

2020 DIETARY GUIDELINES ADVISORY COMMITTEE

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PUBLIC MEETING

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THURSDAY
OCTOBER 24, 2019

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

MEMBERS PRESENT

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

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

2 9:02 a.m.

3 DR. STODY: Good morning. My name is
4 Eve Stody and I'm the Designated Federal Officer
5 to the 2020 Dietary Guidelines Advisory
6 Committee.

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

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

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

17 Mr. Lipps?

18 (Applause.)

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

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

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

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

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

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

1 based and our Committee helps us to meet this
2 goal.

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

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

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

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

1 this very important process.

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

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

15 (Applause.)

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

22 From the start, USDA and HHS have

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

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

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

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

1 healthier as we move forward.

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

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

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

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

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

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

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

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

22 (Applause.)

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

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

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

22 The Economic Research Service which,

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

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

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

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

1 interpretation of the research for this
2 committee.

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

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

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

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

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

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

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

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

1 support of this overall effort.

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

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

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

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

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

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

11 And, Eve?

12 (Applause.)

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

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

1 here with us today.

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

4 Around 200 people, excuse me, around
5 12,000 -- around 12,000 people are registered for
6 this meeting. No, I have a typo. So, around
7 1,200 people have registered for this meeting,
8 so, you know, watch what you say, no.

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

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

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

1 1985 with the purpose of ensuring that the
2 Dietary Guidelines are grounded in scientific
3 advice from independent experts.

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

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

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

1 And, that 12,000 I did mean.

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

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

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

22 The next two meetings in January and

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

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

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

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

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

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

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

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

22 We encourage you to go to

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

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

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

1 there.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 So, these are the sections of the NESR

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 adapting of these inclusion criteria.

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

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

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

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

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

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

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

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

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

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

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

1 for consistency.

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

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

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

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

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

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

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

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

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

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

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

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

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

16 Dr. Obbagy?

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

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

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

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

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

1 reviews on nutrition related topics.

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

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

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

1 where we made updates prior to working with the
2 2020 Committee.

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

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

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

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

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

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

1 science.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 answering the systematic review question.

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

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

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

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

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

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

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

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

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

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

22 They really thoroughly review all of

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

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

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

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

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

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

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

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

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

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

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

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

22 So, NESR's grading process is also

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

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

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

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

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

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

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

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

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

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

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

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

19 (Applause.)

20 CHAIR SCHNEEMAN: So, can we ask
21 questions?

22 DR. OBBAGY: Yes.

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

4 I have one.

5 DR. OBBAGY: Okay.

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

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

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

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

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

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

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

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

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

1 policy.

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

8 DR. OBBAGY: Yes.

9 CHAIR SCHNEEMAN: Or --

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

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

22 CHAIR SCHNEEMAN: Great, thank you so

1 much.

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

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

9 So, the topic areas this subcommittee
10 was tasked with are listed on the slides. The
11 subcommittee is developing the plan for the topic
12 areas related to dietary patterns and body
13 composition/obesity, cardiovascular disease, type
14 2 diabetes, cancer, and bone health.

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

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

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

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

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

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

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

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

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

1 at the DietaryGuidelines.gov.

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

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

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

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

1 cutoffs to be considered.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 is dietary patterns and bone health.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 considered.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 cancer, the date range of publication will be
2 December 2013 to September 2019. This is in
3 addition to the original systematic review which
4 included articles published from January 2000 to
5 2014.

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

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

16 For bone health, the date range of
17 publication that will be researched is March 2014
18 to September 2019. This date range is in
19 addition to the date of publication covered in
20 the original systematic review which included
21 articles published from January 2000 to March
22 2014.

1 The original systematic review did not
2 consider macronutrient proportion diets which
3 will be covered by an additional literature
4 search with a date range of January 2000 to March
5 2014.

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

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

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

1 The subcommittee is moving into the
2 search and screening process. Five NESR analysts
3 have been independently screening approximately
4 38,000 articles from the electronic search
5 results for three questions: dietary patterns and
6 sarcopenia, all-cause mortality, and
7 neurocognitive health questions.

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

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

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

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

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

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

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

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

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

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

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

9 (Laughter.)

10 MEMBER BOUSHEY: Other questions?

11 Jamy?

12 MEMBER ARD: Press harder. Jamy Ard.

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

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

1 that.

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

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

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

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

18 VICE CHAIR KLEINMAN: So, Ron
19 Kleinman.

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

1 the macronutrient distributions in that diet. Is
2 that right?

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

8 VICE CHAIR KLEINMAN: So, you could
9 consider those diets as long as the papers were
10 describing the diet in its entirety rather than -
11 -

12 MEMBER BOUSHEY: That is right.

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

15 MEMBER BOUSHEY: If it's just --

16 VICE CHAIR KLEINMAN: -- carb or the
17 fat?

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

22 VICE CHAIR KLEINMAN: Yes, good.

1 MEMBER HEYMSFIELD: Steve Heymsfield.

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

7 How is frequency different in the food
8 patterns?

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

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

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

22 MEMBER MATTES: Just because it's a

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

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

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

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

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

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

22 I think what's important is the food

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

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

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

19 MEMBER LEIDY: This is Heather Leidy.
20 Just a question that was asked a
21 little bit earlier, but a follow up. And you had
22 commented, too, about the macronutrient specific

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

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

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

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

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

1 microphone to her mouth.

2 (Laughter.)

3 DR. ENGLISH: This is Laural English.

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

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

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

1 papers.

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

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

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

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

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

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

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

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

18 MEMBER LEIDY: Right, so --

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

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

1 MEMBER BOUSHEY: Okay.

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

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

10 MEMBER BOUSHEY: Right.

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

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

21 MEMBER LEIDY: Okay.

22 MEMBER BOUSHEY: Prior to that,

1 really, your driver are the foods.

2 MEMBER LEIDY: Are the foods, okay.

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

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

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

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

1 that's what's driving them.

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

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

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

20 MEMBER BOUSHEY: Rachel?

21 MEMBER NOVOTNY: Rachel Novotny.

22 I want to go back to Rick's question

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

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

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

11 MEMBER NOVOTNY: Right.

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

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

18 MEMBER NOVOTNY: Okay.

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

21 MEMBER NOVOTNY: As a search?

22 MEMBER BOUSHEY: -- models. That's a

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

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

8 MEMBER BOUSHEY: But that's nice to
9 clarify.

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

12 MEMBER BOUSHEY: Absolutely.

13 MEMBER NOVOTNY: Yes, okay.

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

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

2 MEMBER NOVOTNY: Okay, thank you.

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

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

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

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

20 CHAIR SCHNEEMAN: Yes.

21 So, Dr. Sabate?

22 MEMBER SABATE: Yes, Joan Sabate.

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

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

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

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

18 (Off-microphone comments.)

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

1 conclusion statements.

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

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

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

19 (Laughter.)

20 CHAIR SCHNEEMAN: Okay.

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

1 rather than wait until after -- so, okay.

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

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

8 MEMBER SNETSELAAR: Okay.

9 (Off-microphone comments.)

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

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

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

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

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

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

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

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

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

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

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

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

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

22 We believe this update will allow the

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

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

7 We used NESR systematic review to
8 answer the question.

9 The Dietary Fats and Seafood
10 Subcommittee had a joint meeting with the
11 Pregnancy Lactation Subcommittee and the Birth to
12 24 Months Subcommittee members. This was a very
13 important piece to our process because we felt
14 there were many overlapping concepts and it was
15 very important to include those two subcommittees
16 to assist us in looking at the evidence. They
17 also provided feedback on protocols.

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

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

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

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

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

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

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

1 performance, anxiety, and depression outcomes.

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

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

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

20 One question addresses seafood intake
21 during pregnancy and lactation and the second
22 question addresses seafood intake during

1 childhood.

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

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

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

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

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

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

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

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

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

22 Exposures included total seafood with

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

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

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

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

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

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

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

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

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

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

22 And then, draft conclusion statement

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

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

10 And then, moving on to a description
11 of the evidence for autism spectrum disorder,
12 there were three prospective cohort studies.

13 And, the studies were conducted in the
14 Netherlands, Spain, and the UK.

15 Sample sizes ranged from 1,200 to
16 8,000 participants. The mothers, on the average,
17 were 31 years of age, white, and of middle to
18 high socioeconomic status.

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

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

4 No studies assessed maternal seafood
5 intake during lactation.

6 One study looked at the ASD diagnosis
7 by age 11.

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

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

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

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

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

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

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

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

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

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

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

17 Thank you all so very much.

18 And, I am happy to answer any
19 questions.

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

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

7 MEMBER SNETSELAAR: Yes, thank you,
8 very important.

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

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

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

1 kinds of findings. Just a thought.

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

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

13 MEMBER VAN HORN: Linda Van Horn.

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

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

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

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

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

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

21 MEMBER DEWEY: Okay, Kay Dewey.

22 So, I'd like to just remind everyone

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

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

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

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

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

1 Committee. It was very helpful.

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

9 MEMBER SNETSELAAR: That came from
10 previous --

11 MEMBER BOUSHEY: The previous one,
12 too?

13 MEMBER SNETSELAAR: -- yes.

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

19 MEMBER SNETSELAAR: Exactly.

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

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

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

5 MEMBER BOUSHEY: Okay.

6 MEMBER MATTES: Rick Mattes.

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

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

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

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

1 the children, you know, in terms of determining
2 intake. Is that responding to your question or -
3 -

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 Oh, Tim Naimi.

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

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

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

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

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

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

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

14 So, does that answer your question?

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

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

1 MEMBER NAIMI: Yes.

2 (Off-microphone comments.)

3 MEMBER BAILEY: Thank you also.

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

9 MEMBER LEIDY: A different question.

10 So, and this might have been addressed and I
11 missed it.

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

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

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

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

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

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

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

1 MEMBER SNETSELAAR: Definitely, yes.

2 MEMBER LEIDY: Okay.

3 MEMBER MATTES: Ask one other
4 question.

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

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

15 MEMBER BAILEY: This is Regan again.

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

1 for example.

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

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

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

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

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

22 MEMBER NOVOTNY: Just another detail,

1 Rachel Novotny.

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

8 MEMBER SNETSELAAR: Sure, thank you.

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

15 MS. SPAHN: This is Joanne Spahn.

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

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

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

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

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

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

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

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

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

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

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

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

9 So, we're scheduled for a break at
10 11:30. So, I think we'll just start that break
11 now. But we will be back, my understanding is we
12 have to start at 12:15 for the webinar piece of
13 it. So, we will be -- oh, I'm sorry. Oh, 11:30
14 to 12:45, sorry, need to have my glasses on. So,
15 we will be back at 12:45 and start promptly at
16 that time. So, thank you.

17 (Whereupon, the above-entitled matter
18 went off the record at 11:20 a.m. and resumed at
19 12:48 p.m.)

20 CHAIR SCHNEEMAN: So, we would like to
21 get started. I think we're on time for
22 reconvening the Committee. And, we're all here,

1 so we can reconvene the Committee.

2 And, I just wanted to announce that we
3 are making an adjustment to the agenda, so those
4 of you in the room and those of you online, we've
5 asked the Frequency of Eating subgroup, Dr.
6 Heymsfield to add on to the agenda.

7 So, it'll -- he will give his
8 presentation after the Beverages and Added Sugars
9 Subcommittee. So, we're moving that from
10 tomorrow to this afternoon.

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

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

18 MEMBER MAYER-DAVIS: All right,
19 welcome back, everyone.

20 So, first, the Committee is shown here
21 and I want to thank everybody for their
22 engagement. And, also, I noticed that the NESR

1 team is not listed here. I think they are at the
2 last slide, but they are fabulous and I
3 appreciate the tremendous amount of hard work for
4 this effort.

