diet. Okay, so again, the same types of criteria here.

So, that was the conclusion of all the, the new protocols, and so now I'd like to just talk about two where we've actually implemented the plan.

So, even though in July we, we had done the analytical framework for iron first, we decided to actually start implementing the, the plan for folic acid.

So, the questions that we've been investigating is was the relationship between folic acid supplements, from supplements and/or fortified foods consumed before and during pregnancy on human milk composition, and risk of gestational diabetes. So, these are two of the

five outcomes that we're looking at related to folic acid.

So, looking at the first question. So, just a reminder of this analytical framework, which was presented back in July looking at folic acid from supplements, fortified foods, or a combination on human milk folate composition.

And in terms of we really didn't have any different key confounders. These are kind of our standard ones.

So, we from the search, there were four databases that were searched resulting in 7,817, which was reduced to about 4,500 after removal of duplicates. After initial screening, we -- of titles, abstracts and full texts, we ended up with 16. And there were no new articles added.

So, the ones that were then included after going through our inclusion and exclusion criteria, we had four articles. And, of those three were RCTs and one was an uncontrolled before-and-after study.

All four address specifically the question is: What is the relationship between folic acid from supplements during lactation and human milk folate? So, there -- there were none that looked at fortified foods.

So, the sample characteristics of the three randomized controlled trials. They had on average, between 14 and 23 per group. They were conducted in the U.S. and Canada. An average age of 33 years, mostly white and high SES for two studies. The other study was in adolescents, mostly white and low SES.

The intervention doses were 300 mcg, 400 mcg and 1 mg, and also looked at the five methyltetrahydrofolate form as well.

They were initiated within one week postpartum, or three months postpartum, and they lasted between 12 to 16 weeks. All reported human milk folate concentrations. They also, some reported on metabolized milk folate, soluble folate binding milk, milk folate binding protein.

The uncontrolled before-and-after

study, this was conducted in Japan of 16 mothers. There was very little evidence or data presented on the participants. They basically just said the women in the study were from the same SES group. So, basically before and after they were the same mothers. But, it was a weakness of the study.

They gave 1 mg of folic acid, initiated anywhere between three and 25 weeks postpartum and the trial was for four weeks.

So, the studies use slightly different methodological approaches to measure the folate, but none of the studies found an association between folic acid supplementation in lactating women and human milk folate levels. And, the actual levels reported were fairly consistent among the studies.

When we began the assessment, the studies were direct and precise. The results were very consistent. We had some concerns regarding risk of bias and generalization due in large part to that the populations were quite

homogeneous.

So, our again, these are draft preliminary conclusion statements that moderate evidence suggests the consumption of folic acid supplements during lactation, among women in high or very high HDI, high development index countries, does not influence folate levels in human milk.

No evidence is available to draw a conclusion about the relationship between folic acid from supplements consumed before and/or during pregnancy and human milk folate, and no evidence is available to draw a conclusion about the relationship between folic acid from fortified foods before and/or during pregnancy and lactation in human milk folate.

So, for these latter two, we had grade not assignable.

So, the second question, the relationship between folic acid and gestational diabetes and the analytical framework consistent with intermediate and point outcomes that we,

that I previously presented.

Again, searching four databases resulted in 829 articles which we ended up with eight that remained after screening, and only one that was included in the final systematic review.

It was a non-randomized control trial that addressed the question of what is the relationship between folic acid from supplements consumed during pregnancy, and risk of gestational diabetes?

It was a large study of over 7,800 participants conducted in China. Mothers between the ages of 20 and 40, nonsmokers and nondrinkers. They gave doses of 0, 400 or 800 micrograms per day, and they based the dose based on genetic polymorphisms in, of the mothers, and also the stage of pregnancy.

The again, initiation was not clear because they talked about pre-pregnancy, but then they stated that they recruited the mothers during the first trimester. So, as we started looking at the paper it would have been a great

paper but it, you know, there was just some concerns about the details.

So, among the women who consumed folic acid supplementation based on genotype and stage of pregnancy, there was a significantly lower incidence of gestational diabetes compared to women who did not consume folic acid supplements. So, 3.2 in the control and .27 in the intervention.

But when we assessed the evidence, there were concerns regarding risk of bias and we felt there was insufficient evidence to evaluate the directness, precision, consistency or generalizability of the results.

So, our draft conclusion is that there's insufficient evidence is available to draw a conclusion about the relationship between folic acid from supplements and/or fortified foods consumed before and/or during pregnancy, and the risk of gestational diabetes. So, grade not assignable.

So, just to conclude, we have as Kay

mentioned also with B24, we've been having a lot of cross-cutting discussions with the other subcommittees. So, we've had some joint meetings again with Dietary Patterns, Fats and Seafoods, Food Pattern Modeling.

And, we also provided evidence on the analytical frameworks pertinent to pregnancy and lactation to the Beverages and Added Sugars committee.

So, again, I'd just like to thank our committee. We've really, I think, made an incredible amount of progress in the last few months and again, none of this would be done without the support staff and just really appreciate everybody's hard work.

Thank you. You don't have to clap.

(Laughter.)

VICE CHAIR KLEINMAN: Does anybody dare ask a question?

(Laughter.)

MEMBER DONOVAN: And, we're exhausted.

VICE CHAIR KLEINMAN: Rachel?

MEMBER NOVOTNY: I'm on this committee but as I was thinking about it, I'm not clear if, if there's a need to distinguish, or precisely what the distinction is between before pregnancy and pre-pregnancy.

It seems before pregnancy gives an early start date, and then pre-pregnancy gives an end window to the period, but I think they're the same definition, but what do you think?

MEMBER DONOVAN: Well, we had said, and so maybe this is we need to look at the precision of how we're describing it, but we did say that it was six months.

So, we're looking in terms of like, the supplements and fortified foods. But, for in terms of like, BMI outcomes, that, pre-pregnancy weight could be up to a year prior to pregnancy.

MEMBER NOVOTNY: So, I think in our definition we said before pregnancy was six months prior, and pre-pregnancy was up till the first trimester. But, in fact, aren't they both the same window? Whether you're referring -- I

mean it's before pregnancy, what are we measuring before pregnancy? It's also BMI.

So, before pregnancy BMI, the window would be defined as six months prior to up to the first trimester, up to and including. And, so would pre-pregnancy BMI be six months prior and up to and including?

MEMBER DONOVAN: Well, I think in the framework we said that we would consider pre-pregnancy BMI up to a year, and then up through the first trimester.

And I think for the fortified foods and supplements, that was six months. Because we thought many women can be taking supplements who are planning to get pregnant, or some nutrients that could be stored in -- you know, like vitamin D or iron could be influenced.

But there's, you know, there's so many so I want to kind of make sure that we're clear on that.

MEMBER NOVOTNY: I guess, what are we measuring before pregnancy besides BMI I guess is

the other question?

MEMBER DONOVAN: Well, for the supplements and fortified foods, if there was evidence of use of those supplements prior to conception.

MEMBER NOVOTNY: Oh, I see. Okay.

MEMBER DONOVAN: So, women who may be prophylactically or planning to be, you know, using advice that they should be starting to take folate. Things like that.

MEMBER NOVOTNY: Okay. Because I think in our key confounders, we have anthropometry before pregnancy, too. And, so that's where I was getting confused as to how we're distinguishing --

MEMBER DONOVAN: I think that was --

MEMBER NOVOTNY: -- pre-pregnancy BMI and before pregnancy BMI.

MEMBER DONOVAN: Okay. Yes, we can, we can look at it.

MEMBER NOVOTNY: It's just a --

MEMBER DONOVAN: I think that was

primarily --

MEMBER NOVOTNY: -- it's a definition.

MEMBER DONOVAN: -- to capture pre-pregnancy BMI and obesity.

But, yes, I mean if you're on the committee and it's confusing, then we definitely need to go back and make sure that --

(Laughter.)

MEMBER DONOVAN: -- we're precise in that language. I'll make a note.

MEMBER ARD: I have a question.

VICE CHAIR KLEINMAN: Jamy?

MEMBER ARD: Jamy Ard. One quick question.

On the key confounders in the analytic framework related to hypertensive disorders, you mentioned that there was the addition of gestational diabetes because of an association between the two.

But there was not, you don't have hypertensive disorders in the gestational diabetes analytic framework as a key confounder.

Would that -- because I'm not, I, I can't tell, it's just not in my area of clinical expertise, but I don't know if there's a, just a general association or if it's you know, sort of unidirectional, but just something to consider.

MEMBER DONOVAN: Yes, so for the gestational diabetes, we do not have diagnosis of hypertension. So, that's something we can go back and look at. I don't think it's a unidirectional. Oftentimes, they're just co-occurring.

VICE CHAIR KLEINMAN: Steve?

MEMBER HEYMSFIELD: I have a very minor semantic comment. The word -- statement "dietary supplements."

In my world, the obesity world, has very specific meaning in a regulatory framework, which is Dietary Supplement Health and Education Act, DSHEA.

And, so I don't think that's what's meant by dietary supplements here, right? From what I see, these are specific micronutrient

supplementation. It's not dietary supplements like with various herbal constituents and so on, right?

MEMBER DONOVAN: No, because we're specifically looking at these five nutrients. So, we're only looking at these five nutrients as supplements or in fortified foods.

So, if they were using other, you know, St. Johns Wart, or other things, then that's not being captured in any of our searches.

MEMBER HEYMSFIELD: Okay.

MEMBER BAILEY: I think the frameworks have a definition somewhere --

MEMBER DONOVAN: Yes.

