Morning Day 1
https://youtu.be/x4SF4rcgYX4

Dr. Eve 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]

Brandon Lipps: Good morning.

Audience: Good morning.

Brandon Lipps: Let's try one more time. Good morning.

Audience: Good morning.

Brandon Lipps: 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.

[0:01:05] 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 in 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.

[0:01:57] 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 in public health, for the first time, for the entire lifespan. 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 in the meetings of this committee are only a small portion of the time that you have dedicated to this very important process. We know that each of these members are distinguished in their own field, 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.

[0:03:11] 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]

Many thanks also, always, to our staff at the US 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 2020-2025 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.

[0:04:10] 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 stage. Nutrition is one of those factors. It's a very important factor. The Dietary Guidelines are a significant foundational part of that.

It's also important to keep in mind that, with regard to American's 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.

[0:05:06] That's why the 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.

[0:05:58] 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 am honored to serve with Dr. Hutchins, and with that, please come on up.

[Applause]

Scott 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. So…

I'm really pleased to be with you here today again on the journey to develop the 2020 Dietary Guidelines.

You know? Secretary Purdue and all of USDA is very much customer-focused, and we consider both producers and consumers to be our customers.

[0:07:06] 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 US citizens, and in fact, the global population.

As noted, the USDA has four science agencies that 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 showed that food insecurity in the United States has actually been declining over the last 10 years since the recession and has a low period since that period in time, as has, in a separate report, global food insecurity.

[0:08:07] 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 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.

[0:09:10] As indicated, we work in partnerships to provide evidence-based research that helps maintain our strong US food and agriculture system. In fact, the USDA and HHS also cochair the Interagency 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 nutritional research from those subcommittees, and also discussed needed capabilities going forward.

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

Our mission area, with 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, AR 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.

[0:10:10] Very important activities in support of this overall effort.

The 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 scientists 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 in prescriptive nutrition emerge, and these are indeed exciting times, as informed consumers will open up new focus for producers.

[0:11:04] So, either way, whatever the next paradigm is, and the paradigm will continually evolve, US Agriculture and USDA will certainly play a significant role in this regard.

So again, I want to join Deputy Undersecretary Lipps in thanking you all, as members of this committee, for your great service and commitment to the US 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. Eve 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.

[0:12:00] 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 were able to join us in Washington, DC.

19 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—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, 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.

[0:13:09] 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.

[0:14:01] 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, and 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 lifespan, including questions for infants and toddlers.

More information on this new step is available in the interactive timeline that's at DietaryGuidelines.gov.

This is the third of five meetings planned for the 2020 committee.

[0:15:00] 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—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 additional 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 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.

[0:16:01] 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 three.

We encourage you to go to DietaryGuidelines.gov to follow the progress of the committee, and also, to follow today and tomorrow's discussion.

[0:17:05] You'll hear a lot of discussion about protocols. To view the protocols to be discussed today, and also, 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 of the topics and questions. You see a little snapshot from the Dietary Patterns Subcommittee here, which is the first subcommittee to present today.

And if you find a question of interest, click on the question and you're taken to a separate web page 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 that'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.

[0:18:02] ***Dr. Barbara 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, though those subcommittees, have been working very effectively since our last meeting to address the questions that are in our charge.

[0:18:58] 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, 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.

[0:20:03] 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 those subcommittees. We share that burden across the subcommittees.

[0:20:56] 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, 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.

[0:22:00] So, the committee is using three approaches, and this, again, it's just a reminder to folks who were listening in. 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—will be looking at a discussion of the questions that have—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 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.

[0:23:12] As noted in the first meeting, the committee will not be using existing systematic reviews conducted by other organizations to answer 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.

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 papers, and we just need physical help to get to the papers that are most relevant to address the questions.

[0:23:57] 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 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—each protocol details the—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 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.

[0:25:14] 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 analytical 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 a 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.

[0:25:58] 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 analytical framework, 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 papers so the committee is aware of them.

[0:27:18] 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 this. 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 US federal policies, since that's ultimately the role of the Dietary Guidelines.

[0:28:00] 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.

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.

[0:29:01] 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.

Okay, 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.

[0:30:02] 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.

[0:30:58] 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 a disease or clearly have a risk factor.

Likewise, with infants, we're mainly focused on full-term infants, 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.

[0:32:04] 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 as 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.