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

9 (Off-microphone comments.)

10 MEMBER MAYER-DAVIS: All right, so
11 we're going to go over the status of these
12 various questions. So, we're in the process of
13 developing and implementing various of these
14 questions, there are quite a few.

15 So, in terms of developing the plan,
16 working on added sugars with the outcomes of risk
17 for cardiovascular disease, risk of Type II
18 diabetes, and then, growth size, body composition
19 and risk of overweight and obesity.

20 We're looking also at added sugars
21 during pregnancy in relation to gestational
22 weight gain and added sugars during lactation and

1 postpartum weight loss.

2 And so, there's some asterisks there
3 to indicate some protocols that will focus a
4 little bit more on today.

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

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

15 Still to come, we have some work that
16 we'll present preliminarily on the question set
17 related to alcohol consumption with these
18 outcomes that you see listed here, all-cause
19 mortality, certain types of cancer, risk of
20 cardiovascular disease, neurocognitive health as
21 well as growth size, body composition and risk of
22 overweight and obesity including alcohol consumed

1 during lactation and postpartum weight loss.

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

7 Okay, so, now focusing on a question
8 of nonalcoholic beverage consumption, what is the
9 relationship between beverage consumption during
10 lactation and human milk composition and
11 quantity?

12 And so, we're going over the approach
13 to this question and some of what we'll go over
14 applies to other questions related to beverage
15 consumption.

16 So, this is a sort of a chart that
17 allows you to see how we're categorizing
18 beverages so that we can work through this
19 systematically.

20 There are categories related to milk,
21 subcategories of dairy milk, flavored milk, dairy
22 drinks, and substitutes.

1 And then, on the far right, water,
2 plain water, flavored or enhanced water as
3 subcategories.

4 And then, the rest of the nonalcoholic
5 beverages you see in the middle in these
6 categories of 100 percent juice, diet beverages,
7 calorically sweetened beverages, nutritional
8 beverages and coffee and tea.

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

13 So, here are some key definitions and
14 populations for beverages during lactation with
15 respect to human milk composition and quantity.

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

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

1 are exclusively or predominantly breast feeding.

2 And, here are some definitions for a
3 couple of those terms. Exclusive breastfeeding,
4 and these are based on World Health Organization
5 from 2001, in which exclusive breastfeeding is
6 defined as infant receiving no other food or
7 drink, not even water, except for breast milk
8 which can include milk expressed or from a wet
9 nurse.

10 Infants may receive oral rehydration
11 solution, drops or syrups.

12 And then, predominate breast feeding
13 is breast milk, again, including milk expressed
14 or from a wet nurse, breast milk that's the
15 infant's predominant source of nourishment.

16 And, infants in this case may receive
17 liquids including water or water-based drinks or
18 fruit juices, ritual fluids, or oral rehydration
19 solution, drops or syrups. But, again, this is
20 where breast milk is the predominant source of
21 nourishment.

22 In terms of inclusion and exclusion

1 criteria for this question, we're using the
2 standard criteria that we've already heard about
3 earlier this morning with regard to publication
4 status, the language, country, health status of
5 participants.

6 But particular to this question, we
7 are allowing case control and cross sectional
8 studies just because of what we know to be the
9 nature of this literature and what could well be
10 valid study designs for this question.

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

17 Oh, I do want to note, in terms of
18 exclusion criteria, we are excluding studies that
19 exclusively enrolled multiple gestation
20 pregnancies or exclusively present combined
21 analyses of singleton and multiple gestations or
22 human milk from third-parties, banked or donor

1 milk.

2 And then, in terms of health status of
3 study participants, we will include studies that
4 enrolled mothers who are healthy and/or at risk
5 for chronic disease, those that enroll some
6 mothers diagnosed with disease, studies that
7 enroll some mothers who were severely
8 undernourished prior to pregnancy. And, we will
9 also include studies that enroll some or all
10 mothers classified as underweight or obese prior
11 to pregnancy.

12 The studies that are excluded are
13 those in which the study participants exclusively
14 include mothers who gave birth to pre-term
15 infants or studies that exclusively enrolled
16 mothers diagnosed with a particular disease,
17 including severe under nutrition or exclusively
18 enrolled mothers who are hospitalized with an
19 illness or injury. And, those obviously have to
20 do with generalizability.

21 All right, and, this is the analytic
22 framework then for this question of beverages

1 during lactation and human milk composition and
2 quality.

3 You can see the intervention or
4 exposure and that list of beverages reflects the
5 chart that I showed a few minutes ago and how we
6 are sort of thinking about different beverages.

7 And then, the comparator would be
8 different amounts of those beverages or the
9 physical form in which those foods might be
10 consumed.

11 Then, you see below there the
12 population for the human milk composition
13 question and the human milk quantity. And, those
14 are consistent with what I just showed a minute
15 ago.

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

1 proteins.

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

6 And then, in terms of human milk
7 composition, women during lactation, this is the
8 -- I don't need to repeat that, we already talked
9 about the population both for milk composition
10 and also milk quantity.

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

20 Okay, with regard to added sugars,
21 here are some of those questions. What is the
22 relationship between added sugar consumption and

1 risk for cardiovascular disease? Risk for Type II
2 diabetes? Growth, size, body composition, and
3 risk of overweight or obesity?

4 So, we're presenting these in a sort
5 of coordinated fashion because a lot of the
6 analytic framework is common for these outcomes.

7 And then, moving to the question of
8 what is the relationship between added sugars
9 consumption during pregnancy and gestational
10 weight gain?

11 And then, the relationship between
12 added sugars consumption during lactation and
13 postpartum weight loss?

14 So, it's important to first think
15 about what are we considering to be added sugars?
16 And, this is the FDA definition from when -- from
17 2016. You see that here.

18 Sugars that are either added during
19 the processing of foods or are packaged such as,
20 for example, a bag of sugar, and added sugars
21 include, you know, a variety of sugars, sugars
22 from syrups and honey, sugars from concentrated

1 fruit or vegetable juices that are in excess of
2 what would be expected from the same volume of a
3 100 percent of a fruit or a vegetable of the same
4 type.

5 We will consider studies that use a
6 somewhat different definition of added sugars.
7 You know, not everyone would use the same
8 definition, but this FDA 2016 definition is
9 really what we're talking about.

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

13 Additionally, in terms of key
14 definitions for this set of questions, pre-
15 diabetes is defined per the American Diabetes
16 Association. You see that detail here.

17 And, similarly, Type II diabetes
18 defined according to the current ADA definition.

19 All right, in terms of inclusion and
20 exclusion criteria for these added sugars
21 questions, and again, we're talking about added
22 sugars and these outcomes: CVD, Type II diabetes,

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

3 We are using the standard criteria
4 that we've talked about earlier today.

5 And, in terms of inclusion and
6 exclusion criteria with regard to study duration,
7 and this is for the question of relationship
8 between added sugars and growth, size, body
9 composition, and risk of overweight or obesity,
10 we do have a criteria with regard to study
11 duration that we wanted to point out here which
12 is a minimum duration for experimental studies of
13 at least eight weeks.

14 There's not a duration cutoff for
15 observational studies. But when talking about an
16 interventional study and experiment, then that
17 minimum duration is eight weeks.

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

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

3 And then, for Type II diabetes,
4 adolescents 13 to 18, and then, adults 19 and
5 older, including older adults age 65 and older.

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

14 So, we're coordinating with regard to
15 the analytic framework so that the work is
16 coherent, consistent between the two
17 subcommittees and then the NESR team will be, you
18 know, screening, doing the search, screening the
19 literature accordingly. But it is the Birth to
20 24 subcommittee that will really be doing, you
21 know, the lion's share really focusing on that
22 synthesis piece for the question of added sugars

1 for this age group.

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

7 (Laughter.)

8 MEMBER MAYER-DAVIS: All right, so,
9 then continuing, inclusion and exclusion criteria
10 with regard to health status, so, for
11 cardiovascular disease and Type II diabetes,
12 we'll look at studies that enroll participants
13 who are healthy and/or at risk for chronic
14 disease, including those with obesity.

15 Studies can enroll some participants
16 diagnosed with a disease. And, again, for CVD
17 and Type II diabetes, studies can enroll some
18 participants with endpoint outcomes but we will
19 exclude studies that exclusively enroll
20 participants diagnosed with a disease or
21 hospitalized with an illness or injury.

22 In other words, we don't want to be

1 focusing on treatment effects here.

2 And, for CVD only, we will include
3 studies that exclusively enroll participants with
4 high blood pressure, high cholesterol, and are
5 evaluating a CVD endpoint.

6 In other words, studies that aim to
7 prevent cardiovascular disease in individuals who
8 are already at high risk as a consequence of
9 those diagnoses. So, those will be included.

10 In terms of growth, size, body
11 composition, overweight and obesity, we will
12 include studies that enroll participants who are
13 healthy or at risk for chronic disease, studies
14 that enroll some participants with a disease and
15 studies that enroll some participants who are
16 already classified as underweight, stunted,
17 wasted, or obese. But we will exclude studies
18 that enroll individuals diagnosed with disease or
19 hospitalized with an illness or injury or studies
20 that exclusively enroll participants classified
21 as obese for the same reason that we're not
22 focusing on treatment effects.

1 Okay, so, here's the analytic
2 framework for the outcome of cardiovascular
3 disease. The exposure is consumption of added
4 sugars from foods and beverages. And, again, an
5 update, this is for ages 2-plus through older
6 adults.

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

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

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

21 The key confounders are shown here,
22 age, sex, race, ethnicity, SES, alcohol intake

1 for adults, physical activity, anthropometric
2 measures, smoking, and naturally occurring sugar
3 intake.

4 And then, a variety of other factors
5 to be considered, and I'll note here, I can't
6 remember if it's come up earlier today, we are
7 considering total energy intake in these papers.

8 We decided not to include that as a
9 key confounder, though. Because depending on the
10 design of the study, it may be that total energy
11 intake is appropriately considered but not as a
12 confounder per se, again, depending on the design
13 of the study.

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

16 Okay, let's see, this is the analytic
17 framework for type II diabetes, relationship
18 between added sugars and risk of Type II
19 diabetes.

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

22 The comparator the same as the

1 previous slide.

2 The outcome is type II diabetes. And,
3 again, there are some intermediate outcomes that
4 can be considered, hemoglobin A1c when it's not
5 defining the outcome of type II diabetes,
6 glucose, insulin, and pre-diabetes.

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

12 And then, moving to the analytic
13 framework, this is for relationship between added
14 sugars and growth, size, body composition, and
15 risk of overweight and obesity, in which the
16 intervention or exposure is the same and the
17 comparator is the same.

18 And, the outcomes here include weight
19 or weight for age, well, that was there when we
20 still weren't sure what to do with Birth to 24,
21 now we've figured that out.

22 Height, BMI, BMI z-score, various

1 circumferences, body composition and distribution
2 percent, fat mass percent, fat-free masses may be
3 available from the different studies.

4 Also, incidences and prevalence of
5 underweight, stunting, healthy weight,
6 overweight, obesity, et cetera.

7 And then, the key confounders are
8 listed here. Again, similar to what was seen
9 previously and then other factors to be
10 considered also similar to what we saw
11 previously.

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

17 All right, so, this is inclusion and
18 exclusion criteria for the added sugars
19 consumption question.

20 This is what is the relationship
21 between added sugars during pregnancy and
22 gestational weight gain? And what is the

1 relationship between added sugars during
2 lactation and postpartum weight loss? In which
3 we will, again, use the standard criteria, the
4 standard NESR criteria for study design,
5 publications, status, language, country, and
6 health status of participants.