MEMBER BAILEY: -- don't they?

MEMBER DONOVAN: Yes. We're actually using the ODS and --

MEMBER BAILEY: Well, it's the --

MEMBER DONOVAN: -- you're using the DSHEA definition.

MEMBER BAILEY: Yes, you're the DSHEA definition.

MEMBER HEYMSFIELD: Oh, it is. Okay.

MEMBER BAILEY: Yes.

MEMBER DONOVAN: Yes, I have that on our --

CHAIR SCHNEEMAN: Actually though, that reminds me of a question of -- so, with the supplementation, are you looking at it if it might come in with a multi-vitamin supplement? It's not just, or is it only that they have to supplement with one specific nutrient?

MEMBER DONOVAN: Yes, because many of the prenatal supplements are combined.

MEMBER DEWEY: Can I add that --

MEMBER DONOVAN: Yes.

MEMBER DEWEY: -- but that when we look at the evidence and the results have to be a contrast, where the only difference is folic acid.

So, if they're getting multis, it could be multis without and multis with.

CHAIR SCHNEEMAN: I see.

MEMBER DEWEY: That kind of thing.

VICE CHAIR KLEINMAN: Tim?

MEMBER NAIMI: It was very interesting.

When you talk about there are so many possible comparisons between all these micronutrients and different outcomes, and some of them may not have a biologically plausible explanation.

So, are these, and I know we don't get to ask the questions in terms of what's assessed, but is there in terms of summarizing the evidence, how do you, how do you address that?

MEMBER DONOVAN: Great question.

(Laughter.)

MEMBER DONOVAN: I mean many of them are, you know, we can certainly provide the evidence between sort of the omega-3s and neurocognitive outcomes and others.

But again, some of them we'll just have to see how we're able to, to discuss that. Because I would agree that there is, it's not necessarily clear that some of the nutrients and

some of these outcomes have, you know, have clear mechanistically.

MEMBER NAIMI: B12 and diabetes.

MEMBER DONOVAN: Yes.

MEMBER NAIMI: And, there are many examples that have no basis.

VICE CHAIR KLEINMAN: I think the sentence will start although there is no evidence of biological plausibility as to. We're still working on it.

MEMBER DONOVAN: The idea was looking at sort of key nutrients and key important outcomes.

VICE CHAIR KLEINMAN: Yes.

MEMBER DEWEY: Do you want us to speak and talk about folic acid and human milk and why we're not surprised by the results? Oh, you want me to?

(Laughter.)

MEMBER DEWEY: So, with the one conclusion statement, we can really stand behind today is the one that the folic acid supplements

during lactation and in these populations, doesn't affect folate levels in milk.

And honestly, we knew that already from decades of work and the biology of how folic acid is taken in and then what happens in terms of memory gland biology. So, that was not a big surprise.

But I totally agree with the idea that the discussions of our sections of the report need to address biological mechanisms. Not in great depth, but at least allude to what we understand.

VICE CHAIR KLEINMAN: And, there are, you know, potential research questions that will come out of some of these where there isn't an obvious link but potentially, there is some metabolic pathway that could impact it.

And, around folate, I think what we talked about is the absence of studies in folate insufficient mothers and whether there was --

MEMBER DEWEY: Exactly.

VICE CHAIR KLEINMAN: Yes, so, there

is more to learn about this although we addressed this question I think quite correctly.

MEMBER DONOVAN: Yes, so our conclusion statement very specifically says in high HDI countries.

So, we can't conclude whether it would be beneficial in women who are folate deficient. And, also the addition of folate to the food supply through flour has kind of raised everybody's --- but nobody's really specifically looking at that anymore because it's there.

So, you know, that's why we try to think maybe there were some older studies prior to the fortification.

MEMBER BAILEY: So, maybe it would be helpful to just clarify that in your language. Because there are high development index countries that don't have fortification. So, maybe just in highly or in countries with fortification, or in folate replete populations or something like that, it might just be adding a little clarity.

VICE CHAIR KLEINMAN: Yes, that's a good point.

MEMBER DONOVAN: Yes, I think in terms of our statements, you know, we're trying to work with a common language but, you know, in our discussion, we can provide more evidence and flesh things out a bit.

VICE CHAIR KLEINMAN: Yes. Any other comments or questions?

Oh, Regan?

MEMBER BAILEY: So, I'm really interested in the research on the quantity of human milk. What does that literature look like? Isn't there tremendous diurnal variation and how are you guys addressing that?

In addition to all the amazing work you're doing, you have a lot of challenges inherent within each of your questions, so.

MEMBER DONOVAN: Yes, right. Well, we haven't gotten to any of those searches yet. I mean there's several ways to measure milk quantity through 24 hour weighing or stabile

isotopes. But, so we would try to look at the methods that are being used and then, you know, when we're grading the evidence.

But yes, I don't think that a lot of these micronutrients will have much of an effect. But, it actually might be interesting when we get to the beverages. Potentially. The fluid intake.

CHAIR SCHNEEMAN: So, speak up.

MEMBER DEWEY: I would be happy to.

So, we've understood for a while that the regulation of milk production is governed by endocrinological factors and physiological factors, but mostly driven by infant demand.

So, maternal nutrition is a very minor player and particularly in well-nourished populations. And if it is a player, it's more on the level of energy balance and those sort of really macro and micronutrients we don't know of.

I don't know of any mechanisms by which their intake would affect those mechanisms that determine milk production.

Again, the biology here is what we really need to look at. And it's interesting because in, in dairy cows it's different, and maternal nutrition of the cow can make a difference. But they've been bred for very high levels of production, way beyond what human women do.

(Laughter.)

MEMBER DEWEY: So, it's a very different situation. We don't really a great model from the animal literature.

VICE CHAIR KLEINMAN: I thought where you were perhaps going with that also is the, there are differences in concentrations in human milk depending upon when the milk is sampled. Is that what you were -- yes, and so one further need for our group is to be sure that the methodologies for collection are similar between studies, right?

Because if you're collecting early in the lactation or at the end of it, or it happens to be at night vs. the morning, or let's say

early in the lactation cycle versus very late, and, you know, we could go on and on.

So, and sometimes the studies don't actually talk about that at all. And, so that makes comparisons even more challenging.

MEMBER DONOVAN: Yes, so one of the decisions we made was milk after two weeks. So, to try to get some of the colostrum.

But you're 100% correct that if it's foremilk vs. hindmilk, or different times of the day. So, that would be considered as the evidence is being abstracted and we can, we can look at that.

If it's a single sample, you know, and they don't define when it was taken, particularly as we start looking at some of the omega-3 fatty acids and fatty acids, since those tend to be higher in the hindmilk.

So, very good point, Ron.

VICE CHAIR KLEINMAN: Oh, further question.

MEMBER NAIMI: One more question.

You guys are trying to distill out the effect of supplements and, so I was just wondering in the protocols I might have missed it, but how do you try to account for, you know, baseline consumption of a particular thing such as folate, apart from the supplements?

Is it possible to do that and should that be kind of a key confounder for all of those -- for each of the micronutrients?

MEMBER DONOVAN: Well, I mean I think from the dietary from Regan's committee will be getting levels of intake, so we can speak to that more generally.

But unless in those specific papers they did any sort of a diet record, I think it would be very difficult for us to determine, you know, the intake within a specific study.

But we will have intakes of those nutrients, you know, from the NHANES and other, other data sets.

CHAIR SCHNEEMAN: And it also comes back, it also comes back to this point that in a

country that fortifies, chances are you have a pretty high level of intake.

MEMBER DONOVAN: And then one of the things we thought about is, you know, almost gets back to dietary patterns is people are, you know, consuming less carbohydrate, that is a large contributor to folate intake.

So, you know, if we look at dietary patterns, we might actually see differences in folate consumption which, you know, could be problematic.

VICE CHAIR KLEINMAN: Linda?

MEMBER SNETSELAAR: I just wondered, and I don't know how this plays into the equation, but many moms today will pump and you had mentioned the idea of demand and how important that is. Are there any studies that have been done looking at that concept?

MEMBER DEWEY: Yes, you can actually increase the stimulus for milk production by pumping, in addition to nursing directly at the breast. The body interprets that as increased

demand and will respond to that.

So, yes, it gets more and more complicated these days because so many women are pumping.

MEMBER DONOVAN: And then we'll also take into account if it was pumped milk, if it's been frozen and in terms of nutrient composition.

VICE CHAIR KLEINMAN: Joan?

MEMBER SABATE: In the analytical framework for vitamin B12 and I think for other key nutrients, supplements, you put into the key confounders vegan/vegetarian diets. I mean I wonder as far as using these as a confounder.

And the other thing in case, I mean that is the one to proceed. I think it will be wise to separate --

MEMBER DONOVAN: Yes.

MEMBER SABATE: -- I mean vegan versus vegetarian diet, if by vegetarian we interpret lacto-ovo vegetarian.

MEMBER DONOVAN: Certainly that's a good point. So, right now they're combined but

they, that data would be extracted separately so we'll be able to look at those separately.

MEMBER DEWEY: If I could just add, I think one of the important considerations as it being a potential confounder is that many pregnant and lactating women who are at least vegan and maybe even vegetarian, are advised to take vitamin B12. And so the consumption of supplements and the dietary pattern are linked quite strongly.

So, that's why it's an important confounder in my view, because we don't -- when we're looking at the outcomes, we have to figure out what they're related to.

MEMBER SABATE: But beyond being a confounder, I mean it could be also an effect modifier.