[0:33:09] So, you can follow the status of where the subcommittees are with each of the committees, and we'll 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, in 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.

[0:34:03] 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. Those 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, the times are approximate, they're not fixed.

[0:35:10] 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.

[0:36:01] 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.

[0:37:04] 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 7th.

So, that's—you can submit comments anytime, but if you really are commenting on those protocols, please try to get them to us by November 7th.

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.

[0:38:12] 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.

[0:39:09] So, we'll be hearing from Dr. Julie Obbagy about the Nutrition Evidence Systematic Review, overview of the methodology. Dr. Obbagy?

Dr. Julie Obbagy: Thank you, Dr. Schneeman. Good morning, everyone. So, my goal today is to give you all an overview, or 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.

[0:40:11] 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 US 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.

[0:40:56] 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 a 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.

[0:41:59] 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 including, having met all of that criteria they have 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.

[0:43:03] 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 and 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.

[0:44:05] 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.

[0:45:01] 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 a 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.

[0:45:59] 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've 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 the articles that were excluded after full text review, including the rationale for why they were excluded.

[0:47:07] This process of literature searching is very systematic. It's very well-documented so that it's 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.

[0:48:09] 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 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.

[0:49:01] 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 the 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 into 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.

[0:49:58] 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.

[0:51:02] 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've drawn.

[0:52:03] They use some predetermined grading criteria to assess the body of evidence, and I'll talk a little bit more about the 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 the case of a limited conclusion statement, that means that modifications to the conclusion statement are likely.

[0:53:01] 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 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 of bias, consistency, directness, precision, and generalizability.

[0:53:59] 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.

[0:55:05] 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.

[0:55:57] 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]

Dr. Barbara Schneeman: So, anyone has questions?

So, I want to give the committee the opportunity to ask some questions.

I have one. 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 lower-case spelling than an uppercase spelling.

[0:57:01] So, it might be useful if you just commented on that and why are we using something slightly different?

Dr. Julie Obbagy: Yeah, 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 at 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.

[0:58:04] 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 US federal guidance and policy.

Dr. Barbara Schneeman: Great. 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, or…?

Dr. Julie Obbagy: Yeah, I think we're somewhere in the neighborhood of 200,000 articles being screened at the moment, and there are more searches to come.

[0:59:04] 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 in 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.

Dr. Barbara Schneeman: Great. Anything?

Great. Thank you so much.

So, we'll move into our first subcommittee report, and Dr. Boushey is going to talk about the Dietary Patterns, the work the Dietary Patterns subcommittee.

[1:00:10] ***Dr. Carol Boushey:*** Thank you.

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.

[1:01:02] As just a reminder, the key definition for dietary patterns in 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.

[1:02:02] The subcommittee updated—am I on the right one here? Yeah, 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.

[1:02:55] Macronutrient proportion diets will be considered when the macronutrient proportions fall outside of the acceptable macronutrient distribution range, the AMDR, even foods and beverages consumed are not described.

These criteria will be adjusted for 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 in 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.

[1:04:03] 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 or 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.

[1:05:02] It's shown on this slide. It 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 the 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/or adherence to the dietary pattern.

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

[1:06:03] The population of interest for the intervention/exposure is children through older adults who are health and/or 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.

[1:07:21] 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—oops, I thought it 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.

[1:07:57] The comparators are consumption of and/or adherence to a different dietary pattern and different levels of consumption and/or adherence to a dietary pattern.

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

The endpoint outcomes are osteoporosis, osteopenia, Rickett's, 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 OHD levels, calcium supplements, and estrogen replacement therapy.

[1:09:01] 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, postmenarchial age in children, well actually, in young adolescence.

We proposed the standard inclusion and exclusion criteria listed here to be applied for all the 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 in 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.

[1:10:06] Case control studies will be excluded for systematic reviews on breast, colorectal, lung, and prostate cancers due to their higher incidence.

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 proposed 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.

[1:10:59] 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 tested 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 of specific macronutrient proportions that fall outside of the AMDR.

[1:12:10] Specifically, the updated inclusion criteria on the bottom left proposed 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 carbohydrate must be less than 45 percent. For consideration as high fat, the proportion of energy 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.

[1:12:59] On this end, they'll be excluding pending all other criteria.

Additionally, studies not providing a description of the macronutrient breakdown for 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, there is diversity in the ranges.