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

12 And, these are inclusion and exclusion
13 criteria. We will include, you know, females who
14 are pregnant, females capable of becoming
15 pregnant. And, again, excluding hospitalized
16 patients, studies that exclusively enroll based -
17 - subjects based on pregnancies conceived using
18 assisted reproductive technologies, studies that
19 exclusively enroll multiple gestation
20 pregnancies, and studies that enroll both
21 singleton and multiple pregnancies, but do not
22 account for singleton versus multiple gestation

1 in the design or analysis and only present
2 aggregate findings. So, those are excluded.

3 For postpartum weight loss, we will
4 include postpartum women who are lactating.
5 Again, excluding hospitalized patients and
6 excluding studies that enroll both lactating and
7 non-lactating mothers, but only present data in
8 combination for those lactating and non-lactating
9 mothers.

10 All right, and this is inclusion and
11 exclusion criteria in terms of the health status
12 of the study participants for gestational weight
13 gain and postpartum weight loss.

14 So, studies that enroll mothers who
15 are healthy or at risk for chronic disease, those
16 that enroll some mothers with diagnosed disease,
17 studies that enroll some mothers who are severely
18 undernourished prior to pregnancy, and studies
19 that enroll some or all mothers classified as
20 underweight or obese.

21 But we will exclude from this review
22 studies that only enrolled mothers who gave birth

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

6 This is the analytic framework for the
7 outcome of gestational weight gain. The exposure
8 is the same. The comparator is the same as
9 mentioned previously. The population criteria
10 are summarized there on the box on the left.

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

16 And then, weight gain in relationship
17 to weight gain recommendations based on pre-
18 pregnancy BMI.

19 And then, you see here key confounders
20 and other factors to be considered that are
21 specific to this question, very similar to what
22 we've seen previously, including considering

1 first trimester weight gain.

2 Okay, and this is for postpartum
3 weight loss. Same intervention or exposure.
4 Same comparator.

5 And then, the outcome is changed from
6 weight -- or change in weight from baseline
7 postpartum to a later time point in the
8 postpartum period, and postpartum weight
9 retention if gestational weight gain is
10 controlled for -- and the population is shown
11 there.

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

15 So, this is an example of work
16 underway and progress. This is for beverages
17 during pregnancy with respect to birth weight.

18 And, it's just kind of interesting to
19 see the search began with an initial
20 identification of 7,646. Some duplicates were
21 identified which cut this down to 4,447. The
22 screening process occurred and then articles

1 ultimately included number 22. And so, those are
2 the studies that are currently under review at
3 this point in time.

4 So, we don't have results from that
5 effort. They're still under review.

6 So, work underway, I mentioned at the
7 beginning of this section that we've been active
8 with regard to the alcohol questions.

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

12 But just to give you an idea of where
13 we are with this, the exposure with regard to
14 alcohol intake is level of consumption of
15 alcoholic beverages as well as the per occasion
16 consumption of alcoholic beverages such as number
17 of drinks per day or drinks per drinking
18 occasion.

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

22 The comparator will be different

1 levels of alcohol consumption for the population
2 of adults age 21 and older. And, we're in the
3 process of, you know, considering what exactly we
4 will include with regard to the key confounders
5 and the other factors that will need to be
6 considered in this particular literature.

7 So, next up, obviously, we will
8 finalize the alcohol protocols and discuss those
9 more completely at the next public meeting.

10 We'll finish the screening questions
11 with complete search results looking at the four
12 beverage questions and the five added sugar
13 questions, and synthesize findings. Hopefully,
14 we'll have a good amount of that done to present
15 at the next public meeting.

16 And, continue with crosscutting
17 discussions with especially the analysis group
18 and B24 Subcommittee.

19 I think that's it. And, these are our
20 subcommittee members. And, there, we have the
21 support staff named. So, thank you very much.

22 And, this is open for questions.

1 MEMBER DEWEY: Kay Dewey.

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

7 And, I'm just wondering quite what
8 that means? Because one possibility is that it
9 could be a mediator which is a very different
10 interpretation of what's going on than a
11 confounder or something else.

12 So, I wonder if you'd like to speak to
13 that?

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

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

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

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

8 CHAIR SCHNEEMAN: Other questions or
9 comments?

10 Great. Jamy?

11 MEMBER ARD: Jamy Ard.

12 I had a question about the gestational
13 weight gain or actually more specifically, the
14 postpartum weight retention studies.

15 So, is it the intent to exclude
16 studies that are intervention studies in that
17 particular scenario? Because those are kind of a
18 little tricky if based on the inclusion/exclusion
19 criteria, right, you could get randomized
20 controlled trials that would assign women to an
21 intervention for weight reduction compared to one
22 that would be a control.

1 But that's not necessarily a disease,
2 per se, right? And, I don't know if that would
3 be the intent. Would that be the same intent in
4 terms of what we're trying to get at with that
5 particular question?

6 MEMBER MAYER-DAVIS: Right. So, if
7 there's a study that's an RCT looking at
8 approaches to, you know, improve that trajectory
9 of weight following delivery, those would be
10 included.

11 And, unless I missed something in the
12 analytic framework that perhaps needs to be
13 clarified or corrected, we would not want to
14 exclude those kinds of studies.

15 You know, presumably, you know, the
16 women would be, you know, generally healthy women
17 who didn't all have, say, a particular diagnosis.

18 So, for example, if all the women in
19 the study had a diagnosis of gestational
20 diabetes, that would be an example of one that
21 would be excluded because it would be more
22 focused on treatment essentially or prevention of

1 development of diabetes following delivery all in
2 women with gestational diabetes.

3 And, that's a rather different
4 question. So, with that type of exception,
5 otherwise, the kind of study that you're
6 describing, an RCT where the outcome is, you
7 know, optimal postpartum weight loss, those would
8 be included.

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

12 MEMBER ARD: Even if a calorie
13 restriction were prescribed?

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

16 MEMBER MATTES: I think the issue is
17 whether there is control for the beverage. The
18 question is, does drinking something during that
19 period of time have some differential effect?

20 So, as long as that's the independent
21 variable, it would stay in. If it wasn't
22 controlled adequately then it would be confounded

1 for our interpretation.

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

6 CHAIR SCHNEEMAN: I think it is
7 worthwhile to observe that this is the first time
8 there have been beverage questions. So, it has
9 been challenging for the subcommittee to develop
10 the protocols and keep the focus on the beverage
11 aspect of it.

12 So, I don't know if there's anything
13 more you want to add, but it is something unique
14 for this evaluation.

15 MEMBER MAYER-DAVIS: Yes. I mean, it
16 might be good to just note in terms of the
17 comparator, this is maybe where this comes in
18 with beverage as a new sort of component of this
19 process in general.

20 So, the comparator has to do with the
21 amount of intake of whatever beverage is being
22 looked at in a given study or the comparator

1 could be the physical -- could be with respect to
2 the physical form, whether something is in the
3 physical form of a beverage versus a solid
4 physical form.

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

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

13 MEMBER MAYER-DAVIS: Naturally
14 occurring.

15 MEMBER BOUSHEY: Oh, was it naturally
16 occurring sugar or something along those lines?

17 And, I was just curious how widely
18 that is available in these studies that you're
19 reviewing? Maybe you've --

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

1 if it's missing a key confounder.

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

4 MEMBER MAYER-DAVIS: So, yes. This is
5 a rather difficult one because, you know, it is a
6 question, how many studies really adjust for
7 this. And, I can just think of a couple studies
8 just that are going through my mind with respect
9 to, say, fructose, whether it's, you know, added,
10 you know, as an, you know, high fructose corn
11 syrup or something versus naturally occurring
12 fructose.

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

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

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

6 MEMBER MATTES: Just, I mean, just to
7 sort of add to that, one of the issues that we
8 struggled with is the concept of added sugar
9 versus just the physiology of taking in sugar,
10 whether it's added or inherent.

11 And so, we thought it was important
12 that we capture totality of sugar intake if we
13 want to be able to isolate the added sugar
14 intake.

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

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

20 (Laughter.)

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

1 VICE CHAIR KLEINMAN: Yes, so we have
2 a change in the schedule since we're being so
3 effective and efficient.

4 And, we're going to move now to the
5 Frequency of Eating Report. And, Steve
6 Heymsfield is going to give that to us.

7 MEMBER HEYMSFIELD: Thanks, Ron.

8 I want to start by thanking the
9 subcommittee members of which you're one, the
10 federal support staff, the NESR liaisons and the
11 staff leadership. They've been all very helpful
12 in putting this together.

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

17 And, the subcommittee's implementing
18 the plan and currently screening potential
19 articles for the topic areas related to frequency
20 of eating and I'll read these, for body
21 composition, obesity, cardiovascular disease,
22 Type II diabetes, gestational weight gain, and

1 postpartum weight loss.

2 The subcommittee has drafted a
3 conclusion that I'm going to present in a minute
4 on one of these areas which is frequency of
5 eating related to mortality.

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

11 These are posted on
12 DietaryGuidelines.gov so you can look at them
13 there.

14 None of the edits that were made
15 substantially changed the intent of the conduct
16 of the frequency of eating systematic reviews.

17 Specific edits to the key definitions
18 and to the analytic framework will be identified
19 in a few slides that follow.

20 At the second public meeting in July,
21 the Frequency of Eating Subcommittee presented
22 our proposed key definitions. And, you see some

1 of them right here.

2 Based on the full Committee and public
3 comments, the subcommittee has updated a few of
4 these definitions here. And, you'll see that
5 frequency of eating really has two main parts,
6 the number of eating occasions and the timing of
7 daily eating occasions.

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

10 Eating occasion was updated to replace
11 caloric with energy yielding.

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

14 And, the definition of fasting has
15 changed since July to clarify that a fasting
16 period may include the consumption of water.

17 The definition of a meal was removed
18 and secondary eating was added since the July
19 meeting.

20 The subcommittee members have now
21 completed our first review, as I mentioned
22 earlier, answering the question, what is the

1 relationship between frequency of eating and all-
2 cause mortality?

3 And, this slide shows our analytic
4 framework with the intervention exposure being
5 frequency of eating. And, as I mentioned
6 earlier, that includes two main components, the
7 number of daily eating occasions and the timing
8 of daily eating occasions.

9 And, the time of daily eating
10 occasions furthers clarified by adding the timing
11 of weekly eating occasions, for example, weekday
12 and weekend, meal skipping, and fasting time.

13 Now, let me give you a few details
14 about this slide. First of all, the questions
15 that will be looked at in a population of two
16 years and older, not less than that, two years
17 and older.

18 After the last public meeting in July,
19 adjustments have been made to the list of key
20 confounders and other factors to be considered,
21 including moving total energy intake from a key
22 confounder to another factor to be considered and

1 adding chrononutrition factors and secondary
2 eating to the list of other factors in response
3 to Committee feedback. So, that's our analytic
4 framework.

5 This just shows the standard NESR
6 criteria that the Frequency of Eating
7 Subcommittee will be adopting. And, these have
8 all been detailed in previous presentations.

9 These are, let's see, this slide shows
10 the details of the inclusion/exclusion criteria
11 for the intervention exposure.

12 And, two main components are on this
13 slide, as you'll see. First, age of study
14 participants and date of publication. And, these
15 were all presented earlier in July by Dr. Leidy.

16 With respect to age of study
17 participants, all frequency of eating questions
18 will include populations from children to older
19 adults and will exclude studies that exclusively
20 enroll infants and toddlers between the ages of
21 zero and 24 months.