MEMBER DONOVAN: It could be.

MEMBER SABATE: So, I mean stratifying by this parameter will give very useful information.

MEMBER DONOVAN: Absolutely, you know,

but we're dependent on the studies to have done that. And, we think it's a logical thing to do but it isn't always in their papers.

VICE CHAIR KLEINMAN: All right, well --

MEMBER DEWEY: I have a question for Linda. Can I ask that?

So, I have a question for the Dietary Fat and Seafood Subcommittee, because I was looking back over all of the protocols we just presented this morning and, in terms of the omega-3 fats in the B24 protocol.

So, we're looking at intake of that from supplements or fortified foods, and but the outcome domains do not include neurological or cognitive development. That's what we were given.

So, my question is I don't remember what is the definition of the types of dietary fat exposures that you're subcommittee is looking at. Does it include supplements or exclude supplements?

MEMBER SNETSELAAR: What I presented the other day excluded supplements. That doesn't mean that some of our eventual questions might not get into that area when we look at total fat, for example. But what I presented with ADD, ADHD, and ASD excluded supplements.

CHAIR SCHNEEMAN: Because they were seafood questions, right?

MEMBER DEWEY: So, perhaps we can discuss this when we have some cross-talk on the --

MEMBER SNETSELAAR: Yes, most definitely.

MEMBER DEWEY: -- upcoming protocols? Thanks.

MEMBER SNETSELAAR: Most definitely.

VICE CHAIR KLEINMAN: All right, well I think we've earned a little break. So, 15 minutes, is that --

CHAIRMAN SCHNEEMAN: Yes, I think 15 minutes.

VICE CHAIR KLEINMAN: Okay.

CHAIR SCHNEEMAN: And, just before we go on break, I do want to once again remind everyone who's listening, that what we're hearing from the committee reflects their findings and their conclusions. We haven't formulated any recommendations yet.

So it's -- these are sort of our initial findings and conclusions that we're presenting for discussion.

VICE CHAIR KLEINMAN: Work in progress.

CHAIR SCHNEEMAN: Yes. So, what about --

VICE CHAIR KLEINMAN: All right, so 10:55?

CHAIR SCHNEEMAN: Yes, sounds good.

VICE CHAIR KLEINMAN: Great.

(Whereupon, the above-entitled matter went off the record at 10:40 a.m. and resumed at 10:58 a.m.)

CHAIR SCHNEEMAN: Okay, so, Dr. Regan Bailey will be giving the subcommittee report, so

I think we're ready.

MEMBER BAILEY: Okay, last and certainly not least, Data Modeling -- Data Analysis and Food Pattern Modeling.

Again, so I spoke a little bit earlier specific to the B24 group. Now we're going to be looking at the other set of questions that we are addressing, and those are listed here, and we'll go through each one of those so I won't read those to you now.

So, we're implementing the plan for two years and older for all of the protocols that we discussed at the July meeting. And, the final piece as I mentioned previously, is the Food Pattern Modeling and, what changes need to be based on the work that you all are doing in your systematic reviews, and are those food patterns possible for two years and younger?

So, just some general updates to those protocols that we presented in July. So, infants and toddlers again specified as birth to less than 24 months, we added specificity to age

groupings and population subgroups in our analytical plans.

Added sugars and caffeine are being referred to as food components, rather than nutrients, as they are not nutrients. And I'm on this bandwagon to get the word dietary component so that it's representative of foods, beverages and supplements. But right now, it's a food component. And then individual nutrients contributed by beverages that were not specified.

Until we determine what those nutrients of public health concern are, and then we're going to have that discussion towards the end of the talk. But, all of our protocols are aligned with those particular nutrients.

So, some protocol-specific updates. Dietary patterns and beverage consumption, we're looking at changes over time.

So, our comparator group will be NHANES 2005-2006. Current intakes of food groups and nutrients, and changes in average nutrient intakes from food and beverages was added to the

analytical plan for adults and older adults, to be consistent with life stage.

And the prevalence of nutrition related chronic health disease. So, dentition was added to the analytical framework and the analytical plan.

So, for all of the questions that we will be addressing, our, our sample is the United States.

So, we, I mean really all of the data sets that we're looking at are nationally representative, so that these can inform the Dietary Guidelines. And that's the reason why we rely so heavily on these sources.

And we discussed a little bit about this yesterday, but here's the specific slide that I alluded to with the exact life stage groupings, and of course these are not perfect. They aren't set in stone.

Some of the publications that we have have different age groupings. But this is just kind of an overarching framework.

And, then we will have data available to us by sex, race, ethnicity, socio-economic status, and inclusive of food security status.

Again, we will be utilizing the NHANES data What We Eat in America survey components, with the requisite databases that are listed here to get nutrient content, food groups, and foods as they are consumed from foods, beverages, and dietary supplements. So, just as a refresher.

Again, and we've presented these before, but this stage of life is often variable. It can depend on whether it's available in the NHANES the way that the reports are written, and/or by the dietary reference intake groupings.

Socio-economic status is the broad term that can reflect any of the indicators that are listed on this slide.

So, we will be discussing some of the newer protocols and how the relationship to achieving food and nutrient recommendations vary by the frequency of eating, by beverage consumption, and there's a separate protocol for

alcohol from the other beverages, as well as consumption of added sugars.

So, the first question is what is the relationship between the frequency of eating and achieving food group and nutrient intake recommendations?

We will look at the total number of eating events, as well as person described. I didn't want to say subject. Participant described eating occasions such as breakfast, lunch, dinner and snacks. And, their Spanish equivalents.

So, snacks just a note here, that those are inclusive of drinks or extended consumption.

So, there's interest in when people are eating, time of day. Does time of day have an impact on meeting food and nutrient recommendations? But this is something that we are discussing with the frequency of eating. How do we operationalize those times of the day? And that's part of ongoing work and discussions that

we're having.

So, as I mentioned, we'll look at frequency of eating with and without those naming conventions. So, the number of eating events in a 24 hour time period. So, the way that the 24 hour recall is collected is midnight to midnight.

So, we have information available on the hourly consumption of eating events, the number of snacks, which can include beverages, and we've been looking at that inclusive and exclusive of water. Because a water only event really increases the total number of ingestive events in a 24 hour period, as well as time of day.

And then we have the hour time stamps for some of the, for the reports in NHANES.

We're also looking at the proportion of food group and subgroup intakes and dietary components by eating event type, with and without naming conventions. And the naming conventions are what I described earlier.

So, our next question that we'll be

presenting to you is what is the relationship between beverage intakes and achieving food group and nutrient recommendations?

These are the beverage categories that we are looking at, and this is part one of two. So, there are two slides that give you the discrete beverage categories. And, just a reminder that beverage pattern refers to the quantities, proportions, varieties or combination of different beverages within the diet.

So, we'll have these discrete beverage categories as well as those listed on this slide.

So, specific between a diet beverage and a sweetened beverage is the 40 calories per reference amount customarily consumed.

Water from all sources, whether it's carbonated, flavored, if the definition is less than five calories, and then alcoholic beverages. And we'll have a whole discussion on that category coming up in a few slides.

So, for the non-alcoholic beverage questions, we will be looking at the food and

dietary components per eight ounce of discrete beverage consumption, okay?

And so we'll also be providing data on what beverages contribute. So, as the percent of total daily energy, how they contribute to selected nutrients and dietary components, how they contribute to food groups, and how daily beverage cat -- calories, excuse me, vary by discrete beverage type.

Specific questions have been an area of interest is the prevalence of intake of nutritionally fortified beverages, as well as cow's milk and milk substitute beverages.

So, this is the alcohol specific question. So, it would be inappropriate to use the eight ounces there because eight ounces is a very different animal, if you will.

So, we're using the alcoholic drink equivalent here. So, understanding that wine, beer and spirits, differential amounts all provide 14 grams of pure alcohol.

We'll be looking at the prevalence of

binge drinking and frequent binge drinking. So, those are defined here for you. For men, binge drinking is consuming five or more drinks on the same occasion, and that same definition for women is true, with four as the number of drinks.

And then frequent binge drinking is binge drinking that occurs on five or more occasions in the previous 30 days.

So, this is the analytical framework in terms of the data and the age groupings that we have available to us.

So, we'll be looking at dietary intakes relative to alcohol for 20 years and older, alcohol use in terms of underage, the prevalence of underage alcohol consumption from 12 to 20 years, adult alcohol consumption, 21 and over, and then pregnant women in our NHANES analysis is 20-44, but because we're using the BRFSS data for pregnancy, that is inclusive of women 18-44.

So, when we say exceptions noted, those are largely driven by the way that the data

are collected. We have information available to us not only from BRFSS on alcohol, but NSDUH --

(Laughter.)

MEMBER BAILEY: -- the National Survey of Drug Use and Health -- that has to be my favorite acronym ever NSDUH -- but it is cross-sectional nationally representative survey data on drug use and mental health, including alcohol use.

So, as I mentioned, we're looking at the prevalence of alcohol use, binge drinking, and frequent binge drinking. We're interested in how alcohol contributes to energy, caffeine and added sugars specifically, per drink equivalent. And as well as how do alcohol beverages in terms of contribute to a percent of total energy throughout the day, how they contribute to added sugars and caffeine, as well as daily beverage calories.

Our next question that I'd like to get your feedback on is the relationship between added sugars and achieving food group and

nutrient recommendations.

And throughout the last two days we've had the FDA definition of what is an added sugar, so I will not read that to you here, but just a reminder.

