2020 DIETARY GUIDELINES ADVISORY COMMITTEE

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PUBLIC MEETING

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THURSDAY
OCTOBER 24, 2019

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

MEMBERS PRESENT
DR. BARBARA SCHNEEMAN, PhD, Chair
DR. RONALD KLEINMAN, MD, Vice Chair
DR. JAMY ARD, MD, Member
DR. REGAN BAILEY, PhD, MPH, RD, Member
DR. LYDIA BAZZANO, MD, PhD, Member
DR. CAROL BOUSHEY, PhD, MPH, RD, Member
DR. TERESA DAVIS, PhD, Member
DR. KATHRYN DEWEY, PhD, Member
DR. SHARON DONOVAN, PhD, RD, Member
DR. STEVEN HEYMSFIELD, MD, Member
DR. HEATHER LEIDY, PhD, Member
DR. RICHARD MATTES, PhD, MPH, RD, Member
DR. ELIZABETH MAYER-DAVIS, PhD, RD, Member
DR. TIMOTHY NAIMI, MD, MPH, Member
DR. RACHEL NOVOTNY, PhD, RDN, LD, Member
DR. JOAN SABATE, MD, DrPH, Member
DR. LINDA SNETSELAAR, PhD, RD, Member

DR. JAMIE STANG, PhD, MPH, RD, Member

DR. LINDA VAN HORN, PhD, RDN, LD, Member

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

9:02 a.m.

DR. STOODY: Good morning. My name is Eve Stoody and I'm the Designated Federal Officer to the 2020 Dietary Guidelines Advisory Committee.

This morning, we will begin with some opening remarks from USDA leadership.

It is my pleasure to introduce the Deputy Undersecretary of USDA's Food, Nutrition and Consumer Services, or FNCS, Mr. Brandon Lipps.

FNCS works to end hunger and improve health in the United States as it administers federal domestic nutrition assistance programs and develops science-based dietary guidance.

Mr. Lipps?

(Applause.)

MR. LIPPS: Good morning. Let's try one more time. Good morning. We've got to get everybody warmed up. This is a scientific review process which is not too exciting for all of us,

but you do see the smiles on the faces of the 19 individuals up on stage who are very dedicated to this in their careers and do a wonderful job.

Thank you all for joining us here at meeting three of the 2020 Dietary Guidelines Advisory Committee. We're happy to see that we continue to have a lot of folks interested in this process.

While only a handful of you are here in person, we have more than 1,200 people registered to participate and watching the Committee do its work at meeting three of this process. It is an important process and we thank you for joining us over the next two days.

As always, we're joined by our colleagues from the Department of Health and Human Services. And, tomorrow morning, their Assistant Secretary for Health will also be addressing those of you here and the Committee.

We are thankful for our partnership with HHS, together USDA and HHS remain committed to developing dietary guidance that is evidence-

based and our Committee helps us to meet this goal.

Committee, I want to thank you for your continued dedication to the task at hand. As scientific experts in key areas, USDA and HHS are looking at to address in the next edition of the guidelines, you have the important task of looking at nutrition and public health for the first time for the entire life span. We have added to your workload.

We realize that this is no small task and we greatly appreciate and value your expertise and your work in this independent process.

Your work is both rigorous and an independent review of the current body of science. It is vital to informing our work at USDA and HHS to prepare and develop the next edition of the Dietary Guidelines.

The work that the public sees and the meetings of this Committee are only a small portion of the time that you have dedicated to

this very important process.

You know that each of these members are distinguished in their own fields. They have expertise and scientific background in the work that we are doing here and they're spending significant amounts of time preparing for, reviewing, and working to issue a scientific report to the Secretaries of Agriculture and HHS as we move forward in this very important process.

So, I want to take this moment and let's give a round of applause to our Committee members for their dedication to this work and for being away from their families and their work.

(Applause.)

MR. LIPPS: Many thanks also, always, to our staff at the U.S. Department of Agriculture, not only at FNS, but our colleagues at REE who you're going to hear from momentarily, and the many staff at HHS who work with us as partners in this process.

From the start, USDA and HHS have

underscored our commitment that this process to develop the 2020 to 2025 Dietary Guidelines be transparent, inclusive, and science driven.

We put a lot of thought and effort into making sure that the public not only has easier and more access to information along the way, that's transparency, but also, that you have more opportunity to participate and to make your voice heard to ensure that the process is inclusive and that we ensure all perspectives as we move forward.

There are many complex factors that go into keeping Americans healthy, from our littlest ones who the Committee is now looking at, to the adults and through every life stages. Nutrition is one of those factors. It's a very important factor. The Dietary Guidelines are significant, foundational, part of that.

It's also important to keep in mind that with regard to Americans' health, we are but one piece of a very big puzzle. And, we all need to work together to ensure that Americans are

healthier as we move forward.

We at USDA and HHS don't take our responsibility lightly. The nutrition programs across the federal government, many of which we administer at the Food and Nutrition Service and many others nationwide rely on these Dietary Guidelines reaching millions of Americans every day and even more with the addition of the infant and toddler population which we serve at FNS, starting with the next edition of the Dietary Guidelines.

That's why this stage of the process that we're in now, having an external advisory committee of scientific experts conduct an independent review of the current evidence in nutrition and public health is so important, leading up to the final stage of the Department's developing the Dietary Guidelines driven by science.

In closing, Committee members, I want to thank you, again, for your outstanding work to date, for the work that you're doing behind the

scenes, for the time that you devote to this process away from the very important work that you do every day and your families and your obligations back home, the time that you take to be here and interact with the public and on a number of occasions, to hear from them.

Thank you, again, for your dedication to this work. We're excited to hear an update from you and you have our full support and our deepest gratitude for your service.

With that, I'd like to introduce to you our next speaker, Dr. Scott Hutchins, Deputy Undersecretary for the USDA's Research, Education and Economics mission area.

Dr. Hutchins oversees the Agricultural Research Service, which is a partner with us on the Dietary Guidelines, the Economic Research Service, the National Ag Statistics Service, and the National Institute of Food and Agriculture.

I honored to serve with Dr. Hutchins, and with that, please, come on up.

(Applause.)

DR. HUTCHINS: Thank you, Brandon, for that introduction. And, good morning, everyone. And, Brandon, this is science, so, by definition, it's going to be exciting. I'm really pleased to be with you here today, again, on the journey to develop the 2020 Dietary Guidelines.

You know, Secretary Perdue and all of USDA is very much customer-focused and we consider both producers and consumers to be our customers. In fact, his mantra of do right and feed everyone is quite relevant for this committee, as is our mission in USDA to sustainably provide accessible, safe, affordable, and nutritious food to improve the diets and health of U.S. citizens, and, in fact, the global population.

As noted, the USDA has four science agencies that can bring to bear considerable expertise and focus on this effort and many other efforts. And, I'll just outline briefly those, again.

The Economic Research Service which,

if you have not afforded yourself to the many excellent reports and research that that group develops and continues to develop associated with nutrition, you really should investigate that.

In addition, they do a tremendous amount of research in terms of food insecurity and so forth. I'm happy to report some of their recent research has shown that food insecurity in the United States has actually been declining over the last ten years since the recession and is at a low period since that period of time.

As has, in a separate report, global food insecurity. But food insecurity is one of those topics that progress is welcome and acceptable, but of course, there's always more progress to be made.

The National Ag Statistics Service provides statistics on everything agriculture. And, as noted, the Agriculture Research Service is really the principle agency focused in this effort working hand in hand across the -- their agency in order to develop the research and the

interpretation of the research for this committee.

And, then, the National Institute of Food and Agriculture is just a critical component from an extramural standpoint, but also, let's not forget the important role that the extension plays as we develop these guidelines and make them available and make them utilized.

The guidelines are quite important, but the implementation of the guidelines offer a very important opportunity for us to actually move the dial with nutrition and health.

And then, the Office of the Chief Scientist as well serves as somewhat of an umbrella across those agencies and other agencies within the Department as well to ensure that science and the highest standards are upheld.

As indicated, we work in partnerships to provide evidence-based research that helps maintain our strong U.S. food and agriculture system. In fact, at USDA and HHS also co-chair the Inner agency Committee on Human Nutrition

Research which, coincidentally, held a meeting just this week on Tuesday to review current outcomes of the various subcommittees, the current states of nutrition and research from those subcommittees, and also discuss needed capabilities going forward.

So, there's a lot of activity, a lot of focus to make sure that we do across the U.S. government, the right thing in terms of developing nutrition and research and capabilities.

Our mission area within REE also supports the two co-leads here, as indicated, the USDA's Food and Nutrition Service and the HHS Office of Disease Prevention and Health Promotion.

And, specifically, in that regard, ARS scientists are providing scientific research to the Committee and lead the peer review process to evaluate the systematic reviews of the literature provided to the Committee which is voluminous, to say the least. Very important activities in

support of this overall effort.

USDA is dedicated to providing clear, transparent facts for this committee to develop the report, used as the framework for the Dietary Guidelines. And, we embrace our role in supporting public health and remain committed to making our scientific research both relevant and available.

You know, we all recognize that sound nutrition research leads to innovation and better outcomes. We also know that there's a great convergence of sciences occurring, enabled through supercomputing, enabled through a number of breakthroughs in various scientific fields.

And, especially an ability to link individual genome to chronic diseases. And, I personally believe that the next 10 years will see a revolution of personalized precision and prescriptive nutrition emerge. And, these are, indeed, exciting times.

As informed consumers, we'll open up new focus for producers. So, either way,

whatever the next paradigm is, and the paradigm will continually evolve, U.S. agriculture and USDA will certainly play a significant role in this regard.

So, again, I want to join Deputy Under Secretary Lipps in thanking you all as members of this committee for your great service and commitment to the U.S. public in this regard. Thank you for having me here today and I wish the committee all the best in its deliberations.

And, Eve?

(Applause.)

DR. STOODY: Okay, thank you, Mr. Lipps and Dr. Hutchins for your remarks and for your support of this process. We'd like to begin with some just introductory information on the Committee. Sorry, we're having some technical difficulties this morning.

Okay, so first, this slide -- thank you very much -- this slide includes the names of the members who are able to join us in Washington, D.C. Nineteen of our 20 members are

here with us today.

Dr. Elsie Taveras is not in attendance but will join the meeting online as she is able.

Around 200 people, excuse me, around 12,000 -- around 12,000 people are registered for this meeting. No, I have a typo. So, around 1,200 people have registered for this meeting, so, you know, watch what you say, no.

So, around 200 people have registered to attend the meeting in person and about 1,000 online. And, as always, thank you for your interest in the Dietary Guidelines.

So, as Mr. Lipps did mention, the 2020 Dietary Guidelines Advisory Committee was established earlier this year by USDA and HHS to conduct an independent review of current research on nutrition and health to be considered by the Departments in the development of the next edition of the Dietary Guidelines.

USDA and HHS are not required to have an advisory committee to support this process. But doing so has been a standing practice since

1985 with the purpose of ensuring that the Dietary Guidelines are grounded in scientific advice from independent experts.

The charge to the 2020 Committee is outlined on this slide. The charge is to examine the evidence on specific topics and scientific questions identified by the Departments, to develop a report that outlines its review, and to submit the report to the Secretaries of USDA and HHS.

The Federal Advisory Committee Act requires the government to define each advisory committee's mission and specific duties. As discussed at the first meeting, identifying questions for the Committee to address is new to this round. USDA and HHS added this step for a number of reasons including to promote a deliberate and transparent process.

The process used to identify the topics and questions involved input from scientists across multiple federal agencies in consideration of over 12,000 public comments.

And, that 12,000 I did mean.

The topics and questions were prioritized based on four criteria, relevance to the Dietary Guidelines, importance to public health, potential impact to the federal programs that we inform, and to prevent duplication with other federal efforts.

The topics and questions build upon the 2015 Committee's work on dietary patterns and incorporate questions across the life span, including questions for infants and toddlers. More information on this new step is available in the interactive time line that's at DietaryGuidelines.gov.

This is the third of five meetings planned for the 2020 Committee. If you missed the first two meetings, recordings, transcripts, and minutes are archived on our website. Much of the first two meetings did include a lot of orientation and planning of the Committee's scientific reviews.

The next two meetings in January and

March will provide planning, or excuse me, will provide discussion around findings and conclusions. And, this meeting is a little bit of a mix of both. You'll hear some addition discussion around planning for the systematic reviews and the review of the evidence. And, you'll also hear some initial and kind of the first conclusion statements.

Now, this meeting is intended to provide a status update and allow for discussion across members as they initiate their reviews. But we want to be very clear that there is still a lot to come, so stay tuned.

Please note that this meeting is a meeting of the Committee that is open to the public to observe. We do ask the members, as always, to use the microphones that are there in front of you and to provide your name when speaking.

There is not an opportunity for public comments or questions at this meeting. However, in addition to the last meeting that was held in

July, the next meeting in January will include the opportunity to provide oral comments to the Committee. We'll provide more information about that meeting tomorrow afternoon. And, of course, that information will also be made available on our website.

Finally, if you'd like to make comments to the Committee, we encourage you to do so at any time through the written public comment process. That process is now open and will remain open into 2020.

The meeting will be held today and tomorrow from 9:00 a.m. until 4:30 p.m. each day. The agenda is available at DietaryGuidelines.gov and Dr. Schneeman will provide an overview of the agenda in her remarks.

For those here in person, please keep your badge visible at all times. It's required to access the halls of this building. And, if you'd like refreshments or lunch, the USDA cafeteria is down Wing 3.

We encourage you to go to

DietaryGuidelines.gov to follow the progress of the Committee and also to follow today and tomorrow's discussion.

You'll hear a lot of discussion about protocols. To view the protocols to be discussed today, and I'll say all these are posted on the website as of yesterday, go to DietaryGuidelines.gov, click on View Protocols that's in the rotating banner that you see there in orange. From there, you'll be taken to a page that has the list of all the topics and questions. You see a little snapshot from the Dietary Pattern Subcommittee here which is the first subcommittee to present today.

And, if you're -- you know, find the question of interest, click on the question and you are taken to a separate webpage that is specific for that question. And, from there, you can click on the tab or the button that says view full protocol. So, all of it's there. So, some of the slides, the text will be kind of small, but you can go online and see all the details

there.

So, thank you, again, for joining us and I'm now going to turn the meeting over to the Chair of the Committee, Dr. Barbara Schneeman.

DR. SCHNEEMAN: Great. Thank you, Dr. Stoody. And, I will model the behavior that all Committee members are to use. I turned on my microphone, got the green light. And, I'm Barbara Schneeman.

So, first of all, we do appreciate having Mr. Lipps and Dr. Hutchins come to speak to the committee and, again, emphasize the importance of the work that we, as a committee, are doing to evaluate the science related to the questions that have been asked.