22 And then, second, with respect to date

1 of publication, the Frequency of Eating
2 Subcommittee decided to set the date ranges of
3 all searches from 2000 to the present.

4 The rationale for this decision was
5 based on the change in quality of research in
6 this field improving over time.

7 Different, more objective
8 methodologies are available today compared to the
9 past.

10 Additionally, eating patterns in the
11 United States today are so different than 20
12 years ago or more. The controls that are used in
13 studies earlier than 2000 are not appropriate for
14 today's food patterns and food intake.

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

19 First, with respect to health status
20 of study participants, the Frequency of Eating
21 Subcommittee used the standard NESR criteria for
22 health status of study participants as laid out

1 in the prior presentations.

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

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

9 The reason for that is after bariatric
10 surgery, it's common to be told by your physician
11 to eat smaller, more frequent meals throughout
12 the day. Because of this, it was perceived that
13 there may be literature on the frequency of
14 eating space that may fit our criteria and we
15 wanted to ensure that these were not included.

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

22 We felt that it was important to

1 ensure that the studies being included were
2 capturing habitual or usual eating frequency and
3 not just based on one dietary measure.

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

9 Now, with respect to size of study
10 groups, the Frequency of Eating Subcommittee
11 decided to add a criteria around the size of
12 study groups.

13 The study needs to have at least 15
14 participants for studies using within subject
15 analyses or 30 participants for studies using
16 between subject analyses. Or they would need to
17 include a power calculation in the publication.

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

1 This is our flow chart illustrating
2 the literature search and screening results for
3 articles examining the relationship between the
4 frequency of eating and all-cause mortality.

5 The literature search yielded a very
6 large number of articles, 4,791. After
7 duplicates removed from that group, 4,174
8 articles were screened at the title level.

9 And, during the title screening, 4,030
10 articles were screened out.

11 During the abstract screening, 126
12 articles were screened out.

13 And, during full text screening, 18
14 articles were screened out.

15 During the hand search, zero articles
16 were identified to include in the review. So, a
17 total of zero articles were included in the
18 systematic review at the end of the search and
19 screening process, making our report very short -
20 -- null.

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

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

4 Three of the 18 full text articles
5 would have been included for all other criteria
6 except a dietary data collection
7 inclusion/exclusion criteria -- except for the
8 dietary data collection inclusion criteria.

9 All three papers only had one dietary
10 data collection time point. The subcommittee
11 feels strongly that in order to achieve a
12 reliable measure of typical or habitual
13 frequency, more than one dietary data collection
14 time point is required.

15 So, that explains largely why these
16 papers got excluded and why we ended up with zero
17 at the end.

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

22 So, our conclusion statement then is

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

5 And, that spells it out in a little
6 more detail there, but that's pretty much the
7 bottom line of our review of almost 5,000
8 publications.

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

16 Because the significant overlap in
17 search results, these remaining questions will be
18 handled by a combined search strategy to reduce
19 the number of duplicate records being screened.

20 This search includes about 35,000
21 articles that are currently being screened
22 independently by two NESR analysts.

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

5 So, I want to thank, again, the
6 subcommittee members for their hard work on this
7 and we've done one complete project at this
8 point.

9 Thanks very much.

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

12 Kay?

13 MEMBER DEWEY: Thank you, Kay Dewey.

14 So, I have a question about the
15 criteria for the number of dietary days that you
16 described.

17 What if it's an experimental study?
18 Is that criterion only applied to observational
19 studies or is that also for experimental studies
20 where they might manipulate the frequency of
21 eating?

22 MEMBER HEYMSFIELD: I think we had a

1 proviso in there for randomized trials, didn't
2 we, Rick? I want to say Rick weighed in on this
3 to some extent.

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

7 MEMBER HEYMSFIELD: Right.

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

10 MEMBER HEYMSFIELD: Yes.

11 MEMBER LEIDY: We were thinking a lot
12 for the -- more of the observational studies
13 where they would have dietary -- or not dietary
14 recalls of food frequency questionnaires.

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

20 So, the three days, we were in the
21 mind set was randomized controlled trials were
22 what you would think of recalls or that type of

1 collection as a minimum.

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

6 MEMBER DEWEY: So, if I'm
7 understanding that response, is it three days at
8 baseline and three days at the end or a total of
9 three --

10 MEMBER LEIDY: Yes.

11 MEMBER DEWEY: -- days over two time
12 points?

13 MEMBER LEIDY: You need two different
14 time points.

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

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

20 MEMBER BOUSHEY: No, I, well, I might
21 be confused. But I thought if you were using
22 methods that were collecting dietary data one

1 day, and so that can be a dietary record or a
2 dietary recall, we -- there was the decision that
3 at least three days were needed.

4 For the food frequency questionnaire,
5 it was two food frequency questionnaires, not --
6 three never came up in the food frequency
7 questionnaire world.

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

10 MEMBER BOUSHEY: Yes.

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

13 But going back to the two time points
14 and, Rick, to -- the four of us are on the
15 Committee, I was pretty certain that it was two
16 different time points with randomized control
17 trials as well as observational studies that we
18 wanted to capture two different time courses for,
19 in this case, to answer the all-cause mortality
20 question.

21 So, it would have been two different
22 three day --

1 MEMBER BOUSHEY: Right.

2 MEMBER LEIDY: What we didn't
3 establish is the time interval between those.
4 So, to getting to your point, if for some reason
5 a study -- technically, the study collected three
6 days at baseline and then three-day records a
7 week later. That technically meets our criteria
8 because it was two different time points.

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

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

14 MEMBER LEIDY: Right.

15 MEMBER HEYMSFIELD: Right.

16 VICE CHAIR KLEINMAN: When we were
17 actually accurately capturing frequency of eating
18 over some period of time and that we had two,
19 three-day captures so to speak of what was
20 happening.

21 MEMBER DEWEY: Well, but that's
22 relevant for observational studies. If it's an

1 intervention trial and they've manipulated
2 frequency of eating, then capturing data on that
3 is a marker of compliance.

4 VICE CHAIR KLEINMAN: Yes.

5 MEMBER MATTES: Of compliance and --

6 VICE CHAIR KLEINMAN: Both.

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

9 VICE CHAIR KLEINMAN: Yes.

10 MEMBER MATTES: It would be
11 reliability and compliance.

12 MEMBER LEIDY: I think what we were
13 trying to avoid is the one day dietary records or
14 recalls because eating patterns are different
15 depending across the day. We didn't want to
16 establish it longer than that, so we were trying
17 to get away with just the one day of assessment.
18 So, that's why making it three days and then
19 having it over, you know, another time point
20 would be helpful.

21 MEMBER DEWEY: Yes, I don't have any
22 problem with that for observational studies. I

1 am still struggling, though, with how it applies
2 to intervention trials because an intervention
3 trial doesn't necessarily need to even have that
4 at baseline.

5 It just -- if you're randomly
6 assigning people, you assume the sample size is
7 large enough that they're similar on frequency of
8 eating to begin with.

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

13 MEMBER LEIDY: So, I think we have --

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

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

1 response in the intervention.

2 And so, that's why we wanted to have
3 a baseline where you're actually capturing their
4 eating frequency and using that as part of the
5 criteria.

6 MEMBER DEWEY: Well, that's an
7 interesting question, but that's one that would
8 look at, let's say, effect modification so that
9 you only see that effect of that intervention in
10 those who had high frequency to begin with or low
11 frequency to begin with.

12 But that's not the question that you
13 have in front of you necessarily. So, well, I
14 guess, a related question is, are there any
15 intervention trials? Because this is all moot if
16 there aren't.

17 I'm assuming from mortality, none of
18 those three were intervention trials. But for
19 some of your other outcomes, it's possible.

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

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

3 You would need to have more than one
4 day of information. I mean, that was what the
5 essence of the conversations were.

6 Frequency isn't -- frequency doesn't
7 have the same stable occurrence as your foods and
8 your nutrients. I mean, so, and you can also get
9 the same amount of food and nutrients in one
10 sitting or five sittings.

11 And so, that's really where the --
12 what drove the decision was we -- if it's
13 frequency of eating, that's how many times a
14 person ingests one, two, or three items each time
15 throughout a day.

16 And then, if we wanted to somehow let
17 this be a marker, we would need more than one
18 day. And, in the end, we selected three.

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

1 MEMBER DEWEY: No, the application to
2 intervention trials.

3 MEMBER LEIDY: Right, yes.

4 CHAIR SCHNEEMAN: Yes. If I
5 understand the nature of the question, I'm just -
6 - let me try and see.

7 So, I perceive that part of the
8 question is, if food frequency is studied as an
9 intervention, then does it make sense that you
10 might mark it at the beginning and then you do
11 your intervention and figure out if they're
12 following your intervention.

13 Versus, I'm doing another study and
14 I'm collecting food frequency information but I
15 may have only measured it once during the study.
16 I'm just doing it as part of what I measure but
17 it shows up in a literature search.

18 I mean, is -- I'm trying to
19 understand, is that what we're trying to
20 distinguish between?

21 VICE CHAIR KLEINMAN: Yes. And, I
22 think what you're saying is, if you prescribe the

1 frequency of eating in an intervention trial, so,
2 the subjects must consume food three times a day,
3 then this definition doesn't really apply to that
4 circumstance.

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

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

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

13 MEMBER DONOVAN: Gestational weight
14 gain.

15 MEMBER DEWEY: But it's also --

16 MEMBER DONOVAN: Postpartum weight
17 retention.

18 MEMBER DEWEY: Weight gain. Yes, so,
19 there are some schools of thought that eating
20 smaller amounts more frequently during the day is
21 a positive intervention during pregnancy.

22 And so, you may not have even a

1 baseline measure but you may have randomly
2 assigned women to do that or not and your outcome
3 would be gestational weight gain.

4 So, then, it's a question of, do you
5 absolutely need three days of dietary data on
6 their frequency of eating or do you just need
7 anything at all in adherence or you don't even
8 care about whether they measured adherence.

9 So, those are the choices that you
10 have.

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

14 MEMBER HEYMSFIELD: Yes, more than two
15 days.

16 VICE-CHAIR KLEINMAN: -- that
17 obviously wouldn't be a one-day study. I mean,
18 nobody's thinking about that.

19 But so, over some period of time and
20 I don't know whether we need to define that
21 period of time as a criteria but over some period
22 of time more than one day when one is prescribed

1 a frequency of eating, is the outcome related to
2 that prescription?

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

5 MEMBER MATTES: Yeah, you know, part
6 of the motivation here was getting an accurate
7 record of ingestive behavior is hard even in a
8 controlled trial.

9 And so, it would be just as relevant
10 in an RCT as in an epidemiologic trial to want to
11 get at least two estimates of intake to give you
12 some sense of the reliability of what's being
13 reported there.

14 And so, that was a good deal of the
15 motivation. I mean, if you're -- if it's a
16 metabolic ward study, you don't need to do this.
17 But if you're free-living, you can be told to eat
18 x times a day. Whether you do it or not is
19 another matter.

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

1 MEMBER LEIDY: And, just to comment,
2 you brought it up but it might have been conveyed
3 a little bit differently.

4 So, there were 18 studies that
5 initially got down and then to zero. Only three
6 of the 18 were actually excluded because of the
7 dietary collection approach.

8 So, there were still a number of other
9 reasons that would be typical what you'd see in
10 our other included and exclusion.

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

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

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

22 VICE CHAIR KLEINMAN: Just say your

1 name.

2 MEMBER SABATE: I'm sorry, Joan

3 Sabate.

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

8 MEMBER HEYMSFIELD: Observational.

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

13 That you have 15 participants or 30
14 participants or power calculations. I think this
15 in relation to the outcome of total mortality
16 doesn't match. You're trying to do total
17 mortality with only 15 participants or 30.

