Afternoon Day 1
https://youtu.be/M8lPEQAQk2I

Dr. Barbara Schneeman: So, we would like to get started. I think we're on time for reconvening the committee, and we're all here, so we can reconvene the committee.

And I just wanted to announce that we are making an adjustment to the agenda. So, those of you in the room and those of you online, we've asked the Frequency of Eating subgroup, Dr. Heymsfield, to add onto the agenda, so it will—he will give his presentation after the Beverages and Added Sugars subcommittee. So, we're moving that from tomorrow to this afternoon.

And then, the rest of the agenda for tomorrow will be as shown. We'll start with the—after opening remarks, we'll start with the B-24 subcommittee report.

[0:00:59] So, with that, we can turn to the Beverages and Added Sugars, and Beth, Dr. Mayer-Davis?

Dr. Elizabeth Mayer-Davis: Alright, welcome back, everyone. So, first, the committee is shown here, and I want to thank everybody for their engagement, and also, I noticed that the NESR team is not listed here. I think they're at the last slide, but they are fabulous, and I appreciate a tremendous amount of hard work for this effort.

So, this is Beverages and Added Sugars subcommittee, and is there a clicker to advance the next slide? I just realized I was about to advance the slide and I couldn't do it.

Dr. Barbara Schneeman: We made sure that, yeah, we had it in our possession.

Dr. Elizabeth Mayer-Davis: Okay, great. Thank you, Barbara. Alright.

So, we're going to go over the status of these various questions. So, we're in the process of developing and implementing various of these questions. There are quite a few.

[0:02:03] So, in terms of developing the plan, we're working on added sugars with the outcomes of risk for cardiovascular disease, risk of type 2 diabetes, and then growth, size, body composition, and risk of overweight and obesity. We're looking also at added sugars during pregnancy in relation to gestational weight gain and added sugars during lactation and postpartum weight loss.

And so, there's some asterix there to indicate some protocols that we'll focus a little bit more on today.

Then, in terms of implementing the plan, there's work ongoing with beverage consumption and growth, size, body composition, and risk of overweight and obesity, beverage consumption during pregnancy and birth weight, standardized for gestational age and sex, as well as the outcome of gestational weight gain.

And then, the last here is beverage consumption during lactation and postpartum weight loss.

[0:03:00] Still to come, we have some work that we'll present preliminarily on the question set related to alcohol consumption with these outcomes that you see listed here – all-cause mortality, certain types of cancer, risk of cardiovascular disease, neurocognitive health, as well as growth, size, body composition, and risk of overweight and obesity, including alcohol consumed during lactation and postpartum weight loss.

We will also look at alcohol consumption during lactation with respect to infant developmental outcomes, including neurocognitive development, as well as the outcome of human milk composition and quality.

Okay, so now focusing on a question of non-alcoholic beverage consumption, what is the relationship between beverage consumption during lactation and human milk composition and quantity?

[0:04:04] And so, we're going over the approach to this question, and some of what we'll go over applies to other questions related to beverage consumption.

So, this is sort of a chart that allows you to see how we're categorizing beverages so that we can work through this systematically. There are categories related to milk, subcategories of dairy milk, flavored milk, dairy drinks, and substitutes. And then, on the far right, water, plain water, flavored or enhanced water as subcategories.

And then the rest of the non-alcoholic beverages you see in the middle in these categories of 100 percent juice, diet beverages, calorically-sweetened beverages, nutritional beverages, and coffee and tea.

So, this is the way that beverages are being sort of categorized and that applies to other beverage questions, not just the one that we're talking about at the moment.

[0:05:05] So, here are some key definitions and populations for beverages during lactation with respect to human milk composition and quantity.

So, with regard to beverage pattern, we're thinking about quantities, proportions, variety, or combinations of different beverages in diets, and we'll also consider studies that examine specific beverages or beverage groups.

And in terms of population of interest for this question, lactation women who are exclusively or predominantly breastfeeding.

And here's some definitions for a couple of those terms.

Exclusive breastfeeding, and these are based on our World Health Organization from 2001, in which exclusive breastfeeding is defined as infant receiving no other food or drink, not even water, except for breast milk, which can include milk expressed or from a wet nurse.

[0:06:06] Infants may receive oral rehydration solution drops or syrups.

And then predominant breastfeeding is breast milk, again including milk expressed or from a wet nurse, breast milk that's the infant's predominant source of nourishment. And infants in this case may receive liquids, including water or water-based drinks or fruit juices, ritual fluids, or oral rehydration solution drops or syrups. But again, this is where breast milk is the predominant source of nourishment.

In terms of inclusion and exclusion criteria for this question, we're using the standard criteria that we've already heard about earlier this morning with regard to publication status, the language, country, health status of participants.

[0:06:57] But particular to this question, we are allowing case-control and cross-sectional studies just because of what we know to be the nature of this literature and what could well be valid study designs for this question.

These are inclusion and exclusion criteria. In terms of the study participants, this is women during lactation. For the question about milk composition and in terms of quantity, this would be including exclusively or predominantly breastfeeding women.

Oh, I do want to note, in terms of exclusion criteria, we are excluding studies that exclusively enroll multiple gestation pregnancies or exclusively present combined analyses of singleton and multiple gestations, or human milk from third parties, banked or donor milk.

[0:07:55] And then, in terms of health status of study participants, we will include studies that enroll mothers who are healthy and/or at risk for chronic disease, those that enroll some mothers diagnosed with disease, studies that enroll some mothers who were severely undernourished prior to pregnancy, and we will also include studies that enroll some or all mothers classified as underweight or obese prior to pregnancy.

The studies that are excluded are those in which the study participants exclusively include mothers who gave birth to preterm infants or studies that exclusively enroll mothers diagnosed with a particular disease, including severe undernutrition, or exclusively enroll mothers who are hospitalized with an illness or an injury, and those obviously have to do with generalizability.

Right, and this is the analytic framework then for this question of beverages during lactation and human milk composition and quality. You can see the intervention or exposure, and that list of beverages reflects the chart that I showed a few minutes ago and how we're sort of thinking about different

beverages, and then the comparator would be different amounts of those beverages or the physical form in which those foods might be consumed.

[0:09:16] Then you see below there, the population for human milk composition question and the human milk quantity, and those are consistent with what I just showed a minute ago.

And then, in terms of the outcomes for the human milk composition, this would be milk collected greater than or equal to 14 days postpartum, in which we will look at macronutrients, particularly fatty acids and total protein, water-soluble vitamins, fat-soluble vitamins, selected minerals, bioactive proteins.

And then, in terms of human milk quantity, we'll be looking at that assessed in milk collected, again, at least two weeks postpartum.

[0:10:03] And then, in terms of human milk composition, women during lactation, this is the—I don't need to repeat that. We already talked about the population, both for milk composition and also milk quantity.

We then have key confounders that were identified, that we will be paying attention to with regard to risk for bias. You can see those here – maternal age, race, ethnicity, socioeconomic status, anthropometric measurements, gestational age, smoking, supplement intake during lactation, and then a number of other factors that we will consider as well.

Okay, with regard to added sugars, here are some of those questions. What is the relationship between added sugar consumption and risk for cardiovascular disease, risk for type 2 diabetes, growth, size, body composition, and risk of overweight or obesity?

[0:11:05] So, we're presenting these, and it's a coordinated fashion, because a lot of the analytic framework is common for these outcomes.

And then, moving to the question of "What is the relationship between added sugars consumption during pregnancy and gestational weight gain?" and then the relationship between added sugars consumption during lactation and postpartum weight loss.

So, it's important to first think about what are we considering to be added sugars, and this is the FDA definition from when? 2016?

You see that here. Sugars that are either added during the processing of foods or are packaged, such as for example, a bag of sugar, and added sugars include a variety of sugars, sugars from syrups and honeys, sugars from concentrated fruit or vegetable juices, that are in excess of what would be expected from the same volume of a 100 percent of a fruit or vegetable of the same type.

[0:12:08] We will consider studies that use a somewhat different definition of added sugars. Not everyone would use the same definition. But this FDA 2016 definition is really what we're talking about.

And then, there's a variety of examples here that would be part of that definition.

Additionally, in terms of key definitions for this set of questions, pre-diabetes is defined per the American Diabetes Association. You see that detail here. And similarly, type 2 diabetes defined according to the current ADA definition.

Alright, in terms of inclusion and exclusion criteria for these added sugars questions, and again, we're talking about added sugars and these outcomes, CVD, type 2 diabetes, growth, size, body composition, and risk of overweight and obesity.

[0:13:08] We are using the standard criteria that we've talked about earlier today.

And in terms of inclusion and exclusion criteria, with regard to study duration, and this is for the question of relationship between added sugars and growth, size, body composition, and risk of overweight or obesity, we do have a criteria with regard to study duration that we wanted to point out here, which is a minimum duration for experimental studies of at least eight weeks. There's not a duration cutoff for observational studies, but when talking about an interventional study, an experiment, then that minimum duration is eight weeks.

And these are inclusion and exclusion criteria for study participants.

[0:14:00] For CVD, with regard to age, and you'll see later, the intermediate outcomes that would be relevant here. So, again, for CVD, children age 2 to 5, 6 to 12, and then for type 2 diabetes, adolescents 13 to 18, and then adults 19 and older, including older adults age 65 and older.

And then, for growth, size, body composition, and overweight, there's a note here that says this is still in discussion between the Beverages and Added Sugars committee, our committee, and Birth to 24, so I have late-breaking news. We had a lunch meeting just a minute ago, and I'll—this is probably the best time to mention this.

So, we're coordinating with regard to the analytic framework so that the work is coherent, consistent between the two subcommittees, and then the NESR team will be screening, doing the search, screening the literature accordingly, but it is the Birth to 24 Months subcommittee that will really be doing the lion's share, really focusing on that synthesis piece for the question of added sugars for this age group, because they obviously will have a broader context with regard to complimentary feeding, etcetera.

[0:15:21] So, that's the update to this slide, and Kay will tell me if I missed that. She looks happy. Okay. We're good, yep.

Alright, so then, continuing, inclusion and exclusion criteria with regard to health status.

So, for cardiovascular disease and type 2 diabetes, we'll look at studies that enroll participants who are healthy and/or at risk for chronic disease, including those with obesity.

Studies can enroll some participants diagnosed with a disease. And again, for CVD and type 2 diabetes, studies can enroll some participants with endpoint outcomes, but we will exclude studies that exclusively enroll participants diagnosed with a disease or hospitalized with an illness or injury.

[0:16:11] In other words, we don't want to be focusing on treatment effects here.

And for CVD only, we will include studies that exclusively enroll participants with high blood pressure, high cholesterol, and are evaluating a CVD endpoint. In other words, studies that aim to prevent cardiovascular disease in individuals who are already at high risk as a consequence of those diagnoses. So, those will be included.

In terms of growth, size, body composition, overweight and obesity, we will include studies that enroll participants who are health or at risk for chronic disease, studies that enroll some participants with a disease, and studies that enroll some participants who are already classified as underweight, stunt waisted, or obese, but we will exclude studies that enroll individuals diagnosed with disease or hospitalized with an illness or injury or studies that exclusively enroll participants classified as obese for the same reason that we're not focusing on treatment effects.