So, I will add my welcome to those of you here in the room as well as all of you who are online listening to the Committee meeting today. Our Committee members, through their subcommittees, have been working very effectively since our last meeting to address the questions that are in our charge.

And, I do want to acknowledge up front and you'll hear when you hear our progress since the last meeting, that we have had excellent support from the Department of USDA or the Department of Agriculture and Health and Human Services as we've done the work. It's a tremendous amount of screening and screening through papers and pulling papers for the Committee to review and answer the questions.

So, great, so, in terms of the topics that I'm going to touch on in my opening comments, we'll look again at the subcommittee structure just to remind folks look at a reminder of our approaches to examining the evidence, those protocol elements that the Committee is now looking at as it does its work, and the progress we've made since meeting two. And then, just share with you our plan for the agenda for this particular meeting.

So, the Committee has been organized into six subgroups, plus a cross-cutting group so that we can continue to progress the work between

the meetings. And, the topic areas for those subcommittees are dietary patterns, pregnancy and lactation, birth to 24 months, beverages and added sugars, dietary fats and seafood, frequency of eating. And then, one cross-cutting working group, the data analysis and food pattern modeling.

Each Committee member serves on two subcommittees. And, Dr. Kleinman and I participate in each of the subcommittees. We share that burden across the subcommittees. I would note that one thing that we have started to do, the subcommittees have been working intensely, but we found to really progress some of the work, we've had to have some cross-dialogue between the subcommittees just to make sure that the work will come together at the end.

So, the purpose of each subcommittee is to review the evidence and then provide advice to this Committee as a whole. And so, the -- one of the important things to keep in mind is that it's the job of the subcommittees to bring

material back to this committee as a whole for decision-making, to achieve consensus on what it is we will have as our conclusions and our recommendations on the topics.

I do want to emphasize that all decisions will be made by the full Committee in its meetings which are public like this particular one.

So, the Committee used -- is using three approaches and this, again, is just reminder to folks who are listening in. They use -- we use three approaches to examine the evidence, data analysis, food pattern modeling, and systematic reviews. And so, in meeting three, this meeting, we will be looking at a discussion of the questions that have been -- are being answered using data analysis as well as the NESR systematic reviews.

And, each of these protocols has its own rigorous protocol driven methodology and play a unique and complimentary role in examining the science.

So, the NESR systematic reviews conducted by the 2020 Committee to be discussed today include new systematic reviews, and updates to the existing system -- NESR systematic reviews that build upon the work from the 2015 Dietary Guidelines Advisory Committee. Or, they might build upon a previous technical expert collaborative.

As noted in the first meeting, the Committee will not be using existing systematic reviews conducted by other organizations to answers its questions. However, we do plan to include discussion in our report in how our findings relate to existing reviews and/or guidance as appropriate.

It's -- I think it's important to acknowledge the very important support from the federal staff that supports this Committee. You will hear that we're looking at thousands of paper and we just need physical help to get to the papers that are most relevant to address the questions.

It is important while we have that support to get the work done. The decisions are the Committee's decisions that we are the ones evaluating that evidence to come to a conclusion and make recommendations to the Departments.

So, at this meeting, similar to the last meeting, we will be discussing protocols that the Committee has established to -- and each protocol details how the scientific approaches will be used to examine the evidence. We create those protocols for each question that we examine. And, we do it before the Committee begins to -- its review so that we set how it is we're going to approach it.

The aspects of the protocols will be discussed during the presentations at the meeting today. And, the full protocols are posted on DietaryGuidelines.gov. And, Dr. Stoody showed you how to find those dietary protocols by going to the question and clicking through the question to identify the protocols.

So, these are the sections of the NESR

systematic review protocols. So, this is looking at systematic reviews. So, when they're initially developed, protocols include an analytic framework, the inclusion, exclusion criteria, the databases that will be searched.

And, after the search results are available, then a flowchart of search and screening results, the list of included articles, and a list of excluded articles with the rationale for the exclusion will be added to the protocol. So, again, in that interest of transparency, this information will be available through the website.

So, at meeting two, the last meeting, we didn't have any search results, we only had protocols. But some of the questions now do have search results and will be discussed as we hear the subcommittee reports over the next two days.

And, again, I want to remind you that these are our initial discussions. We still have two more meetings. We still have more work to do, but it will be important to get the input

from the full Committee on where we are beginning to see the search results.

So, the analytical framework defines core elements of the diet and health relationship for the questions we're asking. And, it serves as the foundation for the systematic review process.

So, just to remind you of the components of the NESR analytic framework that we have the intervention exposure versus the comparator, the intermediate and health outcomes, and then, any key confounders that, for example, will be considered in the risk of bias assessment or the Committee has also outlined that sometimes there are other factors to consider that need to be extracted from the paper so the Committee is aware of them. And then, any protocol will also define any key terms that need definition.

So, in terms of looking at the inclusion and exclusion criteria, I want to emphasize these are established by the Committee up front so that we provide an objective,

consistent, and transparent framework for identifying the articles to include in each review.

They are framed around relevancy to U.S. federal policies since that's ultimately the role of the Dietary Guidelines. And, standard criteria are being applied across the different protocols to the extent possible. But some criteria have to be tailored for a specific review.

And so, we've listed, for example, the diet related intervention exposure of interest, the health outcome endpoint or intermediate dates of publication, size of the study group, study duration, age of the study participants. Those may need to be tailored.

And, for example, on the date of the publication, in establishing those publication date ranges, the Committee considers a number of factors including, is the question building on evidence reviewed by previous Dietary Guidelines Advisory Committees? Or existing NESR systematic

reviews? So, we have to factor in that building of the evidence. Or, is it an emerging topic that doesn't have earlier research? And, we have to think then, what is the appropriate range?

So, many of the systematic reviews for our particular Committee, the ones being conducted will include or build upon evidence published prior to 2000 going back to 1980 or earlier.

So, then, to look at -- just to remind folks of the standard, inclusion and exclusion criteria, so, these relate to study design, the types of studies that we anticipate would be included, randomized controlled trial, non-randomized controlled trials, including quasi-experimental and controlled before and after, prospective cohorts, retrospective cohorts, and nested case control.

And then, excluded, uncontrolled trials, case controlled trials, cross-sectional uncontrolled before and after. And, again, you might see some protocols that have had to do some

adapting of these inclusion criteria.

So, that also includes publication status. We're looking for peer reviewed articles for inclusion, published in English. And, in terms of where they're coming from, very high or very high human development indices. And then, study participants, humans, male and female, men and women. And then, conversely, you can see the exclusion criteria.

The other important aspect of the inclusion/exclusion criteria relates to the health status of the participants. And, it's particularly important to note that because the Dietary Guidelines relate to the general population, generally, we're looking at studies conducted in individuals who are healthy or who might be at risk for chronic disease, including those with obesity.

And so, we can include studies where some participants have been diagnosed with the disease or clearly have a risk factor. Likewise, with infants, we're mainly focused on full-term

infants and -- but it can include -- if a study includes some infants, it can be included.

We're excluding studies that clearly are aimed at treatment or therapy for individuals with disease. So, if they only enroll subjects with a disease aimed at treatment or infants with low birth weight. And, you'll hear more about those specifics as we go through the individual protocols.

So, some of our questions in the original questions asked of the Committee, I think there were five questions that rely on the data analysis protocols. And so, this just outlines the components of those data analysis protocols, the analytical framework, the analytical plan, and the analysis results. And, you'll hear how those have been used in developing those protocols.

So, again, you can learn about the status of each question at DietaryGuidelines.gov. And, I think Dr. Stoody gave you the pathway to get to each question. But you can see that this

status will show you whether there's still information to come, if we're developing the plan, if we're implementing that plan, and when we're at a point where we're reaching draft conclusions.

So, you can follow the status of where the subcommittees are with each of the Committees and what will be ready then to come back to the full Committee for discussion and decision making.

So, looking at progress since the last meeting, since the second meeting, we have refined many of the 40 protocols that were presented at meeting two, based on our discussion at the meeting as well as our consideration of the public comments that came in.

So, and across subcommittees, we have made some modifications for consistency. So, other factors to be considered have been added for transparencies. And then, how we're defining the key confounders and the terminology that we're using for key confounders has been aligned

for consistency.

Edits that were made simply for clarity are available online. But any substantial edits that were made to those protocols will be brought to the full Committee meeting -- full Committee for discussion at this particular meeting.

So, for this third meeting then, we'll be describing the status and provide updates on the work of the Committee, most findings are still to come. Each of our subcommittees will have up to 90 minutes for the presentation as well as discussion and question and dialogue in the Committee.

Again, the agenda is available at DietaryGuidelines.gov. And, because we don't know exactly how long the discussion will go, that the times are approximate. They're not fixed. My understanding is we will have a fixed time to start after our lunch break, but there may be a little bit of shuffling depending on what -- where we are in the discussion.

So, for today's meeting, we've had opening remarks, which I'm soon to finish. And then, we will have a presentation on the NESR synthesis of the evidence just to remind the Committee since that's the phase we're now moving into. And then, we'll begin with the subcommittee updates. We anticipate today we'll have Dietary Patterns, Dietary Fats and Seafood, and the Beverages and Added Sugars Committee report. And, hopefully, we'll have some opportunity for general discussion with the Committee.

So, for tomorrow, opening remarks will be briefer and we will move into the remaining subcommittee reports, Birth to 24, Pregnancy and Lactation, Frequency of Eating, and the Data Analysis and Food Pattern Modeling working group. And, again, followed by the Committee discussion and closing remarks.

So, in terms of public comments, the Committee has received approximately 16,000 written public comments since March 2019. At this point, we anticipate there are probably

about 1,000 unique public comments in that. We would remind you that the comment period is open during the time that the Committee -- the Dietary Guidelines Advisory Committee is convened.

However, if you have comments specific to the new protocols that will be discussed today, it is most useful to the Committee in terms of our work if we -- if those Committees are submitted before Wednesday, November 7. So, that's -- you can submit comments any time, but if you really are commenting on those protocols, please try to get them to us by November 7.

So, again, it's important to keep in mind that the Committee will be discussing new or updated protocols and for some questions that the subcommittee is bringing forward in the discussion today, the initial or draft findings for consideration will be considered by the whole Dietary Guidelines Advisory Committee.

So, just -- I want to be sure we keep in mind that we are still in the initial phase. We have two meetings, the input from the

Committee today can influence where we go with those drafts that are in progress. So, we're hoping that this Committee really begins to move forward and develop those. But we're still at the initial phase.

So, I'm going to end my comments with that. And, let me just ask the Committee members if you have any questions or if you have any comments at this point?

Okay. So, and, I will remind folks after we hear the presentation on the NESR, remember, hit the green button and say your name. So, we'll be hearing from Dr. Julie Obbagy about the Nutrition Evidence Systematic Review Overview of the Methodology.

Dr. Obbagy?

DR. OBBAGY: Thank you, Dr. Schneeman. Good morning, everyone. So, my goal today is to give you all an overview or a refresher about the NESR systematic review methodology.

This information was also presented at the first meeting back in March so it may sound

familiar to those of you who attended that meeting. But since it's been several months now and the Committee is now moving into the next phase of their review process, we thought it would be helpful to remind everyone of how the process works, setting the stage for those subcommittee presentations that you'll be hearing about later today and tomorrow.

So, before I talk more about the process, I wanted to give a little bit of background about NESR. We were launched almost exactly 11 years ago. And, our core mission has always been to conduct systematic reviews on food and nutrition related topics and systematic reviews specifically that can be used to inform U.S. federal guidance and programs.

You may know of us previously as the Nutrition Evidence Library, or the NEL. But back in January of this year, we updated our name to the Nutrition Evidence Systematic Review, or NESR, to do a better job of communicating that we are a group of scientists who conduct systematic

reviews on nutrition related topics.

As was mentioned by Dr. Schneeman, NESR systematic reviews are one of the three approaches that the 2020 Committee is using in their review of the evidence. And, just so that we're all on the same page as to what a systematic review is, we describe it as a research project that answers the very clearly formulated scientific question by searching for, evaluating, analyzing, and synthesizing nutrition evidence.

And, the image on this slide just gives you a brief snapshot of what that process looks like. I'll be detailing the process more in the subsequent slides of the presentation.

But I did want to take a moment to note that we do routinely evaluate our process and make updates to the process to ensure that we're taking advantage of all of the evolutions that occur in the field of systematic review so that our process remains state of the art. And so, I'll try to highlight some of the places

where we made updates prior to working with the 2020 Committee.

So, this slide briefly describes the roles and responsibilities of the 2020 Advisory Committee and of the NESR team in conducting its systematic reviews. And, I'll speak to these roles again throughout the rest of the presentation, but just wanted to set the stage with sort of an overview of what those roles and responsibilities are.

So, the Advisory Committee really drives the process. They establish the protocols that you've heard about and will hear more about today including the inclusion/exclusion criteria. They review all of the studies that are included having met all of that criteria they've established. They deliberate on and synthesize the body of evidence.

And then, ultimately, they write and grade the conclusion statements that are included in the report that they'll submit to USDA and HHS at the end of the process.

The NESR staff supports the Committee's review by providing expertise in the methodology. We facilitate, execute, and document all of the work necessary to make sure that the reviews are done in a rigorous and transparent way according to our methodology.

And so, this involves, for example, using those Committee protocols to search for all of the included studies, screen those studies, and then, extract data and conduct risk of bias assessments for the Committee to then review and deliberate on.

And, I would like to acknowledge our NESR team members who are supporting the 2020 Committee. They are a dedicated team of scientists who have been trained and have experience in expertise in conducting systematic reviews. And, all of our analysts also have advanced degrees in nutrition science or public health or epidemiology or a very closely related field. And then, we're also supported by two librarians who have advanced degrees in library

science.

So, at the last meeting in July and again at this meeting, you'll be seeing a number of systematic review protocols presented and discussed. And, again, these are the protocols that are posted on DietaryGuidelines.gov.

You heard an excellent overview of what those protocols are and what they include from Dr. Schneeman, so I won't repeat what she said. But I will say that this protocol really is the plan for how the Committee intends to conduct their review of the evidence to answer each of those individual questions that they've been tasked with addressing.

And, again, it includes a number of pieces, the analytic framework and the inclusion and exclusion criteria. And, as the process is continuing, the search results will also be added. And, you'll see some of that, again, at this meeting.

So, picking up from where we left off with development of the protocols, once that

protocol is in place, our NESR librarians take the analytic framework and the inclusion and exclusion criteria and, using them as guides, they create and implement a literature search strategy to find all of those studies that are relevant to the question.

And, each of the search strategies that the librarians develop includes identification of the relevant electronic databases that will be searched along with the key search terms or search strings that will be used to search within those databases.

For every question the 2020 Committee is addressing with the systematic review, we're searching at least three electronic databases. In some cases, we're searching four databases.

And, the literature searches are really designed to cast a very wide net to identify any potential article that could be appropriate for inclusion in the review.