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

22 MEMBER HEYMSFIELD: Thank you.

1 MEMBER NOVOTNY: Rachel Novotny.

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

6 So, do we have one? I'm thinking sort
7 of as a committee, do we have one? I mean, most
8 of the NHANES work is going to be one day. So,
9 just I'm thinking as a committee, we probably
10 should think about that.

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

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

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

1 I guess the challenge is, do we end up
2 with zero for everything that we're looking at?
3 I don't know that we want to get into a
4 discussion about the validity of food frequency
5 or recall for the -- for accurate measurement
6 assessment of intake, but that kind of is what --
7 where we're at right now, isn't it?

8 MEMBER NOVOTNY: Or number of days?

9 VICE CHAIR KLEINMAN: Or number of
10 days.

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

14 VICE CHAIR KLEINMAN: Yes.

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

22 MEMBER BOUSHEY: I mean, that's the

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

3 VICE CHAIR KLEINMAN: Time.

4 MEMBER BOUSHEY: It's just if it
5 occurred. It's just a little, it's like how many
6 times did you get gas in your car last week?

7 MEMBER MAYER-DAVIS: So, can I chime
8 in here? So, I've -- I was a little worried in
9 listening to this about the three days.

10 In an ideal world, absolutely, at
11 least. You know, but I am a little bit concerned
12 about throwing -- just throwing out any study
13 that has two days of dietary data and everything
14 about the study meets criteria rather than three
15 days, for example. I have no idea if that was
16 the case, but just as an example.

17 I'm wondering if there's a way to, you
18 know, make that criteria a little less stringent
19 and have and other factors to be considered kind
20 of aspect to that so that, you know, we don't
21 miss important literature.

22 And, you know, as I sit here, I don't

1 know what the right thing is to do exactly. And,
2 I do think it's a very well taken comment,
3 Rachel, about, you know, this being a
4 consideration really across the subcommittees. I
5 think that is important to do.

6 VICE CHAIR KLEINMAN: Well, I mean, we
7 could reframe that or recast it to say more than
8 one day. I think we talked about that. I don't
9 know what the others on the Committee think.

10 MEMBER BAILEY: Well, I think it
11 depends on whether you're looking at an
12 intervention or an observational study. That's
13 what it comes down to.

14 VICE CHAIR KLEINMAN: Yeah, yeah.

15 MEMBER BAILEY: If you have a large,
16 well-controlled clinical trial looking at
17 postpartum weight loss in a large number of women
18 for six weeks, you would exclude that study based
19 on your criteria. Right? But that might be a
20 relevant study.

21 VICE CHAIR KLEINMAN: Yes, no, yes.
22 No, I think -- I definitely think we need to go

1 back and separate out intervention studies and,
2 versus observational studies and come up with --
3 I don't mean to speak for you but --

4 MEMBER HEYMSFIELD: No, no, I agree.

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

7 Kay?

8 MEMBER DEWEY: Kay Dewey again.

9 Prompted by what Rachel said, I'm
10 wondering whether some of the criteria for risk
11 of bias assessment might be relevant here. And,
12 I don't remember them all, maybe the staff can
13 help me.

14 But is there one for the adequacy of
15 exposure assessment? I think there is and that's
16 really what we're talking about here is the
17 adequacy of exposure assessment.

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

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

3 CHAIR SCHNEEMAN: You know, I think
4 some of these comments are probably particularly
5 important going forward to the other outcomes
6 that you're going to be looking at where
7 presumably there is more evidence and there is --
8 there are going to be more papers.

9 I think all-cause mortality was always
10 one where, yes, where we were going to see a lot
11 of papers in that particular area. But I think
12 you still have that opportunity to take those --
13 these comments into consideration to look at
14 those protocols.

15 VICE CHAIR KLEINMAN: Any other
16 comments?

17 MEMBER HEYMSFIELD: I think that when
18 we framed our final conclusion we did frame it in
19 light of the definitions we used and that, you
20 know, we qualified it a little bit. I don't know
21 if you recall the wording, but there just weren't
22 any papers that had more than one evaluation.

1 So, it was pretty easy for this one.

2 But we're not saying there's no
3 relationship between frequency of eating and all-
4 cause mortality. There's none based on our
5 criteria. So, I think if there were papers --
6 two studies that were available, we excluded them
7 in this case but we qualified our definition at
8 least based on what we had, which is largely
9 empirical. And, I think maybe in the future
10 going forward, the details of those decisions
11 need to be considered further, not just now but
12 maybe for future studies.

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

15 CHAIR SCHNEEMAN: Well, I'm going to
16 suggest we take a short break, a 15-minute break.
17 And then, we will come back, we'll have more
18 opportunity for discussion.

19 And, I'm going to give Eve a heads up,
20 I know several of the Committee members have been
21 asking more questions about the reports. So, I
22 think there could be time for us to maybe get

1 some discussion going on what is it we're working
2 toward, especially now that more of the
3 Committees are reaching that point of developing
4 their conclusions, their evidence portfolios, it
5 would be good to help our thinking now.

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

8 (Whereupon, the above-entitled matter
9 went off the record at 1:59 p.m. and resumed at
10 2:20 p.m.)

11 CHAIR SCHNEEMAN: So, if we could get
12 started again, if we could get the Committee
13 members back. And, so, I just wanted to note,
14 given where we are with the subcommittee reports
15 where we've now finished the Dietary Patterns,
16 the Dietary Fats and Seafood, Beverages and Added
17 Sugars and Frequency of Eating, we'll start again
18 tomorrow morning.

19 But it looks like we'll probably be
20 able to do the three remaining subgroup reports
21 before lunch. So, we're aiming to do that.

22 Again, if we need more time, we will

1 take more time. But I just wanted to alert
2 people that, if, in fact, the schedule goes like
3 today, we will consider moving all of them up to
4 happen before lunch.

5 So, as noted before we took a break,
6 I asked Eve and Janet if we could have some
7 discussion about the nature of the report that
8 the Committee as a whole will be submitting.

9 You know, there are a lot of changes
10 that have been happening with the Dietary
11 Guidelines process. And so, I think it's useful
12 for us to be thinking about what we're aiming for
13 in that report and make sure that there's
14 agreement on -- in the Committee on how we're
15 going to put that forward.

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

18 DR. STODY: Yes, thank you, Barbara.

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

21 DR. STODY: So, maybe just a little
22 bit up front. We've talked to a few Members

1 about the proposed report structure to begin with
2 but haven't touched base with all of you, so just
3 a little bit of background.

4 As I think we've mentioned before, we
5 do have a science writer. And, I think that
6 name, she doesn't literally write, as Barbara's
7 noted. I mean, and, as y'all know, the report,
8 it's your conclusions, it's your findings.

9 She really tries to help pull it all
10 together. So, the last Committee's report was
11 like 470 pages. And, so, you know, it's a lot of
12 coordination to get all the pieces together and
13 look for some consistency, you know, try to
14 propose some consistency in language so y'all are
15 kind of taking things in a consistent way and
16 things like that.

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

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

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

8 So, the structure, these initial
9 discussions, so, Anne has done a lot of
10 outlining. I think when she first sent us
11 documents, we got eight, you know, eight
12 documents.

13 And, just I think some initial
14 discussion, to give you a sense for the general
15 organization.

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

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

1 And, I should say this outline was
2 informed, as I said, by her previous work and our
3 previous Advisory Committees, but also some of
4 your discussion.

5 So, the discussion about wanting to
6 speak to existing reviews, discussion about where
7 to address future directions. So, that is
8 integrated into this as well.

9 So, it is a report from the Committee
10 to the Departments. And, that begins with a
11 letter to the Secretaries. The report is to the
12 Committee -- or excuse me, to the Secretaries of
13 Agriculture and Health and Human Services.

14 Typically, that comes -- the letter
15 comes from the Chair and Vice Chair on behalf of
16 the Committee.

17 There are -- it has historically been
18 divided into four main sections: an Executive
19 Summary, a discussion that is currently -- and I
20 should say, all this is proposed, it really is up
21 for your discussion and refinement.

22 Some of that you can do early on and

1 I think thinking about the end in mind is great.
2 Some of it you can kind of refine now, but some
3 of it, just know that there's flexibility in how
4 it's structured as you move forward.

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

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

15 But a lot of these questions are
16 interrelated. And, even, you know, there are a
17 series of questions on frequency of eating and a
18 series of questions on dietary patterns.

19 And, one of the things that's
20 important in the report, particularly as an end
21 user is that it's pulled together. And so, that,
22 for example, looking across all of the dietary

1 patterns questions, and being -- speaking to the
2 dietary patterns, you know, the finding is about
3 dietary patterns across the health outcomes
4 rather than here's, you know, the answer, you
5 know, the conclusion statement related to dietary
6 patterns and CVD versus all-cause mortality.

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

9 And, it is something that -- it comes
10 a little bit later and it's often something that
11 is pulled together pretty quickly because, I
12 mean, that's just the way the timeline works, but
13 I think as soon as -- and keeping that in mind,
14 and as much integration as possible is wonderful.

15 So, that's in Part B, kind of the big
16 picture.

17 Part C is methodology. So, there will
18 be a lot of discussion on the three approaches to
19 examine the evidence. And, staff will help
20 support writing that up. So, a write-up around
21 the NESR systematic review methodology, data
22 analysis and food pattern modeling analysis.

1 And then Part D, the fourth main
2 section, is a section -- that's the science
3 phase. And so, that's really where you get into
4 the questions and conclusions.

5 And, we're proposing in the actual
6 report that a lot of the content is more of a
7 summary of your systematic reviews, for example,
8 in that the full systematic reviews will post on
9 NESR's website. So, all of the details and all
10 of the included and excluded articles and all of
11 those pieces, the full -- all of the materials
12 for duplication and transparency will be posted
13 on NESR's website.

14 And, what'll be in the actual report
15 will be a summary. And, the intent there is,
16 you've done all this work in those NESR reviews.
17 It's literally some sections that you'll copy and
18 paste, that you've already worked on and put into
19 the report around the specific questions.

20 So, that is where a lot of the kind of
21 discussion around the questions are. A big piece
22 here is that historically, the science-based

1 chapters have been organized by subcommittee
2 which, obviously, makes a lot of sense. That's
3 how, you know, you are talking within
4 subcommittees.

5 However, what we would propose is, in
6 this -- particularly because of the focus around
7 life stages, Birth to 24 Months, Pregnancy and
8 Lactation, to begin that integration and for that
9 -- those sections within the science-based
10 chapter to be organized by life stage.

11 So, all the conversation around B-24
12 be in a section for B-24. All of the
13 conversation, the questions around Pregnancy and
14 Lactation be together.

15 And then, two years and older, and I
16 think that's up to how, you know, if there's any
17 other -- if it's just two and older, if it's some
18 breakdown within that, it would be great if there
19 is, but if it's more collectively, that's great,
20 too.

21 But the notion here, it will take --
22 part of why we wanted to have -- start having the

1 conversation is, if there's going to be, you
2 know, bringing it together by life stage, it's
3 going to require, you know, thinking about that
4 and drafting the conclusions and working to pull
5 those sections together.

6 So, that is one discussion item, is
7 just around the organization.

8 And, I can say from a lot of that is
9 driven from, at the end of the day, we hope to
10 provide guidance around Birth to 24; guidance for
11 Pregnancy and Lactation.

12 And, if y'all have already kind of
13 pulled that evidence together, it helps, you
14 know, not -- there's one piece here and one piece
15 there, it's just, it's more integrating it
16 together in one place.