[1:14:09] 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.

[1:15:00] This is in addition to the original systematic review, which included articles published from January 2000 to 2014. There will 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 this 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 searched 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.

[1:16:02] 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 2 diabetes, these three remaining questions will be handled by a combined search strategy to reduce the number of duplicate records being screened.

[1:17:15] The subcommittee is moving into 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.

[1:17:57] 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're 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, in 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 in making all of these reviews take place.

[1:19:05] And so, now I open the floor for questions from members of the committee, and Rick Mattis, I just see you about ready to hop off your seat, so should I call on you first?

Dr. Richard Mattes: So, 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?

Dr. Carol 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 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.

[1:20:02] That is still in the top definition. I went through the same thing, Rick, even though I worked on it.

Other questions? Jamy?

Dr. Jamy Ard: 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 this—don't have the same sort of definitions as a DASH diet or a Mediterranean diet.

[1:21:01] We didn't have the 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 can 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.

Dr. Carol 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.

[1:21:57] ***Dr. Ronald Kleinman:*** So, Ron Kleinman. So, Carol, that would exclude 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?

Dr. Carol Boushey: Yeah, we do ask that they—that the papers outline what the macronutrient distribution was for the—and they would have thought of it as is, because they were actively doing it, but for us, it's was.

Dr. Ronald Kleinman: So, you could consider those diets as long as the papers were describing the diet in its entirety rather than simply focus on the carb or fat?

Dr. Carol Boushey: Right, 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.

Dr. Ronald Kleinman: Yeah, good.

Dr. Steven Heymsfield: I can ask a question. 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.

[1:23:10] How is frequency different in the food patterns?

Dr. Carol Boushey: I'm not sure that the frequency is any different. This aspirational definition, it's not—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.

[1:23:58] But you can go ahead and do frequency as an independent exposure. Be comfortable with that.

Dr. Richard 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?

Dr. Carol 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. It is up, but no, we have not, unless I missed a meeting.

[1:25:00] ***Dr. Barbara 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, because 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.

Dr. Carol Boushey: And I think that—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.

[1:26:05] 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.

We had our questions assigned to us the way that the—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.

Dr. Heather 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 there a hierarchy of the search when NESR—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?

[1:27:06] 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.

Dr. Carol Boushey: We want to—we can actually—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.

Laurel English: This is Laurel 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.

[1:28:06] 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'd 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 search hedge that will

capture those papers, and then we also run though 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.

[1:29:00] ***Dr. Heather 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—is it that 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 then the next piece is when you compile that, what is the hierarchy I guess in terms of what's the primary and secondary, or maybe they're all at the same level?

Dr. Carol Boushey: We haven't—no, there—let me make sure, Heather, I understand your question. Are you asking that we're going to—that we will actually think of the more traditional dietary patterns being our—having a hierarchy higher than the one that's going by the acceptable—below the acceptable macronutrient range?

[1:30:05] We're not considering them in a hierarchy. We only define them that way because we got—because they weren't there first in our plan, but we're not considering them in any type of hierarchy.

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

Dr. Heather Leidy: Good point, and that was not what I was 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 look at the—examine the body of evidence, and then subsequently, you can talk about whether they are plant-based or animal-based diets.

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 the diet you're focusing on, is that the primary that it is macronutrient-specific first and then a food or quality component second?

[1:30:57] ***Dr. Carol Boushey:*** Macronutrient first really only came up with this with this new addition. Prior to that, really, your driver are the foods.

Dr. Heather Leidy: Oh, the foods, okay.

Dr. Carol 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—

Dr. Heather 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.

Dr. Carol Boushey: Right. And so, this is the aspirational definition, and you can really see that the nutrients are even when available. Because with our more traditional dietary patterns, the way we think of them is really food-based. But then you can see why we couldn't then use that definition for doing these ketogenic-style diets, because then that nutrients when available, that's what's driving them.

[1:32:03] ***Dr. Barbara Schneeman:*** I just wanted to comment on this particular topic, because I think the question 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 it's 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 findings, 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.

Again, it's one question we're trying to answer, but as you go through the literature, there are different findings and conclusions.

[1:33:02] ***Dr. Carol Boushey:*** Rachel?

Dr. Rachel Novotny: Rachel Novotny. I want to go back to Rick's question on NOVA, ultra-processed foods, and just make sure I understand the reason for exclusion.

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

Dr. Carol 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 in order to also match the other studies, other studies that have been done before.

[1:33:58] It isn't that, if indeed, someone has used that, and we pick it up, it's not going to be gone. We're just not using it as one of our primary 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.

[Crosstalk 1:41:10]

Dr. Carol Boushey: If it does meet the—or it could meet the definition.

Dr. Rachel Novotny: Absolutely.

Dr. Carol 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—being—where's this little criteria here, is that we have our—which all of us have.

[1:35:03] This right here. If it matches everything in here, we're going to be in business. It will be included. Yeah.

Dr. Rachel Novotny: Okay, thank you.

Dr. Carol Boushey: It's just not our driving definition.

Dr. Barbara Schneeman: 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 and foods, then it might be excluded. So…

Dr. Carol 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.

Dr. Barbara Schneeman: Dr. Sabate?

[1:36:00] ***Dr. Joan 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. But you're leaving NOVA one simplification? I don't remember that we have thoroughly discussed that.

So, probably something that, in our subcommittee, we have to carefully weight the pros and cons and the ability to do so as far as including this.

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.

[1:37:03] ***Dr. Carol Boushey:*** We can start the list. It's one of 10,000.

Dr. Barbara 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.

Dr. Carol Boushey: Yes. Yes, that is our goal, right, 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.

[1:38:08] But because it's—I actually am really astounded that this while concept of dietary patterns, that is very young in the scheme of our field, has really, has really taken off.

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

Dr. Barbara Schneeman: So, we have plenty of time, but I think Linda, you're also willing to start now rather than wait until after?

[1:39:06] 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.

Dr. Linda Snetselaar: Okay.

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

[1:39:59] 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 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.

[1:41:08] 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 will 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?"

[1:41:57] This review will build upon the evidence 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.

[1:42:56] 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 and 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.

[1:44:01] 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, crabs, and oysters.

[1:44:55] 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 used the standard inclusion and exclusion criteria for these categories, as shown on this slide.

[1:45:56] 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 flowchart 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.

[1:47:02] 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.

[1:48:03] 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.

Then 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.

[1:49:05] The evidence for ADD and ADHD included studies that were done in the UK, three of them, and one in the US. 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.

[1:49:58] 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.

The summary of the evidence synthesis, four 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.

[1:51:22] A draft conclusion statement then for ADD and ADHD-like behaviors or 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.

[1:52:04] 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.

[1:53:03] 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.

[1:54:01] 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 of 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.

[1:55:01] 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.

[1:56:06] 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 conclusion 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.

[1:57:02] 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 Butera, and Janet de Jesus.

Thank you all so very much.

And I am happy to answer any questions.

Dr. Barbara 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.

Dr. Linda Snetselaar: Yes, thank you. Very important.

Dr. Barbara Schneeman: So, I will open it up for the committee.

[1:58:01] ***Dr. Steven Heymsfield:*** I don't want to steer us too far away from the topic, but I'm thinking 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'm 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.

Dr. Linda 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.

[1:59:00] 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.

Dr. Linda Van Horn: Linda Van Horn. I 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, etcetera, 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.

[1:59:58] 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.

Dr. Steven Heymsfield: Well yeah, counting that one step further, I guess I was thinking it's very amenable to a prospective randomized kind of a trial, if you can supplement milk and so on with these ingredients. Just a thought.

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

[2:01:02] ***Dr. Kathryn Dewey:*** Ah, 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, etcetera.

And there's a much larger literature, maybe not much larger, but it's larger. And so, 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.

[2:02:05] ***Dr. Linda Snetselaar:*** Yes, thank you so much. And thank you also for being a part of our committee. It was very helpful.

Dr. Carol Boushey: Okay, this is actually also a little minor thing on a definition. Because 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?

Dr. Linda Snetselaar: That came from previous—

Dr. Carol Boushey: The previous one?

Dr. Linda Snetselaar: Yeah.

Dr. Carol Boushey: So, the—so it's these marine animals, and then the seafood. So, these are—oh, I see. They're just examples. Okay, that's what I wanted to see.

Dr. Linda Snetselaar: Exactly.

[2:02:58] ***Dr. Carol Boushey:*** Because I didn't see clams, and they have definitely—some of the razor clams have been involved with neurocognitive changes, so that was—okay, super.

Dr. Linda Snetselaar: Yes, and thank you for that, because I think we discussed that maybe at the last meeting too but thank you.

Dr. Richard Mattes: Rick Mattis. So, one of the questions that you're working on now is seafood consumption during childhood and adolescence and cardiovascular disease.

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

Dr. Linda 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 adolescent studies and studies in children as well.

[2:03:57] So, often, the situation you're in is working with the parents, maybe also working with children in terms of determining intake. Is that responding to your question?

Dr. Richard 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 be used for the analysis.

And 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.

[2:04:59] ***Dr. Linda 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.

Dr. Barbara Schneeman: I would add perhaps, four studies in children, intermediate outcomes may also be, so in terms of what you're looking at, obviously endpoint is desirable health outcome, but you are looking at intermediate outcomes as well.

Dr. Linda 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.

[2:05:59] But it is true that in our group, one of the things that we identified as a very challenging question is where does maternal intake and lactation of seafood or other foods stop in terms of this 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 10 years after the transition between mom providing those data and the child, him or herself, providing those data.

[2:07:05] So, thankfully, there are a couple, not very many, but there are a few prospective and even randomized control trials that we plan to address as far as further honing in on that question.

Dr. Timothy Naimi: Thanks. That was a really nice presentation. Oh, Tim Naimi.

So, my question was, just to get a sense of how kind of the quality scoring played out for the cohort studies, there's this issue with fish eaters being more—certain people, at least in the US, my understanding is that fish eaters are more socially advantaged, and that can be correlated with neurocognitive outcomes in children.

[2:08:00] 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?

Dr. Linda 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 control trial, also done for several years.

And so, we will be getting into more of those studies as time goes on.

[2:08:57] 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?

Dr. Timothy Naimi: Yeah, that's fine. I was just more interested in the issue of confounding, around people who consumed fish and that they're traditionally, I believe it's suggested—

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

Regan Bailey: [indiscernible 2:16:31] So, if you look at the analytical framework, we did try to assess in the study, socioeconomic status as well as parental education to try to get at some of those, because those are known confounders to this question.

[2:10:06] ***Dr. Heather Leidy:*** This is a different question. So, and this might have been the gist and I missed it. So, I was just wondering, with the seafood question, with 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 connection too with seafood in some of these cognitive function outcomes, that it could be lipid composition, but then also this idea of the mercury content.

Dr. Linda Snetselaar: 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.

[2:11:02] 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. 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.

Dr. Heather Leidy: So, is it in your key factors of concern then?

Dr. Linda Snetselaar: Definitely. Yeah.

Dr. Heather Leidy: Thanks.

[2:12:08] ***Dr. Richard Mattes: [indiscernible 2:18:47]*** You have so few papers to split. Again, this is 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?

Dr. Linda 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.

Dr. Regan 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 freshwater versus saltwater, or farmed versus fresh-caught, for example.

[2:13:04] But not a lot of data, but there's more for the other neurocognitive endpoints than for these questions.

Dr. Carol Boushey: And I'm not sure where to put this. 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 we've come across that, but 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 of them are 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, something.

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

[2:13:59] ***Dr. Rachel Novotny:*** Just another detail, Rachel Novotny, on that fish and seafood. I know 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 seafood and fish. It's not intuitive to me, at least.

Dr. Linda Snetselaar: Sure, thank you.

Dr. Linda 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 care to just offer a comment?

Joanne Spahn: This is Joanne Spahn. The authors in the articles did provide analysis separately for fatty fish, lean fish, shellfish, but there were not really significant findings to highlight in the conclusions.

[2:15:15] But in this body of evidence, the subcommittee did discuss the different types of fish, but just was not a lot to conclude.

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

Dr. Carol Boushey: Joanne, you need to speak up a little. The committee's having a hard time hearing you.

Joanne 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.

[2:16:00] 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.

Dr. Linda Van Horn: Thank you.

Dr. Barbara Schneeman: 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.

[2:17:02] And again, we're not at a recommendation point yet, but the committee is getting to the findings and conclusion 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 adjourn—

Off-Screen Speaker: It's actually 12:45.

Dr. Barbara Schneeman: Oh, I'm sorry. Oh, 11:30 to 12:45. Sorry. I need to have my glasses on. So, we will be back at 12:45 and start promptly at that time. So, thank you.