So, once we've run the search, two of our NESR analysts will independently screen all

of the studies picked up in the search using the inclusion and exclusion criteria that the Committee established. And, the goal of screening is to review every one of those studies picked up in the search and exclude any that don't meet the criteria that the Committee has established.

So, this means that ultimately only studies that meet all of the criteria are included in the systematic review. I'd also note that we do a manual search at this step as well. It's a very standard step in the field of systematic review. It involves searching all of the reference lists from the included articles and also we typically take a look at the references in any existing relevant systematic reviews that have been done on the topic just to make sure that we found every possible article that might be appropriate for the review.

We don't typically find too many studies this way, but it is an extra step just to ensure that we've captured anything that might be out there, that the search is comprehensive.

Occasionally, we might capture a paper, for example, that wasn't indexed very well in PubMed.

So, this complete literature search strategy and the results are documented. The results you'll see today are presented in a flowchart so you can see how they were screened in and out throughout the process. There's also a list of the included articles and then tables of all of the articles that were excluded after full text review including the rationale for why they were excluded.

This process of literature searching is very systematic. It's very well documented so that it is reproducible. And, it's very clear at the end of the day what articles were included in the review and then which articles were excluded and why.

So, next, the Committee determines the data that they would like extracted from each of those included articles, essentially thinking about what data they would like pulled out to review that would be most helpful to them in

answering the systematic review question.

There's some examples of the types of data pulled out on this slide, information about the study design. Information about the participants that are enrolled in the study, details about the exposure assessment methodology, dietary assessment, how the intervention was designed and conducted, how outcomes were measured, how the analysis was done, what confounders were adjusted for, the results that are reported, funding source, all kinds of data along these lines.

Our NESR analysts extract all of that data from each of the included articles. And, they also develop evidence tables to display, summarize, describe the body of evidence that's available to the Committee to review.

In addition, a formal risk of bias assessment is done for each included studies -- each of the included studies. A risk of bias assessment essentially involves looking at how each of those studies was designed and conducted

to identify any potential risks that could either bias or impact upon the trustworthiness of the results reported in that study.

It looks at things like how well randomization was done, the selection of the participants, were they blinded? It looks at confounding of observational studies. It looks at how exposure classification was done. It looks at whether or not the intervention was adhered to or how the fidelity to the intervention was within the study. It looks at missing data, outcome measurements and then selective outcome reporting.

And, this assessment is used later in the process when they body of evidence is synthesized, when the conclusion is drawn, and very directly in the grading process that's used to grade the strength of the evidence.

And, I'll just note that this is one of those places where we made some updates coming in to the 2020 Committee work. We've selected three risk of bias tools to use with this 2020

Committee, again, to align with best practices in the field. And, those tools are tailored to specific study designs. So, they're really tailored to pick up specific risks that are unique to different study designs.

So, there's one for randomized control trials. There's one for non-randomized trials. And, then, a third tool for observational studies. And, I've noted those tools at the bottom of this slide, but there's a lot more information available on our NESR website.

So, next, the Committee uses all of that extracted data, the evidence tables, the risk of bias assessments from all of the included studies to synthesize the body of evidence in order to answer the systematic review question that they are addressing. And, this process is really the process by which evidence is taken from multiple studies. It's described. It's compared, contrasted, and then, combined qualitatively.

They really thoroughly review all of

those included studies looking for overarching themes from the evidence, similarities and differences between the studies, both in terms of how they were conducted and the results they're reporting.

They think about any factors that might be impacting the relationships being examined, thinking about those confounders and factors that they identified up front as part of the analytic framework, considering how well the studies have been designed and conducted. And then, of course, identifying gaps and limitations throughout.

And, the ultimate goal of the synthesis process is to develop a conclusion statement. And, a conclusion statement is a summary statement or a series of statements that reflects the complete body of evidence reviewed, so it doesn't take into consideration evidence that was not included in the systematic review.

And, it's written as an answer to the systematic review question being addressed. And,

in some cases, the conclusion statement may also state that there was not enough evidence or insufficient evidence available to answer the question.

And, then next, the Committee will assign a grade to each of those conclusion statements. And, that grade is really an important piece of the process because it indicates the strength of evidence underlying that conclusion statement or how confident the Committee is in the conclusion statement that they have drawn.

They use some predetermined grading criteria to assess the body of evidence. And, I'll talk a little bit more about that specific criteria on the next slide. But they ultimately will assign one of four grades to each of their conclusion statements, strong, moderate, limited, or grade not assignable.

So, a strong grade is one in which the level of certainty is strong. The Committee is confident in that conclusion statement so that if

new evidence might be published in the future, the chances of the conclusion statement changing is unlikely. As you move into a moderate, the confidence drops a little bit. If new evidence comes out, that might mean that the conclusion statement may need to be revisited.

With a limited conclusion statement, if new evidence emerges that is in a case of a limited conclusion statement, means that modifications to the conclusion statement are likely.

And then, finally, we do have the grade not assignable option. That's when a conclusion statement cannot be drawn either due to there being no evidence available that met the inclusion/exclusion criteria that the Committee set or insufficient evidence was available.

So, there may have been studies but there were too many inconsistencies or too many limitations in those studies in those studies to really be able to confidently draw a conclusion.

So, NESR's grading process is also

designed to provide a very structured and transparent approach for assessing the strength of evidence. This is another area where we have made some updates to our process in supporting the 2020 Committee to align with best practices in the field of systematic review.

Our grading elements are listed on this slide. As I mentioned earlier, we look at risk bias, consistency, directness, precision, and generalizability. And, as is noted at the bottom of this slide, this is another part of the process where we take study design into consideration. All of the criteria you see on this slide are assessed separately for each category of study design included in a review before then an overall grade is assigned to the complete body of evidence.

And, this really allows the Committee to thoroughly consider the strengths and limitations of all of the different designs that they've reviewed. So, this is particularly important when a body of evidence includes a mix

of designs, including randomized control trials and observational studies, for example.

And, again, more details about these criteria and the specific rubric that gets used in this process is available on the NESR website.

And then, finally, throughout the process of conducting the review, gaps and limitations are always identified. And so, as a final step, the Committee does identify recommendations for future research that may address various gaps and limitations that they've identified as they've reviewed all of the included evidence.

I will note, though, I don't think you'll be hearing any research recommendations today. But they will be presented at the meetings that will occur in 2020. And, they are thoroughly detailed both in the full systematic reviews that will be posted online and in the Committee's report.

So, one of NESR's core values is to make our work transparent and accessible to a

wide range of audiences. So, we do encourage everyone to visit our updated website which is nesr.usda.gov. The website, as I've noted a few times today, includes more details about NESR and our methodology, specifically some of the tools that we're using to support the 2020 Committee's work.

It also includes all of the complete documentation from our completed systematic reviews. So, those systematic reviews, for example, that were conducted by the 2015 Advisory Committee.

And then once this Committee has completed its work and submitted its report, we'll be posting their complete systematic reviews on our website as well.

So, I'll stop there for today. And thank everyone for your attention.

(Applause.)

CHAIR SCHNEEMAN: So, can we ask questions?

DR. OBBAGY: Yes.

CHAIR SCHNEEMAN: So, I want to give the Committee the opportunity to ask some questions.

I have one.

DR. OBBAGY: Okay.

CHAIR SCHNEEMAN: And, I think it's a matter of just clarifying on terminology. Because I know many Committee members are familiar with the grade process which is a specific process developed by, well, developed by a group, but used by organizations like Cochrane.

And, we're using the word grade more with a lowercase spelling than an uppercase spelling.

So, it might be useful if you just commented on that and why are we using something slightly different.

DR. OBBAGY: Yes, so, grading the strength of the evidence is a very standard part of any systematic review process. And there are a number of methodologies that are out there for grading the strength of the evidence. And NESR

has always used a grading process similar to what we've shown but have evolved it over time.

There is a methodology known as the GRADE methodology, and that is one example of a method used to grade the underlying strength of evidence. And a number of other systematic review entities use other different methods.

So the Agency for Healthcare Research and Quality, some of the organizations that EPA use a slightly different approach.

And so, we do not use the GRADE process specifically, but we do use our own process which has many similarities I think to GRADE and some of the other methodologies that are out there in the field.

And so, over time, we've adapted our grading methodology to align with other organizations like GRADE and others but have retained some of our own unique features based on some of the more unique aspects of our work, particularly in supporting reviews that are conducted to inform U.S. federal guidance and

policy.

CHAIR SCHNEEMAN: One thing I think would be interesting just for the Committee as a whole to be aware of, I know that many of the staff are actively engaged in screening right now. Do you have an estimate of how many articles we're up to at this point?

DR. OBBAGY: Yes.

CHAIR SCHNEEMAN: Or --

DR. OBBAGY: I think we're somewhere in the neighborhood of 200,000 articles being screened at the moment and there are more searches to come. It's a lot of articles, but it's a testament, I think, to our awesome, dedicated team who are working so hard to screen all those articles.

But also to the comprehensiveness of the searches and really making sure that we have captured any study that might help you make a conclusion about the body of evidence on the topics you've been asked to address.

CHAIR SCHNEEMAN: Great, thank you so

much.

So, we'll move into our first subcommittee report. And, Dr. Boushey is going to talk about the dietary -- the work that the Dietary Patterns Subcommittee.

MEMBER BOUSHEY: Hello, my name is Carol Boushey. And, I'm covering the Dietary Patterns Subcommittee, our progress to date.

So, the topic areas this subcommittee was tasked with are listed on the slides. The subcommittee is developing the plan for the topic areas related to dietary patterns and body composition/obesity, cardiovascular disease, type 2 diabetes, cancer, and bone health.

The subcommittee is implementing the plan for the topic areas related to dietary patterns and all-cause mortality, sarcopenia, and neurocognitive health.

As just a reminder, the key definition for dietary patterns and all 2020 Advisory Committee reviews is the quantities, proportions, variety, or combination of different foods,

drinks, and nutrients, when available in diets and the frequency with which they are habitually consumed.

For this subcommittee, this definition has been and will be applied to all analytical frameworks.

The definition is aspirational and was developed by a panel of international experts for the existing NESR systematic reviews.

All information provided by studies about the dietary patterns tested or examined, including both foods and beverages and macro and micronutrients will be extracted for included articles.

The subcommittee updated -- am I on the right one here? Yes, okay.

The subcommittee updated six protocols based on deliberations of the full Committee at its July 2019 public meeting and consideration of public comments.

Updated protocols have a date of September 2019 on the topics and questions page

at the DietaryGuidelines.gov.

For all the Dietary Patterns Subcommittee protocols, the inclusion and exclusion criteria for the intervention exposure were edited to clarify macronutrient proportion diets will be considered when the macronutrient proportions fall outside of the Acceptable Macronutrient Distribution Range, the AMDR.

Even if foods and beverages consumed are not described, these criteria will be adjusted to further specify only studies describing all macronutrients, carbohydrates, fat, protein in the diet will be included.

I will present the updated inclusion and exclusion criteria in just a few minutes when I review the protocols for dietary patterns and cancer and bone health.

Additional updates were made to the dietary patterns and sarcopenia protocol. For this review, the inclusion criteria for the intermediate outcomes were edited to clarify intermediate outcomes regardless of categorical

cutoffs to be considered.

The previous version specified low muscle mass, low muscle strength, and low muscle performance. The edit was the removal of low from each of those intermediate outcomes.

The exclusion criteria for health status of participants was edited to clarify excluding studies enrolling hospitalized patients or studies enrolling individuals to enhance physical performance fitness who are not at risk for sarcopenia.

Subcommittee members and staff have worked on developing the protocols for two additional systematic reviews since the last public meeting. The two systematic review questions are shown here which I will describe in detail as we move forward.

So, the analytical framework which we have been introduced to today, and I'm going to introduce it again because it's kind of critical.

It's shown on this slide and illustrates the systematic review question

examining the relationship between dietary patterns consumed and risk of certain types of cancer.

The analytical framework provides a foundation for this systematic review and helps to inform the development of the inclusion and exclusion criteria we will discuss later during this presentation.

The intervention or exposure of interest is consumption of or adherence to a dietary pattern.

The comparators are consumption of or adherence to a different dietary pattern and different levels of consumption and their adherence to the dietary pattern.

The endpoint outcomes are incident cases of breast, colorectal, prostate, lung, liver, pancreatic, endometrial cancers, and childhood leukemia.

The population of interest for the intervention exposure is children through older adults who are healthy and are at risk for

chronic disease. The target population for the endpoint outcomes is children through older adults with exception to the outcome of childhood leukemia. The population for outcome of childhood leukemia is children and adolescents.

The key confounders are sex, age, race, ethnicity, socioeconomic status, alcohol intake in adults, physical activity, smoking, anthropometry, family history of cancer outcome.

And then, some of them are distinct, so, hormonal contraceptives for breast and endometrial cancers, menopausal status for breast and endometrial cancers, inflammatory bowel disease for colon and rectum cancer, colorectal polyps for colon and rectum cancer, lung disease for lung cancer, environmental exposures to lung carcinogens for lung cancer, viral liver infection for liver cancer, and pubertal status for childhood leukemia. Total energy intake is included as another factor to be considered.

So, this is the second analytical framework then to be introduced today. And, this

is dietary patterns and bone health.

The intervention or exposure of -- whoops, I thought I was the thing again. I won't go through all the red boxes.

The intervention or exposure of interest is consumption of and/or adherence to a dietary pattern.

The comparators are consumption of and/or adherence to different dietary pattern and different levels of consumption and/or adherence to a dietary pattern.

The intermediate outcomes are bone mass, including bone mineral density and content, and biomarkers of bone metabolism.

The endpoint outcomes are osteoporosis, osteopenia, rickets, and fracture.

The population of interest for the intervention exposure and outcomes includes children through older adults.

The key confounders are sex, age, race, ethnicity, socioeconomic status, anthropometry, smoking, alcohol intake in adults,

physical activity, vitamin D status, that's from sun exposure, use of vitamin D supplements, plasma or serum 25-OH-D levels, calcium supplements, and estrogen replacement therapy.

Other factors to be considered include total energy intake, medication use, family history of bone disease, malabsorptive conditions, lactose maldigestion, perceived milk intolerance, dairy allergy, postmenarcheal age in children, well, actually, in young adolescents.

We propose the standard inclusion and exclusion criteria listed here to be applied for all systematic review questions just presented in the previous slides, examining dietary patterns in relation to multiple health outcomes.

One exception to this is the dietary patterns and cancer where we will include, and this is an example of including other study designs, where we will include case control studies for the outcomes of liver, pancreatic, and endometrial cancers, and childhood leukemia due to their low incidence.

Case control studies will be excluded for systematic reviews on breast, colorectal, lung, and prostate cancers due to their higher incidents.

So, this is, you can see, is a lot of words on here.