Our analytical framework includes the usual distribution of added sugars. That is from the two days of intake.

The percent of the population that is achieving the current recommendation from the 2015 to 2020 Dietary Guidelines, of less than 10% of total energy intake from added sugar, as well as the food category sources of added sugar, and how those contribute to nutrient and food group intakes.

And finally, we would like to have some discussion with the Committee today about how we describe and evaluate nutrients of public health concern.

We propose that we continue to use the established three-pronged approach to identify nutrients of concern, and that includes nutrient

intakes from dietary data, biological end points, and clinical health consequences, when such data are available.

So, in terms of defining what is a nutrient of concern, or what I would like to call dietary component of concern, we'll be looking at intakes from food and beverages alone, and from total sources inclusive of dietary supplements.

We have the DRI benchmarks for risk of inadequacy and risk of potential excess. So, for all nutrients with an EAR, we will use that as the benchmark of inadequacy.

When an EAR is not established, we will utilize the adequate intake and the comparison of the mean intake to the adequate intake.

For nutrients with a UL and CDRR, I think currently sodium is the only nutrient for which we have a CDRR, we will look at that percent of the population that exceed that recommended intake threshold.

We'll look at calorie intakes outside

the acceptable macronutrient distribution range, and then existing guidelines.

So, I've mentioned added sugar, but this is also similar for saturated fat. No more than 10% of total energy from saturated fat.

So, we'll use that information to inform the dietary component of that three-pronged approach.

But in addition to that, we also have to look at what previous guidelines have identified as nutrients or dietary components of public health concern. We will start there with the previously identified.

We'll also incorporate information from the National Academy of Science, Engineering, and Medicine report. Specifically, chapter 7 goes into great detail about how having a priori criteria established to be very transparent, and how we identify nutrients of public health concern.

We also want to be mindful to dovetail our efforts with the extensive work that FDA has

already done on this for the nutrition facts label and the supplement facts label.

So, they have done a tremendous amount of work already and, so we want to be complementary to what's already existing.

As well as sources of scientific agreement. And, this is particularly for special populations like B to 24, or Pregnancy and Lactation, where nutrients of concern haven't been previously identified, particularly for birth to less than 24 months.

So, we'll utilize some of the expert opinions in terms of identifying potential nutrients that way, as well as the three-pronged approach.

And then our next steps of course, would be to integrate nutrients from dietary supplements. I mentioned that right now, what we have available is from foods and beverages only. So, the total sources is very important as there's a high prevalence of nutrient containing supplements in the United States.

We'll review and summarize the analysis that we already have at our disposal. We will begin to draft some conclusion statements, and then end with some Food Pattern Modeling protocols.

So, that is our plan for the moment, and I would greatly welcome committee feedback, input, thoughts, and questions.

I'd like to thank our federal support staff that are listed here on the slide, and the members of the Committee.

CHAIR SCHNEEMAN: So, Regan, I was wondering if in the subcommittee, have you started to develop proposals?

You know, I think from my perspective what you've proposed as the nutrient intake adequacy, you know, what you're looking at and how you're tackling identifying nutrients of public health concern.

But if, for example, looking at the EAR cut-point method, have you talked about what percentage of the population falls below, or

above, the EAR cut-point?

Or with the AI, what kind of discrepancy from the AI would sort of bring a nutrient into looking at it further?

MEMBER BAILEY: Yes, so we have started to have some discussions around that with the federal support staff, as well as the committee.

Ideally, based on what the recommendations in the NASEM report are, is that we establish a threshold that is consistent and transparent. And, so we've talked about what is that threshold?

So, we've done some preliminary analysis looking at nutrients for which 25% or more of the population would be considered inadequate. And, then the next step is that looking at that dietary intake relative to a biomarker.

So, I think if we could establish what those thresholds are before we go into the data would be my preference. And that's been informed

by the work of FDA, who's done that for the food label for different nutrients.

But it varies for different nutrients, and what the severity of low and high intakes are. So, as well as what the DRIs, and the confidence that we have in certain DRIs.

And so that's why it's important that we try to link it whenever possible to a biomarker or a clinical end point.

So, there's certain nutrients as you know, that there's a very high prevalence of dietary inadequacy. For example, folate. There's up to 25% in certain population groups who by the EAR are considered at risk for folate inadequacy from the diet alone. But when we look to the biomarker, it's less than a half a percent who has low serum or red blood cell folate.

So, kind of going through that as an example, then we could eliminate folate as a potential dietary component of concern based on multiple sources of evidence.

MEMBER NOVOTNY: Rachel Novotny. So,

would you say just another couple sentences at a high level about drafting Food Pattern Modeling protocols?

Are they -- would these be to address, to identify food patterns to address nutrients of public health concern, or on what kind of basis would the --

MEMBER BAILEY: Yes, so the -- and I know it was a long time ago, I don't know if I can skip all the way back there, but the three questions that we have are: are there changes needed to the current recommended patterns to enhance things that are identified in your systematic reviews? So, those are the specific questions.

In terms of B to 24, are those food patterns that are existing, are those possible for those two and younger?

And then in terms of Food Pattern Modeling related to nutrient adequacy. So, thinking about things like dietary supplements, fortified foods and added sugars.

So, those are some of the very specific things that we have as questions for the Food Pattern Modeling sections.

CHAIR SCHNEEMAN: I'll ask another question.

Because you mentioned the B through 24 as a group that hasn't had this defined through the Dietary Guidelines.

And, I know that you all are looking at specific nutrients so I'm, I'm just interested to know how did you decide those nutrients, and how does that feed into what this group will look at, or think about how it wants to define nutrients of public health concern for the, particularly the B24, but also pregnancy and lactation?

MEMBER DEWEY: I can start and then you.

So, for B -- this is Kay Dewey. For B24, we've had some side conversations about in the first year of life, we really have to subdivide between 0 to 6 months, and 6 to 12.

So, 0 to 6 because it's all AI values and it's based on the composition of human milk, it's a very different picture.

But, from 6 to 12 months, we do have a couple of nutrients where there's an RDA, but most of them are AI values. So, this is another problem.

And, in that age group, the likelihood of being below an EAR cut-point for example, is, is very small for infants getting a lot of fortified infant formula. Because they're fortified with all those nutrients.

So, that's why stratifying by the human milk fed predominantly, even when they're getting complementary foods, and formula fed infants is so important. And, that's what we're working on.

Once that's done, excuse me, based on other evidence and other kinds of modeling, there will most likely be some nutrients that are most problematic or limiting. Iron and zinc, for example, possibly calcium. And, then potentially

some vitamins depending.

And, so when we start thinking about the food modeling part, I'm, I think we'll have to have a lot of discussion about how that works. Because it would need to include scenarios where it's just the unfortified foods that are getting into the picture, and then option scenarios where fortified foods like baby cereals, et cetera, are in the mix.

And, because we've been tackling the issue of our deficiency in infants in the U.S. for decades with fortified infant products. So, those are some initial thoughts.

You want to say something about it?

MEMBER DONOVAN: Well, I guess in terms of the, I mean obviously in terms of the nutrients that we're focusing on in the systematic reviews were based on the questions we were given, which, you know, identified nutrients or dietary components of concern.

But it will be I think very interesting in this process as you go through, to

help identify, you know, other. Because we hear a lot about fiber, you know, in children, and fiber in, in the whole U.S. population. But again, we don't have any questions related specifically to that.

So, I really see these as, you know, fleshing out some different areas, and, and it's particularly critical I think, in the B24 because we don't know a lot. Particularly with the breast-fed infants.

MEMBER MATTES: This may be overkill, but so in your analysis --

(Simultaneous speaking.)

MEMBER MATTES: But in your analysis of snacks, which will be self-described, will you break it down into snacks early in the day, snacks later in the day? Or snacks will just be a general category?

MEMBER BAILEY: I think that we talked about not the specific details of snacking. I think those are some conversations that our committees should have, and have soon.

But, I think what we've talked about is early morning eating and late night eating, and how that impacts the frequency of eating and meeting nutrient and food group recommendations.

So, and that would vary across the life stages.

So, in children, snacks are contributing quite a bit of energy and, potentially for some of the nutrients of concern.

But, I think your point is well taken that not only is it an issue of when, but what, that is being called.

MEMBER MATTES: Yes, yes.

MEMBER BAILEY: Yes, that's a good point. Thank you.

MEMBER SABATE: On this slide that is now posted, I mean the questions at the bottom. You relate as far as the frequency of eating, beverage consumption, alcohol intakes, so on and so forth.

As far as achieving the food groups and nutrient intakes, I have two questions. One

is the food group intake. I mean I think it's one of the issues that this committee, I mean has to come up with guidelines.

So, how can your committee works, I mean as trying to compare what the sample population consumes, as far as guidelines that has not been issued yet? I mean that's the first question.

MEMBER BAILEY: Yes, so we will utilize the existing food group recommendations from the 2015 to 2020 as a benchmark to inform our report.

MEMBER SABATE: Okay. And, as far as the nutrients, as you know, there are many compounds, I mean now considered very helpful that probably are not still yet labeled as nutrients.

Are you going to also use those as a benchmark, or these are going to be excluded of your analysis?

MEMBER BAILEY: Yes, and I think that is one of the reasons for at least a start to

standardize the language to use dietary components rather than nutrients.

So, there may very well be strong associations with certain bioactive components in foods. But, if we don't have the requisite database amounts of those bioactives available to analyze our data, and that's oftentimes the limitation.