17 So, those are -- and I should say, I
18 can talk a little bit about what's proposed in a
19 chapter. So, let's say, a chapter around Birth
20 to 24 Months, let's say, for example, could have
21 a discussion around -- an introduction to why
22 this topic is important, discuss key -- or excuse

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

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

8 And then, one of the things that we
9 propose based on your discussions to date is a
10 discussion section. So, whether it be by
11 question or by topic area, a discussion where you
12 can talk about how -- compare your findings to
13 existing work. And then, also, talk about the
14 public health impact.

15 So, why is this important to the
16 health of people in the U.S.? And, what advice
17 does the Committee have to the Departments in
18 response to the findings of this section as it
19 relates to the Dietary Guidelines?

20 So, again, kind of taking the
21 individual conclusion statements and pulling it
22 together, integrating it, and ultimately,

1 informing the advice that the Committee has to
2 the Departments.

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

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

8 CHAIR SCHNEEMAN: Great. And, it
9 seems like one of the topics that might be good
10 to get Committee input on is, using this approach
11 around life stage. So, it means more work
12 integrating across the subcommittees.

13 But I guess, in my thinking, it's how
14 I understood the focus of this particular Dietary
15 Guidelines process to be, is around life stage.
16 So, I'm interested in comments or suggestions
17 that the Committee has for consideration because,
18 at the end of the day, we'll be the ones doing
19 the work.

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

1 MEMBER DEWEY: Kay Dewey.

2 Yes, we actually discussed this a
3 little bit yesterday and the people in that
4 meeting at least were in agreement with doing it
5 by life stage.

6 So, in fact, tomorrow, when I present
7 B to 24, I'll be showing you which of all the
8 questions are actually handled -- being handled
9 directly by our subcommittee and which of the B-
10 24 questions are being handled by the other
11 subcommittees that will have to feed into that
12 section of the report.

13 One question I raised yesterday and
14 I'll just raise it again is, what exactly is a
15 topic for the discussion to be organized?

16 And, I don't think it's a very large
17 level topic because you can't get that specific
18 about what you think the implications are unless
19 you really kind of boil it down to, well, how
20 would somebody eat differently or feed their
21 children differently?

22 And so, I guess I would like to

1 propose that each subcommittee think about what
2 the topics are because we're doing lots and lots
3 of reviews.

4 But, for example, I was trying to
5 count up how many we are looking at. And, I
6 think it's about 34, what I would call
7 relationships. That isn't how many searches are
8 going on because a lot of relationships are being
9 examined in a consolidated search.

10 But in terms of how an exposure
11 relates to an outcome, I think we're looking at,
12 at least 34 different relationships.

13 And, part of that is because, when we
14 look at something like micro-nutrient status, you
15 know, we may have five or six different micro-
16 nutrient outcomes that we're looking at. And,
17 those are very different from each other.

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

21 So, I think it will help organize how
22 these chapters and the discussions might actually

1 be structured.

2 MEMBER NOVOTNY: Rachel Novotny.

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

7 DR. STOODY: Yes, and currently, they
8 are, at least the data analysis piece is more a
9 front matter section. But I think that's up for
10 discussion.

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

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

22 So, I'd say, definitely think on the

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

5 Because it addresses all of them. So,
6 you know, does it make sense to do it once or to
7 divide it? So, I think, yes, there's -- we can -
8 - she can propose something to react to, but I
9 think that makes a lot of sense to think that
10 through.

11 But, right now, it's just kind of in
12 its own front section.

13 MEMBER VAN HORN: One thing that I'd
14 like to suggest since this is, again, an initial
15 version of the guidelines offering starting at
16 birth the opportunity to look at primary
17 prevention of disease starting at birth.

18 And, I think, you know, while we've
19 talked a lot more about pregnant women,
20 lactation, and children, we have yet to talk
21 about older people and elderly.

22 But, I think, you know, to try to

1 encourage, since, again, typically, the
2 guidelines are addressed to healthy people and
3 wanting to keep them healthy. I think this is a
4 chance to look, you know, longitudinally over the
5 course of life and to somehow further recommend,
6 especially for young women in their reproductive
7 years, but for everyone, you know, that
8 maintaining a focus on diet early in life is the
9 best chance they have of maintaining a higher
10 quality of life longer term.

11 And, of course, also with the thought
12 of in utero developing a healthy baby.

13 Again, we have a long way to go yet
14 before we have sufficient data to put
15 documentation behind all of that, I would imagine
16 that five years from now, there will be even more
17 data. But I see us kind of setting the stage for
18 that type of evolution with regard to the
19 guidelines that are much more focused on long-
20 term prevention throughout the life course
21 starting in childhood and even in utero.

22 CHAIR SCHNEEMAN: I think you make a

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

4 VICE CHAIR KLEINMAN: I guess -- and
5 I support this as well. I guess we do need to
6 think, though, what stages of life we're going to
7 divide this into. And, is this going to be a
8 sort of a modified DRI approach where we look at
9 infants, toddlers, children, adults, older
10 adults?

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

15 And so, how much work is it going to
16 take to now tease that out and segregate it?

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

22 But how are we going to deal with

1 that question? Have you thought about that? Has
2 the staff thought about it?

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

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

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

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

18 Rick, to your point, you know, if we
19 knew we're doing this, you know, if you know
20 you're writing conclusion statements for
21 children, if you know you're writing conclusion
22 statements for older adults, it's good to know

1 that now.

2 So, I think that's a -- if -- I think
3 it's a discussion for you all or -- and you can
4 just kind of keep it in mind as you get in deeper
5 into some of the reviews of more evidence to see
6 if there is the ability to provide some, you
7 know, break up.

8 And, it could be that you're -- that
9 section is two and older. And then, within the
10 discussion, you talk about the age, you know, any
11 kind of differences across the life span within
12 that chapter, but you may not be able to do it
13 for every single topic.

14 So, I think that's open for you all.

15 VICE CHAIR KLEINMAN: Yes, and I mean,
16 that kind of is -- was my point that if we don't
17 -- if we're going to do that, we need to start
18 approaching it that way now.

19 And, I think to do it two and older,
20 if we really do want to make this useful, and, to
21 just simply say two and older isn't going to
22 really cut it with the public.

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

6 MEMBER MAYER-DAVIS: So, I think
7 that's really a good suggestion, Ron. And, I
8 also think that, you know, when we come to
9 looking at the literature and synthesizing what
10 we get, we're going to have to do that anyway,
11 just because of the nature of the questions and
12 the exposures and what, you know, you would need
13 to consider.

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

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

1 MEMBER BAILEY: So, this Regan Bailey.

2 And, the way that we have our data
3 analysis set up this way is B to 24, two to 19 or
4 18, and 18 and older and then older adults,
5 depending on the NHANES sampling framework or the
6 DRIs, 65 or 71-plus.

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

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

15 MEMBER DEWEY: Kay Dewey.

16 A question, is the current guidance
17 that's out there subdivided into age groups?
18 And, if so, what are those age groups?

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

22 MEMBER BOUSHEY: It depends on what

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

3 (Off-microphone comments.)

4 MEMBER BOUSHEY: Yes, oh yes, Dietary
5 Guidelines.

6 CHAIR SCHNEEMAN: But maybe Janet,
7 Eve, can you comment on the current -- the 2015-
8 2020 Dietary Guidelines? To what extent is there
9 any age thinking in those guidelines?

10 I know there is some there.

11 DR. STODY: Most of it, though, is
12 more in the patterns. So, in the patterns there
13 are 12 different food patterns in the Dietary
14 Guidelines at different calorie levels.

15 And, there is discussion as to what
16 age group the calorie level -- what calorie
17 levels are most appropriate per age group.

18 In some cases, like for the nutrients
19 of concern, there might be nutrients that are
20 particular concerns for different stages of life.
21 But the way the current guidelines are written
22 are not necessarily by stage of life, it's more

1 broad and then the food patterns are more, you
2 know, can be tailored based on the calorie needs
3 which vary based on age.

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

8 It's not that the Dietary Guidelines
9 don't address age, it's just more through the
10 patterning than, you know, specific
11 recommendations.

12 MEMBER NAIMI: Just to make a note, I
13 think the life course approach is good. I think
14 we also have to keep in mind, though, that for
15 there to be different recommendations by age
16 group, there should be, you know, different
17 findings.

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

20 So, I don't -- and, there's the issue
21 of trying to keep the guidelines sort of
22 accessible and simple. If anything, they tend to

1 be too, for a lot of people, detailed.

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

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

11 I don't know that we will, but if we
12 do, then we could systematically say, you know,
13 here's the evidence and there is or there isn't
14 sufficient evidence for more specific
15 recommendations for older adults compared to
16 another group, for example. I think that's very
17 reasonable.

18 VICE CHAIR KLEINMAN: Yes, and I think
19 it often gets -- that nuance often gets lost when
20 we group ages two to 70 together, that, in fact,
21 for the two-year-olds to five-year-olds, there's
22 no evidence and for the 65 and up there's lots of

1 evidence on a particular issue.

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

6 CHAIR SCHNEEMAN: So, it sounds like
7 to several of the points being raised, there
8 really is a need to look at this in the context
9 of the subgroup committees how they're working
10 through the data.

11 And, I think the more we can get the
12 data analysis then we're seeing where the
13 nutrients of concern are across life stages. So,
14 that can also feed into the subcommittees in
15 terms of how they're thinking of integrating the
16 -- their findings and conclusions.

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

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

22 CHAIR SCHNEEMAN: Life stage.

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

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

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

10 But, in general, it's B to 24. Of
11 course, I can't find it right here. We have two
12 to five, six to 12, 13 to 18 and then 19 and
13 older.

14 And then, as adults it's usually 18 or
15 19, depending on what data source we have
16 available.

17 And then, older adults in some reports
18 is 65 and older and in others 71-plus.

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

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

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

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

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

11 VICE CHAIR KLEINMAN: Okay.

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

15 MEMBER BAILEY: That's a good point.

16 MEMBER LEIDY: To have the age groups.

17 DR. STODY: Katrina.

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

20 DR. STODY: Two to five -- three to
21 five, sorry. Three to five, six to 17.

22 DR. PIERCY: So, the Physical Activity

1 Guidelines for Americans, so the Second Edition
2 that came out last November, they break it out.

3 So, it's generally always been the
4 youth or the kids and the adults. And, they were
5 able to come down to another segmentation in this
6 last round and look at youth that were ages three
7 to five, so the preschool and childcare age.

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

11 And then, the youth population stayed
12 from six to 17 and then the adults from 18 and
13 older. Although the Committee, just for
14 reference, did have a lot of discussions about
15 the kind of this transition point and what
16 happens, you know, when you turn 18 and magically
17 the physical activity guidelines change from the
18 60 minutes a day for kids to 150 minutes, this is
19 the aerobic piece, per week.

20 So, there's a big shift and the
21 Committee actually looked to see kind of if there
22 was more evidence around, you know, that

1 transition point.

2 And, a lot of it tends to be where the
3 data is and a lot of times, it's studied in youth
4 or in adults. And so, there wasn't enough data
5 to really look -- it was put in as a research
6 need as something to look at further of what's
7 going on at that point? What's going on in
8 college and high school and things like that that
9 may necessitate a shift in the amount of physical
10 activity.

11 But those were kind of the parameters
12 they used and they did have a separate chapter
13 looking at women who are pregnant and postpartum.
14 So, that population was addressed.

15 They also had separate pieces talking
16 about older adults. So, they did look at the
17 population piece but in terms of the quantitative
18 recommendations for how much physical activity.
19 There was the three kind of main buckets that
20 they discussed.