For all the 2020 Advisory Committee's systematic reviews examining dietary patterns consumed, we propose to apply the inclusion/exclusion criteria shown here for the intervention exposure to operationalize the definition of dietary patterns presented earlier in this presentation.

The inclusion and exclusion criteria for intervention or exposure shown in the first row of this slide are the same proposed for all questions at the last public meeting.

These criteria specify, studies examining consumption of and/or adherence to dietary patterns such as dietary approaches to stop hypertension, DASH, vegetarian, vegan, low carbohydrate, and high fat diets will be

considered.

Dietary patterns may be measured or derived using a variety of approaches as specified in the inclusion criteria.

Studies must describe the dietary pattern being testing or examined, at a minimum providing the foods and beverages consumed in the pattern for inclusion.

Studies not providing the description of the dietary pattern will be excluded. This includes studies labeling a dietary pattern but not describing the foods and beverages consumed or base the pattern solely on nutrients.

As I mentioned earlier, the criteria shown in the second row on this slide were updated since the last public meeting to clarify the intent of the criteria to consider studies examining diets at specific macronutrient proportions that fall outside of the AMDR.

Specifically, the updated inclusion criteria on the bottom left propose studies examining consumption of and/or adherence to

diets that vary by macronutrient proportions such as low carbohydrate diets, will be included if the level of a macronutrient is outside of the acceptable macronutrient distribution range.

For consideration as low carbohydrate, the proportion of energy from carbohydrates must be less than 45 percent. For consideration as high fat, the proportion of energy must -- from fat must be greater than 35 percent.

The updated exclusion criteria proposes studies not providing a description of the macronutrient proportions examined or do not examine macronutrient proportions outside of the AMDR. And, they'll be excluding pending all other criteria.

Additionally, studies not providing the description of the macronutrient breakdown or all of the macronutrients will be excluded.

The inclusion/exclusion criteria for the outcomes are tailored for each systematic review question. The included outcomes on this slide were described earlier in this presentation

when showing each analytical framework. For transparency, the criteria for different outcomes are shown here for the questions of cancer and bone health outcomes. So, it is a repeat, but just to indicate that, indeed, it is in our strategy for moving forward.

We developed a date, and this was also mentioned by Dr. Schneeman, and the date for publication range for these systematic review questions, they -- it's diversity in the ranges.

We considered the original systematic reviews from the previous Advisory Committee as well as topic area. Research examining dietary patterns and health began to emerge shortly after the year 2000. Relative to other topic areas, dietary pattern research is still fairly young.

The existing work for the questions shown on this slide considered articles published from January 2000 to January 2014.

For dietary pattern research regarding cancer and bone health, the subcommittee determined the following date ranges. For

cancer, the date range of publication will be December 2013 to September 2019. This is in addition to the original systematic review which included articles published from January 2000 to 2014.

There'll be additional literature searches run from January 2000 to 2014 to cover any components of this review that were not considered in the existing systematic review.

This is illustrated in the second and third rows of this slide and will include literature searches to ensure that low incident cancers, liver, pancreatic, endometrial, and childhood leukemia and macronutrient proportion diets will be comprehensively searched.

For bone health, the date range of publication that will be researched is March 2014 to September 2019. This date range is in addition to the date of publication covered in the original systematic review which included articles published from January 2000 to March 2014.

The original systematic review did not consider macronutrient proportion diets which will be covered by an additional literature search with a date range of January 2000 to March 2014.

The subcommittee will finalize the protocols for dietary patterns and cancer and bone health based on the deliberations and decisions made by the full Committee today as well as public comments received on these topics.

The protocols for dietary patterns and growth size and body composition, cardiovascular disease, and type 2 diabetes were presented at the last meeting and have already been updated based on discussion and public comments.

Because of significant potential overlap in search results for growth size and body composition, cardiovascular disease, and Type II diabetes, these three remaining questions will be handled by a combined search strategy to reduce the number of duplicate records being screened.

The subcommittee is moving into the search and screening process. Five NESR analysts have been independently screening approximately 38,000 articles from the electronic search results for three questions: dietary patterns and sarcopenia, all-cause mortality, and neurocognitive health questions.

The subcommittee plans to complete screening for dietary patterns and all-cause mortality first ahead of sarcopenia as initially anticipated. We decided to hold on completing the sarcopenia question until the search and screening can be completed for the growth size, body composition, and risk of overweight or obesity question.

Allowing the growth size and obesity and body composition search to be completed first will help to identify articles that may be relevant to the sarcopenia review. For example, papers examining lean body mass or fat-free mass.

Finally, we get further -- as we get further into our reviews, we are planning to

arrange a cross-cutting discussion with the Data Analysis and Food Pattern Modeling Working Group to see how the findings from the dietary pattern reviews can inform their work and vice versa.

So, and this slide lists the members of the Dietary Patterns Subcommittee as well as the support staff which really are doing most of the heavy lifting and making all of these reviews take place.

And so, now, I open the floor for questions from members of the Committee. And, Rick Mattes, I just see you about ready to hop off your seat, so should I call on you first?

MEMBER MATTES: Just, did I understand correctly, the patterns will be defined by macronutrient distributions that fall outside the AMDR, so a pattern would not include, say, a heavily plant-based diet that falls within the AMDR?

MEMBER BOUSHEY: Those are included in the top. Those would all be in the top. What we did not have -- what we didn't account for, since

in the -- in our original, we said that you needed to be within the AMDR.

But now we've separated out that we will also look below, but it doesn't take away what you were concerned about. That is still in the top definition.

I went through the same thing, Rick, even though I worked on it.

(Laughter.)

MEMBER BOUSHEY: Other questions?

Jamy?

MEMBER ARD: Press harder. Jamy Ard.

So, just to follow up Rick, part of that discussion was there's a need -- we felt there's a need to include a review of the evidence around the emergence of dietary patterns considered to be in the, say, low carb category or the high fat category.

And those dietary patterns don't fall in the -- don't have the same sort of definitions as a DASH diet or a Mediterranean diet. We didn't have a mechanism that adequately captured

that.

So, if we took the standard dietary pattern definition, we would probably not be capturing those types of studies.

And so, after a lot of discussion, it was sort of said, well, we can take those things that fall outside of the AMDR and, if they otherwise describe all the macronutrients and there's some consistency, then we could look at those using a different sort of framework.

So, it allows us to be able to do that, whereas otherwise we would not have captured them.

MEMBER BOUSHEY: And, there were a lot of comments on that on our last public meeting. This was -- it came up a lot. So, we really did have to address it, we thought.

VICE CHAIR KLEINMAN: So, Ron Kleinman.

So, Carol, that would exclude a consideration of specific carbohydrate diet or a ketogenic diet because it doesn't describe all of

the macronutrient distributions in that diet. Is that right?

MEMBER BOUSHEY: Yes, we do ask that they -- the papers outline what the macronutrient distribution was for that -- well, and they would have thought of it as is, because they were actively doing that, but risk, it's was.

VICE CHAIR KLEINMAN: So, you could consider those diets as long as the papers were describing the diet in its entirety rather than --

MEMBER BOUSHEY: That is right.

VICE CHAIR KLEINMAN: -- simply a focus on the --

MEMBER BOUSHEY: If it's just --

VICE CHAIR KLEINMAN: -- carb or the fat?

MEMBER BOUSHEY: If it's just -- that's right. If it's just one macronutrient, we need -- we really need to have it all because it's a full distribution of energy sources.

VICE CHAIR KLEINMAN: Yes, good.

MEMBER HEYMSFIELD: Steve Heymsfield.

Carol, in the definition of food patterns, the word frequency is there and tomorrow we'll hear about frequency of eating which is the number of meals ingested over a 24-hour period.

How is frequency different in the food patterns?

MEMBER BOUSHEY: I'm not sure that the frequency is any different. What it -- this aspirational definition, it's what's -- not every -- it would be ideal that every dietary pattern had every component in this aspirational definition.

But the -- you don't necessarily have to have everything that's in that definition but you do need to have at least one of the items in that definition to be thought of as a pattern.

But you can go ahead and do frequency as an independent exposure, be comfortable with that.

MEMBER MATTES: Just because it's a

concept that is working its way into other nations' Dietary Guidelines, are you considering the NOVA system as an issue to consider in terms of its health outcomes?

MEMBER BOUSHEY: We've certainly discussed it, Rick. But, no, we are not.

Now, am I correct on this, am I following the minutes of our meetings correctly? We have not considered the NOVA. We are not going to -- right, except but -- no, we have not, unless I missed a meeting.

CHAIR SCHNEEMAN: I have to work on my finger strength here.

I think you're correct and it would have been brought to the Committee if that were included. And so it wouldn't have been something just left at the subcommittee level.

If you look at the nature of the questions, it's not an overt part of the question. So, the Committee would have to evaluate.

I think what's important is the food

pattern piece of this and the research that will be looked at that tells us something about the foods that are in that pattern and the macronutrient distribution that is in that pattern.

MEMBER BOUSHEY: And, and I think that that might be something that we would consider for putting down for future reference is where I believe that we had discussed that that -- we have that opportunity to be able to -- we're coming across information now that we know will need to be addressed in the future.

You know, we had our questions assigned to us the way that the, you know, having that public involvement. And, this then will be able to inform the next Dietary Guidelines as well as the next public sessions that will inform it, too.

MEMBER LEIDY: This is Heather Leidy.

Just a question that was asked a little bit earlier, but a follow up. And you had commented, too, about the macronutrient specific

diet focus. So, we're really looking at macronutrients but then also the food components.

And so, I guess the question that I have is, is there a hierarchy of the search when NESR or when we start looking at these in the sense that a lot of the diets will be macronutrient specific. But then within that, they may have certain food components that aren't really even acknowledged in the abstract.

And so, a lot of these could get missed. And, it depends on how you focus it. If it is a food specific study, you may not know the macronutrient specific content. It would be within the document, but that's sometimes hard to tease out.

So, I'm just trying to wonder what the hierarchy is for the search.

MEMBER BOUSHEY: Right. We may want to -- we can actually get that clarified completely from the NESR -- they're here, the NESR staff is here. So, we could get that and the NESR staff person that's key already has the

microphone to her mouth.

(Laughter.)

DR. ENGLISH: This is Laural English.

And, to get at your question, I did want to go back as well and mention that the criteria that Dr. Boushey covered is that an important part of this is that the -- at a minimum, the foods and beverages that make up the pattern must be described. And, that's part of our inclusion criteria as for papers that are looking at traditional dietary patterns.

For those papers that are looking at specific macronutrient proportion diets, it's very common that the foods and beverages are not adequately described. If they are, we'll extract that information so we have that in addition to the macronutrient proportion breakdown.

But for that search strategy, we do have included search terms that get at these diets. So, there, for example, the MESH heading for dietary carbohydrates, dietary fats, so we have a whole search hedge that will capture those

papers.

And then, we also run through test papers as part of the process to make sure that we're capturing these macronutrient proportion diets.

So, we do have that and we've tested that and they have come up. We also have the other common MESH headings like ketogenic diet, low carbohydrate, carbohydrate restricted diet. So, all of those search terms are in the search to make sure we're casting that really wide net to capture all of the papers.

MEMBER LEIDY: So, I guess to take it a step further then, in terms of when the data start getting interpreted, I think that's where I'm thinking in the hierarchy and this is for the -- I mean, is it the -- it would be macronutrient specific first and then food specific? Or is it just certain types of dietary patterns? That's just different.

Searching is one thing and the next piece is when you compile that, what is the

hierarchy, I guess, in terms of what you've -- what's the primary and secondary or maybe they're all at the same level?

MEMBER BOUSHEY: No, we haven't -- no, there are -- maybe -- let me make sure, Heather, I understand your question.

What -- are you asking that we're going to -- that we will actually think of the more traditional dietary pattern as being our -- having a hierarchy higher than the one that's going by the acceptable -- below the acceptable macronutrient range?

Because we're not considering them in a hierarchy. We only define them that way because we've got -- because they weren't there first in our plan. But we are not considering them in any type of hierarchy.

MEMBER LEIDY: Right, so --

MEMBER BOUSHEY: They're going to be all equivalent in our reviews.

MEMBER LEIDY: Good point. And, that was not what I was --

MEMBER BOUSHEY: Okay.

MEMBER LEIDY: -- going down that path, but that was great clarification because I hopefully would have thought of that later.

My question is, as an example, with higher protein diets, you can, you know, look at the -- examine the body of evidence and then, subsequently, you can talk about whether they are plant-based or animal-based diets.

MEMBER BOUSHEY: Right.

MEMBER LEIDY: So, that's what I'm trying to figure out in terms of the hierarchy, is it more about macronutrient parts of the diet? Or even with ketogenic diets, or whatever you're -- whatever the diet you're focusing on, is that the primary that it is macronutrient specific first and then a food or a quality component second?

MEMBER BOUSHEY: Well, macronutrient first really only came up with this new addition.

MEMBER LEIDY: Okay.

MEMBER BOUSHEY: Prior to that,

really, your driver are the foods.

MEMBER LEIDY: Are the foods, okay.

MEMBER BOUSHEY: Yes. And, if you look at that aspirational definition, you can see that. I think it's the way that it's structured, too, you can --

MEMBER LEIDY: Because even when you're thinking of low carbohydrate diets or ketogenic diets, it is really, at least in my thinking, macronutrient first as far as how a lot of those diets get developed and implemented and it's not a food first approach.

MEMBER BOUSHEY: Right. And so, this is the aspirational definition and you can really see that the nutrients, or even when available. You see, because with the -- with our more traditional dietary patterns, the way we think of them is really food-based.

And, but then, you can see why we couldn't then use that definition for doing these, you know, these ketogenic style diets. Because then, that nutrient's when available,

that's what's driving them.

CHAIR SCHNEEMAN: I just wanted to comment on this particular topic because I think the question you're -- that you're getting at has to do also with the kind of finding and conclusion statements that the subcommittee will draft for consideration once its looked at all the evidence.

And, we'll see some examples when we get to Fats and Seafood where sometimes the question was written, but you need multiple conclusion, finding conclusion statements given the way the subcommittee and the Committee then tackled that question.

So, I think some of what you're asking may play out in that direction. You know, again, it's one question we're trying to answer but, as you go through the literature, there are different findings and conclusions, so.

MEMBER BOUSHEY: Rachel?

MEMBER NOVOTNY: Rachel Novotny.

I want to go back to Rick's question

on NOVA ultraprocessed foods and just make sure I understand the reason for exclusion.

Is that it doesn't meet the definition of inclusion, that diet or that approach?

MEMBER BOUSHEY: Well, we're not putting it in as one of our guidelines. These are -- this definition really was not even made by our Committee. It was -- it has been developed other -- it has been developed by a larger group which then we adopted.

MEMBER NOVOTNY: Right.

MEMBER BOUSHEY: And, in order to also match the other studies, other studies that have been done before.

It isn't that, if, indeed, someone has used that and we pick it up, it's not going to be gone.