[0:17:13] Okay, so here's the analytic framework for the outcome of cardiovascular disease.

The exposure is consumption of added sugars from foods and beverages. And again, an update, this is for ages 2+ through older adults.

And the comparator would be different levels of added sugars consumed, including no consumption or consumption of various low-calorie sweeteners.

If you look over to the right, these are the health outcomes – cardiovascular disease, as listed there, stroke, venous thrombosis, cardiovascular disease-related mortality.

There are a number of intermediate outcomes as well that can be considered with respect to the added sugars exposure, and those include total cholesterol, LDL, HDL, including total cholesterol to LDL ratios, LDL to HDL ratios, triglycerides, and blood pressure.

[0:18:13] The key confounders are shown here – age, sex, race, ethnicity, SES, alcohol intake for adults, physical activity, anthropometric measures, smoking, and naturally-occurring sugar intake, and then a variety of other factors to be considered.

And I'll note here, I can't remember if it's come up earlier today, we are considering total energy intake in these papers. We decided not to include that as a key confounder though, because depending on the design of the study, it may be the total energy intake is appropriately considered but not as a confounder, per se, again, depending on the design of the study.

So, total energy intake will be considered one way or the other.

[0:19:00] Okay, let's see. This is the analytic framework for type 2 diabetes, relationship between added sugars and risk of type 2 diabetes.

And again, the intervention or exposure is the same as the previous slide, the comparator the same as the previous slide.

The outcome is type 2 diabetes.

And again, there are some intermediate outcomes that can be considered – hemoglobin A1C, when it's not defining the outcome of type 2 diabetes, glucose, insulin, and pre-diabetes.

And again, you'll see key confounders that are similar, and other factors to be considered that are similar as well, with some additions that are specific to this particular outcome, including acanthosis.

[0:19:59] And then, moving to the analytic framework, this is for relationship between added sugars and growth, size, body composition, and risk of overweight and obesity, in which the intervention or exposure is the same, and the comparator is the same.

And the outcomes here include weight, or weight for age—well, that was there when we still weren't sure what to do with Birth to 24. Now we've figured that out. Height, BMI, BMI-Z score, various circumferences, body composition and distribution percent, fat mass percent, fat-free masses may be available from the different studies, also incidence and prevalence of underweight, stunting, healthy weight, overweight, obesity, etcetera.

And then, key confounders are listed here.

[0:20:57] Again, similar to what was seen previously, and then other factors to be considered also similar to what we saw previously.

One thing that I do want to note here, that I didn't mention earlier, is that one of those factors to be considered would be supplements and various medications that we would need to consider.

Alright, so this is inclusion and exclusion criteria for the added sugars consumption question. This is "What is the relationship between added sugars during pregnancy and gestational weight gain?" and "What is the relationship between added sugars during lactation and postpartum weight loss?" in which

we will, again, use the standard criteria, the standard NESR criteria for study design, publication status, language, country, and health status of participants.

And these are inclusion and exclusion criteria for these questions. Again, we will use this minimum duration of eight weeks for experimental studies, same as I mentioned previously.

[0:21:59] And these are inclusion and exclusion criteria. We will include females who are pregnant, females capable of becoming pregnant, and again, excluding hospitalized patients, studies that exclusively enroll subjects based on pregnancies conceived used assisted reproductive technologies, studies that exclusively enroll multiple gestation pregnancies, and studies that enroll both singleton and multiple pregnancies but do not account for singleton versus multiple gestation in the design or analysis and only present aggregate findings.

So, those are excluded.

For postpartum weight loss, we will include postpartum women who are lactating.

[0:23:03] Again, excluding hospitalized patients and excluding studies that enroll both lactating and non-lactating mothers but only present data in combination for those lactating and non-lactating mothers.

Alright, and this is inclusion and exclusion criteria in terms of the health status of the study participants for gestational weight gain and postpartum weight loss. So studies that enroll mothers who are healthy or at risk for chronic disease, those that enroll some mothers with diagnosed disease, studies that enroll some mothers who are severely undernourished prior to pregnancy, and studies that enroll some or all mothers classified as underweight or obese, but we will exclude from this review studies that only enroll mothers who gave birth to preterm infants and those that exclusively enroll individuals diagnosed with a particular relevant disease, including severe undernutrition or those hospitalized with an illness or injury.

[0:24:13] And this is the analytic framework for the outcome of gestational weight gain.

The exposure is the same, the comparator is the same as mentioned previously.

The population criteria are summarized there on the box on the left.

And the outcome here is gestational weight gain as change in maternal body weight from baseline, sometime before or during pregnancy as is available, to a later time point during pregnancy, and/or right before delivery.

And then weight gain in relationship to weight gain recommendations based on pre-pregnancy BMI.

[0:24:56] And then, you see here, key confounders and other factors to be considered that are specific to this question, very similar to what we've seen previously, including considering first trimester weight gain.

Okay, and then this is for postpartum weight loss.

Same intervention or exposure, same comparator.

And then the outcome is changed from weight—or a change in weight from baseline postpartum to a later time point in the postpartum period, and postpartum weight retention if gestational weight gain is controlled for.

And the population is shown there.

And the key confounders and other factors to be considered are similar to what we showed previously.

[0:25:56] So, this is an example of work under way and progress. This is for beverages during pregnancy with respect to birth weight, and it's just kind of interesting to see the search began with an initial identification of 7,646. Some duplicates were identified, which cut this down to 4,447. Screening process occurred, and then articles ultimately included a number of 22.

And so, those are the studies that are currently under review at this point in time. So, we don't have results from that effort. They're still under review.

So, work under way. I mentioned at the beginning of this section that we've been active with regard to the alcohol questions.

So, the complete protocol is not available just yet but will be presented at the next public meeting.

[0:26:56] But just to give you an idea of where we are with this, the exposure with regard to alcohol intake is level of consumption of alcoholic beverages, as well as the per occasion consumption of alcoholic beverages, such as number of drinks per day or drinks per drinking occasion.

And when a study has available, the distinction between beer, wine, and liquor, that will be considered as well.

The comparator will be different levels of alcohol consumption.

For the population of adults age 21 and older.

And we're in the process of considering what exactly we will include with regard to the key confounders and the other factors that will need to be considered in this particular literature.

So, next step, obviously, we will finalize the alcohol protocols and discuss those more completely at the next public meeting, we'll finish the screening questions with complete search results, looking at the four beverage questions and the five added sugar questions, and synthesize findings.

[0:28:08] Hopefully, we'll have a good amount of that done to present at the next public meeting, and continue with cross-cutting discussions with, especially the analysis group and B-24 subcommittee.

I think that's it. And these are our subcommittee members. And there we have the support staff named. So, thank you very much, and this is open for questions.

Dr. Kathryn Dewey: Kay Dewey. I just have a quick question about what you said about treating total energy intake as another factor to be considered so, you would be taking into account if it was handled appropriately.

[0:28:59] And I'm just wondering quite what means, because one possibility is that it could be a mediator, which is a very different interpretation of what's going on than a confounder or something else. So, I wonder if you'd like to speak to that?

Dr. Elizabeth Mayer-Davis: So, that's a great example of a situation in which total energy might not be adjusted for, as is common, especially in epidemiological literature, as a confounder, but when in fact, total energy may not be a confounder, it might a mediator. And if a mediator, that's a different question altogether.

So, that was actually a wonderful example of what we meant by not including total energy as a confounder, but rather, as an other factor to be considered. Confounding is not the only role that total energy plays in any given analysis, depending on the research questions.

So, that was a great example, so thank you for that.

[0:30:02] ***Dr. Barbara Schneeman:*** Other questions or comments? Great, Jamy?

Dr. Jamy Ard: Jamy Ard. I had a question about the gestational weight gain, or actually more specifically, the postpartum weight retention studies. So, is it the intent to exclude studies that are intervention studies in that particular scenario? Because those are kind of a little tricky. If based on the inclusion/exclusion criteria, right, you could get randomized control trials that would assign women to an intervention for weight reduction compared to one that would be a control.

But that's not necessarily a disease, per se, right? And I don't know if that would be the intent.

[0:31:01] Would that be the same intent in terms of what we're trying to get at with that particular question?

Dr. Elizabeth Mayer-Davis: Right. So, if there's a study that's an RCT looking at approaches to improve that trajectory of weight following delivery, those would be included, and unless I missed something in the analytic framework that perhaps needs to be clarified or corrected, we would not want to exclude those kinds of studies.

Presumably, the women would be generally healthy women who didn't all have, say a particular diagnosis. So, for example, if all the women in the study had a diagnosis of gestational diabetes, that would be example of one that would be excluded because it would be more focused on treatment essentially, or prevention of development of diabetes following delivery all in women in gestational diabetes.

[0:32:03] And that's a rather different question.

So, with that type of exception, otherwise, the kind of study that you're describing, an RCT where the outcome is optimal postpartum weight loss, those would be included. And anyone can correct me, and maybe we need to look again at the analytic framework and make sure that that's clear.

Dr. Jamy Ard: Even if a calorie restriction were prescribed?

Dr. Elizabeth Mayer-Davis: I would think—I don't see any reason that that would be excluded.

Dr. Jamy Ard: Okay.

Dr. Richard Mattes: I think the issue is whether there is control for the beverage. The question is does drinking something during that period of time have some differential effect?

So, as long as that's the independent variable, it would stay in. If there wasn't controlled adequately, then it would be confounded for our interpretation.

[0:32:59] ***Dr. Elizabeth Mayer-Davis:*** Right. And thanks for that clarification, because that was my assumption that I didn't articulate. So, thank you for that.

Dr. Barbara Schneeman: I think it is worthwhile to observe that this is the first time there have been beverage questions. So, it has been challenging for the subcommittee to develop the protocols and keep the focus on the beverage aspect of it. So, I don't know if there's anything more you want to add, but it is something unique for this evaluation.

Dr. Elizabeth Mayer-Davis: Yeah. I mean it might be good to just note, in terms of the comparator, this is maybe where this comes in with beverages, a new sort of component of this process in general.

So, the comparator has to do with the amount of intake of whatever beverage is being looked at in a given study, or the comparator could be the physical, could be with respect to the physical form, whether something is in the physical form of a beverage versus a solid physical form.

[0:34:09] So, that's how we're framing the comparator as we're taking this first look at beverages explicitly, as part of the Dietary Guidelines process.

Dr. Carol Boushey: In one of the analytical frameworks, one of the key confounders was other supplemental sugar, and maybe I got that—

Dr. Kathryn Dewey: Naturally.

Dr. Carol Boushey: Oh, other—was it naturally-occurring sugar or something along those lines?

And I was just curious how widely that is available in these studies that you're reviewing. Maybe you—and the reason I was thinking about that is that it was a key confounder, and since a study gets lower rank if it's missing a key confounder.

[0:35:05] And so, I just was wondering how powerful this was that it was a key confounder.

Dr. Elizabeth Mayer-Davis: So yeah, this is a rather difficult one, because it is a question, how many studies really adjust for this? And I can just think of a couple studies just that are going through my mind with respect of, say fructose, whether it's added as high fructose corn syrup or something, versus naturally-occurring fructose.

I mean so it's tricky, and it will be a little tricky in the literature. And so, that's something that will be looked at to really see what was actually measured, how the exposure was very specifically defined, and what analyses were done to try to distinguish between what we're interested in, which is added sugars, versus naturally-occurring sugars.

[0:36:01] So, we're just going to have to see what is possible to discern for different papers, and literature, where we can't sort that out, obviously will not be given the same level of validity.

Dr. Richard Mattes: Just to sort of add to that. One of the issues that we struggled with is the concept of added sugar versus just the physiology of taking in sugar, whether it's added or inherent. And so, we thought it was important that we capture totality of sugar intake if we want to be able to isolate the added sugar intake.

And so, it really is pretty key to get that information.

[0:37:15] ***Dr. Barbara Schneeman:*** Any other questions or comments for those of you strong enough to push that button?

So, I'm going to turn it over to you, Ron, for…

Dr. Ronald Kleinman: Yeah, so we have a change in the schedule, since we're being so effective and efficient. And we're going to move now to the Frequency of Eating report, and Steve Heymsfield is going to give that to us.

[0:38:05] ***Dr. Steven Heymsfield:*** Thanks, Ron. I want to start by thanking the subcommittee members, of which you're one, the federal support staff, the NESR liaisons, and the staff leadership. They've been all very helpful in putting this together.

As you see here, the six topic areas for this subcommittee are listed on this slide, one of which we've got a draft conclusion for you'll hear in a minute.

And the subcommittee is implementing the plan and currently screening potential articles for the topic areas related to frequency of eating, and I'll read these, for body composition, obesity, cardiovascular disease, type 2 diabetes, gestational weight gain and postpartum weight loss.

[0:38:56] The subcommittee has drafted a conclusion that I'm going to present in a minute, on one of those areas, which is frequency of eating related to mortality.

The subcommittee updated these six protocols based on deliberations of the full committee at the July 2019 public meeting, and consideration of public comments that are included in our updated draft you'll see today.

These are posted on DietaryGuidelines.gov, so you can look at them there.

None of the edits that were made substantially change the intent of the conduct of the frequency of eating systematic reviews. Specific edits to the key definitions and to the analytic framework will be identified in a few slides that follow.

At the second public meeting in July, the frequency of eating subcommittee presented our proposed key definitions.

[0:39:59] You'll see some of them right here. Based on the full committee and public comments, the subcommittee has updated a few of these definitions here.

And you'll see that frequency of eating really has two main parts – the number of eating occasions and the timing of daily eating occasions.

And the frequency of eating definition remains the same as it was in July.

Eating occasion was updated to replace caloric with energy yielding.

Timing of daily eating occasions is a new definition since July.

And the definition of fasting has changed since July to clarify that a fasting period may include the consumption of water

The definition of meal was removed, and secondary eating was added since the July meeting.

[0:40:58] The subcommittee members have now completed our first review, as I mentioned earlier, answering the question "What is the relationship between frequency of eating and all-cause mortality?"

This slide shows our analytic framework with the intervention/exposure being frequency of eating, and as I mentioned earlier, that includes two main components: the number of daily eating occasions and the timing of daily eating occasions. And the timing of daily eating occasions further clarified by adding the timing of weekly eating occasions, for example, weekday and weekend, meal skipping, and fasting time.

Now, let me give you a few details about this slide.

First of all, the questions that will be looked at in a population of 2 years and older, not less than that, 2 years and older.

[0:41:59] After the last public meeting in July, adjustments have been made to the list of key confounders and other factors to be considered, including moving total energy intake from a key confounder to another factor to be considered, and adding chrono-nutrition factors and secondary eating to the list of other factors in response to committee feedback. So, that's our analytic framework.

This just shows the standard NESR criteria that the Frequency of Eating subcommittee will be adopting, and these have all been detailed in previous presentations.

These are, let's see, this slide shows the details of the inclusion/exclusion criteria for the intervention and exposure, and two main components are in this slide, as you'll see.

[0:43:01] First, age of study participants and date of publication. And these were all presented earlier in July by Dr. Leidy.

With respect to age of study participants, all Frequency of Eating questions will include populations from children to older adults and will exclude studies that exclusively enroll infants and toddlers between the ages of 0 and 24 months.

And then second, with respect to date of publication, the Frequency of Eating subcommittee decided to set the date ranges of all searches from 2000 to the present. The rationale for this decision was based on the change in quality of research in this field, improving over time. Different, more objective methodologies are available today compared to the past.

Additionally, eating patterns in the United States today are so different than 20 years ago or more.

[0:43:59] The controls that are used in studies earlier than 2000 are not appropriate for today's food patterns and food intake.

This slide shows the details of the inclusion and exclusion criteria for health status of study participants, dietary data collection, and size of study groups.

First, with respect to health status of study participants, the Frequency of Eating subcommittee used the standard NESR criteria for health status of study participant as laid out in the prior presentations. However, the subcommittee decided to add an exclusion criteria that it would exclude studies that exclusively enroll subjects post-bariatric surgery.

[0:44:56] The rationale for this decision was that this population of participants are not generalizable to the general US population. The reason for that is, after bariatric surgery, it's common to be told by your physician to eat smaller, more frequent meals throughout the day. Because of this, it was perceived that there may be literature in the frequency of eating space that may fit our criteria, and we wanted to ensure that these were not included.

Now, with respect to dietary data collection, the Frequency of Eating subcommittee decided to add a criteria that would only include studies with a minimum of three days of dietary data collection on at least two different occasions. This is very critical criteria.

We felt that it was important to ensure that the studies being included were capturing habitual or usual eating frequency and not just based on one dietary measure.

[0:45:59] For this criteria, studies that use a frequency questionnaire on at least two occasions, which measure usual diet over the past month or year, were qualified as fulfilling this criteria.

Now, with respect to size of study groups, the Frequency of Eating subcommittee decided to add a criteria around the size of study groups. The study needs to have at least 15 participants for studies using within-subject analyses, or 30 participants for studies using between-subject analyses, or they would need to include a power calculation in the publication.

The subcommittee felt that it was important to help to ensure that a study was adequately powered to be able to detect differences that will be reported in the systematic reviews.

[0:46:57] This is our flowchart illustrating the literature search and screening results for articles examining the relationship between the frequency of eating and all-cause mortality. The literature search yielded a very large number of articles, 4,791. After duplicates were removed from that group, 4,174 articles were screened at the title level, and during the title screening, 4,030 articles were screened out.

During the abstract screening, 126 articles were screened out, and during full-text screening, 18 articles were screened out. During the hand search, 0 articles were identified to include in the review.

So, a total of 0 articles were included in the systematic review at the end of the search and screening process, making our report very short. Null.

[0:48:00] So, the subcommittee was very interested in the reasons why the systematic review had 0 articles and how their specific inclusion and exclusion criteria was determining the selection.

Three of the 18 full-text articles would have been included for all other criteria except for the dietary data collection inclusion/exclusion criteria. All three papers only had one dietary data collection time point. The subcommittee feels strongly that, in order to achieve a reliable measure of typical or habitual frequency, more than one dietary data collection time point is required.

So, that explains largely why these papers got excluded and why we ended up with 0 at the end.

[0:49:00] The description and summary of the evidence is that no studies published between January 2000 and June 2019 met the inclusion criteria for this systematic review.

So, our conclusion statement then is that there's no evidence based on our criteria to determine if there is a relationship between the frequency of eating and all-cause mortality, and it spells it out in a little more detail there, but that's pretty much the bottom line of our review of almost 5,000 publications.\

A search has been conducted and the subcommittee is currently in the screening process for the questions on frequency of eating and growth, size, body composition, overweight, obesity, cardiovascular disease, type 2 diabetes, gestational weight gain, and postpartum weight loss.

[0:50:03] Because the significant overlap in search results, these remaining questions will be handled by a combined search strategy to reduce the number of duplicate records being screened. This search includes about 35,000 articles that are currently being screened independently by two NESR analysts.

The next question this subcommittee plans to address, the growth, size, body composition, and risk of overweight and obesity is in review.

So, I want to thank, again, the subcommittee members for their hard work on this, and we've done one complete project at this point. Thanks very much.

Dr. Richard Kleinman: So, it's open for comments or questions?

Kay?

[0:50:59] ***Dr. Kathryn Dewey:*** Thank you. Kay Dewey. So, I have a question about the criteria for the number of dietary days that you described. What if it's an experimental study? Is that criterion only applied to observational studies, or is that also for experimental studies where they might manipulate the frequency of eating?

Dr. Steven Heymsfield: I think we had a proviso in there for randomized trials, didn't we, Rick? I want to say Rick weighed in on this to some extent.

Dr. Heather Leidy: No, so I mean the criteria that you talked about was just for—primarily for randomized control trials needing two different time points. We were thinking a lot for the—more the observational studies, where they would have dietary—not dietary recalls of food frequency questionnaires.

When you look at how they're assessed, they're generally over a longer period of time, so technically, they would meet the criteria because it's a minimum of three days when you look at our criteria.

So, the three days, were in the mindset, with randomized control trials, what you would think of recalls, or that type of collection as a minimum.

[0:52:02] But food frequency questionnaires would be included within that criteria because they generally are asking over a long period of time.

Dr. Kathryn Dewey: So, if I'm understanding that response, is it three days at baseline and three days at the end, or a total of three days over two time points.

Dr. Heather Leidy: Yeah, we need two different time points.

Dr. Kathryn Dewey: So, your minimum is three days at baseline and three days at the end? So really, that's a marker of adherence.

Dr. Heather Leidy: Carol, you're shaking your head no?

Dr. Carol Boushey: Well, I might be confused. But I thought if you were using methods that were collecting dietary data one day, and so, that can be a dietary record or a dietary recall, we—there was the decision that at least three days were needed.

For the food frequency questionnaire, it was two food frequency questionnaires, not—three never came up in the food frequency questionnaire world.

[0:53:06] ***Dr. Heather Leidy:*** Right, because it's included three days because it generally asks over a week or a month. But going back to the two time points, so the four of us on the committee, I was pretty certain that it was two different time points with randomized control trials, as well as observational studies, that we wanted to capture two different time courses for, in this case, to answer the all-cause mortality question.

So, it would have been two different three-day—

Dr. Carol Boushey: Right.

Dr. Heather Leidy: What we didn't establish is the time interval between those. So, getting to your point, if for some reason, a study—technically, the study collected three days at baseline, and then three-day records a week later, that technically meets our criteria because it was two different time points.

I think what we were thinking of is at baseline and then some time point later on.

[0:54:00] ***Dr. Ronald Kleinman:*** But it wasn't meant to be a measure of adherence as much as a measure of reliability, that we were actually accurately capturing frequency of eating over some period of time and that we had two three-day captures, so to speak, of what was happening.

Dr. Kathryn Dewey: Well, but that's relevant for observational studies. If it's an intervention trial, and they've manipulated frequency of eating, then capturing data on that is a marker of compliance. So…

Dr. Richard Mattes: Of compliance and…both. In that case, it would sound both prompts.

Dr. Ronald Kleinman: Yeah, it would be reliability and compliance.

Dr. Heather Leidy: I think what we were trying to avoid is the one-day dietary records or recalls, because eating patterns are different depending across the day.

We didn't want to establish it at longer than that, so were trying to get away with just the one day of assessment.

[0:55:00] So, that's why making it three days, and then having it over another time point would be helpful.

Dr. Kathryn Dewey: Yeah, I don't have any problem with that for observational studies. I am still struggling, though, with how it applies to intervention trials, because an intervention trial doesn't necessarily need to even have that at baseline. Just if you're randomly assigning people, you assume the sample size is large enough that they're similar on frequency of eating to begin with.

So, all you really would need would be some marker later in the intervention period that, yes, in fact, they differed the way you intended them, and that's a marker of compliance.

Dr. Heather Leidy: So, I think we have—

Dr. Kathryn Dewey: So, why would three days be required for that? That's a different issue than a precision of the estimate of frequency of eating.

Dr. Heather Leidy: So, one of our points, and then Rick, you can comment, too, was that we think habitual frequency of con—frequency of eating actually is a key confounder, key factor in ours, because how somebody's eating at baseline can affect the response to the intervention.

[0:56:04] And so, that's why we wanted to have a baseline where you're actually capturing their eating frequency and using that as part of the criteria.

Dr. Kathryn Dewey: Well, that's an interesting question, but that's one that would look at, let's say, effect modification so that you only see that effect of that intervention in those who had high frequency to begin with, or low frequency to begin with. But that's not the question that you have in front of you, necessarily.

So, well, I guess a related question is are there any intervention trials? Because this is all moot if there aren't. I'm assuming for mortality, none of those three were intervention trials.

Dr. Steven Heymsfield: Right.

Dr. Kathryn Dewey: But for some of your other outcomes, it's possible.

Dr. Carol Boushey: I think the most important concept was the idea of frequency of eating to be able to establish, get as close as possible, what might be someone's frequency of eating, you would need to have more than one day of information.

[0:57:12] I mean that was what the essence of the conversations were.

Frequency isn't—frequency doesn't have the same stable occurrence as your foods and your nutrients. I mean so, and you can also get the same amount of food and nutrients in one sitting or five sittings. And so, that was really where the—what drove the decision was we, if it's frequency of eating, that's how many times a person ingests one, two, or three items each time throughout a day.

And then, if we wanted to somehow let this be a marker, we would need more than one day.

[0:58:00] And in the end, we selected three.

Dr. Heather Leidy: But I don't think that's the sticking point right now, right?

Dr. Kathryn Dewey: Yeah.

Dr. Heather Leidy: The sticking point is the number of times we're doing that.

[indiscernible 1:17:21]

Dr. Barbara Schneeman: Yeah, if I understand the nature of the question, I'm just—let me try and see. So, I perceive that part of the question is, if food frequency is studies as an intervention, then does it make sense that you might mark it at the beginning, and then you do your intervention and figure out if they're following your intervention, versus I'm doing another study and I'm collecting food frequency information, but I may have only measured it once during the study. I'm just doing it as part of what I measure, but it shows up in a literature search.

I mean is—I'm trying to understand. Is that what we're trying to distinguish between?

[0:58:57] ***Dr. Ronald Kleinman:*** Yeah, and I think what you're saying is if you prescribe, if you prescribe the frequency of eating in an intervention trial, so the subjects must consume food three times a day, then this definition doesn't really apply to that circumstance.

So, I think we should probably take this back and just consider it among the group, because I do think that's a good point.

Dr. Steven Heymsfield: Yeah, that's a good question.

Dr. Kathryn Dewey: If I could just give an example. So, for gestational—what is your outcome? It's—

Dr. Sharon Donovan: Gestational weight gain.

Dr. Kathryn Dewey: But it was also—

Dr. Sharon Donovan: Postpartum weight retention.

Dr. Kathryn Dewey: Yeah. So, there are some schools of thought that eating smaller amounts more frequently during the day is a positive intervention during pregnancy.

And so, you may not have even a baseline measure, but you may have randomly assigned women to do that or not, and your outcome would be gestational weight gain.

[1:00:01] So then, it's a question of do you absolutely need three days of dietary data on their frequency of eating, or do you just need anything at all on adherence, or you don't even care about whether they measured adherence?

So, those are the choices that you have.

Dr. Ronald Kleinman: But then, you would want that study to continue for some period of time at least. So, that couldn't—that obviously wouldn't be a one-day study. I mean nobody's thinking about that. But so, over some period of time, and I don't know whether we need to define that period of time as a criteria, but over some period of time, more than one day, when one is prescribed a frequency of eating, is the outcome related to that prescription?

And so, I think that's what we ought to talk about.

[1:00:57] ***Dr. Richard Mattes:*** I think partly the motivation here was getting an accurate record of ingestive behavior is hard, even in a controlled trial. And so, it would be just as relevant in an RCT as in an epidemiologic trial to want to get at least two estimates of intake to give you some sense of the reliability of what's being reported there.

And so, that was a good deal of the motivation. I mean if it's a metabolic ward study, you don't need to do this.

Dr. Kathryn Dewey: No.

Dr. Richard Mattes: But if you're free-living, you can be told to eat x times a day. Whether you do it or not is another matter.

Dr. Ronald Kleinman: But it becomes an issue of compliance, just as that—in that circumstance, it's an issue of compliance.

Dr. Heather Leidy: And just to comment, you brought it up, but it might have been conveyed a little bit differently. So, there were 18 studies that initially got down, and then to 0.

[1:02:02] Only 3 of the 18 were actually excluded because of the dietary collection approach. So, there were still a number of other reasons that would be typical of what you'd see in our other included and exclusion, and that's what we were worried about initially, that maybe assigning that level of dietary intake might be a problem, but I don't think that's—I don't think that's going to be the case, especially not moving forward, given the number that we have.

Dr. Ronald Kleinman: No.

Dr. Heather Leidy: And then, to your point too, we do have a minimum of eight weeks. So, theoretically, there is a minimum of eight weeks in duration too, for the intervention trials.

Dr. Carol Boushey: That's the same as averages.

Dr. Joan Sabate: I have a question. On these three that—

Dr. Ronald Kleinman: Say your name.

Dr. Joan Sabate: I'm sorry, Joan Sabate. On these three that finally I mean were excluded, I mean those were randomized clinical trials, or were observational studies?

Dr. Steven Heymsfield: Observational.

Dr. Joan Sabate: Okay. Because going back to slide number 8, when you say inclusion criteria, it looks like it is written in a way that is only for intervention trials, that you have 15 participants, or 30 participants, or power calculations.

[1:03:10] I think this iteration to the outcome of total mortality doesn't match. You're trying to do total mortality with only 15 participants or 30.

So, I'm saying there is a mismatch between the methods and the outcome being studied. So, probably this protocol has to be refined or at least edited in a way.

Dr. Steven Heymsfield: Thank you.

Dr. Rachel Novotny: Rachel Novotny. I actually am thinking of a much broader question, that I don't think we had any criteria for diet assessment for any of the other protocols.

[1:03:56] So, do we have one? I'm thinking sort of as a committee, do we have one? I mean most of the NHANES work is going to be one day. So, just I'm thinking as a committee, we probably should think about that.

And I'm trying to reconcile, and Carol you made a comment, maybe you can explain more deeply that foods are more stable than frequency or eating, or something like that.

But to me, it's not so intuitive why any of our other questions wouldn't have the same issues, trying to get daily nutrient or daily food patterns. So, maybe we should be thinking collectively about diet assessment.

[1:04:58] ***Dr. Ronald Kleinman:*** Yeah, I mean we should. I think we've probably all through about this as we were working through this. I guess the challenge is do we end up with 0 for everything that we're looking at.

I don't know that we want to get into a discussion about the validity of food frequency or recall for accurate measurement assessment of intake, but that kind of is what—where we're at right now, isn't it?

Dr. Rachel Novotny: Or number of days.

Dr. Ronald Kleinman: Or number of days.

Dr. Regan Bailey: So, when we're using the NHANES data in one day of intake, that's just when we're looking at the mean, not the population distribution. When we look at the population distribution, we have two days adjusted for usual intake. The mean is really in variant. It's the tails of the distribution that changes. At least for food and nutrients. I don't know as much about frequency of eating.

Dr. Carol Boushey: And that's the unique thing about this one. We are not measuring any foods or nutrients. It's just—

[1:06:02] ***Dr. Ronald Kleinman:*** Time.

Dr. Carol Boushey: It's just if it occurred. It's just a little—it's like how many times did you get gas in your car last week?

Dr. Elizabeth Mayer-Davis: So, can I chime in here? So, I've—I was a little worried, in listening to this, about the three days. In an ideal world, absolutely at least, but I am a little bit concerned about throwing—just throwing out any study that has two days of dietary data and everything else about the study meets criteria, rather than three days, for example. I have no idea if that was the case. But just as an example.

I'm wondering if there's a way to make that criteria a little less stringent and have an other factors to be considered kind of aspect to that so that we don't miss important literature.

[1:06:58] And as I sit here, I don't know what the right thing is to do exactly, and I do think it's a very well-taken comment, Rachel, about this being a consolidation really across the subcommittees. I think that is important to do.

Dr. Ronald Kleinman: Well, I mean we could reframe that, recast it to say more than one day. I think we talked about that. I don't know what the others on the committee think.

Dr. Regan Bailey: Well, I think it depends on whether you're looking at an intervention or an observational study. That's what it comes down to. If you have a large, well-controlled clinical trial looking at postpartum weight loss in a large number of women, for six weeks, you would exclude that study based on your criteria, right?

But that might be a relevant study to question.

Dr. Ronald Kleinman: No, I definitely think we need to go back and separate out intervention studies and versus observational studies and come up with—I don't mean to speak for you, but—

[1:08:04] ***Dr. Steven Heymsfield:*** No, I agree.

Dr. Ronald Kleinman: So, we can take that back. Kay?

Dr. Kathryn Dewey: Kay Dewey again. Prompted by what Rachel said, I'm wondering whether some of the criteria for risk of bias assessment might be relevant here, and I don't remember them all, maybe the staff can help me, but is there one for the adequacy of exposure assessment? I think there is. And that's really what we're talking about here is the adequacy of exposure assessment.

So, you might want to take a look at that, and if that's good enough, it doesn't have to be applied as an exclusion or inclusion criteria for the studies, but it would be applied at the level of the grade given.

And that's how all the other subcommittees I think are handling this now.

[1:09:02] ***Dr. Barbara Schneeman:*** I think some of these comments are probably particularly important going forward to the other outcomes that you're going to be looking at, where presumably, there is more evidence, and there are going to be more papers.

I think all-cause mortality was always one where, yes, where were going to see a lot of papers in that particular area?

But I think you still have that opportunity to take those—these comments into consideration to look at those protocols.

Dr. Ronald Kleinman: Any other comments?

Dr. Steven Heymsfield: I think that when we framed our final conclusion, we did frame it in light of the definitions we used and that we qualified it a little bit.

I don't know if you recall the wording, but there just weren't any papers that had more than one evaluation.

[1:10:07] So, it was pretty easy for this one. But we're not saying there's no relationship between frequency of eating and all-cause mortality. There's none based on our criteria.

So, I think if there was papers, two studies that were available, we excluded them in this case, but we qualified our definition at least based on what we had, which is largely empirical, and I think maybe in

the future, going forward, the details of those decisions need to be considered further, not just now, but maybe for future studies.

Dr. Ronald Kleinman: Alright, what do we do now?

Dr. Barbara Schneeman: Well, I'm going to suggest we take a short break, a 15-minute break, and then we will come back, we'll have more opportunity for discussion.

[1:11:02] And I'm going to give Eve a heads up. I know several of the committee members have been asking more questions about the report, so I think there could be time for us to maybe get some discussion going on what is it we're working toward, especially now that more of the committees are reaching that point of developing their conclusions, their evidence portfolios, it would be good to help our thinking now.

So, let's take a 15-minute break, and then, we'll start with that after the break.

[Break 1:11:33-1:32:16]

Dr. Barbara Schneeman: So, if we could get started again, if we could get the committee members back, and…

So, I just wanted to note, given where we are with the subcommittee reports, where we've now finished the Dietary Patterns, the Dietary Fats and Seafood, Beverages and Added Sugars, and Frequency of Eating, we'll start again tomorrow morning, but it looks like we'll probably be able to do the three remaining subgroup reports before lunch.

[1:33:01] So, we're aiming to do that.

Again, if we need more time, we will take more time, but I just wanted to alert people that, if in fact, the schedule goes like today, we will consider moving all of them up to happen before lunch.

So, as noted before we took break, I asked Eve and Janet if we could have some discussion about the nature of the report that the committee as a whole will be submitting. There are a lot of changes that have been happening with the Dietary Guidelines process.

And so, I think it's useful for us to be thinking about what we're aiming for in that report and make sure that there's agreement in the committee on how we're going to put that forward.

So, I've asked you spontaneously to do this.

Dr. Eve Stoody: Yes, thank you, Barbara.

[1:34:00] ***Dr. Barbara Schneeman:*** And I appreciate your willingness to do that.

Dr. Eve Stoody: So, maybe just a little bit up front. We've talked to a few members about the proposed report structure to begin with but haven't touched base with all of you. So, just a little bit of background.

As I think we've mentioned before, we do have a science writer, and I think that name, she doesn't literally write, as Barbara's noted and as y'all know, the report, it's your conclusions, it's your findings. She really tries to help pull it all together.

So, the last committee's report was like 470 pages. And so, it's a lot of coordination to get all the pieces together and look for some consistency, try to propose some consistency in language so y'all are kind of taking things in a consistent way, and things like that.

She's worked on—and that science writer, her name is Ann Rogers, who, fortunately for her, is on a cruise. Unfortunately for us, this leaves Janet and I to talk about this.

So, Janet and I have talked with her a little bit about the proposed report structure.

[1:35:00] I'll say that Ann has worked with the last two Dietary Guidelines Advisory Committees, as well as I think the last two Physical Activity Guidelines Advisory Committees. So, she's had a lot of experience supporting advisory committees, including the Dietary Guidelines.

So, the structure, these initial discussions—so Ann has done a lot of outlining. I think when she first sent us documents, we got eight documents. And just I think some initial discussion, to give you a sense for the general organization.

And then, there are a couple of decision points that would be good to discuss, particularly around the organization of the science-based chapters.

So, I can do a little bit of an orientation to kind of what has been proposed, and then open it up for all of you to discuss.

And I should say, this outline was informed, as I said, by her previous work in our previous advisory committees, but also, some of your discussion.

[1:36:05] So, a discussion about wanting to speak to existing reviews, discussion about where to address future directions. So, that is integrated into this as well.

So, it is a report from the committee to the Departments, and that begins with a letter to the Secretaries. The report is to the committee—excuse me, to the Secretaries of Agriculture and Health and Human Services. Typically, that comes—the letter comes from the chair and vice-chair on behalf of the committee.

There are—it has historically been divided into four main sections – an executive summary, a discussion that is currently—and I should say, all this is proposed. It really is up for your discussion and refinement.

Some of that, you can do early on, and I think thinking about the end in mind is great.

[1:36:59] Some of it, you can kind of refine now, but some of it, just know that there's flexibility in how it's structured as you move forward.

So, first part is executive summary. The second is currently labeled "Setting the Stage in Integrating the Evidence," and that's really an introduction. And then, "Integrating the Evidence." And one of the really important pieces, there's a lot of discussion around individual conclusion statements, the reviews of evidence and this very specific—answering the specific question, but a lot of these questions are inter-related.

And even, there are a series of questions on frequency of eating, and a series of questions on dietary patterns, and one of the things that's important in the report, particularly as an end-user, is that it's pulled together.

And so, that, for example, looking across all of the dietary patterns questions, it's speaking to the dietary patterns, the findings about dietary patterns across the health outcomes, rather than "Here is the answer, the conclusion statement related to dietary patterns and CVD versus all-cause mortality," I mean bring it together, integrating it is an important part.

[1:38:14] And it is something that, it comes a little bit later, and it's often something that is pulled together pretty quickly, because I mean that's just the way the timeline works. But I think as soon as—keeping that in mind, and then as much integration as possible is wonderful.

So, that's in part B, kind of the big picture. Part C is methodology. So, there will be a lot of discussion on the three approaches to examine the evidence, and staff will help support writing that up, so writeup around the NESR systematic review methodology, data analysis, and food pattern modeling analysis.

And then, part D, the fourth main section is a section, that's the science base.

[1:38:59] And so, that's really where you get into the questions and conclusions. And we're proposing, in the actual report, that a lot of the content is more of a summary of your systematic reviews, for example, and that the full systematic reviews will post on NESR's website, so all of the details and all the included and excluded articles, and all of those pieces, the full, all of the materials for duplication and transparency, will be posted on NESR's website, and what will be in the actual report will be a summary.

And the intent there is you've done all this work in those NESR reviews. It's literally some sections that you'll copy and paste, that you've already worked on and put into the report around the specific questions.

So, that is where a lot of the kind of discussion around the questions are.

A big piece here is that, historically, the science-based chapters have been organized by subcommittee, which obviously makes a lot of sense.

[1:39:59] That's how you're talking within subcommittees. However, what we would propose is, in this, particularly because of the focus around life stages, birth to 24 months, pregnancy and lactation, to begin that integration for those sections within the science-based chapter to be organized by life stage.

So, all the conversation around B-24 be in a section for B-24, all of the conversation, the questions around pregnancy and lactation be together, and then 2 years and older. And I think that's up to how, if there is any other—if it's just 2 and older, if it's some breakdown within that, it would be great if there is, but if it's more collectively, that's great, too.

But the notion here, it will take—part of why we wanted to have—start having the conversation is, if there's going to be bringing it together by life stage, it's going to require thinking about that in drafting the conclusions and working to pull those sections together.

[1:41:04] So, that is one discussion item. It's just around the organization.

And I can say from—a lot of that is driven from, at the end of the day, we hope to provide guidance around birth to 24, guidance for pregnancy and lactation, and if y'all have already kind of pulled that evidence together, it helps not—there's one piece here and one piece there, it's just it's more integrating it together in one place.

So, those are—and I should say, I can talk a little bit about what's proposed in a chapter.

So, let's say a chapter around birth to 24 months, let's say for example, could have a discussion around an introduction to why this topic's important, discuss key definitions, identify the questions that are addressed in that section, and then go through the questions.

[1:42:00] So literally, that brief summary from each systematic review, or in the case of data analysis and food pattern modeling, a writeup of the evidence reviewed.

And then, one of the things that we proposed, based on your discussions to date, is a discussion section. So, whether it be by question, or by topic area, a discussion where you can talk about how—compare your findings to existing work, and then also talk about the public health impact. So, why is this

important to the health of the people in the US, and what advice does the committee have to the Departments in response to the findings of this section as it relates to the Dietary Guidelines?

So again, kind of taking the individual conclusion statements and pulling it together, integrating it, and ultimately, informing the advice that the committee has to the Departments.

And then, that—each chapter would also have a summary as well.

[1:42:58] So, I think that's the high-level overview, but happy to answer any questions, and then open the discussion.

Dr. Barbara Schneeman: Great. It seems like one of the topics that might be good to get committee input on is using this approach around life stage. So, it means more work integrating across the subcommittees, but I guess in my thinking, it's how I understood the focus of this particular Dietary Guidelines process to be, is around life stage.

So, I'm interested in comments or suggestions that the committee has for consideration, because the end of the day, we'll be the ones doing the work.

Dr. Richard Mattes: As long as we know ahead of time, just so we don't go start one path and then go on another.

[1:44:02] ***Dr. Kathryn Dewey:*** Kay Dewey. Yeah, we actually discussed this a little bit yesterday, and the people in that meeting at least were in agreement with doing it by life stage.

So, in fact, tomorrow, when I present B-24, I'll be showing you which of all the questions are actually handled—being handled directly by our subcommittee, and which of the B-24 questions are being handled by the other subcommittees that will have to feed into that section of the report.

One question I raised yesterday, and I'll just raise it again, is what exactly is a topic for the discussion to be organized? And I don't think it's a very large level topic, because you can't get that specific about what you think the implications are unless you really kind of boil it down to, well how would somebody eat differently or feed their children differently?

[1:45:00] And so, I guess I would like to propose that each subcommittee think about what the topics are. Because we're doing lots and lots of reviews, but for example, I was trying to count up how many we are looking at, and I think it's about 34, what I would call relationships. That isn't how many searches are going on, because a lot of relationships are being examined in a consolidated search, but in terms of how an exposure relates to an outcome, I think we're looking at at least 34 different relationships.

And part of that is because, when we look at something like micronutrient status, we may have five or six different micronutrient outcomes that we're looking at, and those are very different from each other.

So, for me, it was helpful to think about this, of how many topics are we really looking at here?

So, I think it will help organize how these chapters and the discussions might actually be structured.

[1:46:00] ***Dr. Rachel Novotny:*** Rachel Novotny. I guess I'm wondering about the data analysis and food pattern sections, whether they'll be like split up into age categories, or be essentially part of the introduction?

Dr. Eve Stoody: Yeah, and currently, they are, at least the data analysis piece, is more a front matter section, but I think that's up for discussion.

And to Kay's point, too, there is—we have a very abbreviated version of the outline, but I think once there's this discussion, a decision around if this life stage approach makes sense, the science writer has actually done a version that literally has all the questions within it.

And so, I think she can give you something to react to. And so, does this make sense, or is there some other organization?

So, I'd say, definitely think on the topic area, but she can give you something to kind of react to more, and I think that can include, yeah, where does the data analysis and food pattern modeling make the most sense?

[1:47:11] Because it addresses all of them. So, does it make sense to do it once, or to divide it?

So, I think, yeah, there is—we can—she can propose something to react to, but I think that makes a lot of sense to think that through. But right now, it's just kind of it its own front section.

Dr. Linda Van Horn: One thing that I'd like to suggest, since this is, again, an initial version of the Guidelines offering, starting at birth, the opportunity to look at primary prevention of disease starting at birth. And I think, while we've talked a lot more about pregnant women, lactation, and children, we have yet to talk about older people and elderly.

[1:47:59] But I think to try to encourage this, again, typically, the Guidelines are addressed to healthy people, and wanting to keep them healthy. I think this is a chance to look longitudinally over the course of life and to somehow further recommend, especially for young women in their reproductive years, but for everyone, that maintaining a focus on diet early in life is the best chance they have of maintaining a higher quality of life longer term.

And of course, also, with the thought of in utero, developing a healthy baby. Again, we have a long way to go yet before we have sufficient data to put documentation behind all of that.

I would imagine that five years from now, there will be even more data.

[1:49:02] But I see us kind of setting the stage for that type of evolution with regard to the Guidelines, that are much more focused on long-term prevention throughout the life course, starting in childhood, and even in utero.

Dr. Barbara Schneeman: I think you make a good argument for the life stage approach in presenting the report that becomes a good rationale.

Dr. Ronald Kleinman: I guess—and I support this as well. I guess we do need to think, though, what stages of life we're going to divide this into, and is this going to be sort of modified DRI approach, where we look at infants, toddlers, children, adults, older adults?

And I don't know that we have the capacity to do that, because we haven't been analyzing our—we haven't been systematically approaching these questions in that framework.

[1:50:07] And so, how much work is it going to take to now tease that out and segregate it?

So, it makes, to me, I think certainly, for the public, who are going to make use of this, this is really a wonderful approach to take, and I like the idea that it's breaking from past approaches.

But, how are we going to deal with that question? Have you thought about that, the staff thought about it?

Dr. Eve Stoody: Well, at the moment, it's—we've just proposed the pregnancy and lactation, birth to 24, and 2 and older. However, I will say, in all of the analytic frameworks, there is, I mean the data is divided by age group, there is a child, adult, older adult.

[1:50:56] I think it's a question, if you were to—I think the discussion about if you keep 2 and older all together, or subdivide it, is a great conversation for y'all to have. For us, I think it'd be fantastic, but to your point, I don't know if it's there, if that's possible this time. But this is the time to have that conversation.

Rick, to your point, if we knew we're doing this, if you know you're writing conclusion statements for children, if you know you're writing conclusion statements for older adults, it's good to know that now.

So, I think that's—if—I think it's a discussion for y'all, or/and you can just kind of keep it in mind as you get deeper into some of the reviews with more evidence to see if there is the ability to provide some dist.-breakup.

And it could be that your—that section is 2 and older, and then within the discussion, you talk about the age, any kind of differences across the life span within that chapter, but you may not be able to do it for every single topic.

So, I think that's a good one for y'all.

[1:52:01] ***Dr. Ronald Kleinman:*** Yeah, and I mean that kind of was my point, that if we don't—if we're going to do that, we need to start approaching it that way now. And I think to do it 2 and older, if we really do want to make this useful, to just simply say 2 and older isn't going to really cut it with the public.

So, my suggestion is that we do it, but we do it right now, starting to look at these three different age groups after the age of 2, if it's going to be 3 or 4, whatever it's going to be.

Dr. Elizabeth Mayer-Davis: So, I think that's really a good suggestion, Ron. And I also think that when we come to looking at the literature and synthesizing what we get, we're going to have to do that anyway, just because of the nature of the questions and the exposures, and what you would need to consider.

[1:53:04] All of these analytic frameworks have other factors to be considered. It will be different if you're talking about childhood than if you're talking about older adults.

So, I think in reality, it isn't less work. In fact, it will help us to be more efficient in the work that we're doing. So, I think that's really a great suggestion.

Dr. Barbara Schneeman: And Regan, I don't know if you want to comment relative to the data analysis.

Dr. Regan Bailey: So, this is Regan Bailey. And the way that we have our data analysis set up this way, is B-24, 2 to 19, or 18, and 18 and older, and then older adults, depending on the NHANES sampling framework, or the DRIs, 65 or 71+.

So, we do have that life stage approach, at least in the way that we're working, but it will be different from, obviously, what you all have.

[1:53:59] ***Dr. Ronald Kleinman:*** So, should we agree now what these categories are so that each subcommittee can go back and consider it that way?

Dr. Kathryn Dewey: Kay Dewey. A question. Is the current guidance that's out there subdivided into age groups? And if so, what are those age groups? Since probably, like 2-5, and then 5-something. I don't know. Does anybody know what those are?

Dr. Carol Boushey: It depends on what professional group you're looking at. I mean it does vary.

Dr. Kathryn Dewey: We're talking about the Dietary Guidelines.

Dr. Carol Boushey: Oh yeah, Dietary Guidelines.

Dr. Barbara Schneeman: Maybe Janet and Eve, can you comment on the current—the 2015-2020 Dietary Guidelines, to what extent is there any age thinking in those guidelines?

I know there is some.

[1:55:00] ***Dr. Eve Stoody:*** Most of it, though, is more in the patterns. So, in the patterns, there are—there are 12 different food patterns in the Dietary Guidelines at different calorie levels, and there is discussion as to what age group the calorie level—what calorie level is most appropriate per age group.

In some cases, like for the nutrients of concern, there might be nutrients that are of particular concerns for different stages of life, but the way the current Guidelines are written are not necessarily by stage of life. It's more broad. And then, the food patterns are more—can be tailored based on the calorie needs, which vary based on age.

I will say the Physical Activity Guidelines do have some breakout by age, which I think they've done a really nice job speaking to recommendations across the life stage.

It's not that the Dietary Guidelines don't address age, it's just more through the patterning than specific recommendations.

[1:56:02] ***Dr. Barbara Schneeman:*** Tim?

Dr. Timothy Naimi: Just to make a note, I think the life course approach is good. I think we also have to keep in mind, though, that for there to be different recommendations by age group, there should be different findings, and there would also need to be adequate data for each of those age groups.

And there's the issue of trying to keep the Guidelines sort of accessible and simple. If anything, they tend to be too, for a lot of people, detailed.

So, I think that it's a useful framework, but that we shouldn't try to add more recommendations unless it's clearly indicated for a particular age group.

Dr. Elizabeth Mayer-Davis: Yeah, I think that's actually very reasonable, and within what we've said so far, I think that that would work well, to say "This is how we're all organized," if we agree to that.

[1:57:04] And I don't know that we will. But if we do, then we could systematically say, "Here's the evidence, and there is or there isn't sufficient evidence for more specific recommendations for older adults compared to another group," for example. I think that's very reasonable.

Dr. Ronald Kleinman: Yeah, and I think it often gets—that nuance often gets lost when we group ages 2 to 70 together, that in fact, for the 2-year-olds to 5-year-olds, there's no evidence, and for the 65 and up, there's lots of evidence on a particular issue.

So, I think, in some ways, this will clarify things rather than make it more challenging for people who are looking at these recommendations.

Dr. Barbara Schneeman: So, it sounds like, to several of the points being raised, there really is a need to look at this in the context of the subgroup committees, how they're working through the data.

[1:58:09] And I think the more we can get the data analysis, then we're seeing where the nutrients of concern are across life stages. So, that can also feed into the subcommittees in terms of how they're thinking of integrating their findings and conclusions.

So, at some point, it all has to come together, right?

Dr. Ronald Kleinman: So, how do we go about deciding what our—it sounds like there's consensus here around doing this by life stage, and how do we go about deciding what those stages are?

Dr. Elizabeth Mayer-Davis: Can we ask Regan, once again, if you could remind us the ages that you said your group is working on?

[1:58:56] ***Dr. Regan Bailey:*** Well, sometimes it depends on the DRI, sometimes it depends on the NHANES sampling framework, but in general, it's B-24, of course, I can't find every—here. We have 2-5, 6-12, 12-18, and then 19 and older, and then as adults, it's usually 18 or 19, depending on what data source we have available, and then older adults, in some reports is 65 and older, and in others, 71+.

So, they're not perfect age groups based on, but they're "ish." They're close enough that I think we could at least form some stages around that kind of grouping.

Dr. Ronald Kleinman: Do you have one for pregnant—pregnancy?

Dr. Regan Bailey: So, for pregnancy and lactation, for the data that we have available, is generally 20-44 years.

Dr. Ronald Kleinman: Are they broken out separately as women who are pregnant and lactating?

[2:00:01] ***Dr. Regan Bailey:*** For the pregnancy and lactation-specific questions, it's 20-44.

Dr. Ronald Kleinman: Okay.

Dr. Heather Leidy: How does that compare to the Physical Activity Guidelines? Because it would be nice to have those together, to have those age groups.

Dr. Eve Stoody: Katrina?

Dr. Heather Leidy: I was trying to look for it online. I didn't know if you had it.

Dr. Eve Stoody: 2-5—3-5, sorry. 3-5, 6-17, so thank you. I'll repeat that.

Katrina: The Physical Activity Guidelines for Americans, so the second edition that came out last November, they break it out. So, it's generally always been the youth, or the kids, and the adults, and they were able to come down to another segmentation in this last round and look at youth that were ages 3-5, so the preschool and childcare age.

There wasn't a quantitative number with that group, but there were separate guidance for that population.

[2:00:55] And then, the youth population stayed from 6-17, and the adults from 18 and older, although the committee, just for reference, did have a lot of discussions about the kind of this transition point, and what happens when you turn 18 and magically, the Physical Activity Guidelines change from the 60 minutes a day for kids to 150 minutes, this is the aerobic piece, per week.

So, there's a big shift, and the committee actually looked to see kind of if there was more evidence around that transition point, and a lot of it tends to be where the data is, and a lot of times, it's studied in youth or in adults.

And so, there wasn't enough data to really look. It was put in as a research need as something to look at further, of what's going on at that point, what's going on in college and high school, and things like that, that may necessitate a shift in the amount of physical activity. But those were kind of the parameters they used, and they did have a separate chapter looking at women who were pregnant and postpartum, so that population was addressed.

They also had separate pieces talking about older adults.

[2:01:56] So, they did look at the population piece, but in terms of the quantitative recommendations for how much physical activity, there was the three kind of main buckets that they discussed.

Dr. Eve Stoody: So, you didn't define older adults with a specific year?

Katrina: Generally, they were talking about 65 and older, but again, it goes back to what was in the literature, and some of the challenges in being able to really define that. For older adults, they still have a set of guidelines that are identical to the adult population guidelines with a few additional caveats, things like talking about multi-component physical activity, and the importance of balance training, the importance of thinking about relative intensity of physical activity versus doing absolute, so thinking about where an older adult is starting, which may put them at a different level of intensity than somebody who's 30 or 40 years old.

So, there was separate guidance for the different populations, but in terms of kind of the overall general recommendations. That may be a way to think about this as well, that your general recommendations for adults are similar, but then being able to tease it out where there's specific guidance and information and nutrients and things by different populations.

[2:03:03] But I think a great thing to be discussing now before you start writing, obviously.

Dr. Ronald Kleinman: I think of it in four stages, crazy active, active, inactive, and dead.

Dr. Barbara Schneeman: Well then, I have to tell you my definition of older adult.

Dr. Ronald Kleinman: Yeah?

Dr. Barbara Schneeman: Older than me.

Dr. Ronald Kleinman: That's my definition of a pediatric patient is anybody who's younger or shorter than I am.

Dr. Barbara Schneeman: I think this is—it's very—and that was very useful to have that, because sometimes, those ages mean that's what we have by those age marks, not that there's something magic that suddenly changed at that age mark.

So, I think we—recognizing the broader categories, I think we still have to wait and see, is there enough in the subcommittees as you're looking at the evidence to say, yeah, there's something different between youth and adult, or young children and adult?

[2:04:12] I'm looking at Linda Snetselaar, because I'm thinking, in the seafood, you are looking across different ages and making—I think your conclusion statements are beginning to look at those different ages. That should come forward in the recommendations.

Dr. Jamy Ard: Well, going back and looking at the original topics and questions in terms of how they were listed, there were two lists, one was by subcommittee, and the other one was by age groups.

And the thing that's notable there is that, in the listing by age groups, it's clear that there's certain conditions and outcomes that just aren't relevant, or less relevant, unless we really get into that sort of really deep primary prevention across, from birth to the grave.

[2:05:13] But things like neurocognitive health mean something different in the 2-18-year-old compared to the 65 and older individual.

So, that might be an interesting framework for us to at least look at that and say, generally, does that make sense? Because it's partly done for us in that way.

And we might say, yeah, that generally makes sense for us to do it, to start from that, and then maybe tweak.

But to me, that seems reasonable as a starting point, and it does allow for us to think about how to segregate some of the outcomes when we're thinking through our analytic frameworks and protocols, because we may, yeah, we may really have a lot of data in one area or another, and that means that we can then refine the conclusions around that for a particular age group.

[2:06:25] ***Dr. Kathryn Dewey:*** Kay Dewey. So, there is a question that is underneath scope for the Data Analysis and Food Pattern Modeling subcommittee that's about tracking of dietary intake, particularly dietary patterns across life stages.

And I think the way that this is being handled so far, I know we'll talk about it tomorrow, is by looking at each of the age groups and what the dietary patterns are.

[2:07:03] But I'm not sure that's going to answer the question of tracking. And it's a really critical question, because if there's strong tracking, then the rationale for certain guidance at young ages isn't built only on the evidence of a relationship at that age, it's on—so their dietary patterns were established, and then they stay that way, and then later, there's a relationship to certain outcomes.

So, I guess I'm raising the question of whether we will have some way of answering the question about tracking?

Dr. Regan Bailey: Yeah, this is Regan Bailey. We've wrestled with that in our subcommittee, because ideally, what you would want is longitudinal data on the same people to make that, but what we have with NHANES is the cross-sectional different age groups.

So, we're trying to cobble together, but it's not the same people over time.

[2:07:56] So, we can make some general statements about what's going on in each life stage, but in terms of tracking, that's not really possible with the data that we have available to us right now.

Dr. Linda Van Horn: The best tracking data in children, though, the only tracking data that exists for as long as they have, I believe, is the STRIP study, which followed children from six months of age until I think they're now 20-22, something like that. And they continue to follow up on those—that population, looking at risk factors for cardiovascular disease.

I think the Bogalusa study, which was—STRIP was an intervention study, Bogalusa and some of the others were observational studies over a long period of time. So, there are data, and thankfully, they appear more in those age groups, those children, for a longer period of time, obviously.

[2:08:59] But there are studies like Framingham, Framingham Offspring, etcetera, that have longitudinal data, observational longitudinal data that are very well characterized and have perpetuated for decades.

So, I don't think it's missing, it's just they're selective as far as what we need to look at. And certainly, from childhood to older age, I think, as I said, I think STRIP, unless somebody else knows of a longer one, is probably the only one that has that much data for that long.

Dr. Regan Bailey: So, this is Regan again. So, for the work that we're doing, it's my understanding that we're only allowed to use data that are within the federal domain, so our national data. We're not able to, at this point, use other data, like that you're mentioning.

So, it definitely exists, but our charge is to use the nationally-representative data that we have.

[2:09:56] ***Dr. Eve Stoody:*** Correct. But there is the discussion section that's been proposed too, so I think putting that kind of in context, or speaking to it there, is a place you could do it, yeah, have that conversation.

Dr. Linda Van Horn: Yeah, I think, again, in the spirit of trying to guide and direct future, yes, that may be a limitation for us, but to ignore it or not to even mention it as existing but not fitting our criteria, I think would be a loss, and again, it would potentially encourage investigators to consider those concepts when moving forward in their work.

Dr. Kathryn Dewey: Also, Kay Dewey again, it was my understanding that the requirement to use federal data had to do with characterizing dietary patterns and nutrient intake, so the descriptive part of the work. This is a question that is a research question, really.

And it could be subject to the same kind of literature review and search, systematic review that we're doing for many other questions, where we use all kinds of studies.

[2:11:04] I know that we have a lot on a plate, and I'm not necessarily suggesting another analytical framework for a systematic review on this question, but I just wanted to throw that out there is that that would be one way to attempt to answer it.

Dr. Elizabeth Mayer-Davis: So, I had another question about the report, and this might be already available in the more detailed outline than what I've seen, which is, within the age categories now that we're talking about, it's the next level of organization has to do with the exposures according to the subcommittees that we have, which makes a lot of sense just practically.

So, my question is, within those, is there sort of a standard order with regard to the outcomes?

[2:11:58] Because many of the committees have the same outcomes. Is that how that is getting organized?

Dr. Eve Stoody: Yeah, I think that's the next layer of the outline, that's getting into that level of detail. And historically, yes, they've been just inconsistently, and I think however y'all—it makes most sense to organize it, but yes, taking a consistent approach is typically how it's been done and makes a lot of sense.

The one item that I did not mention, which I will note, is the reports have historically have a number of appendices. A lot of times, that's kind of where you can point to tables, or additional information. But one of the sections that we proposed is future directions, to speak to the key research recommendations the committee has as you go through your systematic reviews. There's a lot of very focused research recommendations that will travel with the NESR systematic reviews.

[2:12:58] So, you'll do a very specific question on frequency of eating and all-cause mortality and have research recommendations specific to that, that will stay with the NESR review. But in your report, there might be some things that are high level, or broader research recommendations that the committee really wants to highlight. So, that's a place to do that.

And there's also been some discussion about just other items that the committee has wanted to speak to, which y'all have kind of referred to as "Let's put that in the parking lot, or the bike rack." So, kind of just other things that y'all are thinking about.

So, just a note that there is going to be—I mean we're proposing that there's a true home for that, a section in the report that kind of brings that all together.

Dr. Barbara Schneeman: I know I kind of keep some of those in the back of my mind when I hear discussion in the committees, or hear discussion in a subcommittee, that I know it's not within our scope, but it's something important.

[2:14:07] But if you all are keeping those, then we need to make sure we have a process to gather them, either feed them to me, or to Ron, just so we don't lose track of them.

So, any other comments relative to the report, or questions?

Dr. Carol Boushey: I have just one minor, this is really small, but I did notice today on one of the slides, reference to human subjects, and I thought maybe it'd be better that we adopt people first language. We refer to the individuals volunteering for these studies as participants, or partners, or volunteers, rather than the word human subjects, which is rather monarchial.

[2:15:02] ***Dr. Barbara Schneeman:*** And there are probably some other terminology things that, as you work in your subcommittees, if you see things, be sure to flag them. I mean one of the values of having the

discussion around the different protocols is to look for when we can be consistent, we need to be consistent.

Obviously, there are things that are unique to each question, but where we can and should be consistent, we want to be sure and do that.

Dr. Ronald Kleinman: I assume Ann will help us with that, and particularly be sensitive to the names we give people.

Dr. Eve Stoody: Absolutely. As soon as she said that, I thought that's one to go to Ann. Yeah, she'll have a list of those types of items that she can help keep an eye out for, too.

Dr. Carol Boushey: Great.

[2:16:01] ***Dr. Barbara Schneeman:*** Okay, well, thank you very much. I think this is very helpful to the committee and very helpful for thinking about the work going forward.

We're about at the end, but I do want to just go around just to see if there are any other thoughts or comments for the good of the order? And we do have tomorrow still ahead of us, so if there are some particular things, please let me know. Yeah.

Dr. Lydia Bazzano: Well, I just wanted to—this is Lydia Bazzano. I just wanted to say one thing that was on my mind. So, we are looking at all of these through a framework of systematic reviews. And so, with those reviews, we have inclusion and exclusion criteria, and those are quite important, but I think we also need to be realistic about what's out there so that we can come up with something that ultimately has—reflects the preponderance of evidence per what the charter says.

[2:17:05] So, I was thinking in particular, about the—going from the 18 studies to the 0 studies, and I know that that's something you guys are considering and reconsidering. It's just that we have to strike some balance there to be able to say anything about it. We would all love to have the ideal studies. That's not what we have.

So, it's just a thought that we need to account for some way in our own conversations in the subcommittees, etcetera.

Dr. Barbara Schneeman: So, I'm going to suggest, at this point, we just go around, and then if there's some points we need to come back to, we can come back for discussion. So, Beth, you want it?

[2:18:02] ***Dr. Elizabeth Mayer-Davis:*** Actually, I don't think I have anything right now.

Dr. Barbara Schneeman: Linda? Can we grab you before you leave?

Dr. Linda Van Horn: I'm really sorry.

Dr. Ronald Kleinman: No apologies.

Dr. Barbara Schneeman: No apologies needed.

Dr. Linda Van Horn: I'm really sorry. I have to leave. Why? Because Dr. Jeremiah Stanler, who is the founding chairman of our department at Northwestern Department of Preventative Medicine, is turning 100 years old tomorrow, and we have a major celebratory event that I'm supposed to be hosting. So, I need to get to the airport, but I do want to mention that, even as a post-doc, I remember manuscripts that he wrote, you put your ego in your back pocket when you work with Dr. Stanler, he's got red ink all over everything.

[2:18:57] But one of the things that he always wrote was, in terms of the topic of subjects, he would always say, "There have been no subjects since 1776." So, I think being here in Washington, DC is probably the epitome of being able to make that statement.

And pretty much, what I said earlier is that it was really on my mind, as far as taking full advantage of this as an introduction to the idea of life course, and continuous recommendations for healthy eating, beginning early in life and continually throughout. That's probably my number one thing.

I'm sorry.

Dr. Barbara Schneeman: Great. I knew we wanted to capture your wisdom.

So, Joan?

[2:20:00] ***Dr. Joan Sabate:*** I don't have any comment at this point.

Dr. Barbara Schneeman: Okay. Linda?

Dr. Linda Snetselaar: Just I think it's important, as we're looking at studies and sort of the conclusions to those studies, that we think about recommendations that are already out there, and in particular, as we look at children, since—very young children, since that's something new that we're doing, just to be sure that we are remembering, looking at studies that have been done that are benchmarking what should be done.

Dr. Teresa Davis: Sorry, I'm in agreement with organizing our report by life stage, because I think when we think of the ultimate end users, both Health and Human Services, USDA, and ultimately, the public, I think that's more appropriate.

[2:21:06] It does make our task slightly harder and more intensive, but I think it's appropriate.

Dr. Heather Leidy: Just two comments. Just with the discussions that we've had so far today, it occurred to me that there's still a lack of consistency, I think, with some of the analytical frameworks. I just know our example with the eating frequency, it occurred to me that, and even some of the other ones, study duration, sample size, or intake assessments, those bigger things, when we have similar outcomes within our groups, are still not as consistent as I think they maybe could be.

And then, that kind of leads into my other point, too, in terms of what our approach should be. Lydia, you'd commented too about being mindful of all the data that exists, and I think that's one hand.

[2:21:56] And on the other hand is being more conservative and just focusing on the data that are what you would call the gold standard so that we're not making recommendations now, and then five years, we're having to—well, we wouldn't, but others would be retracting what we said and why. So, there's always a balance there. I don't know how we tread with that.

And so, even with the consistency of the analytical frameworks, as the example, we may be including some studies with some subgroups, and then not some studies with others just because we haven't maintained a consistency.

And not to beat this again, but Jamy had brought that up last time, about having that, a table if you will, where—and we went down that path, and we addressed quite a bit, but I think now is more unfolding, I think it is coming back that there's still a level of inconsistency that I think we could at least address still now, moving forward, because it looks like, so far, that we don't have a lot of concluding statements.

And so, that was just something to keep in mind.

Dr. Jamy Ard: Jamy Ard. Yeah, I forgot I said that.

[2:23:01] So, the one notes I may would add is I feel like we need to have a clear rationale or articulation for when we are not considering something in scope. So, the example today was the ultra-processed foods versus as a dietary pattern, if—we've had some discussion on that in our subcommittee, but I don't think we've articulated a written statement that someone could pick up and read and say, "This is our opinion about this particular topic."

And there probably will be several other things that we know, from public comment and from other emerging science, that we don't have the purview to delve into. And people will want to know why we didn't.

And we can't just say, "Oh, it wasn't a question." Like that won't be satisfactory, I think.

[2:23:58] I mean it's nice and simple to say that, but it's not satisfactory.

And I think we can put some of those things in the sort of areas to be addressed in the future, but I think we also need to have very clear rationale for why we didn't consider it in scope and how it would need to be considered in the future.

Dr. Rachel Novotny: Rachel Novotny. I'm thinking about the report, and hoping that we can come up with a framework, a graphical framework of the life stages, and also thinking about what Kay was saying about the topics, however we end up describing them and whether, having got it clear in my head, but whether that could also be illustrated in this framework as some sort of introductory overview, or something like that.

[2:25:06] I'm just pondering that at the moment.

Dr. Regan Bailey: And then, I just wrote down, I know we've been having weekly calls, and we have meeting minutes from each calls, but when we write our report, that we revisit those meeting minutes so that we have in our report why we made certain decisions, so that we're transparent in our report.

As well as I think one of the most important sections that we will write is research recommendations. We've pointed out even today how many limitations exist with the data that we do have, but how do we fix that moving forward? So, think about that in everything that you're doing.

[2:26:01] ***Dr. Jamie Stang:*** Jamie Stang. I guess I echo—I really support the life course approach. I think that that's very important.

And sort of what Heather and Regan have said, it—we are identifying gaps, and I think that we need to be okay with that. I mean there's nothing we can do about it. But I think that our goal is that, five years from now, somebody will have read that report and filled some of those gaps, and that will have been one of our contributions through this process.

Dr. Sharon Donovan: Sharon Donovan. One of the problems with being on this side of the table is most of the good ideas have already been mentioned. I would just like to really strongly reiterate the life cycle approach. Being in pediatric nutrition, I think that we need to really break down childhood however it makes sense.

And also, just reiterating, I think the research gaps are really going to be probably the most important contribution.

[2:26:59] And even if it's just recommendations on how many frequencies, or dietary records should be done. Because we can inform best practices. You know? Nutrition research gets so criticized anyhow for the strength of our evidence, so if we can use this process to improve it.

And being on B-24, we're just finding huge gaps in the knowledge, not only the research, but even how do we look at NHANES? How do we look at databases?

So, that can hopefully inform how we move forward in collecting data as well.

But hopefully, we'll have a really good report, and not a lot of 0 papers making it across the finish line.

Dr. Kathryn Dewey: Kay Dewey. I would like to encourage us to distinguish between research gaps, which I strongly agree with, that we should be listing those, and topics that we're not covering in this particular iteration for the Dietary Guidelines.

[2:28:05] And there's overlap there, but so, I'd like to make a plea, that in, as Regan mentioned, in our meetings and the phone calls, that we become a little more detailed of what gets recorded on those two things. So, if we say anything about "Oh, this needs more research," or "Oh, we're not covering that topic," I hoe that we'll be able to capture that, so we come back.

And as an example of a topic that we're not covering, I was thinking about this issue of the long-term health implications that Linda mentioned, and now she's gone. But there is an enormous body of evidence on what we call the DOHAD hypothesis, the developmental origins of health and disease. And I was looking at the topics that we have for pregnancy and lactation, and we're not covering DOHAD.

So, in other words, we're not looking at whether what the mother eats during pregnancy or lactation affects the offspring's long-term health.

[2:29:00] ***Dr. Sharon Donovan:*** Only for food allergy.

Dr. Kathryn Dewey: For food allergy? Okay. But otherwise, not cardiovascular disease, or blood pressure, or anything like that?

And there is a quite large body of evidence on that. Now, that's fine, we can't cover everything. But it just popped into my mind that that's a pretty important one that's not on our list.

So, just to—I agree. We have to explain that we can't cover everything, we had to be selective, but being clear about the need to come back to those in the future committees.

Dr. Carol Boushey: And mine is sort of—one of the things that you said is a little spinoff of it, because I believe now, in our meetings, we have these meetings that we meet as our small groups over the phone, and we write down all of our minutes. And when we do finish a topic, then I think we should take advantage of creating the summary, if we can, at that point in time.

[2:29:58] Do it right there. Because I think this is—might be a bit overwhelming going back and remembering how we went through all of this, since we're doing them sort of one at a time. And so, that might—

And I think that we can fit it into our meetings that we have. We usually meet for at least an hour. And so, I think we can do that.

And then, I also wanted to make clear that the dietary patterns is—we're searching far and wide for anything that meets the definition of a dietary pattern. And we are not looking for anyone named, the moniker of the dietary pattern is irrelevant.

So, the concern about being able to have NOVA in our pattern search, if there's a paper that works with that, we'll be collecting it. It's all based on patterns and not the names.

[2:30:59] So, I wanted to make sure that you know that this is a broad search of the broad definition of dietary patterns. And we maybe need to articulate that better, but—and we can work with that on our next phone call, to make sure that's really clear.

Dr. Steven Heymsfield: Steve Heymsfield. I have two comments.

One, I want to say how valuable the face-to-face meeting is, and hearing the other presentations, and exposing our drafts to other people, because it was very valuable comments for our session.

And the other thing is, about 50 years ago, I had lunch with Jerry Stanler, and he had ice cream for dessert, and I thought, "If he can do it, so can I." And it's been working so far.

Dr. Barbara Schneeman: So, we do have one more comment. So, I've averaged out the two sides, because Rick goes last.

[2:32:00] ***Dr. Rick Mattes:*** Oh, okay. So, two brief comments about numbers.

I appreciate your point of we want to have some evidence to say something about it, but I do support the view that we should hold the highest standards. And if it results in few papers, then so be it. That's a message for researchers of the future to design their studies to make sure they're of good scientific quality to address it. So, I don't think we compromise on that.

And the other thing is, I think it's just a function of where we are now in doing the reviews and seeing how many we get that we've been talking about numbers, but when we're interpreting the data, one really good study outweighs 47 bad studies. So, even if 47 of them come through, we don't want to be counting numbers. We want to be looking at quality.

[2:32:58] ***Dr. Sharon Donovan:*** I wanted to I guess follow up on sharing of these minutes, because we have had a number of committees meeting together, but I know we're all overwhelmed with this, but if we could see the minutes from the other committees, it might be—or do we have that ability?

Dr. Barbara Schneeman: I think that is a government staff issue. I know they're all viewed as pre-decisional, so they're drafts, they're pre-decisional. But Eve? What is your sense?

Or maybe we need to come back to it. Yeah, we'll come back to it. We'll take the comment just like we're taking all the comments, and we'll figure out a way to do that. So, Ron?

Dr. Ronald Kleinman: Yeah. No, I think, I think this last hour has been incredibly helpful and really moved us towards an understanding of what we actually need to come up with.

[2:34:02] And I think the task now going forward is to how to structure our information gathering and decision-making so that it fits the format that we want to report out.

And perhaps you and I could sit down with Eve and some of the staff at some point in the next few weeks and propose how to do that, and then bring that back to the committee as a working—proposal on how to work this going forward. I think this would be tremendously useful to put this into a framework, for example.

And then, I like Jamy's proposal that he forgot, about putting the information together in a graphic table across ages. I think that will also help us.

And particularly on the summary, Sharon, I think that's really key.

[2:34:58] We could really advance the pace of this work if we have these summaries in mind as we're working this through rather than try to create this all at the end after 500 hours of conversations. So, I think we should talk about that also, after this is over.

Dr. Barbara Schneeman: Okay, great. And I would just add a couple of comments of my own.

First of all, thank you to everyone who's been doing the work of these subcommittees.

But in terms of looking at the evidence, I think people have made good comments about how we're looking at that, and I would just remind you that once we go through the search, and we have the evidence that we're looking at, it's not a yes/no answer.

[2:35:55] Because sometimes we don't have evidence, sometimes we have insufficient evidence, but once you have evidence, you also then will be asked to assign that grade. So, we might wind up where, yes, we got the evidence, but it's limited, or it's moderate. I mean the goal of course is to have high-quality evidence.

But keep in mind that even if there are studies, we're not yes/no. We are trying to evaluate the quality of that evidence, which I think also sends a message about what is needed in the field of nutrition.

One thing that we haven't talked about, but we've alluded to several times, is this concept of future directions, and I'm glad that several of the comments are starting to pick up on that, of what do we want to tell the Departments, but also, tell committees going forward, that we see some important things.

[2:36:57] It can be about the process; it can be about topics that are important.

And I have to say, one of the things that I do keep thinking about, relative to some of those future topics and issues, from the National Academies report that looked at the process and redesigning the process, one of the recommendations that's probably the hardest recommendation to implement is about taking a food system approach. And it recognized that that wasn't going to happen instantly, it's something that required its own level of research, its own level of investigation.

And I'm just myself thinking about how do we work that in, not that we're making recommendations, but we're recognizing that the Dietary Guidelines sit within the context of a food system.

So, just some of the thoughts that occurred to me as I've been listening to the dialogue.

[2:38:03] So, I think we're ready to adjourn for today. Eve, do you have to adjourn us? I wasn't—okay.

Dr. Ronald Kleinman: We have the power.

Dr. Barbara Schneeman: So, again, we will—actually, two additional reminders.

So, I do want to remind people, in listening to the protocols today, if any of our public participants, either here in the room or online, want to submit comments relative to the protocols that you're hearing in this meeting, they will be most helpful to the committee if we hear them—if we get those comments by November 7. So, just to keep that in mind. We'll remind you about that tomorrow.

And then, tomorrow, we will convene at 9:00 a.m.

The agenda has some opening comments, but we're anticipating that we probably will be able to do all three of our subcommittee reports before we adjourn to lunch, just so people are aware that that will be a change to the agenda.

[2:39:11] So, with that, I think we're adjourned. Thank you.