21 DR. STODY: So, you didn't define
22 older adults with a specific year?

1 DR. PIERCY: Generally, they were
2 talking about 65 and older. But, again, it goes
3 back to what was in the literature. And, some of
4 the challenges in being able to really define
5 that.

6 For older adults, they still have a
7 set of guidelines that are identical to the adult
8 population guidelines with a few additional
9 caveats, things like talking about multi
10 component physical activity and the importance of
11 balance training, the importance of thinking
12 about relative intensity of physical activity
13 versus doing absolute.

14 So, thinking about where an older
15 adult is starting which may put them at a
16 different level of intensity compared to somebody
17 who's 30 or 40 years old.

18 So, there was separate guidance for
19 the different populations but in terms of kind of
20 the overall general recommendations. That may be
21 a way to think about this as well, but your
22 general recommendations for adults are similar

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

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

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

10 (Laughter.)

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

13 VICE CHAIR KLEINMAN: Yes?

14 CHAIR SCHNEEMAN: Older than me.

15 (Laughter.)

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

19 (Laughter.)

20 CHAIR SCHNEEMAN: No, I think this is
21 -- it's very -- and that was very useful to have
22 that because sometimes those ages mean that's

1 what we have by those age marks, not that there's
2 something magic that suddenly changed at that age
3 mark.

4 So, I think we -- recognizing the
5 broader categories, I think we still have to wait
6 and see, is there enough in the subcommittees as
7 you're looking at the evidence to say, yes,
8 there's something different between youth and
9 adult or young children and adult.

10 You know, I'm looking at Linda
11 Snetselaar because I'm thinking in the seafood,
12 you are looking across different ages and making
13 -- I think your conclusion statements are
14 beginning to look at those different ages that
15 should come forward in the recommendations.

16 MEMBER ARD: Well, going back and
17 looking at the original topics and questions in
18 terms of how they were listed, there were two
19 lists. One was by subcommittee and the other one
20 was by age groups.

21 And, the thing that's notable there is
22 that, in the listing by age groups, it's clear

1 that there's certain conditions and outcomes
2 that, you know, just aren't relevant or less
3 relevant unless we really get into that, you
4 know, sort of really deep primary prevention
5 across, you know, from, you know, birth to the
6 grave.

7 But things like neuro-cognitive health
8 means something different in the, you know two to
9 18-year-old compared to the 65 and older
10 individual.

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

15 And, we might say, yes, you know, that
16 generally makes sense for us to do it -- to start
17 from that and then maybe tweak.

18 But, to me, that seems reasonable as
19 a starting point. And, it does allow for us to
20 think about how to segregate some of the outcomes
21 when we're thinking through our analytic
22 frameworks and protocols.

1 Because we may, yes, we may really
2 have a lot of data in one area or another, and
3 that means that we can then refine the
4 conclusions around that for a particular age
5 group.

6 MEMBER DEWEY: Kay Dewey.

7 So, there is a question that is
8 underneath the scope for the Data Analysis and
9 the Food Modeling Subcommittee that's about
10 tracking of dietary intake, particularly dietary
11 patterns across life stages.

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

16 But I'm not sure that's going to
17 answer the question of tracking. And, it's a
18 really critical question because, if there's
19 strong tracking, then the rationale for certain
20 guidance at young ages isn't built only on the
21 evidence of a relationship at that age, it's on -
22 - so there are dietary patterns are established

1 and then they stay that way.

2 And then, later, there's a
3 relationship to certain outcomes.

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

7 MEMBER BAILEY: Yes, this is Regan
8 Bailey.

9 We wrestled with that in our
10 subcommittee because, ideally, what you would
11 want is longitudinal data on the same people to
12 make that.

13 But what we have within NHANES is the
14 cross sectional different age groups. So, we're
15 trying to cobble together, but it's not the same
16 people over time.

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

22 MEMBER VAN HORN: The best tracking

1 data in children, though, the only tracking data
2 that exists for, you know, as long as they have,
3 I believe, is the STRIP study which, you know,
4 followed children from six months of age until I
5 think they're now 20, 22, something like that.

6 And, they continue to follow up on
7 those -- that population looking at risk factors
8 for cardiovascular disease.

9 I think the Bogalusa study, which was
10 also -- STRIP was an intervention study, Bogalusa
11 and some of the others were observational studies
12 over a long period of time.

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

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

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

8 MEMBER BAILEY: So, this is Regan
9 again.

10 So, for the work that we're doing,
11 it's my understanding that we're only allowed to
12 use data that are within the federal domain. So,
13 our national data. We're not able to, at this
14 point, use other data like you're mentioning.

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

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

1 MEMBER VAN HORN: Yes, I think, you
2 know, again, in the spirit of trying to guide and
3 direct future, you know, yes, that may be a
4 limitation for us, but to ignore it or not to
5 even, you know, mention it as existing but not
6 fitting our criteria, I think would be a loss.

7 And, again, it would potentially
8 encourage investigators to consider those
9 concepts when moving forward in their work.

10 MEMBER DEWEY: Also -- Kay Dewey again.

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

16 This is a question that is a research
17 question, really, and could be subject to the
18 same kind of literature review and search,
19 systematic review that we're doing for many other
20 questions where we use all kinds of studies.

21 I know that we have a lot on our plate
22 and I'm not necessarily suggesting another

1 analytical framework for a systematic review on
2 this question, but I just wanted to throw that
3 out there is that that would be one way to
4 attempt to answer it.

5 MEMBER MAYER-DAVIS: So, I had another
6 question about the report and this might be
7 already available in the more detailed outline
8 than what I've seen.

9 Which is, within the age categories,
10 now that we're talking about, it's the next level
11 of organization has to do with the exposures
12 according to the subcommittees that we have which
13 makes a lot of sense just practically.

14 So, my question is, within those, is
15 there sort of a standard order with regard to the
16 outcomes because many of the committees have the
17 same outcomes, is that how that is getting
18 organized?

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

22 And, historically, yes. They've been

1 just consistently. I think however you all feel
2 it makes the most sense to organize it. But,
3 yes, taking a consistent approach, is typically
4 how it's been done and makes a lot of sense.

5 The one item that I did not mention
6 and which I will note is the reports have
7 historically had a number of appendices. A lot
8 of times, that's kind of where you can point to
9 tables or additional information.

10 But one of the sections that we
11 proposed is future directions to speak to the key
12 research recommendations the Committee has as you
13 go through your systematic reviews. There's a
14 lot of very focused research recommendations
15 that'll travel with the NESR systematic reviews.

16 So, you'll do a very specific question
17 on frequency of eating and all-cause mortality
18 and have research recommendations specific to
19 that that will stay with the NESR review.

20 But in your report, there might be
21 some things that are high level or, you know,
22 broader research recommendations that the

1 Committee really wants to highlight. So, that's
2 a place to do that.

3 And, there's also been some discussion
4 about just other items that the Committee has
5 wanted to speak to. So, what you all have kind
6 of referred to as let's put that in the parking
7 lot or the bike rack.

8 So, kind of just other things that you
9 all are thinking about. So, just a note that
10 there is going to be, I mean, we're proposing
11 that there's a true home for that, a section in
12 the report that kind of brings that all together.

13 CHAIR SCHNEEMAN: I know I kind of keep
14 some of those in the back of my mind when I hear
15 discussion in the Committees or hear a discussion
16 in a subcommittee that I know, it's not within
17 our scope but it's something important.

18 But if you all are keeping those,
19 then, you know, we need to make sure we have a
20 process to gather them, either feed them to me or
21 to Ron just so we don't lose track of them.

22 So, any other comments relative to the

1 report or questions?

2 MEMBER BOUSHEY: I have just one
3 minor, this is really small. But I did notice
4 today on one of the slides reference to human
5 subjects. And, I thought maybe it'd be better
6 that we adopt people first language.

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

11 CHAIR SCHNEEMAN: And, you know, there
12 are probably some other terminology things that
13 as you work in your subcommittees, if you see
14 things, be sure to flag them.

15 I mean, one of the values of having
16 the discussion around the different protocols is
17 to look for when we can be consistent, we need to
18 be consistent.

19 And, obviously, there are things that
20 are unique to each question, but where we can and
21 should be consistent, we want to be sure and do
22 that.

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

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

8 CHAIR SCHNEEMAN: Okay, well, thank
9 you very much. I think this is very helpful to
10 the Committee and very helpful for thinking about
11 the work going forward.

12 You know, we're about at the end, but
13 I do want to just go around just to see if there
14 are any other thoughts or comments for the good
15 of the order.

16 And, we do have tomorrow still ahead
17 of us. So, if there are some particular things,
18 please let me know, yes.

19 MEMBER BAZZANO: Well, I just wanted
20 -- this is Lydia Bazzano.

21 I just wanted to say one thing that
22 was on my mind. So, we are looking at all of

1 these through a framework of systematic reviews.

2 And so, with those reviews, we have
3 inclusion and exclusion criteria and those are
4 quite important.

5 But I think we also need to be
6 realistic about what's out there so that we can
7 come up with something that ultimately reflects
8 the preponderance of evidence per what the
9 charter says.

10 So, you know, I was thinking in
11 particular about the -- about going from the 18
12 studies to the zero studies. And, I know that
13 that's something you guys are considering and
14 reconsidering.

15 It's just that, we have to strike some
16 balance there to be able to say anything about,
17 you know, we would all love to have the ideal
18 studies, that's not what we have.

19 So, it's just a thought that we need
20 to account for it some way in our own
21 conversations in the subcommittees, et cetera.

22 CHAIR SCHNEEMAN: So, I'm going to

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

4 So, Beth, you want to --

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

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

9 (Off-microphone comments.)

10 CHAIR SCHNEEMAN: You know, just --

11 VICE CHAIR KLEINMAN: No apologies.

12 CHAIR SCHNEEMAN: No, no apologies.

13 MEMBER VAN HORN: I'm really sorry.

14 (Laughter.)

15 MEMBER VAN HORN: I have to leave.

16 Why? Because Dr. Jeremiah Stamler who is the
17 founding chairman of our department at
18 Northwestern, Department of Preventative Medicine
19 is turning 100 years old tomorrow and we have a
20 major celebratory event that I'm supposed to be
21 hosting.

22 (Laughter.)

1 MEMBER VAN HORN: So, I need to get to
2 the airport.

3 But I do want to mention that, even as
4 a post-doc, I remember manuscripts that he wrote,
5 you know, that you put your ego in your back
6 pocket when you work with Dr. Stamler. He's got
7 red ink all over everything.

8 But one of the things that he always
9 wrote was, in terms of the topic of subjects, he
10 would always say, there have been no subjects
11 since 1776.

12 So, I think, you know, being here in
13 Washington, D.C. is probably the epitome of being
14 able to make that statement.

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

22 I'm sorry.

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

3 So, Joan?

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

6 CHAIR SCHNEEMAN: Okay.

7 Linda?

8 MEMBER SNETSELAAR: Just I think it's
9 important as we're looking at studies and sort of
10 the conclusions to those studies that we think
11 about recommendations that are already out there.

12 And, in particular, as we look at
13 children since very young children, since that's
14 something new that we're doing, just to be sure
15 that we are remembering looking at studies that
16 have been done that are benchmarking what should
17 be done.

18 MEMBER DAVIS: So, I'm in agreement
19 with organizing our report by life stage.
20 Because I think when we think of the ultimate end
21 users, both Health and Human Services, USDA, and
22 ultimately, the public, I think that's more

1 appropriate.

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

4 MEMBER LEIDY: Just two comments.
5 Just with the discussions that we've had so far
6 today, it occurred to me that there's still a
7 lack of consistency I think with some of the
8 analytic frameworks.