MEMBER NOVOTNY: Okay.

MEMBER BOUSHEY: We're just not using it as one of our primary --

MEMBER NOVOTNY: As a search?

MEMBER BOUSHEY: -- models. That's a

different -- I mean, as being one of the primary models, that's a different question. We're doing dietary patterns. We may very well pick up studies that specifically use that as a model and it would not be excluded.

MEMBER NOVOTNY: Okay, because that -- it seems to meet --

MEMBER BOUSHEY: But that's nice to clarify.

MEMBER NOVOTNY: -- it does meet the or it could meet the definition --

MEMBER BOUSHEY: Absolutely.

MEMBER NOVOTNY: Yes, okay.

MEMBER BOUSHEY: This is what we're using to guide us and it's quite broad. So, if, indeed, I'm pretty confident if someone used this, they did a study that also met all of our other criteria of having, you know, being a -- where is this little criteria here. You know, it's that we have our -- which all of us have, what, you know, this right here. If it matches everything in here, we're going to be in

business. They'll -- it will be included.

MEMBER NOVOTNY: Okay, thank you.

MEMBER BOUSHEY: Yes. It's just not our driving definition.

CHAIR SCHNEEMAN: Yes, just to add to that, I think if you look at the inclusion/exclusion criteria, if a study has information on the foods and the macronutrients as defined by this subcommittee, then it gets pulled into the review.

My guess is, if the only thing the study said was level of processing, then you don't -- and you don't have information on the macronutrients, the foods, then it might be excluded, so.

MEMBER BOUSHEY: And considering that right now we're looking at over 38,000 papers, I think we're probably being pretty inclusive in our first pass.

CHAIR SCHNEEMAN: Yes.

So, Dr. Sabate?

MEMBER SABATE: Yes, Joan Sabate.

I think our colleagues here in the panel that have not been part of the food patterns, I mean, are raising relevant questions.

And, particularly the NOVA one specification, I don't remember that we have thoroughly discussed that. So, probably something that in our subcommittee, we have to carefully weigh the pros and cons and the ability to do so as far as including this.

And, as far as the hierarchy that you mentioned is an issue that, unless we want to do in the systematic way, it may escape. I mean, the possibility to draw discussions.

So, I think these are two very relevant points that need to be thoroughly discussed and see, I mean, if this is possible to do or not given the resources and the time.

(Off-microphone comments.)

CHAIR SCHNEEMAN: Other questions? Comments? So, the Committee, though, is -- you are in the process now of searching, so we know that you're going to be coming forward with some

conclusion statements.

MEMBER BOUSHEY: Yes, yes, that is our goal is by next time to have some conclusion statements. And, we've really put together -- we met as a Committee yesterday and we really did put together quite a serious game plan, which some of them I did share today.

But because it's -- yes, I actually am really astounded that this whole concept of dietary patterns, and it's very young in the scheme of our field, has really taken off.

And so, as a result of that, we have a lot to go through. And, but it's actually pretty exciting that this concept has been adopted so widely and put into literature. You know, it's been published, peer reviewed, publications. So, it's a blessing and then we'll work with the other part of it.

(Laughter.)

CHAIR SCHNEEMAN: Okay.

So, we have plenty of time. If -- but I think, Linda, you're also willing to start now

rather than wait until after -- so, okay.

So, we will move forward. This is what we meant by the agenda is flexible based on the time the Committee needs to discuss and be confident that we're moving forward.

So, we'll go ahead with the Dietary Fats and Seafood Subcommittee.

MEMBER SNETSELAAR: Okay.

(Off-microphone comments.)

MEMBER SNETSELAAR: Okay, the Dietary Fats and Seafood Subcommittee includes Regan Bailey, Joan Sabate, and Linda Van Horn, along with Barbara Schneeman.

And, during the July Advisory Committee meeting, we presented protocols for all of the questions that this subcommittee will be addressing.

We will be presenting a summary of the evidence draft conclusion statements and grading on Attention Deficit Disorder, Attention Deficit and Hyperactivity Disorder, and Autism Spectrum Disorder.

And, we're doing this portion of the question, have already done a systematic review. And, that's what we will be covering today for the full Committee.

The synthesis for the evidence on the developmental domains portion for the first question is ongoing and will be discussed at our next meeting.

We are implementing the protocols which include conducting the literature search, screening, and data extraction for the next three systematic review questions that are shown here under implementing the plan. These will be addressed in future Advisory Committee meetings.

We will be implementing the protocols for the three systematic review questions under developing the plan and we'll be doing that in the near future.

Updates to protocols that were presented in July are important to this Committee and so we wanted to highlight that here. Before discussing pregnancy results, we want the

Committee to know that the protocol addresses the question, what is the relationship between types of dietary fat consumed and risk of cardiovascular disease.

This review will build upon the evidence review that was conducted by the 2015 Dietary Guidelines Advisory Committee on Dietary Fat and Risk of Cardiovascular Disease in Adult Populations.

This work included evidence on saturated fat and replacement of saturated fat with polyunsaturated fats, monounsaturated fats and carbohydrates.

The 2015 Committee review considered evidence dating back to 1960 when important studies in this area began.

In addition, the current NESR systematic review will look at studies involving children and adolescents dating back to 1990 and more recent studies for adult populations starting at 2010.

We believe this update will allow the

subcommittee to review the evidence on this topic in a comprehensive manner.

The first question we addressed was, what is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development in the infant?

We used NESR systematic review to answer the question.

The Dietary Fats and Seafood Subcommittee had a joint meeting with the Pregnancy Lactation Subcommittee and the Birth to 24 Months Subcommittee members. This was a very important piece to our process because we felt there were many overlapping concepts and it was very important to include those two subcommittees to assist us in looking at the evidence. They also provided feedback on protocols.

And then, additionally, we decided that it was important to have external neurocognitive experts looking at our assessment tools. And so, we had two additional external neurocognitive experts who provided information

on the assessment tools that were a part of the articles that we were reviewing.

It's important to define seafood and for the purposes of this particular subcommittee, seafood is defined as marine animals that live in the sea and in freshwater lakes and rivers.

And, seafood fish would include salmon, tuna, trout, tilapia, and shellfish, shrimp, crab, and oysters.

This analytic framework is really a refresher because we did review this during our July Advisory Committee meeting. And, in this question, the exposure was assessed in pregnant and lactating women and the outcome was measured in children, birth to 18 years of age.

Today, we will be presenting evidence and draft conclusions for ADD, ADHD, and ASD outcomes. At future meetings, we will present the evidence and conclusion statements for developmental domains.

It's important to note here that no studies met the inclusion criteria for academic

performance, anxiety, and depression outcomes.

We use the standard inclusion and exclusion criteria for these categories as shown on this slide. And this particular inclusion/exclusion criteria slide is a reminder of specific intervention, exposure, and comparators.

And, of particular note here is that studies for our particular review must measure seafood consumption. Fish oil or Omega-3 supplement studies and studies that only examine biomarkers of seafood intake are not included. And, that would mean also that studies evaluating infant formula with added DHA and EPA are excluded.

This flow chart illustrates the literature search and screening results for two systematic review questions related to seafood consumption and neurocognitive outcomes.

One question addresses seafood intake during pregnancy and lactation and the second question addresses seafood intake during

childhood.

Twenty-five studies were included in this review of seafood consumption during pregnancy and lactation and neurocognitive development. Of these 25, four of the studies examined ADD, ADHD, and three studies examined ASD, autism spectrum disorder.

This is the draft conclusion and grade relative to academic performance, anxiety, and depression. No evidence is available to draw a conclusion about the relationship between maternal seafood intake during pregnancy and lactation and academic performance, anxiety, and depression in children.

The grade here is not assignable. No evidence was found related to seafood intake during pregnancy or lactation and academic performance, anxiety, and depression. I wanted to restate that. And so, no conclusion could be made.

And then the draft conclusion statement and grade for seafood intake during

lactation: no evidence is available to draw a conclusion about the relationship between maternal seafood intake during lactation and neurocognitive development in children.

The grade here, not assignable and no evidence was found on maternal seafood consumption during lactation.

In a description of the evidence for ADD, ADHD included four prospective studies. I do want to remind you that we did do a joint call with the Pregnancy and Lactation and Birth to 24 Months subcommittees and we did include experts who provided feedback on assessment tools that were used.

The evidence for ADD and ADHD included the studies that were done in the UK, three of them, and one in the U.S. Sample sizes ranged from 217 to 6,580 participants.

Maternal age was predominantly 20 years and older, included white and middle to high socioeconomic status participants.

Exposures included total seafood with

one study also assessing oily fish intake. The timing of intakes varied from the first trimester only, third trimester only, or throughout pregnancy. No studies assessed maternal seafood intake during lactation.

The four studies assessed ADD, ADHD-like traits or behaviors between 4 to 13 years of age. And, no studies assessed a clinical diagnosis of ADD or ADHD.

In summary of the evidence synthesis for prospective cohort studies examined the relationship between maternal seafood intake during pregnancy and ADD and ADHD-like traits or behaviors in children 4 to 13.

Two of the studies provided evidence of a protective association between maternal seafood intake during pregnancy and ADD and ADHD-like traits or behaviors in 8 to 9 year olds.

And then, there were two larger studies, both from a single cohort that used a more rigorous dietary assessment method and found no association between maternal seafood intake

during pregnancy and hyperactivity in children 4 to 13 years of age.

And, as stated before, no studies looked at a clinical diagnosis of ADD or ADHD.

Our draft conclusion statement then for ADD and ADHD-like behavior traits is insufficient evidence is available to draw a conclusion about the relationship between seafood consumption during pregnancy and attention deficit disorder-like or attention deficit hyperactivity disorder-like traits or behaviors.

And, the grade here was not assignable. That grade is primarily due to the fact that there are small numbers of studies and an inconsistency in results. And, these studies, then, to just add a bit of detail, were based on parental report of ADD, ADHD-like traits or behaviors.

I think it's important here in summary to note that no studies reported a clinical diagnosis of ADD or ADHD.

And then, draft conclusion statement

for clinical diagnosis of ADD and ADHD, no evidence is available to draw a conclusion about the relationship between seafood consumption during pregnancy and clinical diagnosis of attention deficit disorder or attention deficit hyperactivity disorder.

Grade not assignable. And, this is primarily due to the small number of studies and inconsistency in results.

And then, moving on to a description of the evidence for autism spectrum disorder, there were three prospective cohort studies. And, the studies were conducted in the Netherlands, Spain, and the UK.

Sample sizes ranged from 1,200 to 8,000 participants. The mothers, on the average, were 31 years of age, white, and of middle to high socioeconomic status.

Exposures included seafood or fish intake and two studies examined oily fish, white fish, large fatty fish, small fatty fish, lean fish, and/or shellfish separately.

Again, the timing of the intake varied from first trimester only, early or late pregnancy, or throughout pregnancy.

No studies assessed maternal seafood intake during lactation.

One study looked at the ASD diagnosis by age 11.

The summary of the evidence synthesis ASD diagnosis is that one prospective cohort study examined the relationship between maternal seafood intake during pregnancy and ASD diagnosis by 11 years and found no association with either oily fish, white fish, or shellfish.

And the summary evidence then regarding ASD-like traits or behaviors, three prospective cohort studies, again, examined the relationship between maternal seafood intake during pregnancy and ASD-like traits or behaviors in children 3 to 9.

One study conducted in a population with high seafood intake, approximately 18 ounces per week. This was done in Spain, found a

protective association between total seafood and fatty fish intake during pregnancy and ASD-like traits or behaviors at age 5 years.

Two other studies that were conducted in Europe with a more moderate seafood intake during pregnancy found no association between seafood intake during pregnancy and ASD-like behaviors or traits in children 3 to 9 years.

So, our draft conclusion statement here for ASD-like traits or behaviors or ASD diagnosis is that there is insufficient evidence available to draw a conclusion about the relationship between seafood consumption during pregnancy and autism spectrum disorder-like traits or behaviors or clinical diagnosis of ASD.

And, the grade here, not assignable. And, that was due to the small number of studies and inconsistency in results.

So, next steps for our Committee include completing the evidence portfolios and conclusions statements for the two questions about seafood intake and neurocognitive

development, completing screening and data extraction for the systematic review question on seafood during childhood, adolescence, and cardiovascular disease and dietary fats and all-cause mortality.

And, we will begin screening for the three remaining questions where we're examining dietary fats and cardiovascular disease, dietary fats and cancer, and dietary fats and neurocognitive development and health.

And, finally, I want to thank the members of my subcommittee. In addition to that, the support staff including Rebecca MacIsaac, Julia Quam, Julie Obbagy, Eve Stoody, Joanne Spahn, Julia Kim, Charlotte Bahnfleth, Gisela Butea, and Janet de Jesus.

Thank you all so very much.

And, I am happy to answer any questions.

CHAIR SCHNEEMAN: Great. So, we will open it for discussion. But I do want to emphasize that, at this point, what you're

hearing are findings and conclusions. Conclusions based on the findings that resulted from the systematic review. These are not recommendations at that point. That's still to come as we put it all together. But it's findings and conclusions.

MEMBER SNETSELAAR: Yes, thank you, very important.

CHAIR SCHNEEMAN: So, I will open it up for the Committee.

MEMBER HEYMSFIELD: I don't want to steer us too far away from the topic, but I think as a translational scientist, the hypothesis is that there are lipid differences between fish and other kinds of foods. I'm just trying to understand why seafood would have those neurocognitive effects during pregnancy? Is that right?

And, I, you know, taking it one step further, it would seem like certain kinds of animal experiments would certainly provide a translational basis for thinking about these

kinds of findings. Just a thought.

MEMBER SNETSELAAR: And, I think, often, what we're looking at, we started with some questions that had probably very small numbers of articles. So, we're really in a situation where we're dealing with some very new ideas.

And, I know at the University of Iowa, I'm working right now with a post-doc who's just beginning to look at some of these kinds of things. So, yes, very early stages at this point.

MEMBER VAN HORN: Linda Van Horn.

Just wanted to add to that comment the fact that, as a group, we were discussing the fact that this in no way changes the overall recommendation for diet and pregnancy and intake of seafood, et cetera.

It's just that as Linda said, I think there's growing interest in whether specific polyunsaturated fats are associated with neurocognitive development.

And, I'm also aware that supplementation of breast milk and/or formula with some of these fatty acids has already been initiated.

And so, I think it's a question of really, from our Committee's point of view, trying to do justice to establishing what the evidence base is and clearly identifying the fact that more research in this area is really needed.

MEMBER HEYMSFIELD: Well, you know, with carrying that one step further, I guess I was thinking this is very amenable to a prospective randomized kind of a trial. If you can supplement milk and so on with these ingredients. Just a thought.

VICE CHAIR KLEINMAN: And, there's lots of those. So, I mean, this has been a work in progress for at least the last 10 to 15 years. So, I think in the B to 24 group we'll be talking about that.