Not only are there not dietary reference intake recommendations for a lot of dietary components, but then we don't have the database information to analyze what current consumption is.

And, I think that's something that we will have to document as limitations and areas for future research.

MEMBER SABATE: Okay.

CHAIR SCHNEEMAN: Other questions or comments from the committee members?

I know that this, when we get to that point of trying to integrate based on what you're finding from the literature, being able to see

whether we are is going to be a crucial part of actually coming up with recommendations.

MEMBER BAILEY: Absolutely.

CHAIR SCHNEEMAN: So, I know everyone's anxious to see all the data.

MEMBER NOVOTNY: I guess just -- Rachel Novotny -- just sort of a general thing I'm thinking about is making a transition from nutrients into foods, and food components or diet components. And, then related to that, trying to address some of the general policy issues that we want to make around foods.

Is looking to this group really to help us see patterns of eating and the population in general?

I'm thinking that we should spend more time about sort of certain segments of the population that we may want to understand their patterns better in order to go a next step.

That's as far as my thinking has gotten, but it's just sort of a general thought.

MEMBER BAILEY: Yes, absolutely.

Thank you.

MEMBER BOUSHEY: You know, in the, in the research space of dietary patterns and then particularly the theoretically driven patterns, but to a certain extent, it also occurs in the hypothetically driven patterns.

But so, a pattern is usually made up of a, a number of different groups of foods and we refer to those as dietary components.

So, I don't know if that blends with what you have in mind for dietary components.

MEMBER BAILEY: I think more or less, to be inclusive of things like added sugar, fiber, caffeine.

These are all things that we're interested in broadly, and different questions that we have. But they're not nutrients per se in the -- I mean we all use it colloquially, but you know, not to be overly pedantic, but I'm a big fan of harmonization of terms.

Recovering Federal employee. Can't help it.

MEMBER MATTES: Do you have particular concerns about the estimates of water intake?

(Laughter.)

MEMBER BAILEY: I think that is a way of you saying you have particular concerns.

(Laughter.)

MEMBER BAILEY: Stated differently.

Yes, I think there are certain things are notoriously difficult to measure. I think water is one. I think alcohol is one. You know, the serving sizes are provided and, they're very hard.

And, I think that we will have to have caveats around that and, in the way that we draft our conclusion statements and in interpreting the data that we have available to us.

There is some prompts in the AMPM procedures. We're doing a 24 hour recall to help participants remember to report beverages or forgotten foods that are often, or difficult to measure.

So, there are prompts built in to the

procedures. But, it remains an issue of concern.

CHAIR SCHNEEMAN: Did you have a follow up, or do you?

(Laughter.)

MEMBER MATTES: He's not willing to risk it.

(Laughter.)

MEMBER BAILEY: But, I actually cite your paper a lot for that tap water provides about 5% of calcium to diets. And, so it's not -- you know, it's not insignificant.

And, so it's an important question and I know that we've been talking through the frequency of eating, but especially, you know, water is an ingestive event because that happens quite regularly for a lot of people.

And, so being mindful of that, and the way that we present and think about the data.

CHAIR SCHNEEMAN: So, other comments from the committee? Did Beth or Joan, did you have some other comments that you wanted to make or -- okay, go ahead, please.

MEMBER MATTES: Can I just make a global?

CHAIR SCHNEEMAN: Okay.

MEMBER MATTES: Okay, I think things may change as, as we progress along, and that we will be dealing with an adequate number of papers to be worrying about all of the key confounders and then other issues.

But, so far, we sort of have a pattern of we start with around 4,000 hits, and we end up with zero, one or four papers. So, it's a moot point that, that we're going to compare across these things.

What strikes me is I know that when the NESR group is going through the, the papers, they, they read them. When the see the first disqualifying criteria, they say okay, that one's out. And, I understand completely why you do that.

But maybe it would be instructive to know why, which of the criteria in each of these searches actually led to the rejections.

It will tell us about where the gaps in the science are. And, so I don't know if we can do it up front because I understand that would be an enormous additional workload on them, but at some point, or some group, that might be a worthwhile exercise.

CHAIR SCHNEEMAN: So, I'm going to suggest that you've now started our final discussion for the committee.

(Laughter.)

CHAIR SCHNEEMAN: And, if we have time, we can as we gather items, if there's some like that, that we may want staff input on we can, we can come at the end and see if there's an opportunity to, to do that.

But, since you were last yesterday, you're first today and we'll go to Steve Heymsfield to be.

MEMBER HEYMSFIELD: It must be telepathy. I had exactly the same question as Rick.

And, you know, I wondered for

mortality in our group, Frequency of Eating, we had thousands, 4,000 papers, and none come up at the other end of the line.

And, I had thoughts about like, is there an error rate in reviewing these papers? And, if there is, then I assume the public can feed in right, and say you missed this paper, or why didn't you consider this? So, there's some checking mechanisms on our screening process.

But also, the same question about is this just bad research or is it unrelated research, or what, what are the underlying rejections due to?

Because there are thousands of papers in there that we're not considering. And, it would really help people in future research to know what's really an acceptable, quality study to make an impact.

That was my thought as well, yes. Okay, so well, I thought we were going to get around to Heather. Heather rightfully is concerned about our criteria for selecting

studies for Frequency of Eating and mortality.

And, we set up certain criteria, and there was quite an extensive discussion yesterday about those criteria. Heather, do you want to make a few more comments on that? Is that okay if we go lateral in that direction?

CHAIR SCHNEEMAN: Yes, I'd just as soon if it's something where you need the committee input on, it's better to talk about it now.

MEMBER LEIDY: So, if you remember yesterday our, we, the Eating Frequency committee had come up with some more, I would say rigorous inclusion/exclusion criteria. Some of those related to sample size, and then how we're including dietary intake.

And, so I went back in and had some, you know, one-on-one conversations with folks and then went back in to all the protocols to see if I was missing something across the boards.

And, consistently to my knowledge, unless feel free to chime in, none of the

subcommittees have established a sample size criteria, whether it's observational studies or experimental.

And, so unless I missed it and I apologize, I went through them fairly quickly. And, so it was just something that came up and then the other piece too, was that outside of the NHANES data, there weren't any criteria in terms of how many dietary recalls that should be included, and what to do with food frequency.

And, then I also found with the Beverage subcommittee that I'm also on, is that I think that's the only group that established a criteria for study duration of experimental studies of eight weeks. And, that was only applied to those that had body composition outcomes, as well as type-2 diabetes outcomes.

And, so I wanted -- that we -- I had a discussion with our Eating Frequency group because I feel like there needs to be a level of consistency among the committee, because a lot of these outcomes are consistent with the

subcommittees. And, so it's how do you wrestle with that? And, we've been back and forth.

A side note that I didn't bring up, yesterday, I didn't think about it until after the discussion, and Kay had brought it up as far as the number of time points that we were including in the Eating Frequency, so just a comment.

When we were talking about the food frequency questionnaires that we include with our eating frequency, just keep in mind we're not really, it's not the standardized food frequency questionnaires that we can include, because we're not dealing with foods, it's the number of eating occasions.

And, so a lot of those frequency questionnaires are not validated, which is okay. We don't have that criteria around the board, but a lot of them don't have an established time interval. So, it might just be in general do you skip breakfast or, or whatever. Or maybe it's the past week or past month.

And, so that was another reason why we felt that having multiple ones of those would be appropriate.

With the recalls, the reason we wanted greater than we have three days right now, was just because the eating frequency concept can be different. Primarily, too, when you have, you know, weekdays vs. weekends, there's a different amount of skipping that occurs whether it's a weekday or weekend.

And, then intermittent fasting also raises the question that if you are recalling just one day, they may not be eating anything vs. one day where they may be overeating in the context of the given day. And, so that was just some context around that.

So, the reason I raised this up is a couple of things that, and I didn't think about it until Barbara brought it up, that, you know, you can identify all studies that generally have this topic and then at the end of the day.

So, for example, with our all-cause

mortality, there are 18 studies that were identified, and then none met the criteria, only three had the diet intake component.

But, you know, is it, this is really a committee decision. Is it appropriate for us to then comment about all of those studies and really have it be that it's really low or poor quality?

Or do we establish that there should be potentially, a certain level of rigor that we say well, you know, maybe these studies really shouldn't even meet the criteria to be included?

And, you know, another example too, with the duration of -- with weight loss. You know, there are studies that will report weight loss of at two weeks or three weeks, or four weeks. Where do you draw the line that says that it's low quality vs. data that really shouldn't have been included in the body of evidence?

And, so that's what we're just trying to figure out if the committee feels that should be a level of consistency, and that maybe our

committee is being too rigorous.

It is a new research question and so we felt the need that for Eating Frequency, again, I can't document this per se, but the folks that are on the Eating Frequency committee have done research in this area, and there seems to be more variability in the number of eating occasions that we have outside of diet or food choices, or food components.

And, so I think that's why we may establish that. But, I think there's just a bigger discussion too, in terms of, you know, when you're dealing with the subcommittees that have outcomes related to body composition, should we collectively establish a certain minimum for experimental studies, and with sample size?

Dr. Sabate, you brought up the fact of, you know, observational studies should have a sample size. But, none of us have done that. And, and we did that with experimental evidence, but then nobody else has it.

And, I don't think for a sample size

question that's not specific to eating frequency. I think that's in general. So, that was very long winded and I apologize.

But, I, we thought it was appropriate to bring this up with the committee because I think that really has long lasting implications because our committee made up with various -- a few number of potentially high quality studies that might be appropriate.

But then we're not really establishing the level of the quality because it's already higher vs. maybe some of the other committees.

So, I, we just wanted to bring that up for comments so, because I feel like at this point moving forward, I think it needs to be a group -- we all decided there should be a group decision how we approach this for all subcommittees. And, then more specifically, comments related to ours.

MEMBER SNETSELAAR: I just had one comment related to that. This also relates to a question that Tim had yesterday, which I did not

hear very well, on quality of studies. And, then I also had a discussion with Rick.

I think in some cases we may have very large randomized controlled trials that have gone on for several years with large populations.

And, maybe there won't be a large number of studies related to some of the questions we're answering. But, there may be very seminal kinds of articles that could come to bear on our questions.

And, just to make sure that if there are those articles available, and they're of very high quality, that that may answer some of our questions. And, we may not have numerous articles, but we have an extremely high quality type of research that's gone on that does answer questions.

MEMBER DEWEY: Kay Dewey.

So, I would like to address what you said, Heather, about at what phase do you impose, you know, these judgments.

And, in terms of the quality of the

exposure assessment, which is what you were talking about in terms of the measurement of frequency of eating, there is a place for that to be done in the risk and bias assessment once the studies have been identified.

I don't know how many subcommittees have actually gone through the whole risk and bias thing, but we in Pregnancy and Lactation, a couple of us did this just the other day for one of the outcomes that we didn't talk about yet.

And, so there were three types of studies in the evidence base. They were randomized controlled trials, non-randomized control trials, and prospective cohort studies. And, the risk of bias table is different for each type of study.

And, so for randomized controlled trials, it includes randomization, deviations from the intended interventions, missing outcome data, outcome measurement, and selection of the report or result.

And, then it's a slightly longer list

for the non-randomized controlled trials. And, for the prospective cohort studies, it includes confounding, selection of participants, and importantly, classification of exposures.

And, that's where I personally would choose to have this criterion around did they assess frequency of eating well enough? Then, they would get a low rating for classification of exposure in that risk of bias table.

And, then there's, there are four others. I won't read them all out here, but I think that helps take care of not excluding too many studies, but making sure that their, their flaws are recognized when writing up and making a judgment about the overall grade. Because once these, all these cells are filled in, there's an overall grade assigned to the entire body of evidence.

And, this is color coded. It's very, very helpful. You know, green, yellow and orange. And, it's based on external kind of recommendations about how this should be done,

and maybe some of the staff members would want to say more.

But, I think it's a useful exercise for each subcommittee to have gone through all that to, to think about how it applies.

For the power calculation and minimum sample size, I think we have some analytical frameworks where we've done that. Maybe you didn't find them and I could be wrong. But, I seem to recall that we did impose that and, I don't remember which ones.

MEMBER LEIDY: So, then I guess the question is should the committee, should all the committee follow that when you're dealing with similar outcomes?

And, I would love to have that shared. I just couldn't find it. I apologize. It was, I was trying to do this very short.

MEMBER DEWEY: Yes.

MEMBER LEIDY: But, for a lot of those, I couldn't find that there was a standardization for the observational, and

definitely not for the experimental studies unless it was with ours.

And, so I guess as a committee, do we feel that we should, we should have that same level? Or does that go under risk of bias? I mean so it's where do you, I guess it's where do you draw the line then of saying well, you know, this should be.

And, it occurred to us that when you put that in the excluded/exclusion criteria, you're excluding studies. You're not even being able to assess risk of bias when you kick them out.

So, even the eight weeks for the beverages, I'm wondering if maybe that's something that should be retracted if we collectively feel like they should be in, and then the risk of bias is assessed.

So, the same thing I guess with sample size. If we have them, should we keep them and if not, we probably should remove them consistently.

CHAIR SCHNEEMAN: So, yes, but I think it would be very helpful to have Julie comment in this.

Because the, the other factor is first of all, you, you are looking at the papers. You will receive the papers. So, it's not just the summary. That's part of the assessment is to actually look at the papers.

And, Kay, I'm glad you brought up the risk of bias, because that's really where you start to get in to many of these, these quality factors. But, I think some of these questions relate to the process as it evolves and, that's why I thought it might be useful to have Julie comment.

And, Julie, before you do, I can't see you, but Tim, did you have another comment you wanted to add to the discussion?

MEMBER NAIMI: Again, Tim Naimi. Just a very brief one. I agree with like, Heather makes some excellent points, but I think Dr. Dewey does as well.

I think there's a middle ground. And, I think that for some of these risk of bias assessments, it's going to differ not only on the basis of the type of study, but the type of outcome and the way that the mechanism is expected to work.

So, a follow-up period for some outcomes in a randomized trial could be, could be as little as, you know, a day. It just depends on what the expected action is.

So, I think we need to be also careful about having blanket decisions about quality criteria applied to all the topics without very careful consideration of that.

MEMBER LEIDY: And, just a real quick follow up just to clarify that.

I, you know, I think my statement was more about when the outcomes are very similar in nature. So, if you're dealing with a body composition, or type-2 diabetes, or some of those, I think a consistency should be fine. But, they can't be, it can't be a blanket

statement across all.

MEMBER NOVOTNY: Rachel Novotny. Just thinking that in terms of the process and I mean I know we want to streamline things as much as we can, but I do think that if, if the committee can explain the reasons that, you know, briefly, in terms of sample size or whatever it is, that studies are excluded, that may be of actually a really big service to helping the public understand why all these things they've heard maybe at the end of the day, we're coming up with a different recommendation than perhaps what they might have thought based on some of the more general information out there.

So, I guess that would argue towards keeping in more studies and screening them out at the risk of bias level, yes.

MEMBER MAYER-DAVIS: If I can chime in, Barbara.

CHAIR SCHNEEMAN: Yes.

MEMBER MAYER-DAVIS: I was just recalling, at some point in one of our

subcommittee calls, we had a lovely table that had been put together by the NESR staff that summarized for, you know, different variables, what would be considered by the different subcommittees for different outcomes as key confounders vs. other factors to be considered.

And, that was exceedingly helpful. And there was a reasonable amount of agreement, but then there were some areas of disagreement so that, you know, the subcommittees had opportunity to say oh, well, you know, let me think about that again.

A couple things for our subcommittee changed; a lot of things stayed the same. Because for our particular questions, we had a rationale for whatever it was we had decided.

So, it might be that while in this moment it might feel like there's, you know, more, you know, inconsistency. There's probably a lot of consistency.

But, I think if we could just identify what we are actually trying to compare now more

broadly than just key confounders and other variables to be considered.

But inclusion, exclusion, some of these other factors that Heather mentioned, whether it's the duration of the experimental study.

You know, then we could actually just look at it and the subcommittees could determine relative to their particular set of questions, you know, what their decisions really should be if they're justified in being different or otherwise.

And, I think Rachel has a great idea and just document that. Because we're probably closer than at this moment, than potentially feared.

CHAIR SCHNEEMAN: So, but you're right. The documentation is important.

MEMBER MAYER-DAVIS: Yes.

CHAIR SCHNEEMAN: And, my understanding is that the NESR process itself does document reasons for excluding papers.

So, Julie, I'll, I'll let you comment. I assume she's down there.

DR. OBBAGY: Yes. I'm here.

I think a lot of -- is this one? There it goes.

I think a lot of the criteria that you're discussing that have come up in terms of inconsistency areas, are ones that we have not historically established NESR standard criteria for some of the exact reasons that you've articulated just now is that there's either not great empirical evidence for why you would select a sample size of 30 vs. 50 vs., you know, 500 vs. 1,000 for an observational study.

So, that's why we don't have standard NESR criteria because it could depend on the population, it could depend on the question being addressed. And, so we don't have a, you know, very strong rationale for establishing some of those standard criteria. So, that's why we haven't.

But, it's certainly within the purview

of your role and, your committee to discuss that and come to agreement.

And, consistency is always nice but if there's some rationale for doing something differently by question or topic area, you know, that's always acceptable as well.

So, that's sort of the point of being able to tailor some of these criteria more specifically to the topics and the populations that you're addressing.

So, I think your discussion is all perfectly in line, and we're open to whatever you can come to agreement on as a committee.

So, we do, not to switch gears totally, but we do document all of the reasons for exclusion. I think some of the discussion comes from the fact that we document the reason for why a paper is excluded, but we don't go through every paper and document every potential reason for why it was excluded.

And, so we can't confidently report exact numbers of X number of studies were

excluded based on study design, X, you know, because we sort of capture some of the most easily identifiable ones from the paper and the abstract.

So, we can't with 100% confidence report exact numbers on that, but I think what we do provide in terms of the rationale for exclusion, should give you a pretty good sense of what the most common reasons for exclusion are.

You know, in the title screening and, I appreciate that it does look like the numbers go from thousands and thousands down to such a little number, but I think if you actually looked at some of the abstracts and titles that come up, you know, the reality is PubMed does not do a very good job with indexing.

And, so if you're looking at a frequency of eating review where you've included a search term like fasting, that's going to pick up all papers on fasting blood glucose and things that are not the fasting you're talking about.

So, it's that lack of specificity

within PubMed that can lead to sort of a lot of noise coming up in the searches, and so that's why the numbers typically look that way.

But I think looking from abstract and title screening rationales will give you a pretty good sense of what the reasons for exclusion would be.

We come across a lot of cross-sectional studies, for example, so that's a common reason. Or studies conducted in a country not on your HDI criteria. So, I think we can work with you to provide some more details around that.

And, then I think just to the points about risk of bias and parts of the process that can address some of these issues that you're sort of uncertain about in terms of how to handle with inclusion/exclusion criteria.

I think Kay, you did a great job of talking about exposure assessment being a really critical part of the risk of bias tool for observational studies in particular.

So, we do have mechanisms in place to be able to consistently assess some of these limitations across a body if you don't feel comfortable making a criteria.

Precision is another place in the grading process where sample size is definitely, you know, part of that assessment for the body of evidence. And, so if you don't establish a sample size criteria, you know, precision in the grading process will allow you to assess that very consistently and transparently.

MEMBER DEWEY: Kay Dewey. So, thank you so much, Julie.

Specific question about the precision criterion. If I remember correctly, that's applied at the level of the entire body of evidence, not study by study. Is that correct?

DR. OBBAGY: Not study by study, but I think in order to really assess the body of evidence, you know, you kind of do have to look across the studies. And, so you'll have all of the effect sizes, confidence intervals.

MEMBER DEWEY: Yes.

DR. OBBAGY: And, looking across that, I think you can make some judgments on a study by study basis, but then bring it up to the body of evidence for.

MEMBER DEWEY: That's right. But, what I'm getting at is that the risk of bias assessment by type of study is at the individual study level.

And, when I was scanning through those criterion, they're between five and eight or so, depending on the type of studies done, I don't think any of those are specifically around power or sample size, correct?

DR. OBBAGY: Correct.

MEMBER DEWEY: Yes.

DR. OBBAGY: Yes.

MEMBER DEWEY: So, what that means is that you wouldn't be, if you don't have an exclusion of studies, of papers based on sample size, it would be at a much later phase when you're looking at the whole body of evidence that

the power issues would come up.

I was looking at some of the other ones because I could remember that we, we had sample size minimum, and I think and maybe Julie or others can again clarify, but I think we may have inherited some of that language from the previous P-B24 project.

Because the one I pulled up was for the human milk and infant formula and other outcomes, and they had a minimum sample size of 30 per group.

So, Julie, am I right? Is that, did I inherit that?

MS. GUNGOR: That's correct. That's inherited from the last project where there was a sample size for the breastfeeding and formula feeding questions that the groups in the study had to have at least 30 per group, or a power analysis that indicated that the sample that they did have was sufficient for the outcome, or the comparison and the outcome of interest that we are interested in.

So, sometimes there might be a power analysis in the paper and it might not have been for what we were drawing from the paper. It might have been for a different analysis and maybe what we were drawing from the paper was a secondary analysis of some sort.

So, that I guess, is a caveat to maybe mention. Sort of a nuance, but, but that is the sort of complete idea was that it was 30 or power analysis.

MEMBER DEWEY: And, I think there's a logistical reason why we might have wanted to inherit that because we -- these are updated. We are updating those reviews and to have to go back and remove that criterion and rescreen and reevaluate everything would be extremely difficult.

So, inheriting it was, was logistically the right choice. But that doesn't mean that it has to be imposed across the board for all of the questions that all subcommittees are looking at.

MEMBER LEIDY: We were comfortable with ours until the, the committee raised the questions. Because we also have a 30, sample size of 30 for between group, and then 15 were cross-over.

And, then the question was made about the observational studies, and I don't think that's in your criteria. It's hard to know whether they were observational or experimental studies.

And, so we just felt like after the conversation that it seemed like there were a lot of not red flags, but flags that were raised with our criteria. So, that's why we just wanted to bring it up for the discussion for today.

CHAIR SCHNEEMAN: Right. I'm glad you brought it up. I know when we were looking at yours, the fact that you had or a power calculation seemed to open the door that it. It's not that it was set in stone, you, you allowed for the power calculation.

What I'm going to propose, and you can

disagree or come up with an alternative. Because so many of the subcommittees now are at the point where you're starting to look at the evidence and now really having to think through the risk of bias, which I know you all heard about it before, but haven't necessarily worked with it when you were in the protocol development.

My suggestion is within the subcommittees there be a discussion of that risk of bias now that we are at that point of looking at the evidence.

Some of the groups have already done it, but to really make sure that your protocol is not duplicating what's in that analysis as far as looking at the, the strength of the evidence for the particular criteria that you've looked at.

So, that's a proposal. Do you think that would help to deal with the issue?

MEMBER LEIDY: Yes, and our biggest problem is we can't really look at risk of bias because when we have our criteria as an excluded inclusion/exclusion, we don't get the, we don't

have the ability to go back and look at those studies for bias.

So, I think I, I can't speak for Steve. I feel like our recommendation -- well, we were proposing to do with our subcommittee is to go back and remove the criteria so we can then do a risk of bias.

CHAIR SCHNEEMAN: I think look at the, yes, look at the risk of bias to see, yes, the tool, just to see if --

MEMBER LEIDY: Right.

CHAIR SCHNEEMAN: -- you're duplicating.

MEMBER LEIDY: You mean, so you propose we do that before we decide --

CHAIR SCHNEEMAN: Yes.

MEMBER LEIDY: -- to remove the criteria?

CHAIR SCHNEEMAN: Yes.

MEMBER LEIDY: So, go back and look at all 18 studies that, that we excluded?

CHAIR SCHNEEMAN: No. I'm suggesting

you start by looking at the, the criteria that are within the risk of bias.

MEMBER LEIDY: Oh, sure.

CHAIR SCHNEEMAN: Yes. The tool, to see, okay, did you really factor that in when you set your exclusion criteria?

So, rather than just going back and changing criteria, start by looking at did you really factor those in?

MEMBER LEIDY: Uh huh.

CHAIR SCHNEEMAN: And, if you, if you didn't, then you have a rationale for why you might need to reexamine your exclusion criteria.

MEMBER DEWEY: Kay Dewey again. I think that's a great idea. But with that said, I was thinking about the fact that the Pregnancy and Lactation conclusion statement that was made on whether folate intake related to human milk folate, I think all of those studies were less than 30.

There were four studies and, I think they were all less than 30 participants, and they

would have all got screened out.

And, so, I think, I would sort of prefer err on the side of not being too stringent on minimum sample size unless you make a really compelling case. Because there is an opportunity at that final stage of assessment of the quality of the evidence to bring this in to bear.

CHAIR SCHNEEMAN: Right. And, I think if you look at some of the statements that were made around the evidence for the seafood, you see that looking at the nature of the study itself in terms of how the committee developed its conclusion.

Is that -- are we good with that? Beth, you look like you're ready to say something.

MEMBER MAYER-DAVIS: Yes. So, this is on a different topic but I think this was a, a good discussion, so that's great.

And, that is thinking about, you know, dietary patterns, food groups, foods, nutrients.

It occurred to me this morning, and we

had some conversation about it, that for the B24 and Pregnancy and Lactation groups' subcommittees, there's attention being paid to looking explicitly at supplements whereas for Beverages and Added Sugars, for example, you know, we at some point decided not to deal with supplements looking at FDA, you know, definition.

And, it was partly because as a matter of scope and likely available data when you think about, you know, various supplements broadly defined that find themselves in smoothies these days, you know, that that was just not something that we, you know, reasonably could addressed.

But, I'm just wondering, you know, Barbara and Ron, what your thoughts are and maybe what discussion we might have as far as, you know, thinking about supplements that may be important to include for specific nutrients of public health concern, for example. Maybe certain, you know, stages in life course, B24, Pregnancy and Lactation.

Then again, we thought well, you know,

in the elderly this can be an issue, too. So, some, I think maybe some general conversation might be helpful in terms of supplements as relates to our work for Dietary Guidelines.

CHAIR SCHNEEMAN: Okay, so I think the first place I might go is to look at what we're going to learn from the data analysis in terms of with and without supplements.

(Laughter.)

VICE CHAIR KLEINMAN: Bye, Tim.

(Laughter.)

CHAIR SCHNEEMAN: So, with that introduction.

MEMBER BAILEY: Yes, bye Tim.

(Laughter.)

MEMBER BAILEY: I think that's why it's an advantage at this point that we don't have the dietary supplement data. Because I think it's important that you look at nutrients from foods and beverages alone, and then in the context of, particularly in pregnancy where more than 70% of pregnant women are using

micronutrient containing supplements.

So, I don't know if that addresses what you're talking about. I think you're talking more about in all of those, the other subcommittees?

MEMBER MAYER-DAVIS: Well, there's another layer to it, which really has to do with focus on nutrients vs. foods. And, so we've really thought in our subcommittee anyway, about beverage as foods.

MEMBER BAILEY: Uh huh.

MEMBER MAYER-DAVIS: And, you know, added sugars as a matter of foods, you know, and so forth, rather than a focus on nutrients and that it is not, in our view, particularly in our remit, to really focus on nutrients that might be contained in say, beverages, with respect to particular outcomes.

So, we're actually not looking at trying to come up with what are the nutrient, or what are the dietary components that might explain an association, for example, between

beverage intake and, you know, type-2 diabetes. We're staying at the food level, essentially.

MEMBER BAILEY: Yes.

MEMBER MAYER-DAVIS: And, that was part of the philosophy around not getting into supplements, because that drives you to a nutrient focus rather than a food focus.

MEMBER BAILEY: Yes.

MEMBER MAYER-DAVIS: So, that was really some of the back drop of our thinking.

MEMBER BAILEY: And, I think that's actually an advantage because the approaches that we're taking complement each other in a lot of ways.

And, we're also taking an approach where we're looking at foods, food category sources of nutrients, and then nutrients in and of themselves.

So, you have like three different levels of data that will inform the Federal government on how to interpret that into actionable guidelines for Americans.

MEMBER MAYER-DAVIS: So, that makes sense as between Beverages and Added Sugar subcommittee, and the work of your committee.

I'm still not quite sure how that fits with the B24 Pregnancy Lactation that does have a specific focus on supplements, which I don't have any personal objection to. I'm just trying to make sure that, you know, you know, we have an understanding about really what the scope is.

MEMBER DEWEY: This is Kay Dewey again.

Well, you know, we were given those questions and, it was just intake from supplements or fortified foods. So, it wasn't the foods, and then did they happen to have something in them as well.

So, and it is because certainly pregnancy is a period with heavy supplement use. And, then there are questions around whether supplements are needed for infants.

MEMBER MAYER-DAVIS: So, that's just a function of the very specific questions given.

Okay, so as long as we're all in agreement that we're sometimes looking at supplements for those, for that reason and sometimes not.

MEMBER BOUSHEY: Liz, in these papers that you've looked at, do they even provide that information? I mean what happens is when you go into different spheres of research questions, it's rare that a paper might even put in supplements.

And, so I don't, you know, so that's a risk if you start adding them, then.

MEMBER MAYER-DAVIS: Yes, and we're not planning on adding them.

MEMBER BOUSHEY: Right.

MEMBER MAYER-DAVIS: I just wanted to make sure that we were all in good communication about what we were doing. So, yes.

MEMBER BOUSHEY: Yes.

MEMBER NOVOTNY: Yes, no, I appreciate the question. I've been struggling with that, too, because I mean I'm, we're the Dietary Guidelines Committee and, but I also sit on the

subcommittee.

So, those were the questions given to us. It does beg the question, I don't know if again, it's going to depend on the papers. Maybe we can kind of as a philosophy, try to articulate sort of the relative role of food and supplements in the outcome if it's there, just to keep the emphasis on food.

CHAIR SCHNEEMAN: I think this is very helpful to have the subcommittees identify if there are additional issues where they really need the input from the full committee, to make sure that you can make great progress between now and the, our next meeting.

So, our time is getting short so I'm just going to sort of quickly go around and see if there's anything else that needs to be brought up along those lines from.

So, Steve, you, you did your thing.

MEMBER HEYMSFIELD: I think I'm good.

CHAIR SCHNEEMAN: Yes.

MEMBER BOUSHEY: I'm good.

CHAIR SCHNEEMAN: Okay, great.

MEMBER BOUSHEY: Thank you.

CHAIR SCHNEEMAN: Kay?

MEMBER DEWEY: I have no further comment.

CHAIR SCHNEEMAN: Okay.

MEMBER DONOVAN: No.

MEMBER STANG: Me, neither.

MEMBER BAILEY: I guess this is not specific to the Committee, but a plea for people who are doing funding, reviewing, and publishing research, that you include or demand that details of the methods are so critical in their applicability to our purposes.

So, if you are a journal editor, if you are a researcher, if you are funding research, the devil is in the details, and those details need to be published. And, a lot of times, you're limited by word count, or, or things like that.

But, just be mindful that in order for your research to be impactful and interpretable

to committees like this, you have to have the details.

MEMBER NOVOTNY: Pass.

MEMBER SABATE: And, I just appreciate the conversation we had, the last one as far as the clarification between the measured emphasis of this group on nutrient vs. foods and food patterns.

And, I am in full agreement that, or at least that was my understanding that, the main purpose of, of this task force is to relate foods and, and food patterns, and with the health outcomes. And, I think that was a very useful conversation as far as understanding the role.

And, we know that these were questions that were asked as far as a specific nutrient supplements.

But in general, I think we have to continue trying to see the connection that exists between foods and food patterns, and health outcomes.

CHAIR SCHNEEMAN: Thank you.

You already had a turn.

(Laughter.)

CHAIR SCHNEEMAN: So, Ron, do you want to?

VICE CHAIR KLEINMAN: No, I have nothing to add. I'm just glad that we were able to come together. I think we really do accomplish a lot when we're seeing each other face-to-face.

Something to be said for staying home and doing it over the phone, but it is great to be able to talk these things through, so thank you all.

CHAIR SCHNEEMAN: Okay, and so I know that I believe Eve has to officially adjourn the meeting, so I won't do that.

But, I will remind you that we, the Committee takes -- as long as the Committee is meeting, public comments can come in. But, if anyone has specific comments on the protocols that, particularly the new protocols that have been discussed, those will be most useful to the

Committee if we receive them by November 7.

So, I will turn it over to Eve.

DR. STOODY: Thank you, Dr. Schneeman, and to the Committee. And, we do just have a few closing remarks before we adjourn for today.

I did want to just make a quick comment regarding the supplement conversation.

Historically, the Dietary Guidelines that have focused on 2 years and older, it has been a focus on meeting nutrient recommendations through foods.

But, as Kay and Regan kind of both noted for these new populations, for, you know, for Birth to 24 months and Pregnancy and Lactation, there were just questions around should there be a recommendation at the population level for supplements in addition to like, a typical diet?

So, that's where those questions came from. So, that's why there's not specific questions related to supplements for the kind of 2-year and older population, but for the Birth to

24 and Pregnancy. So, just a few comments there.

Okay, so thank you for joining us for meeting three of the 2020 Dietary Guidelines Advisory Committee.

I do want to note that materials from this meeting, as always, will be posted at DietaryGuidelines.gov, so that'll include recordings of all of the presentations. There will be transcripts, meeting minutes, all of the slides.

It does take a little bit of time to get the transcripts and all of that stuff finalized. So, please allow about one month for those materials to be posted. But as always, our LISTSERV is the way that we communicate.

So, if you're signed up for a LISTSERV, as soon as those materials are posted, we will send out an announcement so you can come back and view the discussion again.

Okay, did want to spend just a minute talking about meeting four, because it is in a different location.

And, meeting four will be held in Houston, Texas, and who knew when we were setting our meeting locations we were predicting the World Series, so stay tuned for the next round, I guess.

(Laughter.)

DR. STOODY: So, yes, our next meeting is in Houston on January 23 and 24 at USDA's Children Nutrition Research Center. And, the meeting will be held from 9:00 a.m. to 4:30 p.m. each day, if that helps with your planning purposes.

And, as we talked about yesterday, meeting four will include an opportunity for oral comments to the Committee from the public. This will be essentially exactly the same as it was last time.

The public will be able to provide up to three minutes of oral comments to the Committee, and that will be registration is expected to open for that in early January, so registration is not yet open.

Registration will be confirmed on a first come, first served basis and, as with the last time, we ask that we keep it to one representative per organization.

So, watch for an announcement through our LISTSERV for registration. The registration does fill up pretty quickly. I think it filled up in the first day for the last meeting, so stay tuned for that. Be ready.

Similar to last time, when you go to register for oral comments, we do ask for a high level outline of the items you plan to discuss so you can be at the ready when that announcement comes through.

In the meantime, you can follow the work of the Committee at DietaryGuidelines.gov. You can view progress on the scientific questions. As we go, protocols will be updated so between now and the public meeting, we do expect to do an update on the website.

You can also read subcommittee updates, there's a section on the website with

subcommittees, and there's brief updates provided on the work that they've done at various points.

We typically do both of those pieces -- we do it all at once. So, for all of the subcommittees, we'll update the protocols and the subcommittee updates all at once. And, this is another thing. When we do that, we'll send an announcement through our LISTSERV.

So, if you're interested in kind of following the process, be sure to sign up for our LISTSERV.

At DietaryGuidelines.gov, you can also see a link to Regulations.gov, and there you can go as Barbara noted, to submit comments to the Committee. Comments anytime throughout their process. Again, for the comments specific to new protocols, the 19 new protocols, those are asked for by two weeks, November 7.

You can also read all of the written comments that have been submitted to date.

You can check our recently updated most popular questions page. We do update this

page based on the questions that we are receiving. So, that is something that we try to keep updated based on questions that are coming in and that we're hearing.

And you can also learn about continuing professional education credits for viewing the meetings.

Now, as has been discussed by Barbara and others, this is really, it's an independent committee and, their findings are their findings. But it does take a lot of staff to support the process. And, this is staff from across USDA and HHS who support this process in some way.

So, for example, supporting the Committee's scientific review through the systematic reviews, data analysis and food pattern modeling, managing all of the web updates, processing public comments, coordinating the actual meetings and more. And, so really, just thank you to all of the staff for that support.

I do want to pause for just a second

and acknowledge a specific staff member who is retiring next week.

(Laughter.)

DR. STOODY: And, that is Colette Rihane, who is very mad at me right now.

(Laughter.)

(Applause.)

DR. STOODY: So, Colette has supported the Dietary -- four different Dietary Guidelines Advisory Committees.

She's the Director of the Office of Nutrition, Guidance and Analysis at USDA Center for Nutrition Policy and Promotion. And, I just want to say, you know, she has had just huge dedication to this process, just worked so hard and committed so much.

So, thanks for your contributions to this process, and to the Dietary Guidelines, and for your 33 years of service.

So, thank you.

(Applause.)

DR. STOODY: So, with that, we will

adjourn for today. Thank you again for joining us and we look forward to seeing you in Houston in January.

Oh, and I should note that that meeting will be in person and by webcast. We're bringing our YouTube team. So, if you can't make it to Houston, you can always join online.

So, thank you.

(Whereupon, the above-entitled matter went off the record at 12:17 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: Public Meeting

Before: Dietary Guidelines Advisory Committee

Date: 10-25-19

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