9 I just know with the -- our example
10 with the eating frequency, it occurred to me
11 that, you know, and even some of the other ones,
12 you know, study duration, sample size, or intake
13 assessments, those bigger things, when we have
14 similar outcomes within our groups are still not
15 as consistent as I think they maybe could be.

16 And then, that kind of leads into my
17 other point, too, in terms of what our approach
18 should be and, you know, Linda, you had
19 commented, too, about being mindful of all the
20 data that exists.

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

1 conservative and just focusing on the data that
2 are the - what you would call the gold standard
3 so that we're not making recommendations now and
4 then five years, we're having to -- well, we
5 wouldn't but others would be retracting what we
6 said and why.

7 So, there's always a balance then. I
8 don't know how we tread with that. And so, even
9 with the consistency of the analytical
10 frameworks, you know, as the example we may be
11 including some studies with some subgroups and
12 then not some studies with others just because we
13 haven't maintained a consistency.

14 And, not to beat this again, but, you
15 know, Jamy had brought that up last time about
16 having that table, if you will, that we're -- and
17 we went down that path and we addressed quite a
18 bit.

19 But I think now is more unfolding and
20 I think it is coming back that there's still a
21 level of inconsistency that I think we could at
22 least address still now moving forward.

1 Because it looks like, so far, that we
2 don't have a lot of concluding statements. And
3 so, that was just something to keep in mind.

4 MEMBER ARD: Jamy Ard.

5 Yes, I forgot I said that. So, the
6 one note I made was that I feel like we need to
7 have a clear rationale or articulation for when
8 we are not considering something in scope.

9 So, the example today was the ultra-
10 processed foods versus, you know, as a dietary
11 pattern.

12 If, you know, we've had some
13 discussion on that in our subcommittee, but I
14 don't think we've articulated a written statement
15 that, you know, someone could pick up and read
16 and say, this is our opinion about this
17 particular topic.

18 And, there probably will be several
19 other things that we know from public comment and
20 from other emerging science that we don't have
21 the purview to delve into. And, people will want
22 to know why we didn't and we can't just say, oh

1 it wasn't a question, like, that won't be
2 satisfactory, I think.

3 I mean, it's nice and simple to say
4 that, but it's not satisfactory. And, I think we
5 can put some of those things in the, you know,
6 sort of areas to be addressed in the future.

7 But I think we also need to have very
8 clear rationale for why we didn't consider it in
9 scope and, you know, how it would need to be
10 considered in the future.

11 MEMBER NOVOTNY: Rachel Novotny.

12 I'm thinking about the report and
13 hoping that we can come up with a framework, a
14 graphical framework of the life stages.

15 And, also thinking about what Kay was
16 saying about the topics, however we end up
17 describing them and whether having got it clear
18 in my head, but whether that could also be
19 illustrated in this framework as some sort of
20 introductory overview or something like that.
21 I'm just pondering that at the moment.

22 MEMBER BAILEY: And then, I just wrote

1 down, I know we've been having weekly calls and
2 we have meeting minutes from each call, but when
3 we write our report that we revisit those meeting
4 minutes so that we have in our report why we made
5 certain decisions so that we're transparent in
6 our report.

7 As well as, I think one of the most
8 important sections that we will write is research
9 recommendations. We've pointed out, even today,
10 how many limitations exist with the data that we
11 do have but how do we fix that moving forward?

12 So, think about that in everything
13 that you're doing.

14 MEMBER STANG: Jamie Stang.

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

18 And, sort of to what Heather and Regan
19 have said, we are identifying gaps. And, I think
20 that we need to be okay with that. I mean,
21 there's nothing we can do about it, but I think
22 that our goal is that five years from now,

1 somebody will have read that report and filled
2 some of those gaps. And, that will have been one
3 of our contributions through this process.

4 MEMBER DONOVAN: Sharon Donovan.

5 One of the problems with being on this
6 side of the table is most of the good ideas have
7 already been mentioned.

8 I would just like to really strongly
9 reiterate the life cycle approach. Being in
10 pediatric nutrition, I think that we need to
11 really breakdown childhood however it makes
12 sense.

13 And, also, just reiterating, I think
14 the research gaps are really going to be probably
15 the most important contribution. And, even if
16 it's just recommendations on how many frequencies
17 or dietary records should be done because we can
18 inform best practices.

19 You know, nutrition research gets so
20 criticized anyhow for the strength of our
21 evidence. So, if we can use this process to
22 improve it and, you know, being on B-24, we're

1 just finding, you know, huge gaps in the
2 knowledge, not only the research but even how do
3 we do we look at NHANES? How do we look at
4 databases?

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

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

10 MEMBER DEWEY: Kay Dewey.

11 I would like to encourage us to
12 distinguish between research gaps, which I
13 strongly agree with that we should be listing
14 those and topics that we're not covering in this
15 particular iteration for the Dietary Guidelines.

16 And there's overlap there but so, I'd
17 like to make a plea that in -- as Regan
18 mentioned, in our meetings and the phone calls,
19 that we become a little more detailed of what
20 gets recorded on those two things.

21 So, if we say anything about, oh, this
22 needs more research or, oh, we're not covering

1 that topic, I hope that we'll be able to capture
2 that so we come back.

3 And, as an example of a topic that
4 we're not covering, I was thinking about this
5 issue of the long-term health implications that
6 Linda mentioned and now she's gone.

7 But there is an enormous body of
8 evidence on what we call the DOHaD hypothesis,
9 the Developmental Origins of Health and Disease.
10 And, I was looking at the topics that we have for
11 pregnancy and lactation and we're not covering
12 DOHaD.

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

17 MEMBER BAILEY: Only for food allergy.

18 MEMBER DEWEY: For food allergy, okay,
19 but otherwise, not cardiovascular disease or
20 blood pressure or anything like that.

21 And, there is a quite large body of
22 evidence on that. Now, that's fine, we can't

1 cover everything but it just popped into my mind
2 that that's a pretty important one that's not on
3 our list.

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

8 MEMBER BOUSHEY: And, mine is sort of
9 one of the things that you said is a little
10 spinoff of it because I believe now, in our
11 meetings, we have these meetings, you know, that
12 we meet as our small groups over the phone and we
13 write down all of our minutes.

14 And, when we do finish a topic, then
15 I think we should take advantage of creating the
16 summary if we can at that point in time, do it
17 right there.

18 I -- because I think this is -- might
19 be a bit overwhelming going back and remembering
20 how we went through all of this since we're doing
21 them sort of one at a time.

22 And so, that might -- and, I think

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

4 And then, I also wanted to make clear
5 that the dietary patterns, you know, is -- we are
6 searching far and wide for anything that meets
7 the definition of a dietary pattern.

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

14 It's all based on patterns and not the
15 names. So, I wanted to make sure that you know
16 that this is a broad search of the broad
17 definition of dietary patterns.

18 And, we maybe need to articulate that
19 better. But and we can work with that on our
20 next phone call to make sure that's really clear.

21 MEMBER HEYMSFIELD: Steve Heymsfield.

22 I have two comments. One, I want to

1 say how valuable the face to face meeting is and
2 hearing the other presentations and exposing our
3 drafts to other people because it was very
4 valuable comments for our session.

5 And, the other thing is, about 50
6 years ago, I had lunch with Jerry Stamler and he
7 had ice cream for dessert. And, I thought, if he
8 can do it, so can I.

9 (Laughter.)

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

12 (Laughter.)

13 CHAIR SCHNEEMAN: I do, too.

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

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

19 I appreciate your point of we want to
20 have some evidence to say something about. But I
21 do support the view that we should hold the
22 highest standards. And, if it results in few

1 papers, then so be it. That's a message for
2 researchers of the future to design their studies
3 to make sure they are of good scientific quality
4 to address it.

5 So, I don't think we compromise on
6 that.

7 And, the other thing is, I think it's
8 just a function of where we are now in doing the
9 reviews and seeing how many we get that we've
10 been talking about numbers.

11 But when we're interpreting the data,
12 one really good study outweighs 47 bad studies.
13 So, even if 47 of them come through, we don't
14 want to be counting numbers. We want to be
15 looking at quality.

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

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

1 have that ability?

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

6 But, Eve, what is your sense? Or
7 maybe we need to come back to it. Yes, we'll
8 come back to it. We'll take the comment, just
9 like we're taking all the comments and we'll
10 figure out a way to do that.

11 So, Ron, do you want to --

12 VICE CHAIR KLEINMAN: You know, I
13 think this last hour has been incredibly helpful
14 and really moved us towards an understanding of
15 what we actually need to come up with.

16 And, I think the task now going
17 forward is to how to structure our information
18 gathering and decision making so that it fits the
19 format that we want to report out.

20 And, perhaps you and I could sit down
21 with Eve and some of the staff at some point in
22 the next few weeks and propose how to do that and

1 then bring that back to the Committee as a
2 working -- or proposal on how to work this going
3 forward.

4 I think it would be tremendously
5 useful to put this into a framework, for example,
6 and then, I like Jamy's proposal that he forgot
7 about putting the information together in a
8 graphic table across ages. I think that will
9 also help us.

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

18 CHAIR SCHNEEMAN: Great. And, I would
19 just add a couple of comments of my own.

20 First of all, thank you to everyone
21 who's been doing the work of these subcommittees.
22 But, you know, in terms of looking at the

1 evidence, I think people have made good comments
2 about how we're looking at that.

3 And, I would just remind you that,
4 once we go through the search and we have the
5 evidence that we're looking at, it's not a yes,
6 no answer because sometimes we don't have
7 evidence, sometimes we have insufficient
8 evidence.

9 But once you have evidence, you're
10 also then will be asked to assign that grade.
11 So, you know, we might want wind up where, yes,
12 we got the evidence, but it's limited or it's
13 moderate.

14 I mean, the goal, of course, is to
15 have high quality evidence. But keep in mind
16 that, even if there are studies, we're not yes,
17 no, we are trying to evaluate the quality of that
18 evidence which I think also sends a message about
19 what is needed in the field of nutrition.

20 One thing that we haven't talked about
21 but we've alluded to several times is this
22 concept of future directions. And, I'm glad that

1 several of the comments are starting to pick up
2 on that of what do we want to tell the
3 departments, but also tell committees going
4 forward that we see some important things.

5 It can be about the process. It can
6 be about topics that are important.

7 And, I have to say, one of the things
8 that I do keep thinking about relative to some of
9 those future topics and issues, you know, from
10 the National Academy report that looked at the
11 process and redesigning the process, one of the
12 recommendations that's probably the hardest
13 recommendation to implement is about taking a
14 food system approach.

15 And, it recognized that that wasn't
16 going to happen instantly. It's something that
17 required its own level of research, its own level
18 of investigation.

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

1 food system.

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

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

8 VICE CHAIR KLEINMAN: We have the
9 power.

10 CHAIR SCHNEEMAN: So, again, we will
11 -- actually, two additional reminders. So, I do
12 want to remind people in listening to the
13 protocols today, if any of our public
14 participants either here in the room or online
15 want to submit comments relative to the protocols
16 that you're hearing in this meeting, they will be
17 most helpful to the Committee if we hear them --
18 if we get those comments by November 7th. So,
19 just to keep that in mind. We'll remind you
20 about that tomorrow.

21 And then, tomorrow, we will convene at
22 9:00 a.m. The agenda has some opening comments

1 but we're anticipating that we probably will be
2 able to do all three of our subcommittee reports
3 before we adjourn to lunch, just so people are
4 aware that that will be change to the agenda.

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

7 Thank you.

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

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This is to certify that the foregoing transcript

In the matter of: Public Meeting

Before: Dietary Guidelines Advisory Committee

Date: 10-24-19

Place: Washington, DC

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



Court Reporter

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