MEMBER DEWEY: Okay, Kay Dewey.

So, I'd like to just remind everyone

that these two domains were only ASD and ADHD, and related behaviors, so, you're still not seeing the other developmental domains, including cognitive development, motor development, et cetera.

And, there's a much larger literature, maybe not much larger, but it's larger. And so, and, this is, so far, only pregnancy exposure.

So, I think when it comes to thinking about recommendations, we really have to take into account all the domains and all of the exposures.

I had one very minor technical comment about how some of the statements are worded. Yesterday in our subcommittee meeting, we realized that the word pregnancy and lactation could be taken to mean it had to be both. And so, we wanted to revise that to pregnancy and/or lactation if that's truly the way the search was conducted.

MEMBER SNETSELAAR: Yes, thank you so much and thank you also for being a part of our

Committee. It was very helpful.

MEMBER BOUSHEY: Okay, this is actually also a little minor thing on a definition. And, because I -- you had that -- the definition for seafood. And so, were you given your definition like we were given our aspirational definition or did you all put that together?

MEMBER SNETSELAAR: That came from previous --

MEMBER BOUSHEY: The previous one, too?

MEMBER SNETSELAAR: -- yes.

MEMBER BOUSHEY: Yes, it was -- yes. So, the -- so, it's these marine animals and then the seafood and so these are -- oh, I see, they're just examples. Okay, that's what I wanted to see.

MEMBER SNETSELAAR: Exactly.

MEMBER BOUSHEY: Because I didn't see clams and they have definitely -- some of razor clams have been involved with neurocognitive

changes. So, that was -- okay, super.

MEMBER SNETSELAAR: Yes, and thank you for that because I think we discussed that maybe at the last meeting, too. Thank you.

MEMBER BOUSHEY: Okay.

MEMBER MATTES: Rick Mattes.

So, one of the questions that you're working on now, seafood consumption during childhood and adolescence and cardiovascular disease.

So, my question is, what criteria are you using to establish intake in children and adolescence and looking at an outcome many, many years later to know that you really captured customary intake?

MEMBER SNETSELAAR: And, I would love for others on my Committee to respond to this, too. Linda Van Horn and I have been involved in certainly adolescence studies and studies in children as well.

So, often, the situation here and is working with the parents, maybe also working with

the children, you know, in terms of determining intake. Is that responding to your question or --

MEMBER MATTES: Well, I guess what prompted it in some of the other committees, we've started to think about this. And, one criteria that I think we're leaning towards is saying that there have to be at least two periods of measurement of intake so that you can establish at least it's a reliable level of estimated intake to the use for the analysis.

Although, that probably sets a pretty high bar and will exclude a fair number of studies, but there is no point in including studies that you don't have confidence in the dietary data.

So, something built into your decision making to give you the confidence that at least we captured intake at that point of their life reasonably well.

MEMBER SNETSELAAR: Right and you might have noticed in one of the slides that we

even talked about a study that we felt did a relatively adequate job of looking at that. But other studies may not have.

So, no, I think that's incredibly important and we will try to continuously keep that on our radar screen as we're looking at studies. Thank you.

CHAIR SCHNEEMAN: I would add, perhaps, for studies in children, intermediate outcomes may also be.

So, in terms of what you're looking at, obviously, endpoint is desirable, a health outcome. But you are looking at intermediate outcomes as well.

MEMBER VAN HORN: I guess the only thing I would add is, we have yet to really, as Linda pointed out, we have yet to really look at the diet and cardiovascular disease outcomes. So, we're still working on that.

But it is true that in our group, one of the things that we identified is a very challenging question is, where does maternal

intake and lactation of seafood or other foods stop in terms of its influence on children and where does their own intake of these foods really pick up as far as really affecting them?

And, of course, trying to establish those kinds of cut points is very challenging, if not impossible.

But I do think, thankfully, there are several prospective cohort studies that have done a good job of establishing diet in children either assisted by a parent or caregiver's input and/or in one case, the diet intervention study in children which began with kids that were between the ages of 7 to 9 and followed them for almost ten years after the transition between mom providing those data and the child, him or herself, providing those data.

So, you know, thankfully, there are a couple, not very many, but there are a few prospective and even randomized controlled trials that we plan to address as far as further honing in on that question.

MEMBER NAIMI: Well, thanks, that was a really nice presentation.

Oh, Tim Naimi.

So, my question was just to get a sense of how the kind of the quality scoring played out?

For the cohort studies, you know, there's this issue with, you know, fish eaters being more, people at least in the U.S., my understanding that fish eaters are more socially advantaged and that can be correlated with neurocognitive outcomes in children.

So, how is that, do you feel, addressed in the studies and how does that kind of play out in the Committee when you're talking about the evidence?

MEMBER SNETSELAAR: I think that -- I'm not quite sure exactly what you were getting at. But in terms of the work that we have done relative to looking at studies, particularly the ones we've done here, there are only so many studies we can look at.

As Linda Van Horn was indicating, the diet intervention study in children which hasn't come into play yet because we haven't really gotten to that question was a randomized controlled trial also done for several years.

And so, we will be getting into more of those studies as time goes on. We sort of wanted to hit areas where there weren't as large a number of studies and a little bit easier to tackle initially.

But that meant that we were looking at studies where there wasn't a lot of research currently going on either.

So, does that answer your question?

MEMBER NAIMI: Yes, that's fine. I was just more interested in the issue of confounding around people who consume fish and that they're traditionally, I believe --

MEMBER SCHNEEMAN: It might be helpful if you comment on how you're looking at socioeconomic status in the confounders or other factors if that's part of the protocol.

MEMBER NAIMI: Yes.

(Off-microphone comments.)

MEMBER BAILEY: Thank you also.

So, if you look at the analytical framework, we did try to assess in these studies socioeconomic status as well as parental education to try to get at some of those because those are known confounders to this question.

MEMBER LEIDY: A different question. So, and this might have been addressed and I missed it.

So, I was just wondering with the seafood question what some of these health outcomes, is there a covariant in terms of the mercury content within the seafood?

And, I went back to the analytical framework and didn't see it, although I might have missed it. So, I'm wondering if that's the connect to the seafood in some of these cognitive function outcomes that it could be lipid composition but then also this idea of the mercury content.

MEMBER SNETSELAAR: Yes. We are very concerned about that because, often, in terms of recommendations, the recommendations for amount would be based on studies that involved mercury content.

There weren't a lot of studies that we could look at. And, some of the studies did have some problems, but one of the studies we were looking at was focused on mercury levels in cord blood and maternal blood and the differences that often cord blood is higher in mercury content, for example.

And, there were problems with that study. You know, it certainly wasn't the end all in terms of studies.

But my thought is that that's something that we do need to pay particularly close attention to because that will drive some of what we say about amounts. So, we're paying very close attention to that.

MEMBER LEIDY: So, is it in your key factors of concern then?

MEMBER SNETSELAAR: Definitely, yes.

MEMBER LEIDY: Okay.

MEMBER MATTES: Ask one other question.

You have so few papers to split, again, it's probably pointless, but is there equivalence between shellfish and free swimming fish in terms of possible mechanism or are there differences between them that should be explored separately?

MEMBER SNETSELAAR: I think that's a good question. We haven't done that at this point, but that may be something that we need to identify and look at.

MEMBER BAILEY: This is Regan again.

Some of the neurocognitive that we have yet to present that we're just starting to talk about as a group, they separate the types of fish. So, they look at all fish and seafood and then categories so that we can get a sense of if there's a differential response to fresh water versus salt water or farmed versus fresh caught

for example.

But not a lot of data, but there's more for the other neurocognitive endpoints than for these questions.

MEMBER BOUSHEY: And, I'm not sure where to put this and I -- Carol Boushey, sorry.

I'm not sure where to put this, but the other thing that we're facing now, and I don't know if you've come across it, but, you know, we have different algal blooms now than we used to and they last longer, they're larger, and some of them are beneficial but some are more actually very harmful.

So, I'm not sure if you're coming across that, but that would be something to make sure that you -- that there could be studies that they were just investigating these algal blooms which then come maybe every year or every other year or something.

But this is -- we have more now as a result of our changing climate.

MEMBER NOVOTNY: Just another detail,

Rachel Novotny.

On that fish and seafood, I know the question or the word -- the question was worded that way, but it seems like in our response it would be nice to make sure that it's clear that it's seafood and fish. It's not intuitive to me at least.

MEMBER SNETSELAAR: Sure, thank you.

MEMBER VAN HORN: I'm just wondering because we've really tried to drill down on some of these questions if we could ask Joanne Spahn to mention the specifics as far as the details related to this question. If you'd care to just offer a comment?

MS. SPAHN: This is Joanne Spahn.

The authors in these articles did provide analysis separately for fatty fish, lean fish, shellfish. But there were no really significant findings to highlight in the conclusions.

But in this body of evidence, the subcommittee did discuss the different types of

fish, but it was just not a lot to conclude.

The next body of evidence that Dr. Bailey mentioned has a lot more articles in it.

CHAIR SCHNEEMAN: Joanne, you need to speak up a little. The Committee is having a hard time hearing you.

MS. SPAHN: The ASD and the ADD/ADHD articles did split the analysis by type of fish. But there's such a few articles and there was no real difference by type of fish to highlight in the conclusions.

And so, the conclusions cover all of those fish subtypes.

As Dr. Bailey mentioned, we have a lot more literature that addresses the developmental domains. And, again, some of those articles will analyze seafood intake by different types.

And so, as the subcommittee looks at the evidence, if there are findings that are different among the subgroups, those will be highlighted in the summary statements and the conclusions.

CHAIR SCHNEEMAN: Thank you. Other comments or questions from the Committee members?

Great. Well, thank you. And, it's very helpful I think for people to see the kind of conclusion statements.

And, again, it's -- we're not at a recommendation point yet, but the Committee is getting to the findings and conclusions point.

So, we're scheduled for a break at 11:30. So, I think we'll just start that break now. But we will be back, my understanding is we have to start at 12:15 for the webinar piece of it. So, we will be -- oh, I'm sorry. Oh, 11:30 to 12:45, sorry, need to have my glasses on. So, we will be back at 12:45 and start promptly at that time. So, thank you.

(Whereupon, the above-entitled matter went off the record at 11:20 a.m. and resumed at 12:48 p.m.)

CHAIR 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 on to the agenda.

So, it'll -- 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 through 24 subcommittee report.

So, with that, we can turn to the Beverages and Added Sugars, and Beth? Dr. Mayer-Davis?

MEMBER MAYER-DAVIS: All right, 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 are at the last slide, but they are fabulous and I appreciate the 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.

(Off-microphone comments.)

MEMBER MAYER-DAVIS: All right, 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.

So, in terms of developing the plan, working on added sugars with the outcomes of risk for cardiovascular disease, risk of Type II 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 asterisks there to indicate some protocols that will 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.

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 nonalcoholic beverage consumption, what is the relationship between beverage consumption during lactation and human milk composition and quantity?

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 a 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 nonalcoholic 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.

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 and diets. And, we'll also consider studies that examine specific beverages or beverage groups.

And, in terms of population of interest for this question, lactating women who

are exclusively or predominantly breast feeding.

And, here are some definitions for a couple of those terms. Exclusive breastfeeding, and these are based on 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.

Infants may receive oral rehydration solution, drops or syrups.

And then, predominate breast feeding 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.

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 enrolled multiple gestation pregnancies or exclusively present combined analyses of singleton and multiple gestations or human milk from third-parties, banked or donor

milk.

And then, in terms of health status of study participants, we will include studies that enrolled 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 pre-term infants or studies that exclusively enrolled mothers diagnosed with a particular disease, including severe under nutrition or exclusively enrolled mothers who are hospitalized with an illness or injury. And, those obviously have to do with generalizability.

All 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 are 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.

Then, you see below there the population for the 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.

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 II diabetes? Growth, size, body composition, and risk of overweight or obesity?

So, we're presenting these in a sort of 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 -- from 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, you know, a variety of sugars, sugars from syrups and honey, 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 a vegetable of the same type.

We will consider studies that use a somewhat different definition of added sugars. You know, 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 II diabetes defined according to the current ADA definition.

All right, 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 II diabetes,

growth, size, body composition, and risk of overweight and obesity.

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 and experiment, then that minimum duration is eight weeks.

These are inclusion and exclusion criteria for study participants. For CVD, with regard to age, and you'll see later, you know, there are intermediate outcomes that would be relevant here.

So, again, for CVD, children age 2 to 5, 6 to 12.

And then, for Type II 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, you know, screening, doing the search, screening the literature accordingly. But it is the Birth to 24 subcommittee that will really be doing, you know, the lion's share really focusing on that synthesis piece for the question of added sugars

for this age group.

Because, you know, they obviously will have a broader context with regard to complimentary feeding, et cetera. So, that's the update to this slide. And, Kay will tell me if I missed that. She looks happy. Okay, we're good.

(Laughter.)

MEMBER MAYER-DAVIS: All right, so, then continuing, inclusion and exclusion criteria with regard to health status, so, for cardiovascular disease and Type II 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 II 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.

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 healthy 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, stunted, wasted, 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.

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-plus 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.

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 that 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.

Okay, let's see, this is the analytic framework for type II diabetes, relationship between added sugars and risk of Type II 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 II diabetes. And, again, there are some intermediate outcomes that can be considered, hemoglobin A1c when it's not defining the outcome of type II 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.

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, incidences and prevalence of underweight, stunting, healthy weight, overweight, obesity, et cetera.

And then, the key confounders are listed here. 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.

All right, 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, publications, 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.

And, these are inclusion and exclusion criteria. We will include, you know, females who are pregnant, females capable of becoming pregnant. And, again, excluding hospitalized patients, studies that exclusively enroll based -- subjects based on pregnancies conceived using 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. 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.

All right, 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 enrolled mothers who gave birth

to pre-term infants, and those that exclusively enroll individuals diagnosed with a particular relevant disease, including severe under nutrition or those hospitalized with an illness or injury.

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.

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 this is for postpartum weight loss. Same intervention or exposure. Same comparator.

And then, the outcome is changed from weight -- or 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.

So, this is an example of work underway 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. The screening process occurred and then articles

ultimately included number 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 underway, 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.

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, you know, 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 up, 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. Hopefully, we'll have a good amount of that done to present at the next public meeting.

And, continue with crosscutting discussions with especially the analysis group and B24 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.

MEMBER DEWEY: Kay Dewey.

I just have a quick question about what you said about treating total energy intake as another factor to be considered. You said that you would be taking into account if it was handled appropriately.

And, I'm just wondering quite what that 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?

MEMBER MAYER-DAVIS: So, that's a great example of a situation in which total energy might not be adjusted for, as is common, especially epidemiological literature, as a confounder, but when, in fact, total energy may not be a confounder, it might be a mediator.

And, if a mediator, that's a different question all together. So, that was actually a wonderful example of what we meant by not

including total energy as a confounder, but rather as another factor to be considered.

Confounding is not the only role, you know, that total energy plays in any given analysis, depending on the research question. So, that was a great example so thank you for that.

CHAIR SCHNEEMAN: Other questions or comments?

Great. Jamy?

MEMBER 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 controlled 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. Would that be the same intent in terms of what we're trying to get at with that particular question?

MEMBER MAYER-DAVIS: Right. So, if there's a study that's an RCT looking at approaches to, you know, 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.

You know, presumably, you know, the women would be, you know, 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 an 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 with gestational diabetes.

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, you know, optimal postpartum weight loss, those would be included.

And, anyone can correct me and maybe we need to again at the analytic framework and make sure that that's clear.

MEMBER ARD: Even if a calorie restriction were prescribed?

MEMBER MAYER-DAVIS: I would -- I don't see any reason that that would be excluded.

MEMBER 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 it wasn't controlled adequately then it would be confounded

for our interpretation.

MEMBER MAYER-DAVIS: Right, and thanks for that clarification because that was my assumption that I didn't articulate. So, thank you for that.

CHAIR 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.

MEMBER MAYER-DAVIS: Yes. I mean, it might be good to just note in terms of the comparator, this is maybe where this comes in with beverage as 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.

So, that's how we're framing the comparator as we're taking this first look at beverages explicitly, you know, as part of the Dietary Guidelines process.

MEMBER BOUSHEY: In one of the analytical frameworks, one of the key confounders was other supplemental sugar. And, I may have got that --

MEMBER MAYER-DAVIS: Naturally occurring.

MEMBER BOUSHEY: Oh, 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've --

And, the reason I was thinking about that was that it was a key confounder and since, you know, if, you know, a study gets lower rank

if it's missing a key confounder.

And so, I just was wondering how powerful this was that it was a key confounder?

MEMBER MAYER-DAVIS: So, yes. This is a rather difficult one because, you know, 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 to, say, fructose, whether it's, you know, added, you know, as an, you know, high fructose corn syrup or something versus naturally occurring fructose.

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

So, you know, we're just going to have

to see, you know, what is possible to discern for different papers and, you know, literature where we can't sort that out, you know, obviously, will not be given the same, you know, level of validity.

MEMBER MATTES: Just, I mean, 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.

CHAIR SCHNEEMAN: Any other questions or comments for those of you strong enough to push that button?

(Laughter.)

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

VICE CHAIR KLEINMAN: Yes, 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.

MEMBER 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 and you'll hear in a minute.

And, the subcommittee's 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 II diabetes, gestational weight gain, and

postpartum weight loss.

The subcommittee has drafted a conclusion that I'm going to present in a minute on one of these 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 changed 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. And, you 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 a meal was removed and secondary eating was added since the July meeting.

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?

And, 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 time of daily eating occasions furthers 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 two years and older, not less than that, two years and older.

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 chrononutrition 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 exposure.

And, two main components are on this slide, as you'll see. 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 zero 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. 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 of the 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 participants as laid out

in the prior presentations.

However, the subcommittee decided to add an exclusion criteria that would exclude studies that exclusively enroll subjects post-bariatric surgery.

The rationale for this decision was that this population of participants are not generalizable to the general U.S. 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 on 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.

For this criteria, studies that use a food frequency questionnaire on at least two occasions which measure usual diet over the past month or year would qualify 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.

This is our flow chart 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 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, zero articles were identified to include in the review. So, a total of zero articles were included in the systematic review at the end of the search and screening process, making our report very short -- null.

So, the subcommittee was very interested in the reasons why the systematic

review had zero articles and how their specific inclusion and exclusion criteria was determining this selection.

Three of the 18 full text articles would have been included for all other criteria except a dietary data collection inclusion/exclusion criteria -- except for the dietary data collection inclusion 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 zero at the end.

The description and summary of the evidence is that no studies published between January 2000 and June 2019 met the inclusion criteria to this systematic review.

So, our conclusion statement then is

that there's no evidence based on our criteria -- on criteria to determine if there's a relationship between the frequency of eating and all-cause mortality.

And, that 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.

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.

VICE CHAIR KLEINMAN: So, it's open for comments or questions.

Kay?

MEMBER 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?

MEMBER 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.

MEMBER LEIDY: No. So, I mean, the criteria that you talked about was just for primarily for randomized controlled trials --

MEMBER HEYMSFIELD: Right.

MEMBER LEIDY: -- you need two different time points?

MEMBER HEYMSFIELD: Yes.

MEMBER LEIDY: We were thinking a lot for the -- more of the observational studies where they would have dietary -- or 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, we were in the mind set was randomized controlled trials were what you would think of recalls or that type of

collection as a minimum.

The food frequency questionnaires would be included within that criteria because they generally are asking over a long period of time.

MEMBER 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 --

MEMBER LEIDY: Yes.

MEMBER DEWEY: -- days over two time points?

MEMBER LEIDY: You need two different time points.

MEMBER DEWEY: So, your minimum is three days at baseline and three days at the end. So, really, that's a marker of adherence.

MEMBER LEIDY: Carol, you're shaking your head no.

MEMBER BOUSHEY: No, I, 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.

MEMBER LEIDY: Right, because it's included three days because it generally asks --

MEMBER BOUSHEY: Yes.

MEMBER LEIDY: -- over a week or a month.

But going back to the two time points and, Rick, to -- the four of us are 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 --

MEMBER BOUSHEY: Right.

MEMBER LEIDY: What we didn't establish is the time interval between those. So, to 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 that baseline and then some time point later on.

VICE CHAIR KLEINMAN: But it wasn't meant to be a measure of adherence as much as a measure of reliability.

MEMBER LEIDY: Right.

MEMBER HEYMSFIELD: Right.

VICE CHAIR KLEINMAN: When 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.

MEMBER 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.

VICE CHAIR KLEINMAN: Yes.

MEMBER MATTES: Of compliance and --

VICE CHAIR KLEINMAN: Both.

MEMBER MATTES: In that case, it would solve both problems.

VICE CHAIR KLEINMAN: Yes.

MEMBER MATTES: It would be reliability and compliance.

MEMBER 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 longer than that, so we were trying to get away with just the one day of assessment. So, that's why making it three days and then having it over, you know, another time point would be helpful.

MEMBER DEWEY: Yes, 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.

It 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.

MEMBER LEIDY: So, I think we have --

MEMBER DEWEY: So, why would three days be required for that? That's a different issue then, a precision of the estimate of frequency of eating.

MEMBER LEIDY: So, one of our points, and then, Rick, you can comment, too, was that we think habitual frequency of eating actually is a key confounder or a key factor in ours because how somebody is eating at baseline can affect the

response in the intervention.

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.

MEMBER 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 from mortality, none of those three were intervention trials. But for some of your other outcomes, it's possible.

MEMBER BOUSHEY: I think the most important concept was the idea of frequency of eating to be able to establish and, you know, get

as close as possible what might be someone's frequency of eating.

You would need to have more than one day of information. 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's 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. And, in the end, we selected three.

MEMBER LEIDY: But I don't think that's the sticking point right now, right? The sticking point is the number of times we're doing that.

MEMBER DEWEY: No, the application to intervention trials.

MEMBER LEIDY: Right, yes.

CHAIR SCHNEEMAN: Yes. 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 studied 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?

VICE CHAIR KLEINMAN: Yes. And, I think what you're saying is, 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.

MEMBER HEYMSFIELD: Yes, it's a good question.

MEMBER DEWEY: If I could just give an example. So, for gestational -- what is your outcome? It's --

MEMBER DONOVAN: Gestational weight gain.

MEMBER DEWEY: But it's also --

MEMBER DONOVAN: Postpartum weight retention.

MEMBER DEWEY: Weight gain. Yes, 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.

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 in adherence or you don't even care about whether they measured adherence.

So, those are the choices that you have.

VICE CHAIR KLEINMAN: But then you would want that study to continue for some period of time at least. So, that couldn't --

MEMBER HEYMSFIELD: Yes, more than two days.

VICE-CHAIR KLEINMAN: -- 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.

MEMBER MATTES: Yeah, you know, part of 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 you're -- if it's a metabolic ward study, you don't need to do this. 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.

VICE CHAIR KLEINMAN: But it becomes an issue of compliance just as that -- in that circumstance, it's an issue of compliance.

MEMBER 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 zero. Only three 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 what you'd see in our other included and exclusion.

And, that's what we're worried about initially that maybe assigning that level of dietary intake might be a problem but I don't think that's going to be the case, especially not moving forward given the number that we have.

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

MEMBER SABATE: I have a question. On these three --

VICE CHAIR KLEINMAN: Just say your

name.

MEMBER SABATE: I'm sorry, Joan Sabate.

On these three that finally, I mean, were excluded, I mean, those were randomized clinical trials or were they observational studies?

MEMBER HEYMSFIELD: Observational.

MEMBER SABATE: Okay. Because going back to slide number eight, when you say inclusion criteria, it looks like it is written in a way that it's only for intervention trials.

That you have 15 participants or 30 participants or power calculations. I think this in relation 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.

MEMBER HEYMSFIELD: Thank you.

MEMBER NOVOTNY: Rachel Novotny.

I actually, you know, was thinking of a much broader question. I don't think we had any criteria for diet assessment for any of the other protocols.

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 of 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, you know, trying to get daily nutrient or daily food patterns. So, maybe we should be thinking collectively about diet assessment.

VICE CHAIR KLEINMAN: Yeah, I mean we should. I think we've probably all thought about this as we were working through this.

I guess the challenge is, do we end up with zero 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 the -- for accurate measurement assessment of intake, but that kind of is what -- where we're at right now, isn't it?

MEMBER NOVOTNY: Or number of days?

VICE CHAIR KLEINMAN: Or number of days.

MEMBER BAILEY: So, when we're using the NHANES data and one day of intake, that's just when we're looking at the mean --

VICE CHAIR KLEINMAN: Yes.

MEMBER BAILEY: -- not the population distribution? When we look at the population distribution, we have two days adjusted for usual intake. The mean is really invariant. It's the tails of the distributions that change, at least for food and nutrients. I don't know as much about frequency of eating.

MEMBER BOUSHEY: I mean, that's the

unique thing about this one. We are not measuring any foods or nutrients. It's just --

VICE CHAIR KLEINMAN: Time.

MEMBER 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?

MEMBER 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. You know, but I am a little bit concerned about throwing -- just throwing out any study that has two days of dietary data and everything 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, you know, make that criteria a little less stringent and have and other factors to be considered kind of aspect to that so that, you know, we don't miss important literature.

And, you know, 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, you know, this being a consideration really across the subcommittees. I think that is important to do.

VICE CHAIR KLEINMAN: Well, I mean, we could reframe that or 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.

MEMBER 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.

VICE CHAIR KLEINMAN: Yeah, yeah.

MEMBER BAILEY: 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.

VICE CHAIR KLEINMAN: Yes, no, yes. No, I think -- 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 --

MEMBER HEYMSFIELD: No, no, I agree.

VICE CHAIR KLEINMAN: So, we can take that back.

Kay?

MEMBER 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.

CHAIR SCHNEEMAN: You know, 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 is -- there are going to be more papers.

I think all-cause mortality was always one where, yes, where we 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.

VICE CHAIR KLEINMAN: Any other comments?

MEMBER HEYMSFIELD: I think that when we framed our final conclusion we did frame it in light of the definitions we used and that, you know, 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.

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 were 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.

VICE CHAIR KLEINMAN: All right, what do we do now?

CHAIR 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.

And, I'm going to give Eve a heads up, I know several of the Committee members have been asking more questions about the reports. 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.

(Whereupon, the above-entitled matter went off the record at 1:59 p.m. and resumed at 2:20 p.m.)

CHAIR 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. 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 a 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.

You know, 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 on -- in the Committee on how we're going to put that forward.

So, I've asked you spontaneously to do this and --

DR. STOODY: Yes, thank you, Barbara.

CHAIR SCHNEEMAN: -- I appreciate your willingness to do that.

DR. 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. I mean, 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, you know, it's a lot of coordination to get all the pieces together and look for some consistency, you know, try to propose some consistency in language so y'all are kind of taking things in a consistent way and things like that.

She has worked on -- and that science writer, her name is Anne Rogers, who, fortunately for her, is on a cruise. But, unfortunately, for us, leaves Janet and I to talk about this.

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

I'll say that Anne has worked with the last two Dietary Guidelines Advisory Committees as well as the -- I think -- the last two Physical Activity Guidelines Advisory Committees. So, she's had a lot of experience supporting advisory committees and including the Dietary Guidelines.

So, the structure, these initial discussions, so, Anne has done a lot of outlining. I think when she first sent us documents, we got eight, you know, 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 and our previous Advisory Committees, but also some of your discussion.

So, the 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 -- or 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. 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, the first part is the Executive Summary. The second is currently labeled setting the stage and integrating the evidence. And, that's really an introduction.

And then, integrating the evidence. And, one of the really important pieces, and there's a lot of discussion around individual conclusion statements, you know, reviews of evidence and this very specific answering the specific question.

But a lot of these questions are interrelated. And, even, you know, 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, and being -- speaking to the dietary patterns, you know, the finding is about dietary patterns across the health outcomes rather than here's, you know, the answer, you know, the conclusion statement related to dietary patterns and CVD versus all-cause mortality.

I mean, bringing it together, integrating it is an important part.

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 -- and keeping that in mind, and 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, a write-up 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 phase. 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, in that the full systematic reviews will post on NESR's website. So, all of the details and all of 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'll 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. That's how, you know, you are 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 and for that -- 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, two years and older, and I think that's up to how, you know, if there's any other -- if it's just two 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, you know, bringing it together by life stage, it's going to require, you know, thinking about that and drafting the conclusions and working to pull those sections together.

So, that is one discussion item, is 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, you know, 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 is important, discuss key -- or excuse

me, key definitions, identify the questions that are addressed in that section. And then, go through the questions.

So, literally, that brief summary from each systematic review, or in the case of data analysis and food pattern modeling, a write-up of the evidence reviewed.

And then, one of the things that we propose 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 people in the U.S.? 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.

So, I think that's the high-level overview, but happy to answer any questions and then open the discussion.

CHAIR SCHNEEMAN: Great. And, 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, at the end of the day, we'll be the ones doing the work.

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

MEMBER DEWEY: Kay Dewey.

Yes, 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 to 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?

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 micro-nutrient status, you know, we may have five or six different micro-nutrient outcomes that we're looking at. And, those are very different from each other.

So, for me, it was helpful to think about this, like 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.

MEMBER NOVOTNY: Rachel Novotny.

I guess I'm wondering about the data analysis and food patterns sections, whether they'll be like split up into age categories or be essentially part of the introduction?

DR. STOODY: Yes, 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, you know, does this make sense or is there some other organization?

So, I'd say, definitely think on the

topic area that we -- she can give you something to kind of react to more. And, I think that can include, yes, where does the data analysis and food pattern modeling make the most sense?

Because it addresses all of them. So, you know, does it make sense to do it once or to divide it? So, I think, yes, there's -- 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 in its own front section.

MEMBER 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, you know, while we've talked a lot more about pregnant women, lactation, and children, we have yet to talk about older people and elderly.

But, I think, you know, to try to

encourage, since, again, typically, the guidelines are addressed to healthy people and wanting to keep them healthy. I think this is a chance to look, you know, longitudinally over the course of life and to somehow further recommend, especially for young women in their reproductive years, but for everyone, you know, 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. 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.

CHAIR SCHNEEMAN: I think you make a

good argument for the life stage approach and in presenting the report that becomes a good rationale.

VICE CHAIR 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 a sort of a 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.

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? Has the staff thought about it?

DR. STOODY: Well, at the moment, it's -- we just proposed the pregnancy and lactation, birth to 24 and two and older.

However, I will say in all the analytic frameworks, there is, I mean, the data is divided by age group. There is a child, adult, older adult.

I think it's a question, if you were to -- I think the discussion about, if you keep two and older all together or subdivide it is a great conversation for you all to have.

For us, I think it would be fantastic, but to your point, I don't know if it's there, you know, if that's possible at this time. But this is the time to have that conversation.

Rick, to your point, you know, if we knew we're doing this, you know, 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 a -- if -- I think it's a discussion for you all or -- and you can just kind of keep it in mind as you get in deeper into some of the reviews of more evidence to see if there is the ability to provide some, you know, break up.

And, it could be that you're -- that section is two and older. And then, within the discussion, you talk about the age, you know, 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 open for you all.

VICE CHAIR KLEINMAN: Yes, and I mean, that kind of is -- 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 two and older, if we really do want to make this useful, and, to just simply say two and older isn't going to really cut it with the public.

So, I -- 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 two if it's going to be three or four, whatever it's going to be.

MEMBER MAYER-DAVIS: So, I think that's really a good suggestion, Ron. And, I also think that, you know, 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 know, you would need to consider.

You know, all of these analytic, you know, frameworks have other factors to be considered. And, you know, it will be different if you're talking about childhood than if you're talking about older adults.

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

MEMBER BAILEY: So, this Regan Bailey.

And, the way that we have our data analysis set up this way is B to 24, two to 19 or 18, and 18 and older and then older adults, depending on the NHANES sampling framework or the DRIs, 65 or 71-plus.

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.

VICE CHAIR KLEINMAN: So, should we agree now what these categories are so that each subcommittee can go back and consider it that way?

MEMBER 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?

It's probably like two to five and then five to some -- I don't know. Does anybody know what those are?

MEMBER BOUSHEY: It depends on what

professional group you're looking at. I mean, it does vary.

(Off-microphone comments.)

MEMBER BOUSHEY: Yes, oh yes, Dietary Guidelines.

CHAIR SCHNEEMAN: But maybe Janet, 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 there.

DR. STOODY: Most of it, though, is more in the patterns. So, in the patterns 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 levels are most appropriate per age group.

In some cases, like for the nutrients of concern, there might be nutrients that are 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, you know, 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, you know, specific recommendations.

MEMBER 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, you know, different findings.

And, there would also need to be adequate data for each of those age groups.

So, I don't -- 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.

MEMBER MAYER-DAVIS: Yes, I think that's actually very reasonable and within what we've said so far. I think that that would work well, you know, to, you know, say this is how we're all organized, if we agree to that.

I don't know that we will, but if we do, then we could systematically say, you know, 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.

VICE CHAIR KLEINMAN: Yes, and I think it often gets -- that nuance often gets lost when we group ages two to 70 together, that, in fact, for the two-year-olds to five-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.

CHAIR 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.

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 the -- their findings and conclusions.

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

VICE CHAIR KLEINMAN: So, how do we go about deciding what are -- it sounds like there's consensus here around --

CHAIR SCHNEEMAN: Life stage.

VICE CHAIR KLEINMAN: -- doing this by life stage. And, how do we go about deciding what those stages are?

MEMBER MAYER-DAVIS: Can we ask Regan once again, could you remind us the ages that you said your group is working on?

MEMBER BAILEY: Well, sometimes it depends on the DRI, sometimes it depends on the NHANES sampling framework.

But, in general, it's B to 24. Of course, I can't find it right here. We have two to five, six to 12, 13 to 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-plus.

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

VICE CHAIR KLEINMAN: Do you have one for pregnant -- pregnancy?

MEMBER BAILEY: So, for pregnancy and lactation, for the data that we have available is generally 20 to 44 years.

VICE CHAIR KLEINMAN: Are they broken out separately as women who are pregnant and lactating?

MEMBER BAILEY: For the pregnancy and lactation specific questions, it's 20 to 44.

VICE CHAIR KLEINMAN: Okay.

MEMBER LEIDY: How does that compare to the physical activity guidelines? Because it would be nice to have those together.

MEMBER BAILEY: That's a good point.

MEMBER LEIDY: To have the age groups.

DR. STOODY: Katrina.

MEMBER LEIDY: I was trying to look for it online, I didn't know.

DR. STOODY: Two to five -- three to five, sorry. Three to five, six to 17.

DR. PIERCY: So, 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 three to five, so the preschool and childcare age.

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

And then, the youth population stayed from six to 17 and then 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, you know, 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, you know, 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 are pregnant and postpartum. So, that population was addressed.

They also had separate pieces talking about older adults. 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. STOODY: So, you didn't define older adults with a specific year?

DR. PIERCY: 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 compared to 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, but your general recommendations for adults are similar

but then being able to tease it out where there's specific guidance and information on nutrients and things by different populations.

But I think a great thing to be discussing now before you start writing, obviously.

VICE CHAIR KLEINMAN: I think of it in four stages, crazy active, active, inactive, and dead.

(Laughter.)

CHAIR SCHNEEMAN: Well then, I have to tell you my definition of older adult.

VICE CHAIR KLEINMAN: Yes?

CHAIR SCHNEEMAN: Older than me.

(Laughter.)

VICE CHAIR KLEINMAN: My definition of a pediatric patient is anybody who's younger or shorter than I am.

(Laughter.)

CHAIR SCHNEEMAN: No, 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, yes, there's something different between youth and adult or young children and adult.

You know, 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.

MEMBER 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, you know, just aren't relevant or less relevant unless we really get into that, you know, sort of really deep primary prevention across, you know, from, you know, birth to the grave.

But things like neuro-cognitive health means something different in the, you know two to 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, you know, generally, does that make sense? Because it's partly done for us in that way.

And, we might say, yes, you know, 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, yes, 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.

MEMBER DEWEY: Kay Dewey.

So, there is a question that is underneath the scope for the Data Analysis and the Food 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, and you'll talk about it tomorrow, is by looking at each of the age groups and what the dietary patterns are.

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 there are dietary patterns are 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?

MEMBER BAILEY: Yes, this is Regan Bailey.

We 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 within NHANES is the cross sectional different age groups. So, we're trying to cobble together, but it's not the same people over time.

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

MEMBER VAN HORN: The best tracking

data in children, though, the only tracking data that exists for, you know, as long as they have, I believe, is the STRIP study which, you know, 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 also -- STRIP was an intervention study, Bogalusa and some of the others were observational studies over a long period of time.

So, you know, there are data and, thankfully, they appear more in those age groups, those children for a longer period of time, obviously.

But, you know, there are studies like Framingham, Framingham offspring, et cetera, you know, that have longitudinal data, observational longitudinal data that are very well characterized and have perpetuated for decades, you know.

So, I don't think it's missing, it's just, you know, they're selective as far as what we need to look at. And, certainly, from childhood to older age, you know, 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.

MEMBER 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 you're mentioning.

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

DR. STOODY: Correct. But there is the discussion section that's been proposed, too. So, I think putting that kind of context or speaking to it there is a place you could do it, yes, I've had that conversation.

MEMBER VAN HORN: Yes, I think, you know, again, in the spirit of trying to guide and direct future, you know, yes, that may be a limitation for us, but to ignore it or not to even, you know, 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.

MEMBER DEWEY: Also -- Kay Dewey again.

It was my understanding that the requirement to use federal data had to do with characterizing, you know, dietary patterns and nutrient intake so, the descriptive part of the work.

This is a question that is a research question, really, and 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.

I know that we have a lot on our 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.

MEMBER 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 because many of the committees have the same outcomes, is that how that is getting organized?

DR. STOODY: Yes, I think that's the next layer of the outline is getting into that level of detail.

And, historically, yes. They've been

just consistently. I think however you all feel it makes the 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 and which I will note is the reports have historically had 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'll travel with the NESR systematic reviews.

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, you know, 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. So, what you 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 you 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.

CHAIR 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 a discussion in a subcommittee that I know, it's not within our scope but it's something important.

But if you all are keeping those, then, you know, 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?

MEMBER 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.

You know, refer to the individuals volunteering for these studies as participants or partners or volunteers rather than the word human subjects which is, you know, rather monarchial.

CHAIR SCHNEEMAN: And, you know, 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.

And, 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.

VICE CHAIR KLEINMAN: I assume Anne will help us with that and particularly be sensitive to the names we give people.

DR. STOODY: Absolutely. As soon as she said that, I thought that's one to go to Anne, yes. She'll have a list of those types of items that she can help keep an eye out for, too.

CHAIR 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.

You know, 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, yes.

MEMBER BAZZANO: Well, I just wanted -- 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 reflects the preponderance of evidence per what the charter says.

So, you know, I was thinking in particular about the -- about going from the 18 studies to the zero 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, you know, 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 it some way in our own conversations in the subcommittees, et cetera.

CHAIR SCHNEEMAN: So, I'm going to

suggest at this point we just go around and then, you know, if there's some points we need to come back to, we can come back for discussion.

So, Beth, you want to --

MEMBER MAYER-DAVIS: I actually I don't think I have anything right now.

CHAIR SCHNEEMAN: Linda, can we grab you before you leave?

(Off-microphone comments.)

CHAIR SCHNEEMAN: You know, just --

VICE CHAIR KLEINMAN: No apologies.

CHAIR SCHNEEMAN: No, no apologies.

MEMBER VAN HORN: I'm really sorry.

(Laughter.)

MEMBER VAN HORN: I have to leave. Why? Because Dr. Jeremiah Stamler 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.

(Laughter.)

MEMBER VAN HORN: 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 know, that you put your ego in your back pocket when you work with Dr. Stamler. He's got red ink all over everything.

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, you know, being here in Washington, D.C. is probably the epitome of being able to make that statement.

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

I'm sorry.

CHAIR SCHNEEMAN: That's great. I knew we wanted to capture your wisdom.

So, Joan?

MEMBER SABATE: I don't have any comment at this point.

CHAIR SCHNEEMAN: Okay.

Linda?

MEMBER 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.

MEMBER DAVIS: So, 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.

It does make our task slightly harder and more intensive but I think it's appropriate.

MEMBER 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 analytic frameworks.

I just know with the -- our example with the eating frequency, it occurred to me that, you know, and even some of the other ones, you know, 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 and, you know, Linda, you had commented, too, about being mindful of all the data that exists.

And, I think that's one hand. And then, on the other hand is, being more

conservative and just focusing on the data that are the - 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 then. I don't know how we tread with that. And so, even with the consistency of the analytical frameworks, you know, 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, you know, Jamy had brought that up last time about having that table, if you will, that we're -- and we went down that path and we addressed quite a bit.

But I think now is more unfolding and 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.

MEMBER ARD: Jamy Ard.

Yes, I forgot I said that. So, the one note I made was that 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, you know, as a dietary pattern.

If, you know, we've had some discussion on that in our subcommittee, but I don't think we've articulated a written statement that, you know, 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.

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, you know, 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, you know, how it would need to be considered in the future.

MEMBER 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. I'm just pondering that at the moment.

MEMBER BAILEY: And then, I just wrote

down, I know we've been having weekly calls and we have meeting minutes from each call, 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.

MEMBER STANG: Jamie Stang.

I guess I echo -- I really support the life course approach. I think that that's very important.

And, sort of to what Heather and Regan have said, 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.

MEMBER 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 breakdown childhood however it makes sense.

And, also, just reiterating, I think the research gaps are really going to be probably the most important contribution. 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, you know, being on B-24, we're

just finding, you know, huge gaps in the knowledge, not only the research but even how do we 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 zero papers making it across the finish line.

MEMBER 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.

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 hope 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.

MEMBER BAILEY: Only for food allergy.

MEMBER 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.

MEMBER 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, you know, 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, do it right there.

I -- 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, you know, is -- we are searching far and wide for anything that meets the definition of a dietary pattern.

And, we are not looking for any one named the moniker of the dietary pattern is irrelevant. You know, so the concern about being able to have NOVA in our pattern search if there is a paper that works with that, we'll be collecting it.

It's all based on patterns and not the names. 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.

MEMBER 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 Stamler and he had ice cream for dessert. And, I thought, if he can do it, so can I.

(Laughter.)

MEMBER HEYMSFIELD: And, it's been working so far.

(Laughter.)

CHAIR SCHNEEMAN: I do, too.

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

MEMBER MATTERS: Oh, okay. So, two brief comments about numbers.

I appreciate your point of we want to have some evidence to say something about. 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 are 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.

MEMBER DONOVAN: I wanted to, I guess, follow up on sharing of these minutes because, you know, we have had a number of Committees meeting together, but I know we're all overwhelmed with.

But if we could see the minutes from the other Committees, it might be -- or do we

have that ability?

CHAIR SCHNEEMAN: I think that is a government staff issue. I know they're all viewed as pre-decisional. So, you know, there are drafts, they're pre-decisional.

But, Eve, what is your sense? Or maybe we need to come back to it. Yes, 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, do you want to --

VICE CHAIR KLEINMAN: You know, 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.

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 -- or proposal on how to work this going forward.

I think it 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 around the summary, Sharon, I think that's really key. We could really advance the pace of this work if we have these summaries in mind as we are working this through rather than try and create this all at the end after 500 hours of conversations. So, I think we should talk about that also after this is over.

CHAIR SCHNEEMAN: 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, you know, 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 because sometimes we don't have evidence, sometimes we have insufficient evidence.

But once you have evidence, you're also then will be asked to assign that grade. So, you know, we might want 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.

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, you know, from the National Academy 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.

So, I think we're ready to adjourn for today. Eve, do you have to adjourn us? I wasn't -- okay.

VICE CHAIR KLEINMAN: We have the power.

CHAIR 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 7th. 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 change to the agenda.

So, with that, I think we're adjourned.

Thank you.

(Whereupon, the above-entitled matter went off the record at 3:27 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Public Meeting

Before: Dietary Guidelines Advisory Committee

Date: 10-24-19

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter