2020 DIETARY GUIDELINES ADVISORY COMMITTEE

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PUBLIC MEETING

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THURSDAY
JANUARY 23, 2020

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The Dietary Guidelines Advisory Committee met in the Agricultural Research Service, Children's Nutrition Research Center, 1100 Bates Street, Houston, Texas, at 9:00 a.m., Barbara Schneeman, Chair, presiding. The meeting allowed for public viewing, both in-person and by webcast.

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 SABATÉ, MD, DrPH, Member
DR. LINDA SNETSELAAR, PhD, RD, Member
DR. JAMIE STANG, PhD, MPH, RD, Member
DR. ELSIE TAVERAS, MD, MPH, Member

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1	P-R-O-C-E-E-D-I-N-G-S
2	9:03 a.m.
3	DR. STOODY: Okay. Good morning. My
4	name is Eve Stoody, and I'm a Lead Nutritionist for
5	Nutrition Guidance at USDA Center for Nutrition
6	Policy and Promotion, and I'm also the designated
7	federal officer for this 2020 Dietary Guidelines
8	Advisory Committee.
9	It is really my pleasure to welcome you
10	to meeting four of the 2020 Committee and also to
11	welcome you to Texas. We are holding this meeting
12	at the USDA Agricultural Research Service
13	Children's Nutrition Research Center in Houston,
14	Texas, and thanks to Dr. Denny Bier and their team
15	for really welcoming us and for being fantastic
16	hosts for this event.
17	This is the second time that the Dietary
18	Guidelines Advisory Committee has met outside of
19	the Washington, D.C., and the first time was over
20	25 years ago.
21	We also want to welcome all of you who
22	are joining us on YouTube. This meeting, like our

1   previous meetings, will be live-streamed. That

2   means -- hello, I would like to see the slides.

3   So this meeting will be live-streamed.

4   There will be -- and just a note that there will

5   be different links for the morning and afternoon;

6   that's the nature of YouTube. So for those of you

7   who are joining us online, when you registered, in

8   your registration email you should have received

9   four links, two for today and two for tomorrow.

10   We'll try to remind you to change links

11   after lunch. So we are very happy to have 19 of

12   our 20 members here with us today. Unfortunately,

13   Dr. Linda Van Horn was not able to join us here in

14   person, but she is going to join us remotely as much

15   as she is able.

16   We have about 1,000 people who have

17   registered for this meeting, with about 150 who

18   will join us at some point in person here in

19   Houston. And as always, I just thank you for your

20   interest and your support of the Dietary

21   Guidelines.

22   So just a little bit of background and

1   a reminder: The 2020 Committee was established to

2   conduct an independent review of current research

3   on nutrition and health to be considered by the

4   Departments of Agriculture and Health and Human

5   Services, and the development of the 2020-2025

6   Dietary Guidelines for Americans.

7   This Committee was selected by

8   Secretaries Purdue and Azar from USDA and HHS from

9   nominations received from the public, and they were

10 selected based on their education, experience, and

11 expertise, and they were balanced on a number of

12 factors, including things like geographic

13 locations.

14   The Committee was announced in February

15 2019. And just as a reminder, this is not a

16 committee is convened to provide expert opinions

17 or to represent a specific viewpoint, but rather

18 they were selected as independent scientists who

19 will work together to review current evidence on

20 diet and health.

21   Since this is a federal advisory

22 committee, the federal government is required to

1   outline the duties -- the missions and specific

2   duties of the Committee, and we have done this

3   through our charge to the Dietary Guidelines

4   Advisory Committee.

5   You can see this charge on our slide.

6   We presented it every meeting, and it's also on our

7   website, and their charge is to examine the

8   evidence on specific topics and scientific

9   questions identified by the Departments, and I'll

10   talk about those here more in the next few slides,

11   to develop a report that outlines their

12   science-based review and recommendations to the

13   Department with rationale, and then to submit the

14   report to the Secretaries of USDA and HHS for

15   consideration as the Departments develop the next

16   edition of the Dietary Guidelines.

17   So as we've talked about previously,

18   USDA and HHS added a new step to this process to

19   identify the specific topics or the specific

20   questions that the Advisory Committee were asked

21   to address.

22   In the past, we did outline some topic

1   areas, but in general the Committee identified the

2   specific questions that they would consider. For

3   this Committee, we added the step for the Committee

4   where the Departments identified those topics and

5   questions and asked the Committee to address those.

6   We did this for a number of reasons.

7   One, it was in part due to recommendations from the

8   National Academies on our process to kind of have

9   the question development occur in a separate step,

10   and we also really felt like it permitted a more

11   transparent, inclusive, and deliberate process.

12   And I do want to note that the topics

13   and questions were not developed in isolation.

14   The process was led by the Center for Nutrition

15   Policy and Promotion at USDA and the Office of

16   Disease Prevention and Health Promotion, our

17   partners at HHS, but it did include input from a

18   number of federal agencies, as well as

19   consideration of thousands of public comments.

20   And so in that process, specifically

21   CNPP and ODPHP developed an initial list with input

22   from some of our federal partners, we posted a list

1 of topics and questions for public comment for 30

2 days.

3   We received about 6,000 public comments

4 on those topics and questions and refined the list,

5 based on that input. We did prioritize the topics

6 and questions using four criteria: relevance to

7 the Dietary Guidelines -- and I'll talk more about

8 that in just a second; importance to public health;

9 potential impact on the federal programs and

10 policies that we inform; and avoiding duplication

11 of other federal efforts.

12   Now, as I think everyone in this room

13 knows, in the field of nutrition, there are many

14 possible questions of scientific and public input

15 that have the potential to be explored. So this

16 includes things on food groups, on very specific

17 foods, questions on nutrients, food safety, food

18 labeling, menu labeling, food settings, food

19 policies, food behaviors, medical nutrition

20 therapy, and more.

21   And we really feel like the Dietary

22 Guidelines have an important slice of that

1   nutrition conversation. The Dietary Guidelines

2   have a specific goal and a specific time line, and

3   that is to provide food-based dietary guidance to

4   the general public at least every five years.

5   Now, we do have a number of partners who

6   we work with kind of in this larger nutrition

7   conversation. So for example, the National

8   Academies developed the nutrient recommendations

9   known as the Dietary Reference Intakes, and there

10 are a number of federal agencies and others

11 involved in this space, including the Department

12 of Health and Human Services, Food and Drug

13 Administration, who work on food safety and

14 labeling issues, but the point being here that

15 there's a lot of pieces, and the hope is that we

16 all work together to kind of speak to the bigger

17 nutrition picture.

18   Now, the topics and scientific

19 questions we've asked the Committee to address

20 focus on diet and health across the lifespan, and

21 so kind of the main emphasis for this, I would say,

22 is about that emphasis on the lifespan.

1   The topics and questions we asked the

2   Committee to address build on topics and questions

3   examined by previous dietary guidelines -- Dietary

4   Guidelines Advisory Committees, I should say.

5   So we didn't start from scratch. We

6   had a lot to work with from our previous committees.

7   For example, the 2015 Committee did a number of

8   questions on dietary patterns and added sugars.

9   The 2010 Committee had a number of

10 specific questions on seafood and alcohol. A

11 number of committees have addressed kind of

12 elements of dietary fats, beverages and patterns

13 of eating, perhaps not as -- in kind of a broader

14 scope, but in pieces of it.

15   Previous   committees   have   also

16 described current intakes of Americans, as well as

17 status of health across the American population,

18 which will be talked about today. And since 2005,

19 advisory committees have conducted food pattern

20 modeling analysis.

21   So that's kind of the exposure element.

22 In terms of the outcome, the Committee was asked

1   to consider a range of outcomes. So many previous

2   advisory committees have looked at the outcomes of

3   body weight or obesity, cardiovascular disease,

4   type 2 diabetes and cancer, and we asked the

5   Committee to examine those in kind of that health

6   discussion, but also some additional outcomes, so

7   for example, neurocognitive health has become

8   really a more recent interest in nutrition science.

9   So we did include brain health as part

10   of many of the questions that the Committee were

11   asked to consider. Sarcopenia, in particular,

12   trying to think about the older adult population

13   and having more targeted outcomes for that

14   population.

15   Bone health, which is of course

16   important for the older adults, but also children

17   and adolescents, as well as actual all-cause

18   mortality.   We actually haven't had many

19   committees that considered that broader all-cause

20   mortality outcome.

21   Now, each committee that we've had also

22   looks at some unique topic areas, and for 2020

1   process, these are the birth to 24 months

2   performance population. There has been a growing

3   interest in us including this population.

4   Traditional dietary guidance has

5   focused on two years and older. And then the 2014

6   Farm Bill really solidified that inclusion in this

7   edition.

8   And then an expanded focus on pregnancy

9   and lactation. Previous advisory committees

10   hadn't necessarily excluded pregnancy and

11   lactation, but they hadn't had as focused questions

12   on pregnancy and lactation, and perhaps more

13   specific, they hadn't really considered outcomes

14   related to pregnancy and lactation. And so that's

15   been an addition here as well, and both of those

16   are no small additions, as you'll hear today

17   shortly.

18   So in summary, I would say that there

19   are many similarities between the work of this

20   Committee and previous advisory committees, but

21   there are some new topics.

22   I think a lot of what we've been seeing

1 is that a lot of the questions are more expanded,

2 so they're kind of the similar concept areas that

3 kind of broader exposure to more outcomes, and

4 there also are, of course, the new populations.

5 Now, as we've talked about previously,

6 and as with all of our Dietary Guidelines Advisory

7 Committees, the Committee's task is time-limited.

8 As we've discussed, USDA and HHS requested the

9 Committee to report by May 2020, and that is so the

10 Departments can meet our mandate to release the new

11 edition of the Dietary Guidelines within five

12 years, which is by December of this year, December

13 of 2020.

14 So as we move into the last phase of the

15 Committee's work, which is pretty crazy to think,

16 it's similar to previous committees. The 2020

17 Committee and federal staff have been working to

18 refine, streamline, and prioritize the remaining

19 work within the remaining time, and you'll hear

20 more about that over course of the next few days.

21 So all meetings of the full Committee

22 are open to the public. As I noted, this is the

1   fourth meeting. If you were not able to join us

2   for meetings one, two, and three, that information

3   is archived on our website, including the

4   recordings of the meetings, as well as

5   presentations, transcripts, and minutes.

6   Similar to the second meeting, this

7   meeting will include an opportunity for

8   individuals who had registered to provide oral

9   comments to the Committee. However, if you did not

10   have the opportunity to travel here to provide

11   public comments in person, the written public

12   comment period is always open.

13   We opened it in March of 2019, and it

14   will stay open into May of 2020. So this meeting

15   will be held today and tomorrow from 9:00 a.m. until

16   4:30 p.m. Central. I just note that because we

17   usually function on Eastern Time, and some of us

18   arrived early today, thinking we were still there.

19   So -- but we'll be on -- the meeting

20   will be in Central Time. The agenda is available

21   at DietaryGuidelines.gov, and Dr. Schneeman will

22   give an overview of the agenda in her remarks.

1   We do want to announce today that we

2   will host a -- the Committee will host a meeting

3   on its report on May 11, which is a Monday. This

4   will be a meeting -- you know, as we just talked

5   about, we've asked for the Committee's report in

6   May.

7   Their last meeting was scheduled for

8   March, and we wanted to provide the Committee an

9   opportunity to come together to discuss its final

10   recommendations and refine its report, but also for

11   the public to be able to hear some of the discussion

12   around the Committee's final recommendations

13   before they submit their report to the Departments.

14   This is the first time that we have

15   hosted a meeting specifically focused on the

16   Committee's report, and we hope that it is kind of

17   helpful in hearing firsthand about their

18   recommendations before they submit the report.

19   So we'll provide more information about

20   this. We will publish this in the Federal

21   Register. We'll include information on our

22   website. We'll send out listserv messages for

1   those of you who have signed up as we have more

2   information, but for now, please save the date for

3   Monday, May 11. This meeting will be held by

4   webinar only. We will not have -- there won't

5   travel for that meeting.

6   So we encourage you to follow along at

7   DietaryGuidelines.gov in between the meetings, as

8   well as here today. The Committee will talk about

9   a number of different questions that they are

10   reviewing. If you want more information about the

11   questions that they are talking about, you can to

12   go DietaryGuidelines.gov.

13   There is a rotating banner in the middle

14   of that page, the orange banner there, and if you

15   click on "View Protocols," it will take you to a

16   list -- a website with a list of questions, and if

17   you click on your question of interest, then it will

18   take you a webpage devoted to the Committee's

19   review on that question. So if you have something

20   of interest that you really want to learn more

21   about, we encourage you to go to the website.

22   So with that, I turn it over to the Chair

1   of the Committee, Dr. Barbara Schneeman.

2   CHAIR SCHNEEMAN: Thank you, Eve, and

3   let me add my welcome, certainly, to the Committee

4   members. It's great to see you all, and a full -- a

5   fairly full representation from the Committee, and

6   also to the attendees who are in the room, but also

7   to all of those who are listening on the webinar.

8   We do appreciate the interest in the

9   Dietary Guideline process and the work of this

10   Advisory Committee. And I want to extend a special

11   thank you to the CNRC for hosting the Committee

12   here.

13   I see Dr. Bier sitting over here on the

14   side. Thank you very much for the invitation to

15   be here, and the staff has been fantastic in terms

16   of helping us and making sure that things went

17   smoothly.

18   So thank you. So I will move into the

19   slides. So let me start, first of all, by just

20   giving you an overview. Sort of following on from

21   what Dr. Stoody presented, I'm going to talk more

22   specifically about our subcommittee structure, our

1   approaches to examining evidence and the

2   information to be discussed at this meeting.

3   In a sense, I'm now going to talk more

4   about how this Committee has moved forward with the

5   charge that we received from USDA and HHS. So

6   we'll look at the subcommittee status and the

7   agenda for this meeting.

8   So just to remind you, these are the

9   subcommittee structures that were set up, so that

10   between the -- in the time between the public

11   meetings, work can proceed, and we have six

12   subcommittees and one cross-cutting.

13   I know the font is small there.

14   Dietary Patterns, Pregnancy and Lactation, Birth

15   to 24 Months, Beverages and Added Sugars, Dietary

16   Fats and Seafood, and Frequency of Eating, and the

17   cross-cutting group is the Data Analysis and Food

18   Pattern Modeling subcommittee, so aligned with

19   those topics that you've heard.

20   And I'm not going to read out the names,

21   because as we go through the subcommittee reports,

22   you will be getting that information. Just to

1 remind you that the subcommittees review the

2 evidence and provide advice to the parent

3 Committee, so the final decisions are being made

4 by the full Committee, and they're done in this

5 public meeting format, which we'll be having today

6 and tomorrow.

7 So just, again, we've talked about that

8 this each meeting, how the Committee approaches the

9 review of the evidence, the examination of the

10 evidence, and we use three approaches to examine

11 the evidence: data analysis, food pattern

12 modeling, and the NESR systematic reviews.

13 And each of these scientific approaches

14 has a protocol, and the protocol is a plan for how

15 one of the scientific approaches will be used to

16 examine evidence related to one of the questions

17 that the Committee has been asked to address.

18 As they've been developed, each of the

19 protocols are available, and Dr. Stoody gave you

20 the web link for that. And we -- in posting the

21 posting the protocols, we have invited feedback

22 from the public, and we found that feedback to be

1   very helpful. People have provided additional

2   references for additional consideration.

3   So information on the approaches and

4   the protocols have been presented at previous

5   meetings, and additional information that is

6   available at the DietaryGuidelines.gov.

7   So in the next few slides, I'm going to

8   just go through a brief overview of the information

9   to be presented by the subcommittee so you see the

10 general format of how each of the subcommittee's

11 reports is structured.

12   So throughout the presentations, you

13 will see an analytic framework which defines the

14 core elements of the diet and health relationship

15 to be examined. So you can see that that analytic

16 framework includes the intervention, exposures,

17 and the comparators that will be used.

18   In some cases, we have intermediate

19 outcomes -- obviously we're very interested in the

20 health   outcomes   when   available   for   our

21 review -- then key factors that could impact the

22 relationship; confounders, covariates, moderators

1 are specified in the analytical framework, and also

2 key definitions are given.

3   So each of the protocols also look at

4 inclusion and exclusion criteria. And so you will

5 hear discussion of those criteria in each of the

6 systematic reviews, and these criteria are

7 developed up front and are used to screen the

8 articles that will be included or excluded from a

9 review.

10   So there are a number of standard

11 criteria that apply across the different reviews

12 that the subcommittees have used consistently

13 across the reviews, and so these include areas such

14 as the study design.

15   And I'm not going to read all of the

16 inclusion/exclusion, because we have talked about

17 these at each of the public meetings, and it's also

18 available -- completely available to you on the

19 DietaryGuidelines.gov.

20   So standard inclusion criteria include

21 that study design, what kinds of studies are

22 included, what are excluded, the publication

1 status, peer-reviewed articles, the language of

2 publication --   English   is   what   we've

3 included -- the country of origin or the country

4 that studied very high or high human development

5 so it's comparable to the U.S. population and can

6 be generalized to the U.S. population. And then

7 the study participants.   We're primarily

8 interested in studies in humans, males and females,

9 and so exclude animal or in vitro studies.

10 In addition, the health status of the

11 study participants is included in our inclusion and

12 exclusion criteria, and generally you'll see that,

13 while we're obviously interested in participants

14 who are healthy, we do also include participants

15 who may be at risk for chronic disease, including

16 those with obesity, and so that concept applies.

17 What we're excluding are studies in

18 which the participants have been diagnosed with a

19 disease   or   hospitalized   and   that --   or

20 participants with the outcome of interest that

21 we're looking at, and so they're in a treatment

22 study, or infants who were born preterm or low birth

1 weight. So that sets up what we include versus

2 what we exclude in terms of health status.

3   Now, some of the criteria need to be

4 tailored to the specific review, and those kind of

5 tailored criteria might include diet-related

6 interventions or an exposure of interest; health

7 outcomes; the endpoint and/or an intermediate,

8 whether or not that data are available; the date

9 of publication, depending on what we already have

10 from previous versions of the Dietary Guidelines;

11 the work of other advisory committees; the size of

12 the study groups; study duration; and the age of

13 the study participants. And so those will be

14 clearly specified in the protocols that are

15 published.

16   So in the NESR systematic reviews, what

17 you will -- because we're now moving into that

18 phase where the subcommittees have been doing their

19 work, and they are presenting more than the

20 protocols; they're moving into presenting their

21 draft conclusions -- you'll see a flow chart of the

22 literature search and screening results, a

1   description of the evidence that is being examined

2   in depth by the subcommittee, the summary of the

3   evidence synthesis, and some draft conclusion

4   statements and grades for those particular

5   questions.

6   And I do want to highlight that what

7   we're going to be presenting, just in the interest

8   of time, are in fact summary statements. The

9   Committee's review includes a much more detailed

10   discussion and review of the included articles,

11   which will be provided in the Committee's final

12   report and supporting online materials.

13   The intent is to summarize the

14   information today and tomorrow for discussion

15   across the full Committee. And again, a lot of

16   what we're doing now, because it does involve a

17   Committee discussion, we're presenting things that

18   are in their draft format and it will only be

19   finalized once we submit our report.

20   So there will be data analysis

21   questions that are presented today, and they

22   include -- they also follow a protocol and may

1   include some similar elements, including the

2   analytical framework, the analytical plan, the

3   results, and then draft conclusion statements that

4   the Committee will be discussing today.

5   So for both the NESR systematic reviews

6   and the data analysis questions discussed today and

7   tomorrow, conclusion statements -- draft

8   conclusion statements will be presented, and so

9   that draft conclusion statement is an answer to the

10   question of the evidence that is being reviewed.

11   They have been drafted by the

12   subcommittees, and they're being brought to the

13   full Committee for discussion at these public

14   meetings. And again, these are considered draft

15   until the Committee submits its report to the

16   Secretaries, so they shouldn't be interpreted as

17   the Committee's final view or recommendations. The

18   Committee is working toward its final decisions.

19   So I do want to note that after the

20   conclusion statements are discussed by the

21   Committee at the public meetings, the systematic

22   reviews will go through a peer-review process, and

1 that is being coordinated by USDA's Agricultural

2 Research Service, so that these reviews will be

3 peer-reviewed before the Committee finalizes.

4 And we have, in fact, invited Dr. David

5 Klurfeld from ARS to provide remarks at the next

6 meeting, the March meeting, on the process that is

7 being used for the peer-review process.

8 And we will then post the draft

9 conclusion statements online after that peer

10 review is completed. So you'll be learning more

11 about that as we move forward, and that is a new

12 part of the DGAC process, so we're learning about

13 it as we go.

14 So subcommittee status. They're -- I

15 just want to summarize so you understand the full

16 scope of the work. I can assure you that the

17 subcommittees have been very busy, and there's a

18 lot of demand in terms of time.

19 I also would note that I know everyone

20 on this Committee is fully appreciative of the

21 excellent staff that has been working with us,

22 keeping us on schedule, keeping us on track, and

1   doing the tremendous of work that it takes to pull

2   the evidence together so that the Committee can do

3   its evaluation.

4   So if we could go back to that slide,

5   please?   So just the draft conclusions for

6   approximately 30 questions will be presented at

7   this meeting, including both NESR's systematic

8   reviews and data analysis evaluation.

9   And so across the subcommittees, NESR

10   has screened over 265,000 articles and extracted

11   data and assessed risk of bias for over 500

12   articles. And I can assure you those numbers will

13   only still grow as we keep moving forward.

14   We are utilizing nearly 50 different

15   types of data analysis from the NHANES What We Eat

16   in America. We have begun to work on the food

17   pattern modeling, and we've refined a report

18   outline and are beginning to prepare some of the

19   report content.

20   So the task at hand is large. There's

21   a huge amount of work that has been done. We know

22   that there's still a huge amount of work to be done.

1   So members and staff, members of the Committee and

2   the staff have been working to refine, streamline,

3   and prioritize the remaining work so that we can

4   meet the timeline.

5   So in our meeting number four, the

6   meeting that we're at, we'll describe the status

7   and provide updates on the work of the Committee.

8   As Dr. Stoody noted, there's an agenda available

9   at DietaryGuidelines.gov.

10   So just to make sure we -- sort of make

11   sure we connect with our YouTube participants,

12   we'll be sure that the meeting begins at 9:00 a.m.

13   Central Time, and the afternoon session will begin

14   at 1:00 p.m. Central Time.

15   Breaks, however, can't really be set at

16   a specific time, because of the nature of the

17   reporting that we're doing, but we'll take breaks

18   as they fit within the discussion framework.

19   So for today's agenda, following the

20   opening remarks, we'll start with the subcommittee

21   updates, and the subcommittees we expect to hear

22   from today are Birth to 24, Pregnancy and

1 Lactation, Dietary Fats and Seafood, Beverages and

2 Added Sugar, and the Data Analysis and Food Pattern

3 Modeling, the cross-cutting working group, and

4 obviously, with each of those subcommittees, we

5 anticipate there will be Committee discussion.

6 So for tomorrow's agenda, again, we'll

7 start at 9:00 a.m., and the subcommittee updates

8 that will be held tomorrow are the Dietary Pattern

9 subcommittee, the Frequency of Eating, some

10 Committee discussion, and then we've also

11 scheduled public comments, which will take place

12 in the afternoon, and we are looking forward to

13 those public comments.

14 And just to note that, yes, there's been

15 a lot of interest in the DGAC work. The Committee

16 has received approximately 17,775 written public

17 comments, since the work began.

18 If there's interest in commenting on

19 the new protocols that are presented in today and

20 tomorrow's public meetings, it's most useful to the

21 Committee if those comments on the protocols are

22 received by Friday, February 7.

1   And again, we've found the comments on

2   the protocols to be helpful, but for the Committee

3   to keep progressing with its work, we need them by

4   February 7. But as noted by Dr. Stoody, the

5   written public comment period for more general

6   comments is open until we complete our work in May

7   of 2020.

8   So with that, that concludes my

9   comments, and I'll just turn to the Committee

10   members just to see if there's anything, question

11   or comments that any Committee members may want to

12   make?

13   (No response.)

14   CHAIR SCHNEEMAN: So with that, I'm

15   going to -- Dr. Kleinman, you may have some

16   comments as well, but I'll turn it over to you for

17   the first subcommittee reports.

18   VICE CHAIR KLEINMAN: Thank you.

19   Thanks, Barbara. That was very complete, and I

20   have very little to add. This is our fourth

21   meeting together, and so it's an opportunity for

22   us all to be here with each of the subcommittees

1   that's been working on, and a great deal of work

2   has taken place since the last meeting, so the

3   remainder of the day today and tomorrow will be

4   these report outs of the subcommittees.

5   I think we'll go right into the first

6   one now and then in terms of breaks, we recognize

7   that there are some biological imperatives here,

8   and so we will try to take a brief break, perhaps,

9   between the first and second.

10   So with that, I'm going to go ahead and

11   turn this over to Kay Dewey, and she will talk

12   about the subcommittee for Birth to 24 Months.

13   MEMBER DEWEY: Thank you very much, Ron

14   and Barbara. I am very pleased to be able to report

15   to you today on behalf of this subcommittee. And

16   the members of this subcommittee have been working

17   very hard, many hours every week, to get to this

18   point.

19   We have a number of questions that have

20   been addressed, and the NESR staff have been

21   extremely busy screening the literature, preparing

22   the results, extracting the data, and preparing

1   evidence portfolios for us to review.

2   And so today we will be presenting draft

3   conclusion statements for the eight topics shown

4   here. Although it's eight topics, there are

5   66 conclusion statements we need to go through, and

6   if I did read every single one of them in full, it

7   would take more than an hour.

8   So I'm going to try to go through them

9   as quickly as I can, while not skipping anything

10   important. Those include three questions or

11   topics on the relationship between human milk and

12   infant   formula   and   three   outcome   areas:

13   micronutrient   status,   atopic   disease,   and

14   long-term health outcomes.

15   Then   there   are   five   questions   on

16   complementary feeding, and five outcome areas:

17   atopic disease, developmental milestones, growth,

18   size, and body composition, micronutrient status

19   and bone health.

20   We still have work to do for five other

21   topics that are listed here, two additional

22   questions related to human milk and infant formula,

1   and those relate to growth, size, and body

2   composition and developmental milestones.

3   And then the three new questions that

4   we have on nutrients from supplements or fortified

5   foods, and three outcome domains: growth, size and

6   body composition, bone health and micronutrient

7   status.

8   These are some of the key definitions

9   for our reviews, which we have presented

10   previously, but to remind you of those and the scope

11   of the questions we're investigating, I wanted to

12   go through them.

13   Human milk refers to mother's own milk,

14   so our reviews did not include examinations of

15   donor milk. And we've used the term human milk

16   feeding, instead of breastfeeding, to be clear that

17   we have examined human milk fed at the breast, as

18   well as human milk that has been expressed and fed

19   fresh or after refrigeration or freezing.

20   Infant formula refers to commercially

21   prepared infant formulas that meet FDA or Codex

22   Alimentarius standards. In practice, this has

1 been a tricky definition to apply because there are

2 a lot of studies that examine experimental infant

3 formulas with ingredients such as dietary

4 nucleotides or DHA, prior to putting them on the

5 market.

6 So we have included this evidence if the

7 formulas met the FDA or Codex standards. We did

8 this because we thought it was important to examine

9 infant formulas with ingredients that are

10 commercially available.

11 And lastly, complementary foods and

12 beverages refers to foods and beverages other than

13 human milk or infant formula. That includes

14 liquids, semisolids, and solids that are provided

15 to an infant or young child to provide nutrients

16 and energy.

17 I want to thank the public for

18 submitting comments on the work that was presented

19 during meeting three. We carefully reviewed and

20 discussed all of those comments, and we would very

21 much welcome public comments on what we present

22 today, as Dr. Schneeman mentioned, by February 7.

1   So to begin, I will review some draft

2   conclusions for the relationship between duration,

3   frequency, and volume of exclusive human milk

4   and/or   infant   formula   consumption   and

5   micronutrient status.

6   This is the analytical framework that

7   we developed that shows the scope of this question,

8   and we divided the duration, frequency, and volume

9   of exclusive milk, of human milk or infant formula,

10   into a series of four comparisons that align with

11   the first feeding decisions that caregivers make,

12   and those include whether or not to feed human milk;

13   and then, for caregivers who do decide to do so,

14   how long to feed human milk, so the duration of

15   human milk consumption, and then how long to feed

16   human milk exclusively.

17   So you'll note that we examined

18   exclusive human milk consumption prior to the

19   introduction of infant formula only, and that's to

20   avoid overlap with another review which we will

21   also present today that examines the timing of the

22   introduction of complementary foods and beverages.

1   And then if caregivers have decided to

2   supplement human milk with infant formula, our

3   final comparison examines the intensity or

4   proportion or amount of human milk that is fed to

5   mixed-fed infants.

6   And then on the right, you can see that

7   we examined iron, zinc, iodine, vitamins C and B12,

8   and fatty acid status from birth to 24 months.

9   This flow chart shows the literature review and

10   screening results, and we used two different

11   literature searches which are noted with the

12   letters A and B in the flow chart.

13   Literature Search A was from the

14   Pregnancy and Birth to 24 Months Project, which

15   used a search date range of January 1980 to March

16   2016, and this literature search was very large,

17   because it was intended to find studies for several

18   questions related to human milk and infant formula.

19   Literature Search B was smaller,

20   because it was intended to capture just the

21   literature published in the last three years. And

22   you can see that ultimately 23 articles were

1   identified that met the inclusion criteria for the

2   question about feeding human milk and infant

3   formula and micronutrient status outcomes.

4   On this slide, we want to give you a

5   snapshot of the evidence by showing how many of

6   those 23 studies provided evidence for each

7   component of our analytical framework. And you

8   can see that where there was evidence to address

9   a topic, the number of studies was small.

10   Now, a small number of studies may

11   provide   sufficient   evidence   to   determine

12   associations, for example, if the evidence is

13   consistent and has a low risk of bias. However,

14   that was generally not the case in this body of

15   evidence.

16   You can also see the majority of

17   evidence addressed ever, compared with never,

18   consuming human milk. So we'll go one by one

19   through those comparisons.

20   This is the evidence related to ever

21   versus never consuming human milk, and these were

22   generally studies that compare infants who were fed

1   human milk with infants who were fed infant formula

2   that had a novel composition at the time of the

3   study, such as added DHA or different levels of

4   iron, and infants who were fed conventional infant

5   formula.

6   Now, as you can imagine, the evidence

7   would show that the formula's composition can

8   impact nutrient status outcomes. For example,

9   formula with DHA can impact DHA status, and this

10   complicates our synthesis of the evidence, because

11   infants in the studies were fed a wide variety of

12   infant formulas.

13   The 23 studies in this body of evidence

14   generally studied healthy full-term infants who

15   were recruited at or close to birth and who were

16   from the U.S. and several other countries.

17   As I've already mentioned, the majority

18   of evidence examines ever compared with never

19   consuming human milk and the duration of human milk

20   consumption. It's important to note that other

21   components of the infants' diets varied between

22   studies and also didn't tend to be well reported.

1   For example, the exclusivity of human

2 milk, the types and amount of formula fed in

3 addition to human milk, the types and amount of

4 complementary foods and beverages in addition to

5 human milk or infant formula, and any intake of

6 supplements.

7   At the bottom of the slide, you can see

8 the outcomes that were reported by the studies for

9 each of these nutrients. Now, there was evidence

10 available from a small number of studies, and

11 generally they did not show consistent

12 associations between the comparisons that are

13 shown in this slide.

14   So for ever -- compared with never

15 consuming human milk, there were not consistent

16 associations with anemia, hemoglobin, hematocrit

17 and the other indicators of iron status shown here,

18 or with zinc status.

19   Also, that was true for the duration of

20 any human milk consumption among infants fed human

21 milk, and anemia and markers of iron status, zinc

22 status, vitamin D status and fatty acid status.

1   And lastly, the same was true for the

2   duration of exclusive human milk consumption

3   before the introduction of infant formula and fatty

4   acid status.

5   The most substantial evidence that we

6   reviewed was from seven studies that examine the

7   relationship between ever compared with never

8   consuming human milk and fatty acid status.

9   And these studies indicated that there

10   may be an association between feeding human milk

11   compared with infant formula and fatty acid status.

12   And this body of evidence had an adequate number

13   of sufficiently powered studies, with some

14   inconsistencies that can likely be explained by

15   methodological differences; for example, the use

16   of formulas with different fatty acid composition.

17   There were several limitations that

18   included the risk of bias, especially confounding;

19   the study directness, because these studies are

20   mostly designed to examine the effects of infant

21   formula composition rather than to directly

22   compare infants fed human milk with those fed

1   infant formula.

2   And also generalizability.   For

3   example, in two studies, there were no non-white

4   participants, and other studies did not report race

5   or ethnicity. Also, it's unclear whether the

6   experimental formulas are similar to current

7   formulas on the market in the U.S.

8   But we did draft a conclusion statement

9   regarding ever versus never consuming human milk,

10   and this states that moderate evidence indicates

11   that ever compared with never consuming human milk

12   may be associated with fatty acid status. The

13   difference in fatty acid status between infants who

14   are fed human milk and infant formula likely

15   depends on the fatty acid composition of the human

16   milk and the infant formula being compared.

17   We   found   insufficient   evidence

18   available to determine the relationship between

19   ever compared with never consuming human milk and

20   iron and zinc status from birth to 24 months, and

21   no evidence for the relationship between ever

22   versus never consuming human milk and the other

1 micronutrient status outcomes: iodine, vitamin

2 B12 and vitamin D status.

3   Continuing on with regard to duration

4 of human milk feeding, insufficient evidence was

5 available to examine this relationship for iron,

6 zinc, vitamin D and fatty acid status, and there

7 was no evidence to determine that relationship for

8 iodine and vitamin B12 status.

9   In addition, regarding duration of

10 exclusive human milk consumption, there was

11 insufficient evidence for the relationship to

12 fatty acid status, and no evidence for the

13 relationship to iron, zinc, iodine, vitamin B12 and

14 vitamin D status.

15   And finally, with regard to intensity,

16 proportion or amount of human milk in mixed-fed

17 infants, there was no evidence to examine the

18 relationship to iron, zinc, iodine, B12, vitamin

19 D, or fatty acid status.

20   So next we will review the draft

21 conclusions for the relationship between duration

22 of exclusive human milk or infant formula

1 consumption, and food allergies and atopic

2 allergic diseases and long-term health outcomes.

3   Now, these questions have been answered

4 with existing NESR systematic reviews, and our

5 updated protocols, which are available at

6 DietaryGuidelines.gov, describe that we will use

7 these reviews as is, because they were completed

8 recently and capture over 35 years of evidence.

9 The papers from those reviews were published in the

10 American Journal of Clinical Nutrition in 2019.

11   However, we would like to ask the public

12 to please submit public comments if you know of any

13 articles published since 2016 that meet the

14 inclusion criteria and would also significantly

15 affect these conclusions.

16   The Committee did carefully review the

17 conclusion statements in the existing NESR

18 systematic reviews; and we flagged those that we

19 thought warranted an informal search to identify

20 new evidence that has emerged since 2016, focusing

21 on other published systematic reviews.

22   We did not locate any studies that would

1 have modified the conclusions, but again we do

2 appreciate any comment the public would like to

3 provide. So as I mentioned the Committee will be

4 answering these questions using the nine existing

5 NESR systematic reviews completed as part of the

6 Pregnancy and Birth to 24 Months Project by the

7 Infant Milk-Feeding Practices Technical Expert

8 Collaborative, and the link to the documentation

9 is provided here.

10 We would like to sincerely acknowledge

11 the work of this group of scientists who comprised

12 this technical expert collaborative and conducted

13 these reviews with NESR.

14 For this set of reviews, the literature

15 search was conducted between January 1980 and March

16 2016. For never versus ever feeding human milk and

17 atopic disease, 44 articles met the inclusion

18 criteria, and you can see the distribution of the

19 outcome that was examined. Almost all of this

20 evidence was from observational studies.

21 For duration of any human milk feeding

22 and atopic disease, 35 articles met the criteria,

1   and almost all the evidence was from observational

2   studies.

3   For duration of exclusive human milk

4   feeding prior to the introduction of infant

5   formula, only one article met the inclusion

6   criteria.

7   This summarizes what was concluded

8   regarding the relationship between never versus

9   ever feeding human milk and these outcomes.

10   Firstly, moderate evidence suggests that never, in

11   comparison to ever being fed human milk, is

12   associated with a higher risk of childhood asthma.

13   Again, just to emphasize, these

14   statements are worded so that the risk is related

15   to never feeding human milk. And in this case,

16   there were 17 independent studies contributing to

17   that conclusion statement.

18   For the second one, limited evidence

19   does not suggest a relationship between never

20   versus ever being fed human milk and atopic

21   dermatitis in childhood.

22   For the other relationships, evidence

1   about never versus ever being fed human milk and

2   atopic dermatitis was inconclusive, and there was

3   insufficient evidence to examine how it related to

4   the other outcomes that are listed here.

5   Again, I'm not going to read every word.

6   All of these statements are available in the

7   published articles.

8   This shows the conclusion statements

9   for the relationship between shorter versus longer

10   duration of any human milk feeding and these

11   outcomes.

12   Moderate   evidence,   mostly   from

13   observational studies, suggests that among infants

14   fed human milk, a shorter versus a longer duration

15   of any human milk feeding is associated with a

16   higher risk of asthma in childhood and adolescence.

17   This included 20 independent studies.

18   Limited evidence does not suggest a

19   relationship between duration of any human milk

20   feeding and allergic rhinitis or atopic dermatitis

21   in childhood.

22   Evidence   about   the   relationship

1 between shorter or longer duration of human milk

2 feeding and atopic dermatitis from birth to 24

3 months is inconclusive, and there's insufficient

4 evidence to determine the relationship with the

5 other outcomes in this set.

6   In terms of the shorter or longer

7 duration of exclusive human milk feeding before

8 introduction of infant formula, there is

9 insufficient evidence to examine this relationship

10 to all of the outcomes that were examined.

11   Moving on, then, to the long-term

12 outcomes, this shows the evidence that was

13 available to examine those. First, with regard to

14 never versus ever feeding human milk and

15 cardiovascular disease outcomes, there were 13

16 articles that met the inclusion criteria, and you

17 can see the types of outcomes that these studies

18 examined.

19   For duration of any human milk feeding,

20 there were 24 articles, and for duration of

21 exclusive human milk feeding and cardiovascular

22 disease outcomes, there were six articles

1 included.

2 So I'll go through those conclusion

3 statements as well. For never versus ever feeding

4 human milk, limited evidence suggests that never

5 versus ever being fed human milk is associated with

6 higher blood pressure, within a normal range, at

7 six to seven years of age.

8 The evidence about the relationship of

9 never versus ever being fed human milk with blood

10 lipids in childhood was inconclusive and there was

11 insufficient evidence for the relationship to the

12 other CVD outcomes examined.

13 In terms of shorter versus longer

14 duration of any human milk feeding, moderate

15 evidence suggests that there is no association

16 between the duration of any human milk feeding and

17 blood pressure in childhood.

18 And I wanted to call out one study here

19 that was quite important. There was compelling

20 evidence from the Promotion of Breastfeeding

21 Intervention trial that is the only randomized

22 trial in this body of evidence, and it showed no

1   significant relationship between duration of any

2   human milk feeding and blood pressure at six and

3   a half or 11-1/2 years of age.

4   There was also inconsistent evidence

5   across six independent prospective cohort studies.

6   The second bullet here, the evidence about the

7   relationship of shorter versus longer duration of

8   human milk with blood lipids in childhood and

9   adulthood and with metabolic syndrome, was

10 inconclusive, and there was insufficient evidence

11 to determine the relationship to the other CVD

12 outcomes.

13   Continuing on with shorter versus

14 longer duration, limited evidence suggests that

15 there is no association between the duration of

16 exclusive human milk feeding and blood pressure in

17 childhood or metabolic syndrome at 11.5 years of

18 age, and most of this evidence comes from this one

19 non-U.S. sample that was assessed using a very

20 strong study design.

21   And there was insufficient evidence to

22 determine the relationship of the duration of

1 exclusive human milk feeding with the other

2 endpoint CVD outcomes.

3 The other long-term outcome examined

4 was diabetes, and in this case, there were 21

5 articles that met the inclusion criteria for the

6 comparison of never versus ever feeding human milk.

7 You can see that most of those are

8 regard -- with regard to type 1 diabetes. For

9 duration of any human milk feeding and diabetes,

10 37 articles met the criteria, and 30 were focused

11 on type 1 diabetes.

12 For duration of exclusive human milk

13 feeding, there were 18 articles that met the

14 criteria; again, 17 about type 1 diabetes. So this

15 summarizes what was concluded about never versus

16 ever feeding human milk.

17 Limited evidence from observational

18 studies suggests that never versus ever being fed

19 human milk is associated with a higher risk of type

20 1 diabetes. There's insufficient evidence to

21 determine whether or not there is a relationship

22 between never versus ever feeding human milk and

1   type 2 diabetes, prediabetes and the other outcomes

2   shown here.

3   In terms of the duration of human milk

4   feeding, moderate evidence from observational

5   studies suggests that among infants fed some amount

6   of human milk, a shorter versus a longer duration

7   of human milk feeding is associated with a higher

8   risk of type 1 diabetes.

9   Limited   but   consistent   evidence

10 suggests that the duration of any human milk

11 feeding is not associated with fasting glucose or

12 insulin resistance in childhood or during the

13 transition from childhood into adolescence. And

14 there's insufficient evidence for the relationship

15 to type 2 diabetes, prediabetes or the other

16 outcomes shown here.

17   And then in terms of shorter versus

18 longer duration of exclusive human milk feeding,

19 limited   evidence   from   observational   studies

20 suggests that a shorter duration is associated with

21 a higher risk of type 1 diabetes.

22   Limited evidence from a single study

1   that used the strong design also suggests that the

2   duration of exclusive human milk feeding is not

3   associated with fasting glucose or insulin

4   resistance at 11.5 years of age. And there's

5   insufficient evidence to determine the

6   relationship with type 2 diabetes, prediabetes and

7   the other outcomes shown here.

8   Moving on, next we'll review the draft

9   conclusions for the relationship between

10   complementary feeding and the five outcome domains

11   that are listed here: micronutrient status;

12   growth, size and body composition; developmental

13   milestones, including neurocognitive development;

14   food allergies and atopic allergic diseases; and

15   bone health.

16   These have also been answered with

17   existing NESR systematic reviews, and the

18   protocols again are at DietaryGuidelines.gov.

19   And we will be using these reviews as is, again,

20   because they were completed recently and capture

21   over 35 years of evidence.

22   These papers were also published in the

1   American Journal of Clinical Nutrition in 2019.

2   However, as mentioned previously, we would like to

3   ask the public to please submit public comments if

4   you know of any articles published since 2016 that

5   meet the inclusion criteria and would

6   significantly affect the conclusions that I will

7   be presenting.

8   So the Committee will be answering

9   these questions using 10 existing NESR systematic

10   reviews completed as part of the Pregnancy and

11   Birth to 24 Months Project by the Complementary

12   Feeding Technical Expert Collaborative, and this

13   gives the link for the complete documentation of

14   that work.

15   Again, we would like to acknowledge the

16   work of this group of scientists who comprise the

17   complementary feeding TEC, who conducted these

18   reviews with NESR. This literature search spanned

19   from January 1980 to July 2016.

20   For complementary foods and beverages,

21   they were divided into two overarching types of

22   questions: the timing of introduction of

1   complementary foods and beverages, and the types

2   of amounts.

3   So for this first set of outcomes, which

4   are micronutrient status, there were nine studies

5   that met the criteria for the timing of

6   introduction. Most of these examined iron status;

7   a few examined zinc, vitamin D, vitamin B12, folate

8   and/or fatty acid status. For the types and

9   amounts of complementary foods and beverages, 31

10   articles met the criteria. Most examined

11   iron-fortified cereals and meats with respect to

12   iron status. Several examined zinc and fatty acid

13   status. And very few studies examined vitamin D,

14   vitamin B12, and folate status.

15   So I'll begin with the relationship

16   between the timing of introduction of

17   complementary foods and beverages and

18   micronutrient status.

19   Moderate evidence suggests that

20   introducing complementary foods and beverages at

21   four months of age compared to six months of age

22   offers no long-term advantages or disadvantages in

1   terms of iron status among healthy, full-term

2   infants who are breastfed, fed iron-fortified

3   formula, or both. And there were nine studies that

4   met the criteria for this question.

5   There is not enough evidence to

6   determine the relationship between timing of

7   introduction and zinc, vitamin D, vitamin B12,

8   folate, or fatty acid status.

9   Additional factors that need to be

10 considered in examining the relationship between

11 the age at which complementary foods and beverages

12 are introduced and micronutrient status include

13 birth weight and timing of umbilical cord clamping,

14 both of which affect iron stores of the newborn;

15 postnatal growth; type of feeding, at the breast

16 or formula or mixed feeding; and intake and

17 absorption of iron from sources other than human

18 milk, including the types and amounts of

19 complementary foods and beverages being consumed.

20   This summarizes the conclusions for the

21 types and amounts of complementary foods and

22 micronutrient status. Thirty-one studies met the

1   inclusion criteria for this review. And strong

2   evidence suggests that consuming complementary

3   foods and beverages that contain substantial

4   amounts of iron, such as meats or iron-fortified

5   cereal, helps maintain adequate iron status or

6   prevent iron deficiency during the first year of

7   life among infants with insufficient iron stores

8   or breastfed infants who are not receiving adequate

9   iron from another source.

10   However, the benefit of these types of

11   complementary foods and beverages for infants with

12   sufficient iron stores, such as those consuming

13   iron-fortified infant formula, is less evident.

14   There's not enough evidence to

15   determine the relationship between other types and

16   amounts of complementary foods and beverages

17   containing lesser amounts of iron, such as fruits

18   and vegetables and iron status.

19   Then in terms of the other nutrients of

20   interest, limited evidence suggests that consuming

21   complementary foods and beverages that contain

22   substantial amounts of zinc, such as meats or

1   cereals fortified with zinc, support zinc status

2   during the first year of life, particularly among

3   breastfed infants who are not receiving adequate

4   zinc from another source.

5   However, the benefit of these types of

6   complementary foods for infants consuming

7   fortified infant formula is less evident.

8   Moderate evidence suggests that consuming

9   complementary foods and beverages with differing

10 fatty acid profiles, particularly long-chain

11 polyunsaturated fatty acids, can influence fatty

12 acid status.

13   Continuing on this theme, during the

14 second year of life, food sources of micronutrients

15 are still needed, but there's limited evidence to

16 indicate which types and amounts of complementary

17 foods and beverages are associated with adequate

18 micronutrient status, and there's not enough

19 evidence to determine the relationship between the

20 types and amounts of complementary foods and

21 beverages and vitamin B-12, vitamin D, or folate

22 status.

1   Now I'm going to move on to the next

2   outcome domain, and that is food allergies and

3   atopic allergic diseases. For the timing of

4   introduction of complementary foods and beverages,

5   31 studies met the inclusion criteria, and most of

6   them examined food allergies. For types and

7   amounts of complementary foods and beverages, 39

8   met the criteria and most examined the most common

9   allergenic foods.

10   This has to do with the timing of

11   introduction of complementary foods and beverages.

12   Moderate evidence suggests that there is no

13   relationship   between   the   age   at   which

14   complementary feeding first begins and the risk of

15   developing food allergy, atopic dermatitis or

16   eczema, or asthma during childhood.

17   There's insufficient evidence to

18   determine the relationship between age at which

19   complementary foods or beverages are first

20   introduced and risk of developing allergic

21   rhinitis during childhood.

22   Now, the rest of the series of slides

1 focuses on the specific types of complementary

2 foods being introduced, and so these are divided

3 into several different slides.

4 I wanted to mention that the studies are

5 mostly focused on food allergy to that particular

6 food component. And in this case, we will be

7 talking about peanut, tree nuts and seeds.

8 There is strong evidence to suggest

9 that introducing peanut in the first year of life

10 after four months of age may reduce the risk of food

11 allergy to peanuts, and this evidence is strongest

12 for introducing peanut in infants at the highest

13 risk with severe atopic dermatitis and/or egg

14 allergy to prevent peanut allergy, but it is also

15 applicable to infants at lower risk.

16 However, the evidence for tree nuts and sesame

17 seeds is limited.

18 Limited evidence also suggests that

19 there is no relationship between consumption of

20 peanut, tree nuts or sesame seeds during the

21 complementary feeding period and the risk of atopic

22 dermatitis or eczema and asthma.

1   And there is not enough evidence to

2   determine if there is a relationship between

3   consuming peanut, tree nuts or seeds and allergic

4   rhinitis.

5   What I want to also mention is that many

6   of the studies included in this review exclusively

7   enrolled or primarily enrolled subjects who were

8   at a greater risk of allergies and/or atopic

9   disease than the general population on the basis

10   of family history.

11   However, despite this, the reviewers

12   concluded   that   the   results   are   probably

13   generalizable to infants and toddlers who are at

14   lower risk for atopic disease, although the

15   magnitude of the associations may be smaller.

16   There were 28 studies that examined the

17   consumption of eggs as a complementary food in

18   relationship to the risk of developing any atopic

19   disease,   including   six   randomized   controlled

20   trials.

21   From that body of evidence, it was

22   concluded that moderate evidence suggests that

1   introducing egg in the first year of life, after

2   four months of age, may reduce the risk of food

3   allergy to egg.

4   Limited evidence suggests that there is

5   no relationship between the age of introduction to

6   egg and the risk of atopic dermatitis or eczema and

7   asthma, and there's not enough evidence to

8   determine the relationship between egg and

9   allergic rhinitis.

10   For fish, 24 studies examined fish as

11   a complementary food, including one randomized

12   controlled trial. From this body of evidence,

13   there is limited evidence that suggests that

14   introducing fish in the first year of life after

15   four months of age may reduce the risk of atopic

16   dermatitis and eczema, and there is not enough

17   evidence to determine this relationship to the risk

18   of allergy to fish or other foods, asthma or

19   allergic rhinitis, and also not enough evidence for

20   the relationship to the risk of food allergy,

21   atopic dermatitis, eczema, asthma or allergic

22   rhinitis.

1   There were 17 studies that examined the

2 consumption of wheat or cereals and these outcomes,

3 and all of these were observational studies. So

4 limited evidence suggests that there is no

5 relationship between the age of introduction or

6 cow's milk products such as cheese and yogurt and

7 the risk of food allergy and atopic dermatitis and

8 eczema.

9   There's not enough evidence to

10 determine if there's a relationship between

11 consuming milk products during the complementary

12 feeding period and the risk of asthma or allergic

13 rhinitis.

14   Did I skip something? I'm going to go

15 back a second. Here we go. Sorry. There are a lot

16 of outcomes here. So sorry. I'm going to go back

17 to wheat and soy. And I did mention there were 17

18 studies that examined the consumption of wheat or

19 cereals, and these were all observational, and

20 there's not enough evidence for those related to

21 wheat to determine the relationship to risk of food

22 allergy, atopic dermatitis and eczema, asthma or

1   allergic rhinitis.

2   For soy, there were four prospective

3   studies that examined this relationship and that

4   indicated that there was not enough evidence to

5   determine if there was a relationship between

6   soybean consumption and the risk of any of these

7   outcomes. Okay, I think I will move on.

8   There were several observational

9   studies that also examined the relationship

10   between other types of complementary foods and

11   beverages that are generally not considered to be

12   major allergens; for example, fruit, vegetables,

13   and meats, and this conclusion was that there was

14   limited evidence from observational studies that

15   suggest that introducing foods not commonly

16   considered to be allergens in the first year of life

17   after four months of age is not associated with risk

18   of food allergy, atopic dermatitis or eczema,

19   asthma or allergic rhinitis.

20   There were also several observational

21   studies that examined dietary diversity or dietary

22   patterns, and these were 11 prospective cohort

1   studies and three case control studies, but there

2   was not enough evidence to determine a relationship

3   between these aspects of the diet and any of these

4   outcomes.

5   Okay. Moving on to the next set of

6   outcomes, which is growth, size, and body

7   composition, there were 81 studies that met the

8   inclusion criteria for the timing of introduction

9   of complementary foods and beverages, and 49 that

10 met the criteria for types and amounts.

11 So in terms of timing of introduction,

12 moderate evidence suggests that the first

13 introduction of any complementary food or beverage

14 between four to five months, compared to

15 approximately six months of age, is not associated

16 with weight status, body composition, body

17 circumferences, weight, or length, among generally

18 healthy, full-term infants.

19 Limited evidence suggests that

20 introducing complementary foods and beverages

21 before four months of age may be associated with

22 higher odds of overweight and obesity. And

1   there's not enough evidence to determine the

2   relationship between introduction of

3   complementary foods and beverages at seven months

4   or later on growth, size, and body composition.

5   In terms of types and amounts of

6   complementary foods, moderate evidence indicates

7   that a higher versus lower meat intake or meat

8   versus iron-fortified cereal intake over a shorter

9   duration during the complementary feeding period,

10   does not favorably or unfavorably influence

11   growth, size and/or body composition.

12   And there's insufficient evidence to

13   determine the relationship between meat intake and

14   prevalence or incidence of overweight or obesity.

15   Limited evidence suggests that the type or amount

16   of cereal given does not favorably or unfavorably

17   affect these outcomes.

18   In terms of fatty acids, moderate

19   evidence suggests that consumption of

20   complementary foods with different fats and/or

21   fatty acids composition does not favorably or

22   unfavorably influence growth, size, or body

1   composition.

2   And there's not enough evidence to

3   determine the relationship to the prevalence or

4   incidence of overweight or obesity. Limited

5   evidence suggests that sugar-sweetened beverage

6   consumption during the complementary feeding

7   period is associated with decreased risk of obesity

8   in childhood, but it is not associated with other

9   measures of growth, size, and body composition.

10   There is limited evidence that showed

11   a positive association between juice intake and

12   infant weight-for-length and child BMI z-scores.

13   No conclusion could be made about the

14   relationship about other complementary foods as

15   listed here and growth, size, body composition, or

16   overweight or obesity.

17   And also no conclusion could be made

18   about the relationship between distinct dietary

19   patterns during the complementary feeding period

20   and growth, size, body composition, or these other

21   outcomes.

22   There was a much smaller body of

1   evidence regarding developmental outcomes. For

2   the timing of introduction of complementary foods

3   and beverages, only three studies met the criteria,

4   and for types and amounts, only eight studies met

5   those criteria.

6   So not surprisingly, given that small

7   evidence base, there was insufficient evidence to

8   draw conclusions about the relationship between

9   the timing of the introduction of complementary

10   foods and beverages and developmental milestones.

11   One of the issues with this body of

12   evidence is that there is the potential for reverse

13   causation. In other words, the child might be more

14   developed and therefore be more demanding of

15   introduction of other foods and beverages. And so

16   with observational studies, it's very difficult to

17   study this relationship.

18   There was also insufficient evidence to

19   draw a conclusion about the relationships between

20   the types and amounts of complementary foods and

21   beverages consumed and developmental milestones.

22   There was also a very small evidence

1 base in terms of bone health. Three studies met

2 the criteria for timing of introduction of

3 complementary foods and beverages, and eight met

4 the criteria for types and amounts.

5 So again, not surprisingly, the

6 conclusion was that there was insufficient

7 evidence to draw conclusions about the

8 relationship of timing of introduction of

9 complementary foods and beverages and bone health.

10 And similarly, insufficient evidence

11 was available between the types and amounts of

12 complementary foods and beverages and bone health.

13 Okay. So those are the 66 conclusion

14 statements we had to get through today, and now I'm

15 going to present some of the discussions that we've

16 had related to refining and prioritizing the

17 remaining work in front of us.

18 So as I mentioned, we have two questions

19 regarding human milk and infant formula and outcome

20 domains, including growth, size, and body

21 composition. So for this one, it's a very, very

22 large literature, and for this purpose, we've

1 decided to examine outcomes related to body

2 composition only, which includes obesity and

3 overweight.

4 Our rationale for this is that we

5 already know that growth curves differ between

6 infants fed human milk and those fed infant

7 formula. In fact, the U.S. Government convened an

8 expert panel several years ago to review such

9 evidence, and as a result, the CDC adopted the World

10 Health Organization growth curves from birth to age

11 two years, which reflect the growth of breastfed

12 children.

13 On the other hand, the relationship

14 between human milk or infant formula consumption

15 and body composition outcomes, including obesity,

16 warrants further examination, and for that reason,

17 we have altered the protocol for this, which is

18 going to be available on DietaryGuidelines.gov.

19 We also discussed the remaining

20 questions that examine intake of nutrients from

21 supplements and fortified foods, and for this, we

22 decided to prioritize for the first question

1   related to growth, size and body composition, to

2   focus only on iron and iron from supplements.

3   For the second one related to bone

4   health, we decided to focus only on vitamin D and,

5   again, only from supplements. And for the third

6   question related to nutrient status, we decided to

7   focus on iron and vitamin D from supplements only.

8   Our rationale for limiting these

9   reviews to the nutrients from supplements is that

10   the existing reviews from the previous project,

11   which I just reviewed with you today, examined

12   complementary foods and beverages and included

13   fortified foods.

14   So we feel that the real need for new

15   work here is on these nutrients from supplements.

16   Our rationale for examining iron and vitamin D only

17   is that we would like to review evidence about

18   nutrient supplements that are currently

19   recommended for this age group.

20   So that is where we will be moving

21   forward as we continue the work. So our next steps

22   are summarized here. There will be a literature

1   search on iron and vitamin D from supplements and

2   nutrient status.

3   There will be screening of the

4   literature also for iron and vitamin D from

5   supplements. Oh, that will include a screening of

6   the literature, as well as vitamin D from

7   supplements and bone health.

8   We will then have to extract the data,

9   assess risk of bias, and develop conclusions and

10 grades for the five questions that are listed here.

11 And again, those are human milk and infant formula

12 consumption, growth, size and body composition,

13 and developmental outcomes, and then the specific

14 nutrients from supplements and the three outcome

15 areas that I mentioned.

16   And then lastly, we will be

17 drafting -- going through the peer-review process

18 and drafting the report. And with that, I would

19 like to again thank the members of the subcommittee

20 very much, thank and acknowledge the very hard and

21 extensive work by our support staff, who are listed

22 on this slide.

1   Thank you very much.

2   (Applause.)

3   VICE CHAIR KLEINMAN: Thank you, Kay,

4   for an incredibly complete summary of the work of

5   the subcommittee. So we've already had some

6   cross-cutting conversations between a few of the

7   subcommittees, but this is our opportunity now as

8   a full Committee to ask any further questions or

9   to comment on what Kay has presented.

10   So I'll open it up to the Committee now

11   for questions. Rick. And don't forget to say your

12   name.

13   MEMBER MATTES: Rick Mattes. So I

14   have five questions, but a lot of them will be

15   really short, I think, responses. The first is, you

16   used the term "intensity" of feeding. I'm just not

17   clear on what intensity means, so a clarification,

18   that would be helpful.

19   Your   recommendation   regarding   fat

20   intake and fatty acid status just referred to

21   association, whereas all the other recommendations

22   had directionality to them.

1   If it's possible to tweak that, I think

2   it would be more useful. If it's not, it's not.

3   In the report on never versus ever and

4   risk of type 1 diabetes, you found an association

5   there; this is my lack of knowledge, is there a

6   plausibility? Is there a mechanism that would make

7   that make sense?

8   With   the   peanut

9   recommendation -- again I'm old school -- is there

10   some subset of people that may actually be at risk

11   so a general recommendation saying early

12   introduction is okay, holds risk for some subgroup

13   of the population, or it really is a clear bill of

14   health for such a recommendation?

15   MEMBER DEWEY: Can you repeat that

16   again?

17   MEMBER MATTES: So the recommendation

18   for early exposure to peanut seemed to be just

19   generally positive, and I'm just wondering if there

20   is a subgroup of individuals that might be at risk?

21   Because if people just look at that recommendation,

22   they'd think that it's good to go, but maybe there

1   are some that would be at risk. I don't know.

2   And lastly, for the sugar

3   recommendation, it says that sugar-sweetened

4   beverage consumption during complementary feeding

5   is associated with increase of obesity, but not

6   associated with body composition. I'm just not

7   clear how to juxtapose those.

8   MEMBER DEWEY: So those are very good

9   questions, and I'm going to rely on others in the

10   room to help with some of the answers.

11   For the intensity of breastfeeding,

12   this is part of three different aspects of when

13   children are fed both infant formula and human

14   milk.

15   It relates to how many of the feeds are

16   human milk versus formula or the amounts, or in some

17   other way judging the proportion.   So the

18   intensity refers to how much of that is human milk.

19   It's a guesstimate, in most cases,

20   because they're not measuring human milk intake.

21   So that's why different words are used by different

22   researchers.

1   Is there any -- if anybody wants to add

2   anything from the staff who knows these definitions

3   by heart?

4   Yes, please, Darcy.

5   MS. GUNGOR: Just one clarification,

6   which is that intensity, proportionate amount, be

7   included in any evidence that was examined, either

8   at a single point in time or over a duration of time,

9   and that might have included another variable in

10   the definition such as months or years, that sort

11   of thing.

12   MEMBER MATTES: So in any write-up,

13   that will be defined somewhere?

14   MEMBER DEWEY: In the paper that was

15   published, that is given, yes.

16   And then in terms of fat composition of

17   complementary foods, and that we said there is an

18   association without the direction, and that was on

19   purpose, because it really depends on what fatty

20   acids are in those foods.

21   So if there is an increased amount of

22   polyunsaturated fatty acids, for example, that

1   will generally show up in the fatty acid status as

2   a positive relationship in the child. But it's not

3   simple to summarize that in the conclusion

4   statement.

5   So in the paper that was published, it

6   goes through exactly what all those relationships

7   were. We can talk further about whether there is

8   some way to modify that, but for that question,

9   we're relying on the existing review that's been

10   published already, and that's their exact wording.

11   MEMBER MATTES: So it is possible for

12   it to be inverse in some instances, or could it just

13   be stated as a direct relationship?

14   MEMBER DEWEY: Well, I would have to

15   read again exactly which studies that -- there's

16   always theoretically the possibility that if you

17   increase intake of omega-6, you might reduce

18   omega-3 status, or vice -- I mean, so -- and that's

19   why I don't want to get too specific about it right

20   now.

21   MEMBER DONOVAN: Yeah. And I think in

22   some the ever versus never types of questions,

1 because the composition of breast milk fatty acids

2 differ from formula, because the breastfeeding

3 moms' maternal diet, and formulas are added oil,

4 so I think in some cases they're higher, and in some

5 cases, they're lower.

6 So rather than have a conclusion

7 statement that was three paragraphs long to go

8 through each of them, it was basically a general

9 statement of there is associations between dietary

10 intake and the outcome.

11 MEMBER DEWEY: So I thought you were

12 referring to fatty acids from complementary foods

13 and beverages, but we've been also referring to the

14 never versus ever human milk and those questions?

15 MEMBER MATTES: I'm not sure where my

16 brain kicked off as you were going through, but for

17 either of them, I'm --

18 MEMBER DEWEY: Okay. So there were

19 two different questions where fatty acid status was

20 an outcome. One was from complementary foods and

21 beverages. That's what I was answering.

22 For human milk, ever versus never,

1 duration et cetera, we also shied away, as Sharon

2 explained, from stating a direction, because

3 it's -- as we were talking yesterday in our

4 subcommittee meeting, it's complicated, because of

5 the composition of human milk and the possibility

6 that the mammary gland has endogenous synthesis of

7 many of these fatty acids. And so it's

8 something that we will describe in more detail in

9 the write-up.

10 And then you asked about never versus

11 ever breastfeeding in type 1 diabetes and the

12 plausibility of that argument.

13 Yes, there is a biological rationale

14 for that. I'm not sure I'm ready to explain it

15 thoroughly here, but it relates to the components

16 that are in human milk and their relationship to

17 development of physiological function, immune

18 status and reaction to antigens.

19 If anyone else wants to go further than

20 that, be my guest.

21 VICE CHAIR KLEINMAN: That's an

22 absolutely fair summary. But one of the things

1   that I think is a little bit confusing is the

2   absence of any relationship to prediabetes, yeah

3   type 2.

4   You'd expect that those same markers

5   would be present in type 1 in advance of that

6   disease expressing itself. So we might want to pay

7   a little bit more attention to that, as we put this

8   together, because you'd expect insulin resistance,

9   glucose intolerance, A1Cs.

10   They don't -- you know, they rise

11 gradually both in type 1 and in type 2.

12   MEMBER DEWEY: Uh-huh.

13   VICE CHAIR KLEINMAN: Just a point

14 of -- for further discussion in the statement.

15   MEMBER DEWEY: That's a great idea. I

16 think we will take that up.

17   And then your fourth question was

18 regarding peanut exposure in the first year of

19 life, and I think the question was, are there

20 infants who are risk from that exposure because

21 they are at high risk to begin with?

22   Now, I am, again, going to defer, I

1 think, to the clinicians, but my understanding is

2 that those with a family history are usually

3 advised to be under the sort of supervision of the

4 health care provider when they first introduce that

5 allergen, to be careful about that.

6 So do you want to go further than that?

7 VICE CHAIR KLEINMAN: No. I think

8 that's absolutely right, and the studies use

9 test -- use individuals, infants, who have strong

10 family history, so these are the highest-risk

11 infants. So presumably, if they pass this test,

12 everyone else who is at lesser risk isn't going to

13 be put at greater risk as a result of the

14 introduction.

15 So that -- is that your question?

16 MEMBER MATTES: Yeah, yeah, that's --

17 VICE CHAIR KLEINMAN: Yeah.

18 MEMBER MATTES: -- exactly my

19 question. So the follow-up is does the

20 recommendation need to have that caveat in it, or

21 does that group of high-risk people sort of fall

22 out of the definition of the healthy population

1   that we're making recommendations for, and so it's

2   not necessary?

3   MEMBER DEWEY: Well, I'd like to say

4   we're not yet at the point of making dietary

5   recommendations. Right now we're only drafting

6   conclusion statements from the evidence. How to

7   put all this together into a recommendation is the

8   next challenge.

9   Yeah. There was one more question from

10   Rick --

11   VICE CHAIR KLEINMAN: Uh-huh?

12   MEMBER DEWEY: -- and that had to do

13   with sugar-sweetened beverages and why were those

14   related to overweight or obesity and not to the

15   continuous markers of body size or composition?

16   I think that the strongest evidence we

17   have is from one very large study where the outcomes

18   were dichotomous only, and so that's why we felt

19   comfortable saying that. We didn't have the same

20   amount or strength of evidence for the direct

21   continuous measures of weight for height or BMI or

22   anything like that.

1   That's my recollection. I'd have to go

2   back to that paper and look at it again, but that

3   was what I remember. Any additions to that?

4   MEMBER MAYER-DAVIS: So is this on?

5   They'll pick it up. Just start talking. I can start

6   talking. Okay. So back to the -- so this is Beth

7   Mayer-Davis. So, Kay, I have a question to follow

8   up to Rick's about type 1 diabetes. It's not

9   specified in the question itself, but I wonder if,

10   in your look at infant feeding with regard to type 1

11   diabetes, you were looking also as the occurrence

12   or appearance of diabetes autoimmunity?

13   MEMBER DEWEY: What was that?

14   MEMBER MAYER-DAVIS: The appearance of

15   diabetes autoimmunity, markers of diabetes

16   auto-antibodies, as a prelude to development of

17   Type 1 diabetes, because that's where some of the

18   mechanism comes in, in answer to your question,

19   Rick. And there is some literature on that.

20   MEMBER DEWEY: Oh. Darcy is quicker

21   than me. I'm looking here.

22   You're shaking your head, so those

1   markers were not --

2   MS. GUNGOR: No.

3   MEMBER DEWEY: Okay. So it was only

4   the other ones that we defined. Yeah. And again,

5   that was just done by the Complementary Feeding

6   TEC, and all of those definitions of outcomes are

7   in those published papers.

8   MEMBER SABATÉ: Yes. Joan Sabaté.

9   Regarding the timing and regarding the types of

10   foods and the outcomes that you have examined,

11   basically anthropometrics, biological measures of

12   fatty acids and minerals so on and so forth, and

13   also allergy, what was the outcome measured of

14   these studies?

15   I mean, within the 24 months, including

16   to the childhood, in adolescence or in adulthood,

17   or all this above?

18   MEMBER DEWEY: The age of outcome

19   assessment, if I'm correct, varied, depending on

20   the outcome domain. So if I remember correctly,

21   micronutrient status was generally the more short

22   term within the first two years of life.

1   I'm looking at Julie. She remembers.

2   Growth, size and body composition went up to -- was

3   it 18 or adulthood? Development went, I think, as

4   far as -- was available -- atopic and allergic

5   disease went all the way to adulthood?

6   Is that right?

7   DR. OBBAGY: Yes.

8   MEMBER DEWEY: Up to 18. And bone

9   health?

10   DR. OBBAGY: Eighteen.

11   MEMBER DEWEY: So most of them went

12   pretty long term. But the evidence base or may not

13   have been very strong out of those longer-term time

14   points.

15   VICE CHAIR KLEINMAN: Are there other

16   questions?

17   CHAIR SCHNEEMAN: So given the number

18   of conclusion statements where you've had, let's

19   say, insufficient evidence or no evidence, I'm

20   interested to know, is the subcommittee working on

21   the research agenda and particularly prioritizing

22   some of the most critical needs as far as this

1 research?

2 MEMBER DEWEY: Yeah. We are trying to

3 keep track of research recommendations as we go.

4 From the previous reviews that have been published,

5 they also did a good job of summarizing the research

6 needs. So that's kind of already there.

7 It's going to be a huge list, as you can

8 imagine. So prioritizing them is something that

9 I feel we need to discuss. In the context of

10 dietary guidelines, it might revolve around not

11 necessarily one of the most interesting questions

12 but which ones might have the biggest influence on

13 what we advise people to do.

14 So if there's already compelling

15 evidence from outcomes X, Y and Z for, let's say,

16 breastfeeding, well, do we need to go further

17 than -- and find outcomes -- you know, other

18 outcomes to add to that or not?

19 Whereas for some of the other dietary

20 recommendations for this age group, there's almost

21 nothing, and in those cases, we may not know what

22 to say at all, and so in that case, it might be a

1   higher priority.

2   So I'm just thinking out loud,

3   actually, about would you prioritize in this

4   particular situation.

5   VICE CHAIR KLEINMAN: All right. So I

6   think adults need to have a little break, and we've

7   been going for over an hour and a half, so we're

8   going to take exactly 10 minutes. Get up and

9   stretch or do whatever else you need to do.

10   And then we'll return and hear from

11   Sharon Donovan and the Pregnancy and Lactation

12   Subcommittee report.

13   Thank you. So 10:48.

14   (A short recess was taken.)

15   DR. STOODY: Thank you. Thanks for

16   joining us again after the break. I do want to just

17   make a quick announcement. We are in a multistory

18   building, and sometimes fire alarms do happen, so

19   if you hear one, please hold tight. We are told

20   if we are asked to evacuate, we'll hear an

21   announcement.

22   Sometimes they just evacuate the floor

1   that's involved and the floor above and below, so

2   if that is to happen, we'll hear an announcement,

3   and the exit is just right there at the top of the

4   stairs.

5   And thank y'all. I know several

6   have -- that is the preferred kind of in-and-out

7   for the meeting, if you can help that happen, just

8   to help kind of minimize some of the distraction

9   here at the front of the room.

10   So just a quick announcement, and I'll

11   turn it back over to the Committee.

12   VICE CHAIR KLEINMAN: Thank you very

13   much, Eve. I'm going to turn it over now to Sharon

14   Donovan, and she's going to summarize the work of

15   the Pregnancy and Lactation Subcommittee.

16   MEMBER   DONOVAN: Okay.   My

17   microphone's on. So my name is Sharon Donovan, and

18   it's my pleasure to present on behalf of the

19   Pregnancy and Lactation subcommittee. If I can

20   have the slides, please.

21   VICE CHAIR KLEINMAN: We need to have

22   the slides brought up, please.

1   MEMBER DONOVAN: So I'll go ahead and

2   start talking while that's coming. So this shows

3   the subcommittee members, and I'd like to thank

4   them all for all of their hard work, on our weekly

5   call, and on the work between the calls.

6   So my goal today will be to discuss the

7   evidence synthesis creating a conclusion for eight

8   reviews. But before we get started, I wanted to

9   just provide just kind of an overview to remind

10   people of the questions that were assigned to our

11   subcommittee.

12   So there were three major categories.

13   One -- the first was nutrients and supplements in

14   fortified foods, and this could be consumed before

15   and during pregnancy and lactation.

16   So we looked at up to six months prior

17   to conception, and during pregnancy and/or

18   lactation. We are examining six nutrients, so

19   B-12, folate, iron, iodine, vitamin D, and

20   omega-3s -- they should sound fairly familiar from

21   Kay's presentation -- and five outcomes, so human

22   milk composition, gestational diabetes,

1   hypertensive   disorders   of   pregnancy,

2   neurocognitive development of the infant, and

3   micronutrient status of the mother.

4   So that was our first set of questions.

5   The second relates to dietary patterns during

6   pregnancy and with five outcomes. I'm not going

7   to read all of those, but you can see these are

8   related to the maternal dietary patterns during

9   pregnancy, and three outcomes during lactation, so

10   milk   composition,   infant   neurocognitive

11   development, and postpartum weight loss.

12   We also had a third area, which was

13   maternal diet and food allergies and atopic

14   diseases in the infant. So as noted, the NESR

15   staff has been working very diligently, and thus

16   far has screened 21,500 articles and extracted the

17   data and assessed risk of bias from 42. And

18   obviously, additional searches and extraction are

19   underway.

20   So again, just -- within each of these

21   three areas, just to briefly remind you of where

22   we are in the process:

1   So for folate, we have addressed all

2   five questions. And so the effect of maternal

3   folate from supplements or fortified foods on human

4   milk composition and gestational diabetes was

5   presented in meeting three, and that information

6   is available on the Dietary Guidelines.gov.

7   Today, I will be presenting on maternal

8   folate from supplements and fortified foods on

9   hypertensive   disorders   of   pregnancy,

10   neurocognitive development of the infant, and

11   micronutrient status of the mother.

12   As noted, our committee is currently in

13   the process of refining and prioritizing the

14   additional searches for these -- the rest of the

15   nutrients and these outcomes. So you can just do

16   the math to see this would have been quite a number

17   of systematic reviews to address all of these.

18   So in terms of dietary patterns, today

19   I'll be presenting a new systematic review on the

20   impact of dietary patterns on human milk

21   composition, and as with the B-24 Project, there

22   were four previous NESR systematic reviews that

1   were developed as part of the Pregnancy and Birth

2   to 24 Project.

3   So we examined those, as Kay described.

4   We looked at the -- we ran through each of the

5   statements. We also looked at any papers that have

6   been published since January 2017, which was the

7   end of the these reviews, to see whether any primary

8   research -- and we also looked at existing

9   systematic reviews published since that time to see

10   whether they caught any papers, mainly with an eye

11   to has there anything really been published in the

12   last two years that would impact the conclusions

13   made in those systematic reviews?

14   And as with B-24, we decided to accept

15   those existing reviews, NESR reviews, and so I'll

16   review those outcomes. Currently, we're looking

17   at the dietary patterns on gestational weight gain,

18   postpartum weight loss, micronutrient status, and

19   infant neurocognitive development, and the plan is

20   to present those at meeting five. Also underway

21   is the question on maternal diet and food allergies

22   and atopic diseases, which will also be presented

1   in March.

2   So jumping into our first folic acid

3   questions, what is the relationship between folic

4   acid supplements and/or fortified foods consumed

5   before and during pregnancy on the risk of

6   hypertensive disorders?

7   So just as a reminder, the definitions

8   that we've used for dietary supplements, basically

9   from the Dietary Supplement and Health Education

10   Act, so products other than tobacco that is

11   intended to supplement the diet. And

12   fortification, again, the FDA definition -- the

13   deliberate addition of one or more essential

14   nutrients.

15   So briefly, you've seen the layout for

16   the analytical framework. So in terms of folic

17   acid, our interventions and exposures were

18   exposure to and including intake of folic acid from

19   supplements, fortified foods or the combination,

20   and the comparators were a different level of

21   exposure, including no exposure from supplements,

22   fortified foods, or a combination.

1   In this case, the population was the

2   women before and during pregnancy, either healthy

3   or at risk for chronic diseases, and in this case,

4   hypertensive disorders of pregnancy.

5   We had intermediate outcomes that we

6   examined, including blood pressure and

7   proteinuria, and then we have the longer-term

8   outcomes of eclampsia, preeclampsia, and

9   gestational hypertension.

10   Summarized at the bottom are the key

11   confounders, and most of those are ones that we're

12   including in all of our systematic reviews. We

13   also have other factors to continue -- or consider

14   for the hypertension -- hypertensive disorders,

15   which include physical activity and substance

16   abuse and gestational age.

17   So this search was done in

18   combination -- oh, I'm sorry. This one. This

19   search was -- actually, it was. I'm sorry. So

20   this was done in combination with the search for

21   folic acid and hypertension and gestational

22   diabetes, and as I mentioned, gestational diabetes

1   was presented at the last meeting.

2   So we screened 622 articles and we

3   included eight related to hypertension, and you can

4   see on the right that the included articles were

5   three RCTs, two non-randomized controlled trials,

6   and three prospective cohorts.

7   And all of them directly asked the

8   question of the relationship between folic acid

9   supplements consumed during -- before and during

10   pregnancy -- and we basically will present later,

11   but we did not find evidence on fortified foods --

12   in folate in fortified foods.

13   So describing first the three RCTs, the

14   sample characteristics between 123 and 450, all of

15   these RCTs were conducted in Iran, and two were from

16   the same study. The interventions -- so again,

17   they were 25 in a normal pre-pregnancy BMI. The

18   race and ethnicity and SES were not reported, but

19   again they were all conducted in the same country.

20   The interventions varied by dose, so

21   .5, 1, or five milligrams of folic acid, and they

22   were all initiated in the first trimester and

1   continued through delivery. All reported

2   preeclampsia and blood pressure, and some reported

3   other outcomes, proteinuria, eclampsia,

4   gestational hypertension.

5   So the two non-randomized controlled

6   trials, one was conducted in Italy and one in China,

7   range from 146 to nearly 5,000 subjects.

8   Again, Caucasian, and race and ethnicity in China

9   was not directly reported, nor was SES.

10   The group in Italy had pre -- this was

11   in a higher-risk group, so these were women who had

12   preeclampsia in a previous pregnancy, and so this

13   will factor into some of our conclusions.

14   So this was the one thing that you can

15   imagine, with these different studies, they have

16   different levels of exposure, and also in this

17   study, they had 5-methyltetrahydrofolate as a

18   supplement, and they ranged in initiation, but they

19   all went through delivery.

20   And then the three prospective cohort

21   studies, you can see the n's. These were in

22   Australia, Canada, and Denmark. The women were

1 between 20 and 30 years of age, and you can see the

2 race and ethnicity. They range from low to high

3 SES within these countries.

4 So in these, they actually compared no

5 supplement with a folate or folic acid alone. And

6 they had initiation and duration of various times,

7 so you know, by trying to look at the evidence we're

8 taking into account when the timing of the

9 initiation and the duration was, and the primary

10 outcome was preeclampsia.

11 So the summary of the evidence. So

12 none of the RCTs found an association between folic

13 acid supplementation and the incidence of

14 hypertensive disorders of pregnancy, including

15 gestational hypertension, preeclampsia, or

16 eclampsia, and none of the studies compared folic

17 acid supplementation to a control group that had

18 no supplementation. So in these studies, the

19 control did have a low level -- lower level of

20 exposure.

21 In contrast, when we looked at the

22 non-randomized controlled trials, both found a

1   significant association between folic acid

2   supplementation from early pregnancy through

3   delivery and reduced risk of preeclampsia and

4   gestational hypertension, compared to controls

5   with no folic acid supplementation.

6   And you can see, for preeclampsia,

7   significant reduction, both in this case -- both

8   for high risk and low risk, and for gestational

9   hypertension, again, a significant reduction.

10   And one non-controlled RCT was among high-risk

11   population of women who had previously been

12   diagnosed with preeclampsia.

13   So when we looked at the three

14   prospective cohort studies, the results were

15   mixed. One found an association with folic acid

16   in the first trimester and lower incidence of

17   preeclampsia, but specifically for women with a

18   higher BMI.

19   Another found an

20   association -- significant association between

21   folic acid use between 12 and 20 weeks of gestation

22   and preeclampsia, again, in women at high risk, and

1   a third found no association.

2   So our draft conclusion statement is

3   that limited evidence suggests that folic acid

4   supplementation during early pregnancy may have a

5   beneficial effect on reducing the risk of

6   hypertensive disorders during pregnancy among

7   women at high risk, either having a history of

8   preeclampsia or a higher pre-pregnancy BMI,

9   compared to no folic acid supplementation.

10   This conclusion was supported by

11   three -- or two non-randomized controlled and the

12   three prospective cohorts. The studies were all

13   direct in terms of the question, and they were

14   consistent for the higher-risk women.

15   And as with all of the studies, there

16   were some concerns about risk of bias, precision,

17   and generalizability, particularly for some of the

18   studies that were not done in the U.S.

19   So there was moderate evidence

20   suggesting that higher levels of folic acid

21   supplementation during pregnancy, compared to

22   lower levels, including no folic acid, does not

1 affect the risk of hypertensive disorders during

2 pregnancy among women at low risk. So we had a

3 separate conclusion for women at high versus low

4 risk.

5 And there's no evidence available to

6 draw a conclusion about the relationship between

7 folic acid from fortified foods before and during

8 pregnancy and the risk of hypertensive disorders

9 during pregnancy.

10 So turning now to the relationship

11 between folic acid supplements and/or fortified

12 foods consumed by the mother before and during

13 pregnancy and developmental milestones, including

14 neurocognitive development of the infants. This

15 is another new systematic review.

16 So the analytical framework,

17 intervention/exposure were the same in terms of the

18 outcomes. In this case, the population for the

19 outcome is the infant.

20 So we had infants and toddlers, birth

21 to 24 months, but we also incorporated children and

22 adolescents from two to 18 for some of the

1 developmental outcomes, and you can see these are

2 listed, because not all of the evidence is

3 available in early childhood.

4   So for example, we were looking at

5 academic performance, also attention deficit

6 disorder, ADHD, anxiety, depression, and autism.

7 So in addition to some of the developmental

8 milestones, we needed to extend the search

9 criteria.

10   So with key confounders, some of the

11 aspects that we added to this one were child sex,

12 breastfeeding practices, intensity and duration,

13 and you can see in other factors to be considered,

14 we also looked at -- took into account, a family

15 history of a diagnosis of a neurocognitive

16 disorder.

17   So we had a total of 1,831 articles that

18 were screened, and six were included. There were

19 actually four studies that produced the six

20 articles. Two RCTs that have three articles.

21 One prospective cohort published in two articles,

22 and one nested case-control. And they all

1   addressed the question of again, folic acid

2   supplements consumed during pregnancy on the

3   neurocognitive outcomes.

4   So the sample characteristics are

5   shown, range of 39 to 130, 17 to 37 children, that

6   were conducted in the U.K., Germany, and then a

7   study that incorporated participants from three

8   countries in Europe.

9   You can see the mothers were 20 to 31,

10   mostly white and higher SES, and the outcomes of

11   children for -- were older, so the children in

12   these studies were between six and a half and eight

13   and a half.

14   The interventions, again, varied by

15   dose. They also had an intervention with or

16   without fish oil. The initiation was at 14 or 20

17   weeks gestation and through delivery. And again,

18   the outcomes are shown below, but we'll go through

19   those.

20   So the one prospective cohort was done

21   in Norway. This was a very large study. Again,

22   the maternal age and high SES, and in this case,

1   the children were assessed at three years of age.

2   The dose basically was determined from

3   a questionnaire of folic acid supplementation.

4   And they looked at kind of two different phases.

5   So they looked at early, which could be four weeks

6   before conception to eight weeks of gestation, and

7   then those mothers who are supplemented, who

8   reported the folate between nine and 29 weeks of

9   gestation. So we're looking at the two different,

10   early and late.

11   So   the   outcomes   were   language

12   competence and then language delay. The nested

13   case-control was a study from Israel which, in this

14   case, 60 percent were low SES.

15   They assessed the children between six

16   and 12. The major outcome was AS -- autism

17   spectrum disorder diagnosis, and in this case, the

18   folic acid exposure was assessed by pharmaceutical

19   prescriptions.

20   So they basically were able to look at

21   the women who were prescribed folic acid or not,

22   and they looked before and during pregnancy and the

1   duration assessed before and during pregnancy or

2   birth.

3   So the summary of the evidence that

4   generally folic acid supplementation before or

5   during pregnancy was either not associated with or

6   had a beneficial association with the following

7   outcomes:

8   So language development. Two articles

9   from the prospective cohort study showed a lower

10   risk of severe language delay in three-year-olds

11   whose mothers consumed folic acid supplements

12   during early pregnancy.

13   For ASD, the one nested case-control

14   found a significant association between folic acid

15   supplementation before and during pregnancy and

16   lower ASD risk in eight-to-12-year-old children.

17   So for cognitive development, the

18   findings were inconsistent and no conclusions can

19   be drawn. For social-emotional development, we

20   included one study with concerns and no conclusion

21   could be drawn.

22   When we looked at movement or physical

1 development, academic performance, ADD or ADHD,

2 anxiety and depression, there was no evidence on

3 supplementation before or during pregnancy. And

4 developmental milestones and neurocognitive

5 development, there's no evidence on

6 supplementation during lactation and/or intake of

7 folic acid from fortified foods consumed before or

8 during pregnancy and lactation.

9   So the draft conclusion statement:

10 Limited evidence suggests folic acid

11 supplementation during early pregnancy may be

12 associated with lower risk of delayed language

13 development in the child.

14   So that, again, the conclusions were

15 based on two studies from one prospective cohort

16 study. The study -- they were direct in terms of

17 the question. We had some issues with

18 consistency, and there were some concerns, again,

19 regarding risk of bias, precision, and

20 generalizability, because it was one study, one

21 prospective cohort study.

22   There was limited evidence to suggest

1   that folic acid supplementation before and during

2   pregnancy may be associated with lower risk of

3   autism spectrum disorder in the child.

4   So again, this was based on the one

5   nested case-control study from Israel.

6   Consistency cannot be assigned, and there were some

7   concerns regarding risk of bias, precision, and

8   generalizability.

9   Insufficient evidence is available to

10   determine a relationship between folic acid from

11   supplements and fortified foods consumed before

12   and during pregnancy on cognitive development or

13   social-emotional development.

14   And there's no evidence on supplements

15   or fortified foods, folate, on movement or physical

16   development of the child, academic performance of

17   the child, and also the ADD or ADHD. So these are

18   supplements and/or fortified foods. And so for

19   these, these are grades not assignable.

20   There was also no evidence for the

21   relationship between folate supplements and

22   fortified   foods   performed   during

1   lactation -- pregnancy and lactation on anxiety or

2   depression. So a grade is not assignable.

3   So basically this was looking at

4   lactation. So there was no evidence available to

5   look at supplements consumed during lactation on

6   development milestones, including neurobehavioral

7   development, and no evidence on fortified foods

8   consumed either during pregnancy or lactation.

9   So all the conclusions were based on

10   some folate from supplements before or during

11   pregnancy.

12   So the final folate question from a new

13   systematic review is looking at the relationship

14   between folic acid consumption and maternal

15   micronutrient status.

16   Again, similar framework, basically if

17   you look at the health outcomes, when we looked at

18   the folate status, we looked at: plasma blood

19   folate, B12, hemoglobin, mean corpuscular volume

20   and red cell -- red blood cell distribution width,

21   were the outcomes.

22   4,512 articles were screened, of which

1 there were four -- I'm sorry -- for the -- I'm

2 sorry -- 14 for micronutrient status, and of those

3 14, there were nine RCTs, three prospective

4 cohorts, one randomized cohort and one

5 uncontrolled before-and-after study.

6 All of the studies addressed directly

7 the question of supplements consumed before and

8 during pregnancy and lactation and micronutrient

9 status.

10 So to go through the nine RCTs, they

11 range from a very small study to a study of 189.

12 Three were conducted in Canada, two in the U.S.,

13 and one each in Iran, the U.K., Mexico, and France.

14 The women in most studies were between the ages of

15 26 and 34, mostly Caucasian and high SES, but one

16 study was in lower -- teenaged mothers with lower

17 SES. And in one study, it was conducted in 100

18 percent iron-deficient anemic women.

19 So the interventions varied across the

20 nine RCTs, ranging from 300 micrograms to five

21 milligrams of folic acid. And also, one study

22 looked at the methyltetrahydrofolate, and one

1 study looked at folinic acid.

2   The initiation varied from

3 pre-conception during pregnancy as well as

4 postpartum, and the duration was between one and

5 12 months. And most included serum plasma or red

6 blood cell folate, and other outcomes, common

7 outcomes, were B12, hemoglobin and mean

8 corpuscular volume.

9   So the three prospective

10 cohorts -- again, we're -- you can see the n,

11 conducted in Ireland, Germany and Canada, again,

12 29- to 30-year-old women, and within these

13 countries, race, ethnicity and SES were not

14 reported.

15   They looked at folic acid

16 supplementation via questionnaire versus none.

17 And there was various times of initiation and

18 duration of the study. So again, when we're

19 looking at the literature, we're trying to take

20 into account dose as well as the timing of exposure.

21 All of these reported plasma folate, and two

22 reported red blood cell folate, and one incidence

1   of folate deficiency.

2   The retrospective cohort -- Sorry. I

3   think I said that wrong before. The retrospective

4   cohort was conducted in Turkey. They compared

5   zero versus 400 micrograms per day of folic acid.

6   They initiated pre-conception, but the timing of

7   assessment varied by the participant. So they

8   all -- they didn't have a specific time point.

9   The   outcomes,   again,   folate,

10   hemoglobin, and incidences of folic deficiency.

11   And there was a -- one uncontrolled

12   before-and-after study conducted -- a small study

13   conducted in Japan, and there was a limitation

14   of -- was -- that was not a lot in terms of the

15   participant characteristics, other than all from

16   the same SES.

17   So these were women that they gave a

18   supplement of one milligram per day of folic acid,

19   and then they were each -- sort of -- their own

20   control. They initiated this anywhere between

21   three and 25 weeks postpartum, and the duration was

22   four weeks.

1   So, all but one study found a

2   significant association between folic acid

3   supplementation and at least one outcome measure.

4   So, nine of 13 found positive association between

5   folic acid supplementation and plasma or serum

6   folate.

7   Nine of the 10 found positive

8   association between supplementation and red blood

9   cell folate. And two of five reported positive

10   association between folic acid supplementation and

11   hemoglobin. And there was no association found

12   between folic acid supplementation and these other

13   measures that we had included.

14   So, based on that, we've drafted a

15   conclusion that strong evidence suggests that

16   folic acid supplementation before and during

17   pregnancy is positively associated with folic acid

18   status using the outcomes of serum and plasma

19   and/or red blood cell folate.

20   The studies, again, were direct and

21   precise and consistent. Some concerns regarding

22   generalizability, but we felt that the evidence was

1   strong.

2   There was moderate evidence suggesting

3   that folic acid supplementation during lactation

4   is positively associated with red blood folate and

5   may be positively associated with serum and plasma

6   folate.

7   There was insufficient evidence

8   available to determine the relationship between

9   folic acid supplements before and during pregnancy

10   or during lactation on hemoglobin, MCV or B12, so

11   grade not assignable.

12   And no evidence to determine a

13   relationship with folic acid supplemented during

14   this time on red blood cell distribution width.

15   And again, there was no data, no evidence on folic

16   acid from fortified foods before and during

17   pregnancy and folate status.

18   So that's the summary of the three, and

19   our final three searches on folic acid. And so now

20   I'm going to turn to the question related to dietary

21   patterns. So, the first is a new NESR systematic

22   review on dietary patterns consumed during

1   lactation and human milk composition and quantity.

2   So again, a dietary pattern, as is being

3   defined and used by all of the subcommittees: so,

4   we're looking at quantities, proportions,

5   varieties, combinations, of the different foods.

6   So, to set up the analytical framework

7   for dietary patterns, the intervention and

8   exposure is consumption of and/or adherence to a

9   dietary pattern versus consumption or adherence to

10   a different dietary pattern or a different level

11   of consumption.

12   For example, we'll discuss studies that

13   have different fatty acids. So, the population

14   for milk composition, again, women during

15   lactation, healthy or at risk of chronic disease,

16   human milk quantity. These are exclusively or

17   predominantly breastfeeding women who are healthy

18   or at risk of chronic disease.

19   So we had a number of outcomes for human

20   milk composition. And these -- the milk samples

21   were all collected -- needed to be collected after

22   14 days postpartum, so we were looking at more

1   So, all of them address the

2   relationship between maternal dietary pattern

3   during lactation and either human milk composition

4   or quantity.   So, the three RCTs, again,

5   relatively small studies, seven to 15 mothers,

6   conducted in the U.S. and Canada, 29 years of age,

7   and SES and race and ethnicity not reported.

8   So, the initiation between six weeks

9   and six months postpartum. The durations were

10   four to 14 days.   And they were reporting

11   different -- varied patterns. So carbohydrate,

12   either lower carbohydrate or higher fat versus

13   within the acceptable macronutrient distribution

14   range, or the AMDR. Another looked at higher fat,

15   and a higher carbohydrate and lower fat, and

16   another, higher fat versus consumption within the

17   AMDR.

18   So, you can see the various outcomes.

19   Most of the studies reported outcomes on fatty

20   acids, and one for B12.

21   So, for the cross-sectional studies,

22   these were conducted in the U.S. and Canada. They

1   were, on average, 30 -- nearly 30 -- I'm

2   sorry -- U.S. and China. The moms in the U.S. were

3   highly educated and in China, high-middle income,

4   and within the U.S., the race/ethnicity, reported

5   mostly white.

6   So, initiation, between 21 days

7   postpartum and six months, and nine and a half

8   months postpartum. So, these were ones that

9   looked more at the overall dietary patterns. So,

10 the study in the U.S. compared milk composition

11 with vegan, vegetarian, and non-vegetarian

12 mothers. And the study from China basically divided

13 the mothers into four different dietary patterns.

14 So, it's mushrooms, meat, seafood; soy, nuts,

15 dairy; fruits, vegetables; and then grains,

16 potato, beans and eggs.

17   So, summary of the evidence. So, one

18 cross-sectional study assessed the relationship

19 between maternal dietary patterns and total fat

20 levels in human milk and found no association.

21   Three RCTs assessed the relationship

22 between maternal diet based on macronutrient

1   proportions and total fat level in milk. Two found

2   a positive association -- positive relationship

3   between greater than 35 percent of energy from fat

4   and total fat in human milk, and one study found

5   no association between macronutrient proportions

6   and maternal diet and total fat.

7   So, the draft conclusion statements for

8   total fats is that insufficient evidence is

9   available to determine the relationship between

10   dietary patterns consumed during lactation and

11   total fat in milk, and there's limited evidence to

12   suggest that maternal consumptions of diets higher

13   in fat during lactation is related to higher total

14   fat, with a grade of Limited.

15   The studies were consistent, but there

16   were concerns about precision, generalizability,

17   and consistency, and we had a long conversation

18   yesterday, because these are also being used for

19   other outcomes that -- probably measuring fat in

20   human milk is one of the most difficult components,

21   because some studies were measuring during the fed

22   state versus the fasting state, and because the

1   content of milk differs from fore-milk to

2   hind-milk, so within a single feeding, if they're

3   just taking a single sample or not a full breast

4   expression or sampling over 24-hour periods, all

5   of these things can really affect the composition.

6   So that was, you know, some of the concerns that

7   we have about the precision.

8   So two cross-sectional studies and

9   three RCTs assessed the relationship between

10   maternal dietary patterns, including based on

11   macronutrient proportions and levels of saturated

12   fatty acids, MUFAs and PUFAs, and there were mixed

13   results.

14   So in terms of saturated fats, MUFAs and

15   PUFAs, there's limited evidence to suggest the

16   maternal dietary patterns during lactation,

17   including diets based on macronutrient

18   distributions, are related to the relative

19   portions of saturated fat, MUFAs and PUFAs.

20   And we meant to very specifically say

21   relative proportions, because studies also

22   presented concentrations, and they were not

1   effects on concentrations, there were primarily

2   with the proportions of these fatty acids. So

3   again, some concerns about risk of bias and limited

4   precision and generalizability were some of the

5   concerns the committee had.

6   So, one RCT assessed the relationship

7   between maternal diet based on macronutrient

8   proportions and milk quantity, and there was no

9   association.

10   Also, there was one that looked

11 at -- one RCT -- on the relationship with total

12 protein levels in milk, and there was no

13 association. And the last, one cross-sectional

14 study assessed the relationship between maternal

15 dietary patterns and B12, and this was the study

16 that compared the vegan, vegetarian and

17 non-vegetarian, and while there is no association

18 with dietary patterns, we found that 56 percent of

19 the vegan women were taking a B12 supplement, and

20 so we thought that they were really kind of unable

21 to determine the impact of dietary patterns on B12.

22   So, in terms of the draft conclusion

1   statements, on quantity, there's no evidence

2   available to determine a relationship between

3   dietary patterns and milk quantity, and

4   insufficient evidence to determine a relationship

5   on maternal diets differing in macronutrient

6   distribution during lactation and milk quantity.

7   Again, similar -- so for total protein,

8   no evidence for dietary patterns and no evidence

9   for dietary patterns differing in macronutrient

10   composition. And for B12, again, insufficient

11   evidence is available to determine the

12   relationship between maternal dietary patterns

13   during lactation and vitamin B12 concentrations in

14   human milk.

15   So, there were no studies found that

16   assessed the relationship between maternal dietary

17   patterns and human milk levels of these other

18   nutrients that were part of our framework, so our

19   water-soluble vitamins, fat-soluble vitamins,

20   iodine, selenium, human milk oligosaccharides or

21   bioactive proteins.

22   So, I'm not going to read all these, but

1 basically these are the draft conclusion

2 statements that there was no evidence, and so all

3 are grades not assignable.

4   So now I just -- we'll go through

5 summarizing the results from the existing NESR

6 reviews. So as was mentioned, as part of the

7 Pregnancy B-24 project, there were four systematic

8 reviews that were conducted that are pertinent to

9 the Pregnancy and Lactation Subcommittee.

10   So, the first was the relationship

11 between dietary patterns during pregnancy and the

12 risk of hypertensive disorders during pregnancy,

13 and the second was risk of gestational diabetes.

14   Then there were two systematic reviews

15 looking at dietary patterns during pregnancy on

16 infant outcomes, so gestational age at birth and

17 birth weight standardized by gestational age and

18 sex.

19   So we are, as I mentioned, adopting the

20 existing reviews. But new protocols are posted on

21 DietaryGuidelines.gov. So again, if you're

22 interested in the complete documentation, they're

1   available at DietaryGuidelines.gov.

2   In addition, just to acknowledge this

3   was the member of the Pregnancy Technical Expert

4   Collaborative, or TEC, who worked on this and

5   drafted the conclusions.   And these four

6   systematic reviews, as with the ones that Kay

7   mentioned, were published in the American Journal

8   of Clinical Nutrition in 2019.

9   So, the two maternal outcome systematic

10   reviews were combined in one paper, and the two

11   infant systematic -- pregnancy outcome, birth

12   outcomes, were in another. So you can not only

13   review the actual results of the systematic reviews

14   on DietaryGuidelines.gov. But, you can also refer

15   to these manuscripts.

16   So just to briefly review the evidence,

17   so for the first, what is the relationship between

18   dietary patterns during pregnancy and the risk of

19   hypertensive disorders?

20   So, this systematic review included

21   eight studies from four cohorts and one RTC, and

22   this was over a 37-year range of evidence. So,

1   I'll just reiterate, and I mentioned before what

2   Kay mentioned, but we also did then look to see what

3   was published after January 2017 in order to make

4   our final decision on whether we would go ahead and

5   accept the existing reviews.

6   So for these questions related to

7   dietary patterns and risk of hypertensive

8   disorders, the limited evidence in healthy

9   Caucasian women with access to health care suggest

10   the dietary patterns before and during pregnancy

11   higher in vegetables, fruits, whole grains, nuts,

12   legumes, fish and vegetable oils and lower in meats

13   and refined grains are associated with reduced risk

14   of hypertensive disorders during pregnancy,

15   including   preeclampsia   and   gestational

16   hypertension.

17   Not all components of the assessed

18   dietary patterns were associated with all

19   hypertensive disorders. So limited -- the grade

20   was limited.

21   Evidence is insufficient to estimate

22   the association between dietary patterns before

1   and during pregnancy and the risk of hypertensive

2   disorders in minority women and those of lower

3   socioeconomic status. So, grade not assignable.

4   So, the relationship between dietary

5   patterns during pregnancy and gestational

6   diabetes. This was -- included 10 prospective

7   cohorts and one pilot RCT, again, collected between

8   publication January 1980 and January 2017.

9   So, this systematic review concluded

10 there was limited but consistent evidence

11 suggesting certain dietary patterns before

12 pregnancy are associated with a reduced risk of

13 gestational diabetes.

14   These protective dietary patterns are

15 higher in fruits, vegetables, whole grains, nuts,

16 legumes and fish, and lower in bread and processed

17 meats. Most of the research was conducted in

18 healthy Caucasian women with access to health care.

19   Evidence is insufficient to estimate

20 the association between dietary patterns during

21 pregnancy and the risk of gestational diabetes.

22 So, again a conclusion on diet before pregnancy,

1   but not actually during pregnancy, so grade not

2   assignable.

3   So, in turning now to the infant

4   outcomes.   The relationship between dietary

5   patterns in pregnancy and gestational age at birth.

6   There were 10 prospective cohorts and one RCT,

7   again, over the same time range.

8   So, limited but consistent evidence

9   suggests that certain dietary patterns during

10   pregnancy are associated with lower risk of preterm

11   birth and spontaneous preterm birth. Protective

12   dietary patterns are higher in vegetables, fruits,

13   whole grains, nuts, legumes and seeds, and seafood,

14   for preterm birth only; and lower in red meat,

15   processed meats, and fried foods. Again, noting

16   a limitation, most of the research was conducted

17   in healthy Caucasian women with access to health

18   care.

19   And this is kind of the opposite, that

20   the evidence was insufficient to estimate the

21   association on dietary patterns before pregnancy

22   and gestational age at birth, as well as preterm

1   birth.

2   So, the last relationship between

3   dietary patterns during pregnancy and birth

4   weights, standardized by gestational age and sex,

5   there were 18 prospective cohorts, one

6   retrospective cohort, and two randomized

7   controlled trials.

8   So, the conclusion is that no

9   conclusion can be drawn on the association between

10   dietary patterns during pregnancy and birth weight

11   outcomes. Although research is available, the

12   ability to draw conclusions is restricted by

13   inconsistency of study findings, inadequate

14   adjustment of birth weight for gestational age and

15   sex, and variation in study design, dietary

16   assessment methodology, and adjustment for key

17   confounding factors.

18   And insufficient evidence exists to

19   estimate the association between dietary patterns

20   before pregnancy and birth weight outcomes. In

21   this case, there were not enough studies available

22   to answer the question.

1   So, our ongoing work is -- I mentioned

2   that we are refining and prioritizing work on

3   dietary   patterns   during   pregnancy   and

4   micronutrient status; dietary patterns during

5   lactation and developmental milestones of the

6   child, including neurocognitive development; and

7   dietary supplements and fortified foods for all the

8   other nutrients besides folate.

9   So as noted, we'll review the evidence,

10   grade, and draft conclusion statements for these

11   following   questions: dietary   patterns   in

12   pregnancy and gestational weight gain; patterns

13   during lactation and postpartum weight loss; the

14   maternal diet during pregnancy and lactation on the

15   risk of child food allergies and atopic diseases.

16   And the plan is then to present these at the meeting

17   in March.

18   So again, thanking the subcommittee

19   members, as well as our support staff, which we

20   would not be able to get through all of this work

21   without all their hard behind-the-work scenes.

22   So, I will be happy to take questions.

1   (Applause.)

2   VICE CHAIR KLEINMAN: That was a great

3   summary. So, any questions from the Committee?

4   Rick?

5   MEMBER MATTES: Only one this time.

6   Rick Mattes. So, what's known about the validity

7   of self-reported supplement use during pregnancy

8   and lactation? Is it different from the general

9   population? Can we believe this data more or less

10   than general studies about diet and outcomes?

11   And in any of these trials, was there

12   objective verification of compliance with a

13   prescribed dose?

14   MEMBER BAILEY: So, you can get a

15   compliance sometimes in a clinical trial -- this

16   is Regan answering with Sharon, not for Sharon.

17   So, there are ways to look at the supplements by

18   putting PABA in and getting recovery from urine,

19   so that's one way to test it.

20   I can't speak to whether or not that was

21   done in your studies, but I just wanted to make that

22   comment.

1   MEMBER DONOVAN: I think it's a great

2   question, and I don't know if anyone else is aware

3   of studies where they've looked at self-reported

4   compliance of pregnant versus non-pregnant women.

5   Obviously, women during pregnancy may

6   be taking supplements more often and may be more

7   motivated, but I don't think there's the evidence

8   and -- just thinking offhand -- and if anyone can

9   speak to that in terms of the studies that we

10   reported; I'm not sure that anyone actually

11   confirmed intake of the folate supplements.

12   MEMBER STANG: Jamie Stang. Yeah. I

13   was on the Pregnancy TEC, and studies for the most

14   part did not report compliance. I know from

15   unpublished work that the compliance rates start

16   out high, and as you go through pregnancy, they drop

17   off, but in terms of actual published documentation

18   of what that compliance would be, I'm not aware of

19   any.

20   MEMBER MATTES: So just -- this is a

21   comment that may be a good point to add into the

22   discussion of this section.

1   MEMBER DONOVAN: That's a great point,

2   and also research needs -- to have better

3   collection of that type of data.

4   (Off-mic comments.)

5   MEMBER DONOVAN: Perfect.

6   MEMBER BOUSHEY: So, this is Carol

7   Boushey. And I'm looking at the analytical

8   framework for the folic acid with supplements.

9   And you don't have to look at it; you have it

10   memorized. So -- but folic acid and supplements

11   and the fortified foods, before and during

12   pregnancy and lactation.

13   And one of the studies, I think, had 11

14   people or 15 or something like that, and you had

15   said it was a small sample size, and in the

16   frequency-of-eating group, we actually did -- went

17   through the process of figuring out sample size so

18   that we could screen out some of the smaller

19   studies.

20   And I wonder if you might consider doing

21   that for some of your studies, so that you can

22   determine if those studies actually didn't meet

1   sample size.

2   So it wasn't that you, you know, went

3   crazy over it anyway, but still it might be nice

4   to have that documentation.

5   MEMBER DONOVAN: Yeah. No.   That's a

6   great point. I remember we had this conversation

7   at the last meeting, and I think -- we also talked

8   about for the RCTs, that, because they're more

9   controlled, that the n was not as -- necessarily

10   as much of a consideration, but I think -- I don't

11   remember if this study with 11 was an RCT or -- so

12   I can't speak to that directly, but I think it's

13   an excellent point.

14   And as you could see, the studies varied

15   from 11 to 45,000, so it's quite a mixed literature

16   that we're trying to assess and draw conclusions

17   from.

18   CHAIR SCHNEEMAN: I had a quick -- this

19   is Barbara Schneeman. I had a question, again,

20   going back to the supplementation.

21   I know that in your protocol, you

22   allowed for multivitamin supplements, and I'm just

1 wondering then, as you went through the data and

2 the evidence where you're trying to then look at

3 the impact of one nutrient, folic acid, how did you

4 deal with the multivitamin side of it?

5   DR. DONOVAN: So, I think when we

6 looked at that then the control group would have

7 had that exposure without the folic acid. So, we

8 didn't just look at folate within a multivitamin

9 supplement alone.

10   So, if they needed, they could have

11 other vitamins without folic acid or those vitamins

12 with the folic acid.

13   VICE CHAIR KLEINMAN: Any other

14 comments or questions? Everybody must be very

15 hungry.

16   (No response.)

17   VICE CHAIR KLEINMAN: All right, then.

18 Any concluding remarks?

19   CHAIR SCHNEEMAN: My only concluding

20 remarks would be to thank the subcommittees, you've

21 covered a lot of information in a -- in actually

22 a relatively short period of time, and also thank

1   you to the staff for the work that's done to help

2   pull this together.

3   So, I think -- you know, our next

4   subcommittee is doing to be Dietary Fats and

5   Seafood Subcommittee, but I think we're best to

6   start that after the lunch break, because I know

7   they have a lot to report back on as well. Correct?

8   So, I'll just open it up to the

9   Committee. Do you have any general comments at

10 this point before we break, particularly if you

11 start to see things where you're seeing threads

12 across the different subcommittee work or things

13 that sort of tie these areas together?

14   (No response.)

15   VICE CHAIR KLEINMAN: Hunger wins.

16   CHAIR SCHNEEMAN: Okay. So, we'll

17 adjourn for now, and then reconvene at one o'clock,

18 and it is important that we start at one o'clock,

19 because that's for the webinar folks. That's when

20 we'll start the YouTube again.

21   So have a good lunch.

22   (A lunch recess was taken.)

1   CHAIR SCHNEEMAN: It's time to get

2 started, and I think they have the YouTube set up.

3 Just a couple of reminders to the Committee: A

4 couple of people pointed out that they couldn't

5 hear as well, so when you're using the microphone,

6 please make sure it's in front of you when you use

7 the microphone, just to make sure people can hear

8 the questions.

9   And I just want to repeat something that

10 I said in my opening remarks, that what you're

11 hearing are summary statements, draft conclusions,

12 and they're being presented here for the full

13 Committee consideration in their decision-making

14 process.

15   And the final decisions are what will

16 be in the report. So I just want to, once again,

17 highlight that what you're hearing about our draft

18 conclusions, summaries of statements.

19   The committee themselves are looking in

20 much more detail at all of the publications that

21 are being presented. So with that, we're ready to

22 go to our next subcommittee report, and that's the

1   Dietary Fats and Seafood Subcommittee.

2   Dr. Linda Snetselaar is going to give

3   the report.

4   MEMBER SNETSELAAR: I want to

5   acknowledge my committee, Dr. Regan Bailey, Joan

6   Sabaté, and Linda Van Horn, who is here by phone,

7   and also our Advisory Chair, Barbara Schneeman.

8   The   NESR,   or   NESR   staff,   is

9   implementing protocols for the first two dietary

10   questions that you see on this particular slide,

11   and the topics will be addressed at a future

12   Advisory Committee meeting.

13   We will be presenting a summary of the

14   evidence, draft conclusion statements, and grades

15   on the three seafood questions today. They are in

16   red. And the remaining questions focus on dietary

17   fats and neurocognitive outcomes, along with

18   dietary fats and cancer.

19   As a reminder, we are defining seafood

20   in the following manner. It is marine animals that

21   live in the sea and in freshwater lakes and rivers,

22   and seafood here includes fish and shellfish.

1   And this particular slide is designed

2   to sort of orient you to the three questions that

3   we will be focusing on today during my

4   presentation, and we're doing this because the

5   first two questions have a lot of similarities and

6   some subtle differences.

7   The first question is seafood intake

8   during pregnancy or lactation and neurocognitive

9   development of the child. And the second question

10   is seafood intake during childhood and adolescence

11   and neurocognitive outcomes.

12   As you will see in the upcoming slides,

13   there are many neurocognitive outcomes, and it's

14   easy to get confused between these two questions

15   and the various outcomes on which we are reporting.

16   Because the neurocognitive outcomes

17   are varied and most studies did not examine all

18   components of the outcomes, we decided to develop

19   separate conclusion statements for each component.

20   And then the third question, the

21   seafood question here, is looking at seafood intake

22   during   childhood   and   adolescence   and

1   cardiovascular disease outcomes.

2   So the first question we addressed was,

3   what is the relationship between seafood

4   consumption during pregnancy and lactation and

5   neurocognitive development of the infant?

6   And we used NESR systematic review to

7   answer this particular question. As a refresher,

8   here is the analytic framework we used to approach

9   this question. And we did review this framework

10   in detail during the July Advisory Committee

11   meeting.

12   And in this question, the exposure was

13   assessed in pregnant and lactating women, and the

14   outcome was measured in children, birth to 18

15   years. This is a reminder of the specific

16   intervention exposure and comparators that we

17   focused on.

18   The criteria apply to all of our seafood

19   protocols. And the particular item here to note

20   is that studies must measure seafood consumption.

21   So biomarkers of seafood intake, which might

22   include fish oil or omega-3 polyunsaturated fatty

1   acid supplement studies, or studies that evaluated

2   infant formula with added DHA or EPA were not

3   included.

4   This flowchart illustrates the

5   literature search and screening results for two

6   systematic review questions related to seafood

7   consumption and neurocognitive outcomes. One

8   question addresses seafood intake during pregnancy

9   and lactation, and the second question, as I noted

10   before, addresses seafood intake during childhood.

11   There were 25 studies that were

12   included in this review of seafood consumption

13   during pregnancy and lactation and neurocognitive

14   development of the infant, and that's highlighted

15   in red there.

16   As a reminder, we decided to develop

17   separate conclusion statements for each

18   neurocognitive outcome. The outcomes shown in

19   blue here are the ones we presented draft

20   conclusion statements for during the October

21   public meeting.

22   And I'm going to briefly review these

1 draft conclusion statements that have been

2 previously presented. So as a review from the

3 October public meeting, our subcommittee found

4 insufficient evidence was available to determine

5 the relationship between seafood intake during

6 pregnancy and attention deficit disorder, ADD;

7 also attention deficit hyperactivity disorder,

8 ADHD; and autism spectrum disorder-like traits or

9 behaviors or an ASD diagnosis in a child.

10 And due to there being no included

11 studies examining the bottom three outcomes, no

12 evidence was available to determine the

13 relationship between seafood intake during

14 pregnancy and academic performance, anxiety, and

15 depression.

16 The grade was not assignable for all of

17 these outcomes, and that then concludes our review

18 of the statements presented at the last public

19 meeting.

20 I will now present draft conclusion

21 statements for the developmental domain outcomes

22 for the very same question: What is the

1 relationship between seafood consumption during

2 pregnancy and lactation and neurocognitive

3 development of the infant?

4 Our subcommittee reviewed evidence

5 pertaining to four developmental domains, and they

6 are shown here on this slide, and we then drafted

7 conclusion statements for each. This evidence was

8 reported during the last public meeting, but it

9 does bear repeating.

10 No studies that met inclusion criteria

11 assessed the relationship between maternal seafood

12 intake during lactation and neurocognitive

13 outcomes, including developmental domains in the

14 child.

15 Twenty-four articles from 18

16 prospective cohort studies assessed seafood intake

17 during pregnancy and developmental domains

18 outcomes. These studies were primarily conducted

19 in the U.S. and also in Europe.

20 Maternal seafood exposure was

21 primarily measured using food frequency

22 questionnaires, though the timing, the type, and

1   the amounts of seafood intake were varied. The

2   categorization of seafood intake also varied

3   across studies, so that one study might look at

4   quintiles, and another study might look at servings

5   per week. There was a variety of assessment tools

6   used within each outcome domain.   Now I

7   will focus on the first domain, developmental

8   domain, cognitive development. There were 20

9   articles from 15 prospective cohorts which met

10   inclusionary criteria.

11   The majority of the studies detected

12   positive or null associations between seafood

13   intake during pregnancy and cognitive development

14   in children five months to 11 years. And then

15   looking at IQ, or composite intelligence measures,

16   that was done in children four to 11 years.

17   Few studies accounted for all of the key

18   confounders, and there was heterogeneity across

19   the studies in seafood intake categories used in

20   analyses and cognitive assessment methods. This

21   tended to limit the specificity of the conclusion.

22   So our draft conclusion statements are

1 moderate evidence suggests that seafood intake

2 during pregnancy is associated with improvements

3 in cognitive development in the child.

4 The grade here is moderate for

5 specifically pregnancy. No evidence is available

6 to determine the relationship between seafood

7 intake during lactation and cognitive development

8 in the child, and the grade here is not assignable,

9 specifically for lactation.

10 Next, we looked at the second

11 developmental domain, language and communication

12 development. There were 14 articles from 12

13 prospective cohorts which met inclusionary

14 criteria.

15 The majority of studies

16 detected a beneficial or null association between

17 seafood intake during pregnancy and language

18 development or verbal IQ in children six months to

19 11 years of age.

20 Few of these studies accounted for key

21 confounders, and there was heterogeneity in

22 maternal seafood intake, such as the timing, during
pregnancy, the type and the amount of seafood

1   intake.

2   Seafood categorization and analysis

3   was varied.   Outcome assessment tools and

4   measurements were varied, and the ages of children

5   at assessment was also varied.

6   So our conclusion draft statements are

7   moderate evidence suggests that seafood intake

8   during pregnancy is associated with improvements

9   in language and communication development in the

10   child. The grade here is moderate, specifically

11   for pregnancy.

12   No evidence is available to determine

13   the relationship between seafood intake during

14   lactation   and   language   and   communication

15   development in the child. So the grade here is not

16   assignable, specifically for lactation.

17   Then our third developmental domain

18   involved   movement   and   physical   development.

19   There were 13 articles from nine prospective

20   cohorts which met the inclusion criteria.

21   The majority of the studies found

22   either null or beneficial associations between

1   seafood intake during pregnancy and movement and

2   physical development in the child. Few of the

3   studies accounted for key confounders, and there

4   was heterogeneity in, again, maternal seafood

5   intake, timing, type and amount, and types of

6   movement and physical development examined were

7   varied.

8   The outcome assessment tools were

9   varied, and the ages of children at follow-up was

10   also varied. Our draft conclusion statement is

11   insufficient evidence is available to determine

12   the relationship between seafood intake during

13   pregnancy and movement and physical development in

14   the child.

15   No evidence is available to determine

16   the relationship between seafood intake during

17   lactation and movement and physical development in

18   the child, so the grade here is not unassignable

19   for pregnancy and lactation.

20   Now, for the fourth developmental

21   domain, social, emotional and behavioral

22   development, there were nine articles from six

1   prospective cohorts which met the inclusion

2   criteria.

3   There were no apparent trends across

4   studies, since there were mostly non-significant

5   associations. There was a concern for risk of

6   bias, which we cared greatly about, and as we're

7   working on these questions, we do focus on this,

8   and this risk of bias was due to few studies

9   accounting for all key confounders, differences in

10   measurement of exposure and outcomes, heavy

11   reliance on parental report for most of the

12   outcomes. And it was difficult to determine the

13   relationship due to heterogeneity. And again,

14   maternal seafood intake, the timing, type and

15   amount, the ages of children at follow-up, six

16   months to 13 years, so variable there, and outcome

17   assessment tools varied. The dimension of social,

18   emotional and behavioral development was also

19   varied in these studies.

20   Our draft conclusion statement is

21   insufficient evidence is available to determine

22   the relationship between seafood intake during

1   pregnancy and social, emotional and behavioral

2   development in the child.

3   No evidence is available to determine

4   the relationship between seafood intake during

5   lactation and social, emotional and behavioral

6   development in the child. And the grade here is

7   not assignable for pregnancy and lactation.

8   Moving on now to question two, this

9   particular question is, what is the relationship

10   between seafood consumption during childhood and

11   adolescence and neurocognitive development? And

12   we did again using NESR's systematic review to

13   answer this particular question.

14   This is the analytic framework we used

15   to approach this question. This was reviewed in

16   detail during the July Advisory Committee meeting,

17   and in that particular meeting, we discussed the

18   exposure, childhood and adolescence, through 18

19   years of age, and the outcome was measured in

20   individuals two years and older.

21   This flowchart highlights studies

22   which met the inclusion criteria. Thirteen

1 studies were included in this review of seafood

2 consumption during childhood and adolescence and

3 neurocognitive development.

4 Thirteen studies from both randomized

5 controlled trials, RCTs, and prospective cohort

6 studies met inclusion criteria for this review.

7 There were six articles from three randomized

8 controlled trials.

9 Two randomized controlled trials

10 evaluated fish intake in children between the ages

11 of four and six, and the intervention for both the

12 RCTs consisted of fatty fish meals compared to meat

13 meals three times a week for 16 weeks.

14 The third RCT, the FINS-TEEN study, was

15 conducted with adolescents 14 to 15 years, and

16 participants in this particular study consumed

17 fish meals compared to meat meals three times a week

18 for 12 weeks.

19 Outcomes were assessed before and after

20 the trial, and assessment tools tended to vary.

21 There were seven articles from six prospective

22 cohort studies which evaluated seafood intake

1 during childhood and neurocognitive development.

2 These studies were done in the U.K. and

3 Sweden and China and Canada. Seafood intake was

4 reported as oily fish or just fish intake, and the

5 majority of studies assessed fish intake using a

6 food frequency questionnaire.

7 Outcomes were assessed in children

8 three to 18 years of age, and there were a variety

9 of assessment tools used. For this particular

10 question, no prospective cohort study accounted

11 for all key confounders.

12 Now I will focus on the evidence which

13 evaluated the developmental domains. The four

14 developmental domains are shown here, along with

15 how many articles. We evaluated outcomes from

16 these specific domains. And the majority of

17 studies were conducted in Northern Europe,

18 particularly in Scandinavian countries.

19 For the first developmental domain,

20 cognitive development, there were seven articles

21 included in our review. Of these seven, four

22 articles were from three randomized controlled

1 trials and three articles were from prospective

2 cohort studies.

3 The four articles from three randomized

4 controlled trials found predominantly null or

5 beneficial effects of seafood, compared to meat

6 meals in children four to six years, and 14- to

7 15-year-old adolescents.

8 There were three articles from three

9 prospective cohorts. Beneficial associations

10 were found between child seafood intake at nine to

11 15 years and cognitive development in children 12

12 to 18 years of age.

13 No association was found between child

14 seafood intake and cognitive development at 3.5

15 years. Our draft conclusion statement then is

16 insufficient evidence is available to determine

17 whether seafood intake during childhood and

18 adolescence is associated with improvements in

19 cognitive development in children and adolescents.

20 Grade not assignable here for a specific

21 improvement.

22 Then moderate evidence suggests that

1 seafood intake during childhood and adolescence

2 does not have detrimental impact on cognitive

3 development in children and adolescents. And

4 here, the grade is moderate relative to no

5 detrimental impact.

6   For the second domain, language and

7 communication development, five articles were

8 included, three from two RCTs and two from

9 prospective cohort studies.

10   Evidence from the two RCTs found no

11 effect of fish compared to meat meals on language

12 and communication development at four to six years

13 in primary analysis. The two prospective cohort

14 studies found a positive association between

15 seafood intake during childhood and adolescence

16 and language and communication development and

17 verbal IQ in children 12 to 18 years of age.

18   Heterogeneity was found in child

19 seafood intake, looking at timing, type, amount and

20 duration, and the age of children at assessment was

21 variable, and outcome assessment tools were also

22 variable in these studies.

1   So our draft conclusion statement here

2   is insufficient evidence is available to determine

3   whether seafood intake during childhood and

4   adolescence is associated with improvements in

5   language and communication development in those

6   children and adolescents. And the grade here is

7   not unassignable, specifically focusing on

8   improvement.

9   Moderate   evidence   suggests   that

10   seafood intake during childhood and adolescence

11   does not have detrimental impacts on language and

12   communication development in children and

13   adolescents.   The grade is moderate for no

14   detrimental impact.

15   For the third domain, movement and

16   physical development, there were two randomized

17   controlled trials included in our review. Both

18   randomized controlled trials used the nine-hole

19   peg test as the assessment tool.

20   In children four to six years of age,

21   intake of fatty fish meals compared to meat meals

22   have predominantly null effects on manual

1 dexterity and fine motor coordination.

2 One study found that fish meals had a

3 beneficial effects on fine manual dexterity, and

4 the fine motor coordination only applied in the

5 non-dominant hand.

6 Due to limited amounts of studies, our

7 draft conclusion statement is insufficient

8 evidence is available to determine the

9 relationship between seafood intake during

10 childhood and movement and physical development in

11 children. The grade here is not assignable.

12 For the fourth domain then, social,

13 emotional and behavioral development, three

14 studies were included in the review, two randomized

15 controlled trials. One was conducted in four- to

16 six-year-olds, and one in 14- to 15-year-olds, and

17 they did not find a significant effect of fish meals

18 compared to meat meals on change in behavioral

19 symptoms in primary analysis.

20 In the one article from the one

21 prospective cohort study, there was a null

22 association between seafood intake at three years

1   and social, emotional and behavioral development

2   in children at four to 13 years of age.

3   All of these studies used strength -- a

4   strength and difficulties questionnaire, and there

5   was heterogeneity in the ages of the children at

6   intervention, exposure and outcome assessment.

7   And child seafood intake varied in terms of timing,

8   type, amount and duration.

9   Our draft conclusion statement is

10 insufficient evidence is available to determine

11 the relationship between seafood intake during

12 childhood and adolescence and social, emotional

13 and behavioral development in children and

14 adolescents, and the grade here is not assignable.

15   So moving on to attention deficit

16 disorder, ADD; and attention deficit hyperactivity

17 disorder, ADHD-like behavior for seafood intake

18 during childhood and adolescence, there were two

19 randomized controlled trials included in our

20 review, and these studies found fish meals three

21 times a week compared to meat meals had a null

22 effect on ADD, ADHD-like behavior at four to six

1 years, and 14 to 15 years.

2 It was difficult to determine a

3 relationship due to the inadequate number of

4 studies, and outcome assessment relied mostly on

5 parental report.

6 So our draft conclusion statement is

7 insufficient evidence is available to determine

8 the relationship between seafood consumption

9 during childhood and adolescence and attention

10 deficit disorder or attention deficit

11 hyperactivity disorder-like traits or behaviors.

12 And the grade here then is not assignable.

13 No studies included examined autism

14 spectrum disorder as an outcome. Therefore, our

15 draft conclusion statement is no evidence is

16 available to determine the relationship between

17 seafood intake during childhood and adolescence

18 and autism spectrum disorder-like traits or

19 behaviors or autism spectrum disorder diagnosis,

20 and here the grade is not assignable.

21 Moving onto academic performance for

22 seafood intake during childhood and adolescence,

1 there was one prospective cohort study included in

2 our review, and this study found a significant

3 positive association between frequency of

4 consumption of meals containing fish at 15 years

5 and higher total school grade at 16 years.

6 However, it's important to keep in mind

7 that it's difficult to determine a conclusion here

8 due to an inadequate number of studies and concern

9 for risk of bias from measurement of exposure and

10 outcome.

11 So our draft conclusion statement is

12 insufficient evidence is available to determine

13 the relationship between seafood consumption

14 during adolescence and academic performance in

15 those adolescents. And the grade here is not

16 assignable.

17 For the outcomes of anxiety and

18 depression for seafood intake during childhood and

19 adolescence, there were two prospective cohort

20 studies included in our review.

21 One prospective cohort study found a

22 significant positive association between greater

1 fish intake at 10 to 11 years and lower odds of the

2 diagnosis of internalizing disorder; that included

3 anxiety or depression at 10 to 14 years.

4 And then one prospective study did not

5 find an association between fish intake at 14.5

6 years and depressive symptoms at 17.5 years. It's

7 difficult to determine a relationship here due to

8 an inadequate number of studies, inconsistent

9 results, and little information describing

10 exposure.

11 So our draft conclusion statement is

12 insufficient evidence is available to determine

13 the relationship between seafood consumption

14 during childhood and adolescence and anxiety and

15 depression in children and adolescents. The grade

16 here is not assignable.

17 No included studies examined

18 neurocognitive health in adulthood as an outcome,

19 and therefore our draft conclusion statement is no

20 evidence is available to determine the

21 relationship between seafood intake during

22 childhood and adolescence and neurocognitive

1   health, which includes cognitive decline, anxiety,

2   and depression in adulthood, and the grade here is

3   not assignable.

4   That concludes our review of the second

5   seafood question.

6   And the third seafood question we

7   reviewed was, what is the relationship between

8   seafood   consumption   during   childhood   and

9   adolescence and risk of cardiovascular disease, so

10   we're moving away from the neurocognitive area.

11   We used NESR's systematic review to

12   answer this particular question. This is the

13   analytic framework we used to approach this

14   particular question.

15   This was reviewed in detail during the

16   July Advisory Committee meeting, and in this

17   question, the seafood exposure was assessed in

18   childhood and adolescence through age 18 years of

19   age, and intermediate outcomes were measured in

20   children and adults, while endpoint outcomes were

21   only measured in adults.

22   This is a flowchart for the literature

1 search and screening results for the third seafood

2 question addressing seafood intake during

3 childhood and adolescence and risk of

4 cardiovascular disease.

5 And there were four studies included.

6 Of the four studies included, two were randomized

7 controlled trials. In both randomized controlled

8 trials, children were 10 to 12 years of age.

9 The first study provided children with

10 school meals, and that included either 100 grams

11 of oily fish or a cheese salad sandwich five times

12 per week for 12 weeks. The second randomized

13 controlled trial provided schoolchildren with six,

14 seven or eight grams of tuna fish. And the

15 intervention frequency, duration and control

16 conditions in this particular study were not

17 recorded. These studies measured blood pressure

18 and blood lipids.

19 The other two studies included in the

20 review were prospective cohort studies, and one

21 study assessed fish intake of 10 years using a

22 seven-day food record at baseline, three and six

1 months, and outcomes were assessed looking at blood

2 pressure and blood lipids.

3 The other study assessed fish and oily

4 fish intake at 7.5 years. This was done in the late

5 1930s, and it included a household inventory. And

6 those outcomes looked at were stroke mortality and

7 coronary heart disease mortality, and these

8 particular outcomes were measured during 60 years

9 of follow-up.

10 Results from the few available studies

11 were not consistent. It's difficult to determine

12 a relationship due to an inadequate number of

13 studies and serious methodological limitations in

14 some of the studies.

15 So our draft conclusion statement here

16 is insufficient evidence is currently available to

17 accurately determine the relationship between

18 seafood consumption during childhood and

19 adolescence and risk of developing cardiovascular

20 disease. The grade here is not assignable.

21 We have completed the systematic review

22 of the three seafood questions, and these now will

1   undergo peer review, and we will begin drafting

2   this section of the report.

3   Our subcommittee will now move to

4   examining dietary fats with a series of questions

5   related to that topic, and we will be starting with

6   the relationship between dietary fat and risk of

7   cardiovascular disease.

8   I   want   to   thank   the   subcommittee

9   members, and additionally thank the staff for the

10   huge amount of work that goes into doing these

11   systematic reviews, and thank you all for being

12   here today to listen to what we have synthesized

13   relative to this particular topic.

14   Thank you.

15   (Applause.)

16   CHAIR SCHNEEMAN: So if we could have

17   comments or questions from the Committee?

18   MEMBER DEWEY: Thank you very much.

19   That was very clear and nicely laid out. The

20   question has mainly to do with the seafood intake

21   during childhood and adolescence and cognitive

22   development outcomes.

1   As I recall, there were three

2   randomized controlled trials, but the duration of

3   those was 12 or 16 weeks, and so the question is

4   whether you think it's plausible that that's long

5   enough to create the kind of tissue changes that

6   one might think would be the link between seafood

7   and something in the brain?

8   And if it's not long enough, you know,

9   what is the feasibility of addressing that question

10   with randomized controlled trials of sufficient

11   duration? And should we then look more carefully

12   at the prospective cohort studies?

13   In that situation, I think you said

14   there were three, and that two showed a

15   relationship, and one with the younger age group

16   does not.

17   So in this situation, the value of

18   prospective cohort studies might be pretty high,

19   and I would like to know what your group felt were

20   the key limitations that led you, I think, to the

21   conclusion of insufficient evidence, despite those

22   positive relationships?

1   MEMBER SNETSELAAR: Yes. I think we

2   did look at type of study. You're right. I do

3   think that in many instances -- and we are coming

4   up with some future direction kinds of things, that

5   it would be great to certainly include more

6   prospective studies possibly.

7   But in addition to that, we as a

8   committee have looked at what are some of the

9   concerns that went into looking at prospective

10   studies and, in addition, randomized controlled

11   trials?

12   And do we need additional studies that

13   would focus on more consistency among the

14   assessment, the timing, those things, the duration

15   of the study, those kinds of things. So I think

16   everything you're bringing up is 100 percent

17   correct.

18   We looked at this and came to a

19   conclusion. I think that one of the things

20   following a list of our conclusions is to work

21   closely with your committee as well and come up with

22   some final conclusions that would incorporate both

1 ideas from your committee, and the work your

2 committee has done as well, along with our

3 committee, has been helpful.

4 MEMBER DEWEY: If I could just follow

5 up with that? I don't think you mentioned it, I

6 did know that you didn't find any studies for

7 exposure from birth to 24 months and where the

8 outcome was assessed after 24 months of age.

9 So we actually don't have anything to

10 say about seafood consumption in the first two

11 years of life and developmental outcomes.

12 MEMBER SNETSELAAR: So that may be a

13 future direction.

14 MEMBER DEWEY: Yeah.

15 VICE CHAIR KLEINMAN: Linda, that was

16 just great. My question is about, again,

17 neurocognitive outcomes and the positive results

18 of seafood consumption during pregnancy. And I

19 wonder, is there a dose-response in those studies

20 or was that examined, I guess?

21 And then a second question was, you

22 noted that none of those studies adequately

1   controlled for confounders. And I'm wondering

2   whether the effect diminished significantly when

3   confounders were considered?

4   MEMBER SNETSELAAR: Yes. I think -- I

5   remember beginning to talk about this question, and

6   then working very carefully on what should our

7   confounders be? Because the more confounders you

8   have, the more likely you are to end up with no

9   results.

10   And so you know, I think that's an

11   important question. It was just something that

12   came up again and again, but particularly the

13   prospective cohort studies. And then what was

14   your first question again? I'm sorry.

15   VICE CHAIR KLEINMAN: Whether there is

16   a dosed response in consumption of seafood and the

17   outcome. So, as the exposure increased -- did any

18   of the studies look at increasing exposure and the

19   consequence of that, to lend more credibility to

20   the intervention?

21   MEMBER SNETSELAAR: Yeah. I think we

22   need more studies on, certainly, increased

1 exposure, more specifics on the studies we looked

2 at, I'd look to our NESR team to answer that

3 question.

4 But certainly, exposure is incredibly

5 important. And when you look at the amount of

6 seafood in some of the studies, it was incredibly

7 small.

8 CHAIR SCHNEEMAN: Dr. Sabaté.

9 MEMBER SABATÉ: In some of the studies,

10 and I don't remember exactly which on the slide,

11 as far as answering your question on the

12 dose-response, I mean in some studies it was flat.

13 I mean, for some studies there was a

14 dose response and others had a U-shape. So the

15 intermediate, I mean, had some relationship at the

16 highest amount -- I mean, lower back to no

17 exposure, so it had a U-shape in some of the

18 studies.

19 MEMBER BAILEY: There was a lot of

20 variability. Some studies reported fish intake in

21 grams, others reported it in servings, and so it

22 was kind of hard to synthesize how much actually

1 was the exposure.

2 MEMBER NAIMI: Tim Naimi, Boston

3 University. Linda, that was a really nice

4 presentation, and I guess my question is similar

5 to Ron's and related also to the dose-response, but

6 more along the lines of -- for those ones in which

7 you had exclusively observational studies and none

8 of them had all of the key confounders, and you know

9 the confounding is likely to bias in the direction

10 you found, can you talk about giving it a moderate

11 evidence grade, as opposed to a limited one? I

12 guess that's where I feel a little bit

13 uncomfortable.

14 VICE CHAIR KLEINMAN: I didn't push

15 that far, but that's where I was going as well.

16 MEMBER SNETSELAAR: I think that's a

17 very good point, and certainly, as we look at these

18 conclusion statements, again, these are not carved

19 in stone, as Barbara has been mentioning several

20 times.

21 And I think as we look at these

22 statements and maybe work with some of the other

1 subcommittees, we may make some changes. So very

2 good point.

3   MEMBER BAILEY: For most of the studies

4 there was a beneficial association or a null

5 association, and so we really -- I think there was

6 one study in one subgroup that there was a

7 detrimental association.

8   So the vast majority of the literature

9 was either beneficial or null, which is why we went

10 with a moderate, because of all of the

11 consistency -- and the inconsistency.

12   MEMBER SNETSELAAR: But those

13 decisions were hard-fought and we spent a great

14 deal of time thinking about it.

15   MEMBER SCHNEEMAN: But certainly part

16 of the point here is from the discussion for the

17 subcommittee to take the information and consider

18 the points being raised, also to look where we need

19 cross-talk between the subcommittees.

20   MEMBER MATTES: Rick Mattes. Two

21 questions that are bit more global. So your group,

22 I think singularly reports effects of positive and

1 negative, and in this case, there was no

2 significant effect, which could also be said

3 there's no association, which is the way all the

4 rest of our recommendations seem to read, and I

5 think we should be consistent.

6   Either we're going to say that there's

7 effects this way or that way, or we're just going

8 to say there's no association, and that difference

9 is between the groups now. We --

10   MEMBER SNETSELAAR: Yes. And --

11   MEMBER MATTES: -- probably can report

12 that --

13   MEMBER SNETSELAAR: Yeah. I think

14 your 100 percent correct, that we do need to be very

15 consistent across the subcommittees. And I think

16 that process is being thought about, and will be

17 in the works soon.

18   MEMBER MATTES: One other, in terms of

19 consistency. So in at least one other subgroup,

20 where you have -- like your question one you have

21 all prospective cohort studies. Did you downgrade

22 trials that only had a single estimate of intake

1   at baseline and then track for 10 years and look

2   at an outcome, as opposed to trials that repeated,

3   say, a food frequency question or whatever, so you

4   have some sense that that level of exposure was

5   maintained during that 10-year interval or that the

6   response on that question there was reliable.

7   We held, in another group, a higher

8   standard, and I'm just wondering how you use that?

9   MEMBER SNETSELAAR: Good question.

10   Can I defer to Joanne?

11   MS. SPAHN: What was the question?

12   Specifically address seafood intake during

13   pregnancy.

14   (Off-mic comments.)

15   MS. SPAHN: So when we extracted the

16   data, there were maybe a third and maybe a little

17   less than a third of the studies that measured

18   seafood intake more than once during pregnancy, and

19   then during childhood, the tables will indicate

20   whether or not there were repeat measures.

21   Certainly, the RCTs, you know, were a

22   definitive measure of time. I don't recall the

1   childhood having a lot of repeat measures.

2   MEMBER MATTES: Yeah. I would just

3   suggest that when you assign the strength, that

4   that would be a factor that you put into the

5   consideration.

6   MEMBER SABATÉ: Joan Sabaté. I think

7   this is a good point. I recall in the discussions,

8   and I think there was no studies which had repeated

9   measures in childhood that I remember.

10   MEMBER DEWEY: Kay Dewey. I want to

11   follow up on the comment about -- I think you

12   mentioned, Rick, the statement that said that

13   moderate evidence suggests that seafood intake

14   during childhood and adolescence does not have

15   detrimental impact, and that's been one that you

16   thought you'd just say there's no association?

17   Is that the one you were --

18   MEMBER MATTES: Well, there are --

19   MEMBER DEWEY: -- referring to?

20   MEMBER MATTES: -- a couple where there

21   is a report of whatever the evidence is pro and

22   whatever the evidence is negative, in no case was

1 there a significant association in either

2 direction.

3 In some cases, there was insufficient

4 evidence, but if there's evidence of no

5 detrimental, is that different from no evidence of

6 association?

7 MEMBER DEWEY: Right. And so I just

8 want to clarify that we're talking about the same

9 conclusion statement. And I'm not sure if this is

10 explained, but my understanding is that this was

11 driven in part by the concern about mercury

12 exposure, and that there is the concern about

13 detrimental effects.

14 MEMBER SNETSELAAR: Uh-huh.

15 MEMBER DEWEY: Now -- so in -- on one

16 hand, I think having a statement about no harm is

17 useful, but on the other hand, the way you approach

18 that question is different than when you're trying

19 to show a relationship in the sense of it being a

20 safety kind of study analysis.

21 And so I don't know if the studies

22 looked at it the right way in terms of ruling out

1 harm, which is different from the way you approach

2 it when you are saying that there is a benefit.

3   So that might be something to look at

4 again. If they did it the appropriate way --

5   MEMBER SNETSELAAR: Uh-huh.

6   MEMBER DEWEY: -- I think it's

7 important to say that --

8   MEMBER SNETSELAAR: Uh-huh.

9   MEMBER DEWEY: -- and which -- how many

10 did, because if the statement is possible about no

11 harm, that would be extremely useful.

12   MEMBER SNETSELAAR: Good point.

13 Thank you.

14   MEMBER SABATÉ: Again, Joan Sabaté.

15 The no harm relates to the cognition, not to any

16 other factors. You know we had a series of studies

17 -- maybe 14 or 15, I don't remember of which only

18 two or three seems to have some relationship that

19 was significant, one with a U-shape included, but

20 many had basically flat, no relationship.

21   So we can do the conclusion that seems

22 there was none that has a detrimental effect as far

1   as cognition. And we can do this conclusion. The

2   no harm relates only to cognition, not to any other

3   parameter. As far as the studies, especially the

4   prospective studies, not all, as a matter of fact,

5   if I remember correctly, many of them were not

6   originally designed to test the fish effect; it was

7   mainly to design the harmful effects of mercury.

8   And by the way, in the second

9   publication, there was something as far as the

10   consumption of fish and cognition. So we have some

11   of the studies of the prospective studies that were

12   not originally designed for, you know, fish intake

13   and cognition.

14   MEMBER ARD: Jamy Ard. So just to

15   continue on in terms of how we're describing

16   certain effects, my initial impression if, after

17   seeing the words around -- associated with

18   "improvements in," et cetera, makes me feel like

19   that's a treatment effect or that something started

20   from a deficit, and I don't know if that is shared

21   by others, but I just wanted to share that, in terms

22   of it's not the same to me as something that might

1   say it had a beneficial effect or -- I don't know

2   exactly the other ways that you -- these things are

3   quantified in terms of cognition or language and

4   communication and those types of things.

5   But that may be something to think

6   about.

7   MEMBER SNETSELAAR: Good point.

8   MEMBER NOVOTNY: Rachel Novotny.

9   This is a little bit out of place, but related to

10   this conversation about language and how we're

11   reporting -- and it makes me wonder with most of

12   our questions whether we don't want to consider

13   both protective effects.

14   At any rate, to consider whether

15   there's another pass at our questions for some of

16   these things, I'm thinking specifically about --

17   which I've been talking to Sharon about -- the upper

18   limit for folic acid, which was not specifically

19   our question, but it feels like we should say

20   something about that.

21   So we may need to make another pass at

22   our studies as well to see if there's something we

1 could legitimately say about that. I think it's

2 a general question for us as to whether we're

3 considered sort of both ends of the spectrum for

4 many of our questions.

5   CHAIR SCHNEEMAN: Other comments or

6 questions?

7   MEMBER BAILEY: Linda Van Horn is on

8 the line, I don't know if she - if we want to give

9 her an opportunity to comment, or if she has

10 anything to say.

11   CHAIR SCHNEEMAN: Is she on the line?

12 She is mainly listening, so she'll let us know.

13   (Laughter.)

14   CHAIR SCHNEEMAN: I think these were

15 all useful comments for the subcommittee to take

16 back and look at.

17   MEMBER SNETSELAAR: Uh-huh.

18   CHAIR SCHNEEMAN: And also working

19 with the staff to make sure we do have consistency

20 across the subcommittee. So I think then we'll

21 move to our next subcommittee report, which is the

22 Beverages and Added Sugars subcommittee, and Dr.

1 Mayer-Davis will do that report.

2 MEMBER MAYER-DAVIS: Thank you very

3 much. So first I do want to recognize the great

4 work of the Committee, Drs. Leidy, Mattes, Naimi

5 and Novotny, and Schneeman, to say nothing of, of

6 course, the NESR staff that just continues to amaze

7 us every day.

8 So let's see. I'm clicking the

9 clicker, but see myself instead of a slide. That's

10 not really that I want to see, actually. So let's

11 see. What do I need to do here? Oh, that's way

12 farther than I need to be.

13 Let's see.

14 (Pause.)

15 MEMBER MAYER-DAVIS: All right.

16 There we go. So let me just overview what we will

17 go over in this session today. This is just a brief

18 summary of the questions that we addressing in this

19 particular committee, questions related to

20 non-alcoholic beverages, added sugars and alcohol.

21 So we have completed our work towards

22 our draft conclusions for birth weight

1   standardized for gestational age and sex as an

2   outcome related to non-alcohol beverages underway;

3   a set of questions related to various non-alcoholic

4   beverages in relation growth, size, body

5   composition, and risk of overweight and obesity,

6   for which there's been a screening of some 17,000

7   articles and 214 articles identified to be included

8   for that set of questions, with 70 articles

9   currently under review for a subset of questions

10 that are focused on milk.

11   I won't be presenting details on that

12 particular piece today because that is -- we are

13 in the midst of that effort. Also underway are

14 questions related to added sugars and risk of

15 cardiovascular disease, screening is underway

16 relatively early on for that with 5,000 articles

17 screened.

18   Coming up next are questions related to

19 added sugars and risk of type 2 diabetes and also

20 outcomes of growth, size, body composition, and

21 risk of overweight and obesity.

22   We are also working on questions

1   related to alcohol and all-cause mortality, and I

2   will be presenting some more information about that

3   today, as well as presenting information about

4   non-alcoholic beverages and birth weight.

5   So that's the overview. So now we will

6   focus on this particular question that you see here

7   on the screen. What is the relationship between

8   beverage consumption during pregnancy and birth

9   weight standardized for gestational age and sex?

10   And this is approached via the NESR systematic

11   review process.

12   This is our analytic framework, and I

13   do want to take a moment on this, because there are

14   actually quite a large number of decisions embedded

15   in this analytic framework that took a fair amount

16   of time to sort through and that follow for much

17   of our work for a range of questions.

18   So you'll see in terms of intervention

19   and exposure, you know, we set out these various

20   sub-types of beverages, and you can see the list

21   here. We've shown this before. That's the same

22   list that we've had.

1   The comparator is something that I want

2   to highlight, because that does impact on the

3   studies that we review. So for our comparator,

4   we're looking at differences in amount of the same

5   beverage consumed, which could include milk

6   consumption, of a particular beverage, or versions

7   of the beverage diluted with water.

8   We also consider as a comparator a given

9   beverage versus a solid form of that same food,

10   broadly speaking, a given beverage versus water.

11   And then specifically we are looking at

12   sugar-sweetened beverages compared to low- or

13   no-calorie sweetened beverages, and we're looking

14   at dairy milk with different amounts of fat.

15   So this provides the scope, really, of

16   what we're doing. Otherwise, you know, if you just

17   have beverages with no clarity with regard to

18   comparator, you would not be able to go through this

19   in any kind of coherent manner.

20   So then for outcomes for this

21   particular question, we're looking at birth weight

22   that could be presented in a continuous fashion or

1   in categories, small for gestational age or large

2   for gestational age, or birth weight for length.

3   The population then for exposure would

4   be women either before or during pregnancy, and

5   then the outcome is infants at birth. You'll see

6   key confounders here: child sex and gestational

7   age, maternal age, race/ethnicity, SES, and a

8   variety of additional confounders listed there.

9   Other factors that are considered are

10   total energy intake -- that definitely becomes

11   important in a good amount of this work -- and then

12   a variety of other variables related to other

13   components of diet, as well as parity, medications,

14   and supplement use.

15   So for the question here related to

16   beverages during pregnancy and birth weight, these

17   are the numbers of studies. We started out with

18   some 7600, and that got pared down through

19   screening of titles, abstracts and then full text,

20   relative to our criteria, and the articles that

21   emerged then for complete review are 19 in number,

22   to be included in our systematic review.

1   So this is a table that we've shown

2   before, just showing how we're sort of categorizing

3   beverages so that we, you know, can go through this

4   work systematically. What you see highlighted are

5   the types of beverages for which there was a

6   literature available for us to look at.

7   So milk, low- and no-calorie sweetened

8   beverages, sugar-sweetened beverages, coffee and

9   tea, and plain water are the relevant categories.

10   And we'll start here with sugar-sweetened

11   beverages and low- or no-calorie sweetened

12   beverages.

13   Now, for this particular segment of the

14   presentation, our subcommittee opted to provide

15   more detail here than we will subsequently, and the

16   reason that we're doing that is that we wanted to

17   make sure that it was clear to all of you, you know,

18   really what is the way in which we're proceeding

19   with this work?

20   How are we looking at the data? What does this

21   really look like?

22   So we're giving a little bit more

1 specifics here, just for that purpose, of providing

2 that kind of an example.

3 So starting again here, beverages

4 during pregnancy and birth weight, for these

5 exposures there were seven studies, all of which

6 are prospective cohort studies.

7 And in terms of the exposures across

8 those studies, three of them examined

9 sugar-sweetened beverages independently. Two of

10 the studies examined low- or no-calorie sweetened

11 beverages, independently. And then two of them

12 had a combined category of sugar-sweetened

13 beverages and low- and no-calorie sweetened

14 beverages intake.

15 The outcomes included continuous birth

16 weight and categorical small for gestational age

17 and large for gestational age. So this is an

18 example of three studies -- and one of the various

19 types of summary tables that we look at, where you

20 can see, for each study, the sample size, the

21 country where the study was conducted, the exposure

22 and the comparator.

1   For the first study, sugar-sweetened

2   beverage estimated intake in servings per week

3   assessed in the second or third trimester by

4   validated food frequency, representing current

5   intake.

6   And you can see, glancing through here,

7   there is variability across studies in terms of how

8   the exposure was measured, the timing of the

9   measurement as well. And then the outcomes and

10   whether or not the outcome of birth weight was

11   adjusted for gestational age and/or sex or not.

12   I need to take a moment for a glass of

13   water here. Excuse me. Sorry about that.

14   And for these studies, TEI, we're

15   looking for adjustment for total energy intake.

16   You can see the first couple did not address this

17   at all, but the last adjusted, albeit a step-wise

18   process.

19   And   then   you   see   participant

20   characteristics here, just to give you sort of a

21   glimpse at, you know, what's considered here.

22   I'm not walking through all this detail. Don't

1   worry. That would be not good.

2   But this just shows sort of a -- some --

3   a couple of reminder of comments about this study,

4   and then the actual results for continuous birth

5   weight and the categorical birth weight, with some

6   color-coding to identify where statistically

7   significant findings were available.

8   Does anyone have a cough drop? That

9   was an actual question.

10   FEMALE VOICE: We have one.

11   (Pause.)

12   MEMBER MAYER-DAVIS: All right. Back

13   to pregnancy and birth weight, looking at

14   sugar-sweetened beverages only, those three

15   studies. So here we found mixed findings, so very

16   mixed findings.

17   So in one study, it was found a greater

18   intake of sugar-sweetened beverages was related to

19   higher birth weight. Another study found the

20   opposite, and then the third study, the

21   relationship was not statistically significant.

22   And none of these particular studies

1 used the same categorical outcome, so there wasn't

2 a way to compare across. This is a view of risk

3 of bias. Many of the presentations have mentioned

4 an evaluation of risk of bias, and there is this

5 specific tool that's used that considers

6 confounding.

7 Confounding is based on the specific

8 key confounders listed in the analytic framework

9 in this case, as I showed at the beginning, and

10 those -- the risk of bias is then classified as low,

11 moderate, serious or critical, and then as well,

12 selection of participants, classification of

13 exposures, deviation from intended exposures,

14 missing data, outcome measurement, selection of

15 the reported result from the paper as a whole, and

16 the most common risk for bias in this particular

17 set, inadequate adjustment for key confounders and

18 inadequate description or definition of the

19 exposures.

20 So then moving towards the literature

21 that focused on low- and no-calorie sweetened

22 beverages or the combination of those, plus

1 sugar-sweetened beverage, two studies examined the

2 low- and no-calorie sweetened beverages

3 independently.

4 One of those studies reported greater

5 intake was related to lower birth weight, and

6 another study relationship was found to be not

7 statistically significant, and neither of those

8 studies examined the categorical birth weight

9 outcomes.

10 There were two studies that combined

11 those categories of beverages, sugar-sweetened and

12 low- and no-calorie sweetened beverages, and for

13 those, one study reported a greater combined intake

14 in relation to lower birth weight.

15 Another study reported greater intake

16 related to higher risk of small for gestational

17 age, and then the third study reporting a

18 relationship between combined intake and small for

19 gestational age that was not statistically

20 significant.

21 So our conclusion then for this

22 particular question is here: insufficient

1 evidence is available to determine the

2 relationship between consumption of

3 sugar-sweetened beverages or low- and no-calorie

4 sweetened beverages during pregnancy and birth

5 weight outcomes, so the grade is not assignable.

6 Moving then to the question of

7 beverages during pregnancy and birth weight,

8 focusing now on dairy milk, there were six studies

9 that assessed dairy milk intake: one RCT and then

10 five prospective cohort studies. And the exposure

11 was commercially available dairy milk of varying

12 fat and sweetener content.

13 The outcomes here were five studies

14 that assessed continuous birth weight and three

15 studies that assessed categorical birth weight

16 outcomes.

17 In terms of findings, four studies

18 found greater milk intake related to higher birth

19 weight. One study found lower milk intake related

20 to higher birth weight. With the outcome of SGA,

21 one study found greater dairy milk intake related

22 to lower risk of SGA. Another study found the

1   relationship to be not statistically significant.

2   A study that looked at large for

3   gestational age did not find a statistically

4   significant association. And then a study that

5   looked at low birth weight, greater milk intake was

6   related to lower risk.

7   The conclusion statement here was that

8   there was insufficient evidence is available to

9   determine the relationship between consumption of

10   dairy milk during pregnancy and birth weight

11   outcomes, with the grade not assignable.

12   And I'll just fill in here a little bit.

13   And I'm not sure on all the details of those studies

14   reviewed, but the risk of bias was considerable

15   across studies, primarily due to concerns with

16   adjustment for key confounders, particularly total

17   energy intake, and also very little evidence or no

18   evidence, and certainly not consistent evidence

19   with regard to dose response. So that's a little

20   bit of, you know, some background that led us to

21   this particular conclusion.

22   Turning then to tea, as the beverage of

1   interest, there were eight studies that assessed

2   tea intake. All of these were prospective cohort

3   studies.

4   Most of the studies combined tea into

5   a single exposure variable, although some looked

6   at some specific types of tea, oolong, black, green

7   tea, and three of the studies specifically looked

8   at caffeinated tea versus tea that is without

9   caffeine.

10   Six of the studies assessed birth

11   weight in a continuous fashion. Eight studies

12   looked at categories of birth weight outcomes.

13   And in terms of findings, three of the studies

14   reported greater intake of tea related to lower

15   birth weight. Three studies showed a relationship

16   with birth weight that was not statistically

17   significant.

18   In terms of SGA, three studies showed

19   a   relationship   to   be   not   statistically

20   significant, while two studies showed greater tea

21   intake in relation to higher risk of SGA.

22   In terms of low birth weight as an

1   outcome, three studies showed a relationship that

2   was not statistically significant. And for large

3   for gestational age, one study showed highest

4   intake level was related to higher risk for LGA.

5   And so the conclusion here was also

6   insufficient evidence is available to determine

7   the relationship between consumption of tea during

8   pregnancy and birth weight outcomes, grade not

9   assignable.

10   Moving then to coffee. There were

11   seven studies that assessed coffee intake in

12   relation to birth weight, and again, these were all

13   prospective cohort studies.   The exposure

14   generally was average coffee intake.

15   Three out of those studies examined

16   caffeinated coffees specifically. Five studies

17   assessed continuous birth weight. Six assessed

18   categorical birth weight outcomes.

19   From three of those studies, greater

20   coffee intake was related to lower birth weight.

21   In two studies, the relationship with birth weight

22   was not significant. For SGA, in two studies,

1   greater coffee intake was associated with higher

2   risk, and in two studies, the relationship was not

3   significant.

4   Low birth weight, similarly, two

5   studies, relationship was not significant. One

6   study, greater coffee intake was associated with

7   higher risk.

8   In terms of our conclusion statement,

9   insufficient evidence is available to determine

10   the relationship between consumption of coffee

11   during pregnancy and birth weight outcomes, grade

12   not assignable for coffee.

13   And again, in terms of risk of bias,

14   there were considerable concerns with regard to

15   adjustment for key confounders, particularly

16   energy intake, and also the difficulty of this

17   issue of, you know, coffee versus caffeine. Now,

18   that may or may not be important, so we

19   just -- there was overall, again, insufficient

20   evidence, grade not assignable.

21   Plain water. Again this is intake

22   during pregnancy with respect to the outcome of

1 birth weight. So there were two studies that

2 assessed plain water intake, both of which were

3 prospective cohort studies. The studies looked at

4 tap and bottled water, and did not include

5 flavored, carbonated or fortified water by way of

6 how the exposure was specified.

7 Outcomes: again, two studies assessed

8 continuous birth weight and two assessed

9 categorical birth weight outcomes. In terms of

10 findings, for two studies, the relationship with

11 birth weight was not significant, and two studies

12 found the relationship to not be significant for

13 the outcomes, categorical of small for gestational

14 age or low birth weight.

15 So again, the conclusion:

16 insufficient evidence is available to determine

17 the relationship between consumption of plain

18 water during pregnancy and birth weight outcomes,

19 grade not assignable.

20 So I've mentioned some of these, but

21 just in summary, across this literature, with

22 regard to beverage consumption during pregnancy

1 and birth weight, there were quite a few of these

2 studies where the attrition was greater than 25

3 percent, which provides a risk of bias in terms of

4 selection.

5 Total energy intake was considered in

6 some studies, but in many studies was not

7 considered. Some of the samples had poor

8 generalizability with respect to lower

9 socioeconomic status and minority populations.

10 In terms of concerns regarding

11 exposure, variation in fat or sweetener levels in

12 these different beverages, that information was

13 generally not available. I mentioned a moment ago

14 that about half of the tea and coffee evidence

15 examined only caffeinated versions or the

16 difference wasn't clear, between the caffeinated

17 and uncaffeinated.

18 There were a lot of issues regarding

19 exposure definitions and assessment methods and

20 timing of the assessment of intake of those

21 beverages during pregnancy.

22 Birth weight -- and I hadn't mentioned

1   this, and should have highlighted this probably a

2   little bit more -- definitely contributed to some

3   of these conclusions. Birth weight was

4   inconsistently adjusted for gestational age and

5   sex, and actually, our original question specified

6   birth weight for gestational age and sex.

7   Many studies adjusted for one but not

8   the other. Some adjusted for neither. Again,

9   inconsistency in the outcomes assessed and

10   definitions used. And for some of the studies

11   where there was a statistically significant

12   result, the effect size, in some cases, was quite

13   small, with the practical and clinical

14   significance of that was unclear.

15   So moving now to alcohol as an exposure.

16   We are working on the question of what is the

17   relationship between alcohol consumption and

18   all-cause mortality? And again, this is via the

19   NESR systematic review process.

20   We do have a new protocol, compared to

21   what we've discussed about before that's posted on

22   DietaryGuidelines.gov. And we'll talk about it

1   here, but it is posted as well.

2   So first, in terms of definition, for

3   this question of all-cause mortality in relation

4   to alcohol consumption, all-cause mortality is

5   defined as the total number of deaths from any and

6   all causes during a specified time period, and this

7   does not include, then, studies of cause-specific

8   mortality; in other words, total number of deaths

9   from a specific cause, CVD, cancer or otherwise.

10   So that's the outcome all-cause mortality.

11   So this is the analytic framework, and

12   this -- you know, the alcohol field is one that has

13   a number of unique characteristics that we really

14   thought through carefully with regard to

15   establishing our analytic framework, and so I

16   wanted to highlight a number of things here.

17   In terms of our intervention and

18   exposure, the primary exposure is average

19   consumption of alcoholic beverages, as well as the

20   pattern of consumption of alcoholic beverages,

21   meaning, for example, number of drinks per drinking

22   day or drinks per drinking occasion.

1   In terms of comparator, the comparator

2   would be different average alcohol consumption or

3   different pattern of alcohol consumption among

4   current drinkers as a primary comparator.

5   A secondary comparator would be intake

6   compared to never drinkers. And you'll notice

7   that former drinkers are not shown here, because

8   there are a whole variety of reasons that people

9   are former drinkers such that that group as a

10   comparator would not be appropriate. So primary

11   and secondary comparators here are important to

12   note.

13   The   population,   we're   focusing

14   primarily on adults 21 years and older, which means

15   that if there are studies that, you know, are

16   primarily adults but happen to include some

17   individuals younger than the drinking age, that's

18   fine, but we're not looking at studies that would

19   be specifically focused on underage drinking.

20   And then outcome -- you know, all-cause

21   mortality, I already discussed, and so this again,

22   primarily, adults, 21 years and older. Now, in

1   terms of key confounders, we're looking at sex,

2   age, race, ethnicity; some markers of SES we

3   consider to be quite important in this work, as well

4   as consideration of eating pattern or diet quality,

5   physical activity, and smoking. These are our key

6   confounders.

7   In addition, as a key confounder for

8   average consumption exposure, pattern of

9   consumption would be considered important. And

10   then on the flip side of that, for pattern of

11   consumption as the exposure, average consumption

12   would be important to consider.

13   In addition, other factors to be

14   considered: total energy intake, ideally without

15   alcohol; and then age distribution of the study

16   sample, anthropometric measurements,

17   hypertension, blood pressure, diabetes, glucose,

18   lipids, medications, as well as family history of

19   chronic disease, and beverage type.

20   So we started with the standard

21   criteria for study design, publication status,

22   language, country, and health status of

1 participants, as we discussed earlier, and a little

2 bit more detail here, again, because of this

3 particular topic of alcohol. I already mentioned

4 the exposure, and so it's important in terms of

5 inclusion criteria that the exposure is that which

6 we've defined.

7 Information on type of beverage will be

8 collected if available, but we don't exclude a

9 study if that's not available; it's just good if

10 we can have it.

11 And again, in terms of exclusion

12 criteria, data on non-drinker groups, where never

13 and former are combined, say, in an observational

14 study, would actually be excluded, just because of

15 the potential problems and bias with combining and

16 including the former drinker group along with the

17 never drinker group.

18 So the never drinker group is a

19 secondary comparator, but a study would be excluded

20 if the study includes former drinkers. And the

21 comparator, I've already focused on that, so don't

22 need to repeat that.

1   And again, in terms of exclusion

2   criteria with regard to the comparator, again, the

3   former drinker issue needs to be considered, and

4   that would be excluded if there was a study where

5   the comparison with never and former drinkers was

6   combined.

7   In terms of the dates here, we include

8   studies from January 2000 to now, January 2020, and

9   exclude articles published prior to January 2000,

10   and again, I already mentioned about the age of

11   participants.

12   So we saw from a couple of the earlier

13   examples for this particular subcommittee, the

14   numbers of studies is very high, and so we, you

15   know, have had to really think about prioritizing

16   our remaining work, and what we're doing is, with

17   regard to added sugars and health outcomes for

18   cardiovascular disease, we are approaching that,

19   building on the 2015 NESR systematic review.

20   In terms of type 2 diabetes, we'll be

21   building on the 2015 Advisory Committee report, as

22   well as for growth, size, body composition and risk

1   of overweight and obesity, and building on the

2   2015.

3   For alcohol and health outcomes, we are

4   prioritizing all-cause mortality as the first

5   outcome to be examined. I just discussed about

6   that work underway, and as time allows, we will move

7   then to address as outcomes CVD, cancer,

8   neurocognitive health, as well as growth, size, and

9   body composition.

10   So that's where we are.   Again,

11   thanking the members of the subcommittee, as well

12   as the support staff, doing wonderful work.

13   Okay. So questions?

14   CHAIR SCHNEEMAN: Thank you.

15   (Applause.)

16   CHAIR SCHNEEMAN: So questions for the

17   subcommittee? Ron?

18   VICE CHAIR KLEINMAN: That was a great

19   presentation. This is a minor comment, and you

20   alluded to it. It has to do with the outcome of

21   birth weight, and I think you mentioned the small

22   effect size and whether these are biologically

1 significant so I wonder if it's worth just noting

2 that when you say higher birth weight studies,

3 either in parentheses or something, within normal

4 reference weight values or something to indicate,

5 these are still normal children.

6 (Off-mic comments.)

7 MEMBER MAYER-DAVIS: Correct, and that

8 is the case. So yes, that's a good comment. So

9 in the report, it will be important to provide that

10 framework. Yeah. Thank you for that. Yeah.

11 MEMBER DEWEY: Kay Dewey. With regard

12 to the dairy milk and birth weight analyses, one

13 of them was, I think, one of the five studies for

14 birth weight showed a positive relationship, and

15 one didn't.

16 I was wondering what the sample sizes

17 were for all those studies, and I know that you gave

18 the conclusion statement as insufficient evidence.

19 I'm just curious about the choice between limited

20 and insufficient, and knowing in our subcommittee

21 when most of the studies are going in a certain

22 direction, we might have chosen limited. And this

1 one seems to be a case where that might be the

2 situation. I know you mentioned some important

3 limitations in -- but one that you mentioned was

4 adjusting for total intake.

5   And I feel that that's one that is one

6 of those gray areas, because it could be on the

7 causal pathway. So it's a little bit different

8 than a regular comparator. And so I wondered if

9 you could speak to that and the differing

10 conclusion.

11   MEMBER MAYER-DAVIS: Yeah, yeah. So

12 that -- first of all, it was the case that for those

13 four studies, there were concerns in terms of risk

14 of bias and accounting for key confounders was one

15 of the primary concern.

16   Total energy intake was a concern, and

17 you know, the role of total energy in this kind of

18 situation is always a question. Whether you

19 consider that to be part of a causal pathway or not

20 could be debated probably for hours.

21   So I appreciate that concern. One of

22 the problems with that literature also had to do

1 with dose response. So for example, I'm recalling

2 now, although the NESR people will recall better,

3 but I recall now, at least one of the studies where

4 there was a significant effect -- there was no

5 evidence for dose response.

6   So there were quartiles, so any

7 quartile compared to the first, once you got to the

8 second quartile, that was it; flat thereafter.

9 So that's just an example of one of the several

10 problems across that literature.

11   But I appreciate that, and one of the

12 reasons that I could answer the question with that

13 level of detail in terms of that one study is

14 because I looked at that myself, and again, I said,

15 now, let me make sure I remember why we made that

16 decision.

17   So that was a great comment. And I'm

18 looking over here at Brittany, and I don't know if

19 you want to add to that. That would be helpful,

20 too.

21   MS. KINGSHIPP: Sure.   Brittany

22 Kingshipp. So I was also just glancing at the milk

1   literature, the sample size question, and it ranges

2   from the mid 100s up to about 3,000 depending on

3   what cohort they were looking at.

4   And so there were concerns about the

5   things Beth has noted. Also, as was noted, kind

6   across this body of evidence. That body of

7   evidence in particular had multiple studies with

8   very attrition rates, and so that, combined with

9   inconsistency in whether birth weight was adjusted

10   for gestational age and sex or not, half the studies

11   did, half did not.

12   The same was true for total energy

13   intake. So what we did is look at total energy

14   intake kind of beyond the scale of a regular

15   confounder, so that we were interested, if they did

16   adjust for it, that's answering one question. If

17   they did not, that's answering another question,

18   both of which we are interested in.

19   And so it wasn't necessarily that they

20   got penalized if they did not. They just got

21   treated differently in interpreting findings, and

22   so because that was also done inconsistently in

1   that body of evidence, all of those inconsistencies

2   kind of snowballed to the point that no clear, even

3   limited, conclusion can be drawn.

4   MEMBER MAYER-DAVIS: Any other

5   questions?

6   (No response.)

7   CHAIR SCHNEEMAN: Okay. Seeing none,

8   I suggest we take a break right now.

9   (A short recess was taken.)

10   CHAIR SCHNEEMAN: So we're now ready

11   for our last subcommittee report of the day. Is

12   it -- no, it's working now. So -- and that will

13   be the Data Analysis and Food Pattern Modeling, the

14   Cross-Cutting Working Group.

15   And so Dr. Regan Bailey will be giving

16   that subcommittee report.

17   MEMBER BAILEY: It's my great pleasure

18   to do so and represent the people on the committee

19   and Jamy Ard, Jamie Stang, Tim Naimi, and Teresa

20   Davis, and supported by Dr. TusaRebecca Pannucci.

21   Wow, I look tired. It's a very strange

22   thing to see your face that big. So today we will

1 be presenting very summary types of statements,

2 draft conclusions of summaries of so much data.

3   So in your Committees, I'm hearing a

4 constant theme of we have insufficient evidence.

5 Subcommittee seven has nothing but evidence. We

6 have so much data. And we can't -- we will share

7 it all with you in the report, but what I'd like

8 to attempt to do is to show you some of the

9 highlights, the top-level kind of findings today,

10 and where we're thinking.

11   So you'll see those. And then the

12 remaining work we have to do is, we have to work

13 within our committee with the B-24, as well as the

14 Pregnancy and Lactation committee, to refine some

15 of those questions as they relate to food and

16 nutrient intakes and nutrients of public health

17 concern.

18   And then the last part, of course, our

19 subcommittee is responsible for the food pattern

20 modeling that will be informed by the evidence that

21 we all have from your committees.

22   So today, we will focus primarily on

1 Americans two years and older. So infants and

2 toddlers, the B-24, and pregnant and lactating

3 women aren't going to be the focus of the data I'm

4 presenting today.

5 So all of the data that we will be

6 talking about, we have as age groups, by sex, by

7 race/ ethnicity, and socioeconomic status, and

8 again, I can't show you all those, but I'm going

9 to give you some high-level takeaways.

10 And just a reminder of the analytic

11 framework. So we're using for the dietary

12 intakes, the NHANES What We Eat in America. At

13 this point, the data I'm presenting today are just

14 from foods and beverages, so the nutrient intake

15 data are not inclusive of dietary supplements at

16 this point.

17 We're presenting data on chronic

18 diseases from these sources, and again, this is all

19 posted online, and we've gone over it, but just to

20 have it fresh in your mind.

21 So the first question that we will be

22 presenting evidence on is to describe and evaluate

1 current intakes of food groups and nutrients. And

2 so we'll go through these at a pretty high level.

3   So for fruit, the top contributors to

4 fruit are whole fruit, 100 percent fruit juice, and

5 sweetened beverages. And then in bold, I have the

6 intakes, the mean or average intakes for Americans

7 two and older, so about one cup-equivalent per day

8 of fruit.

9   For vegetables, vegetables are

10 primarily being consumed as part of burgers and

11 sandwiches and mixed dishes.   So less than

12 50 percent of the vegetables that are being

13 consumed are discrete vegetables.

14   And if there's one thing you're going

15 to hear me say today, again, over and over, is

16 burgers and sandwiches.   Okay?   So that's

17 something that really will come through in this

18 data, and that is kind of reflective of the American

19 dietary pattern.

20   Dairy: So most of dairy intake, about

21 one and a half cups per day on average coming from

22 fluid milk and cheese.   Fluid milk intake

1 decreases with age, and over time, since 2007-08,

2 total dairy intake has decreased in the United

3 States.

4 Whole grains is coming primarily

5 through breakfast cereals and bars. So we have

6 seen increases in whole grain intake across time,

7 but only 2 percent of Americans are currently

8 meeting whole grain recommendations.

9 And then protein foods, primarily

10 coming from animal-based sources. In general,

11 it's adequate for most Americans, except for

12 females ages 12 to 19 and 70 years and older, with

13 about 5.8 ounce-equivalents per day.

14 The majority of the American population

15 for all groups examined are exceeding recommended

16 energy intake from solid fats and added sugars.

17 The main source of solid fats is burgers and

18 sandwiches, desserts and sweet snacks.

19 And then in children less than 11 years

20 of age, high-fat dairy is also a significant source

21 of solid fat. So the main source of added sugar

22 is sweetened beverages, desserts and sweets and

1   snacks, and coffee and tea.

2   And so I use the ampersand to keep food

3   groups together. I don't generally like the

4   ampersand, but just for clarity. So burgers and

5   sandwiches together, desserts and sweet snacks

6   together, coffee and tea together.

7   So our draft conclusion statement is

8   that for Americans ages two and older, intakes of

9   fruits, vegetables, dairy and whole grains are

10   generally below recommended amounts and have not

11   changed over time. Intake of total grains and

12   total protein generally meet recommended amounts.

13   Okay.

14   For ages one and older -- because the

15   food group, we're looking at compliance with

16   previous dietary guidelines. When we're looking

17   at nutrients, we're looking at one and older,

18   because the dietary reference intake age groupings

19   are one to three. So sometimes you'll see

20   two-plus, one-plus, so just for some clarity there.

21   So 9 percent of children and 58 percent

22   of males, 67 percent of females have carbohydrate

1   intakes within the AMDR. Across all age groups,

2   protein intake is within the AMDR.

3   Protein also has an EAR, and I mentioned

4   that older adults and teenaged females have intakes

5   that are below the EAR. So the proportion of the

6   population with fat within the AMDR is about 60

7   percent for children and 50 percent for adults, and

8   for all ages, sodium, saturated fats and added

9   sugars are overconsumed.

10   In   terms   of   nutrients   that   are

11 underconsumed, we have several, including vitamins

12 A, C, D, E, K, calcium, magnesium, fiber, choline,

13 and potassium. In addition to those, other

14 population   groups   have   nutrients   or   food

15 components that are underconsumed.

16   And so we're going to focus on these a

17 little bit more when we do the last question,

18 question 5, on nutrients of public health concerns.

19 So keep these in your mind. We're going to come

20 back to them.

21   And then in young children, retinol,

22 zinc, copper and selenium are overconsumed,

1   relative to the upper level.

2   So moving on to dietary patterns and

3   beverage consumption, just a reminder of the

4   analytic framework.

5   At this point, we have the average HEI,

6   total and component scores, but we are awaiting the

7   distribution of those scores. We'll be looking at

8   that, as well as food category contributions to

9   total energy intake.

10   And so where we're talking about

11   dietary patterns, just a reminder that we don't

12   have self-reported patterns of intake. So we're

13   looking at reported intakes relative to the HEI,

14   not necessarily able to categorize patterns as

15   vegetarian or Mediterranean. Okay?

16   So for children and adults, we will look

17   at beverage intake data in the following ways, and

18   we've talked about this, by the population groups,

19   mean intakes, and the percent of energy and

20   nutrients coming from beverages, as well as

21   calories.

22   Just a reminder of the definitions of

1   the beverage categories that we'll be talking about

2   today. We've seen these before. Okay. We've

3   seen this slide before. Out of 100 points, the

4   American diet is currently at a score of 59.

5   And what's encouraging is that it has

6   increased slightly over the last decade, from 56

7   to 59. And we do see age differences. So young

8   children, two to five, and adults over the age of

9   65 tend to have higher scores than all other age

10   groups.

11   So this might look complicated, but

12   let's walk through it. So all of the ways that the

13   100 points are divided are around the edge of this

14   spider web here. So if you start with total fruits

15   and start going clockwise, you get higher points

16   for more compliance, whereas if you went

17   counterclockwise from total fruits, lower intakes

18   are associated with a higher point score.

19   So in an ideal spider web -- I don't

20   know what these are actually called, but -- and

21   what is called?

22   MALE VOICE: Radar plot.

1   MEMBER BAILEY: Radar plot. Okay.

2   In an ideal radar plot, you would have the

3   whole -- if you had a score of 100, it would be all

4   around the outside. So in this slide, we can see

5   some differences among race/ethnic groups.

6   So non-Hispanic Asians have the highest

7   HEI score, and those are represented with the color

8   red on the radar plot. And you'll see differences

9   and -- within certain food categories. For

10   example, look at greens and beans, how more

11   compliant that race/ethnic group is with the

12   recommendations. Non-Hispanic blacks have the

13   lowest HEI score relative to the other groups.

14   So our draft conclusion one from some

15   of that data is that, while average diet quality

16   has slightly improved, scores are not necessarily

17   consistent with the current recommendations, and

18   we do see differences with sex, age, race,

19   ethnicity and income, but the differences are

20   generally small.

21   This is where the food categories that

22   are contributing to energy. And the -- I'm just

1 going to take a second to walk through these,

2 because I know we've looked at them before, but just

3 to remind you.

4   So the first bar is for all Americans

5 two and older. All the different colors represent

6 the top 10 food categories. And one thing that is

7 surprisingly consistent is those food categories

8 do not change. What changes is the proportion by

9 age group.

10   So these are food category sources.

11 You can see that for children two to five, there

12 is less proportion from burgers and sandwiches

13 than, say, in adulthood.

14   And we'll come back and look at some of

15 those when we look at how patterns track across

16 life, but just to give you a sense of food category

17 source of energy for this context right now.

18   So our second draft conclusion is that

19 foods and beverages consumed via mixed dishes, such

20 as sandwiches, casseroles and pizza, sweets and

21 snacks, and beverages, contribute about 50 to 60

22 percent of total energy intake.

1   Food subcategory source contributions

2   to energy vary by all of the population

3   demographics that we've talked about, but for the

4   total population, about five subcategories make up

5   most of the energy, and that's burgers and

6   sandwiches, desserts and sweet snacks, rice, pasta

7   and grain-based mixed dishes, sweetened beverages,

8   and chips, crackers and savory snacks.

9   So this is looking at where beverages

10   are contributing to energy intakes.   So in

11   general, about 15 percent of energy comes from

12   beverages, and this is specifically among two- to

13   19-year-olds.

14   So beverages contribute about

15   40 percent or more of added sugar in two- to

16   19-year-olds. The percent of added sugar from

17   beverages significantly increases with age, and so

18   when milk is decreasing, it tends to be replaced

19   with sweetened beverages.

20   But all is not lost in the beverage

21   category, for 40 percent of vitamin C and D and more

22   than 20 percent of carbohydrates, calcium,

1   potassium, and magnesium are coming from

2   beverages, mainly milk and 100 percent fruit juice.

3   And not surprisingly, more than

4   80 percent of caffeine comes from beverages. This

5   is looking at adults. So this is a pie chart

6   showing, of all the beverages' calories, what

7   specific foods they are coming from.

8   And the three top sources are sweetened

9   beverages, alcohol, and coffee and tea. And

10   what's interesting here is there are sex

11   differences. So males have more energy intake in

12   terms of beverage calories from alcohol, whereas

13   women are more likely to have coffee and tea

14   calories, which brings me to conclusion number

15   three.

16   Calories from total beverage account to

17   15 to 18 percent of total energy for Americans.

18   Fluid milk as a beverage decreases, starting in

19   early childhood, and intake of sweetened beverages

20   increases.

21   And beverages account for 40 to

22   50 percent of added sugars in the diet, and

1 alcoholic beverages contribute 21 among females

2 and 31 percent among males of total beverage

3 calories.

4 We are probably only about 20 percent

5 of the way through my slides. So I just wanted to

6 give you, like, some context. Just take a deep

7 breath. We're going to do this.

8 Okay. So this question asks about how

9 patterns track across life stages, and ideally, to

10 answer this type of question we'd have longitudinal

11 data.

12 What we have is cross-sectional data,

13 so we can look at different age groups and try to

14 get some trends and some patterns, but we can't

15 necessarily say how they track within an individual

16 or within populations or subgroups.

17 So we will use this analytic framework,

18 again looking at food category source, means,

19 beverage contributions, as well as HEI scores,

20 across different life stages for two and above.

21 This radar plot shows you how diet

22 quality and different components of the HEI changes

1 by age. So remember, I said the youngest children

2 and older adults have the highest diet quality.

3   When we put the two- and 19-year-olds

4 together, in blue, that kind of changes the story

5 a little bit, but nevertheless, you can see that

6 older adults have a higher HEI score in what foods

7 are represented in the diets of older adults:

8 things like total vegetables, greens, beans,

9 seafood and plant proteins, as well as fruit,

10 refined grains, and lower added sugars, as we

11 talked about before.

12   So once children begin to age, their

13 milk intake goes down, and so do scores in the dairy

14 component. You can see that clearly from this

15 plot.

16   So this is going to be the start of a

17 marathon of slides that look exactly like this, but

18 the title is going to change. And the colors are

19 not always consistent. So if you want me to stop

20 and you want to look at them in a little bit more

21 detail, our safe word in our subcommittee is

22 tangerine.

1 So if you want me to stop, just say,

2 tangerine, and I'll know it's time to stop. Okay.

3 So this is looking at energy. You've already seen

4 this one, so we won't spend too much time here.

5 But next, looking at vegetables, and

6 how those change with different age groups. So the

7 green is represented by vegetables, including

8 beans and peas that are not starchy. As I

9 mentioned earlier, less than 50 percent of

10 vegetables are consumed as a vegetable alone.

11 Chips, crackers, and savory snacks and

12 pizza are a larger source of vegetables for

13 children than for adults or older adults. And mean

14 vegetable intakes tend to increase with age.

15 Looking at fruit, you can see, as I told

16 you earlier, that primarily coming from, you know,

17 whole fruit, but it does decrease after the age of

18 five, and then pretty much levels off and stays

19 about the same after the age of five.

20 And 100 percent fruit juice decreases after

21 adolescence.

22 This is looking at whole grain intake,

1 and we talked about the mean intake earlier, but

2 chips, crackers, and savory snacks as a source of

3 whole grains decreases, and yeast bread and

4 tortillas increases as a source of whole grains

5 among individuals in older age groups.

6   So you can just see some of the

7 patterns. The number-one contributors generally

8 stay the same, but the proportions change with

9 different age groups.

10   So going on to dairy, there is a food

11 category source shift from higher fat among young

12 children to burgers and sandwiches among young and

13 middle-aged adults, and older adults, desserts and

14 sweets and snacks are really a large contributing

15 source to dairy.

16   This is looking at protein foods. So

17 mean total protein is generally within recommended

18 ranges. We talked about those groups that it's

19 not. For older children and younger adults,

20 burgers and sandwiches is the main category source,

21 and mixed dishes contribute a smaller proportion

22 of protein to the intakes of older adults.

1   Looking at added sugars, mean added

2   sugar intake is highest in adolescence and early

3   adulthood. The food category sources here change

4   across the life course. So desserts and sweet

5   snacks are a large contributor for both young

6   children and older adults, whereas in between those

7   age groups, it's really sweetened beverages, so

8   from six to 50.

9   And for adults, coffee and tea are also

10   a source of added sugar. These are -- coffee and

11   tea are not naturally contained in this, so this

12   inclusive of the additions. I should have made

13   that point earlier.

14   This is looking at calcium. The slide

15   is set up in just the same way. So high-fat milk

16   and yogurt is the largest contributor among young

17   children, and it shifts to burgers and sandwiches

18   for adolescents and adults. And water makes up a

19   large contributor among adults to calcium intakes.

20   This is looking at potassium, so milk

21   and yogurt is a large contributor for young

22   children, and that shifts to --

1   VOICE: burgers and sandwiches.

2   MEMBER BAILEY: -- burgers and

3 sandwiches. Thank you. Somebody's awake. All

4 right. And then coffee and tea and vegetables in

5 adulthood, as a large contributor.

6   This is looking at sodium, and as we

7 mentioned earlier, it's overconsumed across all

8 life stages, and this is primarily coming from

9 burgers and sandwiches, and that's pretty

10 consistent across most age groups.

11   This is looking at vitamin D. And

12 remember, I'm only showing you the highlight reel.

13 Okay? So you can imagine how much data we've been

14 looking at.

15   So vitamin D is underconsumed across

16 all life stages. Again, children are getting

17 vitamin D, similarly to calcium, from high-fat,

18 low-fat dairy and milk, and in adults, it's burgers

19 and sandwiches.

20   So this is our draft conclusion

21 statement. There is general consistencies in diet

22 quality seen across life stages. Diet quality is

1 better among young children and older adults, but

2 even so, it still does not align with existing

3 guidance.

4 Food category sources of food groups

5 and nutrients differ across life stages. In

6 particular, in the case of milk and yogurt, after

7 early childhood decrease, and intakes of added

8 sugar from beverages increase.

9 Fruit and vegetable intake declines

10 through adolescence and adulthood, and then

11 increases among older adults. Intakes of burgers

12 and sandwiches contribute to most food groups,

13 nutrients and food components which fall outside

14 of recommended ranges.

15 So burgers and sandwiches help

16 contribute to underconsumed nutrients, because

17 they're so ubiquitously consumed, but they also,

18 at the same time, contribute to those nutrients and

19 food components that we want to limit, such as

20 sodium and saturated fat.

21 Deep breath. Okay. So for the

22 prevalence of nutrition-related chronic

1   conditions, we have, as I mentioned earlier,

2   several data sources. What I'm going to do here

3   is a word that I learned yesterday called bookend.

4   So I'm going to tell you the conclusion,

5   and then I'm going to show you the data, and then

6   we'll revisit the conclusion as a group to get some

7   input, because there is a lot of information I'm

8   going to give to you, and distilling it into a

9   couple of sentences is very complicated. So we'd

10   really love to hear the Committee's feedback on

11   what you think are the most salient points to

12   include in this section.

13   So we are looking at this with a life

14   stage approach, and the colors are simply there to

15   show you that there are certain things, like body

16   composition, that we will looking at in most age

17   groups, cardiovascular endpoints. So we'll start

18   with young children.

19   We only have two outcomes in young

20   children. We have body composition. So more U.S.

21   children under the age of 24 months are overweight,

22   about 9 percent, than underweight, based on weight

1 for recumbent length.

2   The prevalence of low birth weight and

3 very low birth weight are 8.3 and 1.4 percent

4 respectively. Non-Hispanic black mothers have

5 the highest prevalence of low birth weight babies,

6 and this has increased over time.

7   We have a different age group for

8 allergies.   So based on proxy report, the

9 prevalence of food allergy is 6.6 percent. So this

10 is not clinically confirmed data. It's -- I felt

11 strange using the word self-report, because it was

12 birth to four.

13   And I'm just imagining like a little

14 baby trying to tell you -- anyway. So proxy

15 report. So you know, there's obvious limitations

16 with that kind of data; it's not clinically

17 confirmed.

18   So looking at the data that we have

19 available in children in the following categories,

20 the prevalence of overweight is about 17 percent,

21 obesity, 18.5 percent, and underweight, 3 percent.

22   Prevalence of underweight is higher in

1   boys than girls and increases with age. However,

2   the prevalence of underweight has decreased over

3   time. The prevalence of obesity is higher in boys

4   than girls. It increases with age, and has

5   increased since 2007 and 2008.

6   Among girls, the race/ethnic group with

7   the highest prevalence of obesity is non-Hispanic

8   black, whereas among boys, highest prevalence is

9   in Hispanic and Mexican-Americans.

10   The prevalence of obesity is lowest

11   among children whose head of household has a

12   college degree or higher.

13   So our draft conclusions for CVD

14   intermediate outcomes: the prevalence of

15   hypertension is 4 percent, and it's higher in

16   males, non-Hispanic blacks, 18- to 19-year-olds,

17   and those with obesity relative to their peer

18   counterparts.

19   Prevalence of high LDL is 5 percent, and

20   prevalence of low HDL is 15.5 percent. The

21   prevalence of high LDL is higher in non-Hispanic

22   whites, and Hispanic and Mexican-Americans -- you

1   can see the percentages there -- when compared with

2   non-Hispanic black and Asian youth.

3   The prevalence of low HDL cholesterol

4   is higher in males, non-Hispanic whites and youths

5   with obesity.   So   for   each   chronic   health

6   condition we've examined in children, the highest

7   prevalence is among those with obesity.

8   We have one cancer outcome, and that is

9   leukemia, and you can see the incidence and

10   mortality rate, both of which are higher among boys

11   than girls, and so this is inclusive of birth to

12   19 years of age, from the SEER data.

13   In terms of diabetes and prediabetes,

14   we have data on 12- to 19-year-olds, and the

15   prevalence of those combined is 23 percent. This

16   is coming from NHANES data.

17   Dental caries: So first, looking at

18   two- to 19-year-olds, the prevalence is about

19   46 percent, and then untreated dental caries is

20   about 13 percent, so this tends to be associated

21   with age.

22   Again, this is cross-sectional data, so

1   we can't say the prevalence of caries increases

2   with age, but the age groups and the prevalence

3   track in the same way.

4   Hispanic youths have the highest

5   prevalence of dental caries, but non-Hispanic

6   blacks have the highest prevalence of untreated

7   dental caries. The prevalence of both caries and

8   untreated caries is lower among families with a

9   higher income. And there has been a slight

10   downward trend over time for the prevalence of

11   total and untreated dental caries.

12   Moving on to adults, the overall

13   prevalence of underweight among adults is 1.5

14   percent. The prevalence of overweight and obesity

15   and severe obesity are highlighted there in

16   parentheses. The prevalence of overweight has

17   decreased, while the prevalence of obesity and

18   severe obesity has increased.

19   And the prevalence of obesity and

20   severe obesity is higher in women than it is in men.

21   Mean body weight, weight circumference, and BMI

22   have increased over time.

1   Adults 40 to 59 have the highest

2   prevalence of obesity. Hispanic and

3   Mexican-Americans have the highest prevalence

4   among men, and among women, it's non-Hispanic black

5   women.

6   Looking at the data, the overall

7   prevalence of dental caries among adults age 20 to

8   64 is 90 percent, and 96 percent among adults ages

9   65 and older.

10   Women have a slightly higher prevalence

11   than men among 20- to 64-year-olds, but the

12   prevalence converges after the age of 65.

13   Non-Hispanic blacks have the highest prevalence of

14   untreated dental caries, and the overall

15   prevalence of complete tooth loss is 2 percent in

16   20 to 64, but increases to 17 percent among those

17   age 65 and older.

18   So looking at cardiovascular,

19   intermediate and outcomes, high cholesterol among

20   adults is 12 percent. Low HDL, 18 percent.

21   Hypertension, 29 percent. Coronary heart

22   disease, 6 percent, and stroke, around 3 percent.

1   So when we talk about adults in general,

2   we're talking about 19 and older, but some of the

3   data come from different surveys, so that is why

4   we have 18 and 19 for some of these age groups here.

5   The prevalence of high cholesterol and

6   low HDL has decreased since 2007-08. Women have

7   a higher prevalence of high cholesterol. Men have

8   a higher prevalence of hypertension, low HDL, CHD

9   and stroke.

10   Adults 40 to 59 have the highest

11   prevalence of total cholesterol and low HDL.

12   However, adults ages 65 and older have the highest

13   prevalence of hypertension, CHD and stroke.

14   So some more key findings here.

15   Non-Hispanic whites have the highest prevalence of

16   high cholesterol among women. However, Hispanics

17   have the highest prevalence of high total

18   cholesterol among men.

19   Hispanics have the highest prevalence

20   of low HDL for both men and women. Non-Hispanic

21   blacks have the highest prevalence of hypertension

22   and stroke. American Indian and Alaska Natives

1   have the highest prevalence of coronary heart

2   disease.

3   The   prevalence   of   hypertension,

4   coronary heart disease and stroke are lower among

5   those with higher education levels, and those with

6   a college degree tend to have the lowest prevalence

7   of these cardiovascular outcomes.

8   In terms of diabetes and metabolic

9   syndrome, diabetes is prevalent in about 14 percent

10   of U.S. adults; prediabetes, 34 percent; and

11   metabolic syndrome, almost 35 percent.

12   So men have a higher prevalence of

13   diabetes and prediabetes, but there's no

14   differences for metabolic syndrome. So the

15   prevalence of diabetes and metabolic syndrome is

16   higher among older age groups.

17   In fact, 52 percent of older adults have

18   metabolic syndrome. The prevalence of diabetes is

19   higher among those with higher BMIs, and Hispanics

20   and Mexican-Americans have the highest prevalence

21   of diabetes and metabolic syndrome.

22   In terms of chronic liver disease, we

1　　have two different measures.　First is

2　　self-report, which is about 2 percent, but then

3　　looking at ALT and AST, ALT is elevated in about

4　　10 percent, and AST in 16 percent of U.S. adults.

5　　　　　　　Hispanics have a higher prevalence of

6　　liver disease, high ALT and high AST, when compared

7　　with non-Hispanics.　American Indian and Alaska

8　　Natives have the highest prevalence of liver

9　　disease.

10　　　　　　Men and women have the same prevalence,

11　　and mortality rates differ.　So men have a higher

12　　mortality rate than women.　And mortality rates

13　　have increased over time, particularly in men.

14　　And then men age 55 to 64 have the highest mortality

15　　rate from chronic liver disease.

16　　　　　　So these are a different data source.

17　　So this is from the National Vital Statistics

18　　System.　These are the age-adjusted prevalence

19　　rates for chronic liver disease and cirrhosis, and

20　　you can see that they have increased since 2006 to

21　　2016 in every age group, except for males 45 to 54.

22　　And men 55 to 64 have the highest mortality rate

1   from chronic liver disease, and the lowest rate is

2   among females 25 to 34.

3   Moving on to cancer, so the cancer with

4   the highest incidence rate among females is breast

5   cancer, followed by male prostate cancer.

6   Age group and cancer type with the

7   highest incidence rate is prostate cancer for men

8   among ages 65 and older. Mortality rate is highest

9   for lung and bronchus cancer, and the age group is

10   the highest mortality rate from that cancer is

11   among older adults, 65 and older.

12   Men   have   a   higher   incidence   and

13   mortality rates than women across all shared cancer

14   types, and the incidence and mortality rates for

15   every cancer type are highest among individuals 65

16   and older.

17   So we'll talk last in this section about

18   pregnant women. We're just going to talk about

19   gestational diabetes today, because the 2018

20   pregnancy-induced hypertension data is just coming

21   into our emails now, so we'll hold off on that until

22   next time, and just focus on gestational diabetes

1   right now.

2   Total prevalence, about 6 percent. It

3   is higher in women who are older than 40. There's

4   some race/ethnic differences. So non-Hispanic

5   Asians, 11 percent have gestational diabetes.

6   Also very high in American Indian and Alaska

7   Natives and Native Hawaiians and Pacific

8   Islanders.

9   The prevalence remains relatively

10   stable across educational status, but among those

11   with obesity, particularly Class III obesity, the

12   prevalence is 14 percent.

13   So older adults, we have two outcomes

14   here, muscle strength and osteoporosis and bone

15   health. So 19 percent of older adults have reduced

16   muscle strength. This is data coming from NHANES.

17   And there's really an increase with

18   age. So 48.6 percent of adults over the age of 80

19   have reduced muscle strength. So the age-adjusted

20   prevalence is not different between men and women.

21   It's about 19 percent, and similarly, women who are

22   older than 80, it's slightly higher in women than

1   men, but not substantially different, so 49 versus

2   47.

3   Non-Hispanic Asians have the highest

4   age-adjusted prevalence rate, followed by

5   Hispanics, and then Non-Hispanic blacks have a

6   prevalence that is about 19 percent, and

7   non-Hispanic whites, about 18 percent.

8   In terms of osteoporosis, it's

9   estimated that about 11 percent of adults over the

10   age of 50 have osteoporosis, and about 45 percent

11   have low bone mass, and as we know, women are

12   disproportionately affected by both osteoporosis

13   and low bone mass, and that's amplified here in the

14   last bullet point.

15   So again, given all of the complexity

16   of the data that we showed you, it was very hard

17   to come to a conclusion statement. So this is a

18   work in progress, and we really want it to be

19   informed by you.

20   But we kind of started with this large

21   umbrella, to try to be inclusive of all the things

22   that we found, but we'd like to drill down and have

1   some more specific conclusions. Okay.

2   We are on the last question. Evaluate

3   nutrients of public health concern. So we've

4   talked a lot about intakes of food groups,

5   short/long nutrients, and this will be our last

6   question.

7   So with nutrients of public health

8   concern, we have tried to use the terminology food

9   component, because there's things that we're

10   talking about that aren't essentially nutrients.

11   So if you are confused, that is why.

12   The question was written for nutrients, but we are

13   trying to use food components. So we developed

14   this flowchart ahead of time. That's where we

15   looked at the data to make decisions.

16   So sometimes we had dietary data available.

17   Sometimes we have biomarkers. Sometimes we have

18   clinical outcomes.

19   So we had a decision tree in place

20   before we looked at the data to try to be as

21   transparent as possible. And I don't expect you

22   to read that, because it's very small. It will be

1   in the report.

2   So we first started by casting a wide

3   net. We defined underconsumed or overconsumed

4   when a food component was not within the range of

5   5 percent or higher relative to a dietary reference

6   intake   or   a   quantitative   authoritative

7   recommendation,   such   as   a   previous   dietary

8   guideline recommendation for saturated fat.

9   Similarly, for overconsumed. Then

10   those are elevated to a nutrient or food component

11   of potential public health concern when supporting

12   data through biomarkers, functional indicators,

13   that these low intakes or high intakes are directly

14   related to a health condition.

15   Then we are proposing this category

16   called nutrient or food component that poses

17   special challenges. This is a term that was used

18   by the 2005 Committee to identify food components

19   for   which   dietary   guidelines   to   meet

20   recommendations was challenging.

21   But we've extended this to also include

22   nutrients or food components that pose special

1 challenges in identifying at-risk groups. And

2 I'll show you what I mean on the next couple of

3 slides.

4   So casting our wide net of 5 percent for

5 underconsumed nutrients, there were a number of

6 nutrients that were either in the population or in

7 specific subgroups, noted with an asterisk, that

8 were not well aligned with recommendation, either

9 the EAR or the AI.

10   So when we next evaluated whether there

11 was a biomarker or clinical endpoint that we could

12 tie low intakes to, we were able to eliminate

13 several nutrients, and those that are listed in

14 bold have previously been linked to a health

15 outcome or biomarker, whereas we still have a few

16 that are listed there in red that are special

17 challenges.

18   In terms of overconsumption, we've

19 already talked about sodium, saturated fat and

20 added sugars, but compared to the UL, young

21 children are exceeding the UL for retinol, zinc,

22 selenium and copper, and you can see those

1   prevalence estimates in the parenthesis there,

2   ranging from about 6 percent for copper to

3   50 percent for zinc and selenium.

4   So then we come to these food components

5   that pose special challenges, and this is where we

6   can also use some of the Committee feedback and

7   guidance.   So I mentioned that protein was

8   underconsumed in adolescent and older females.

9   Vitamin B12 might be a concern in older

10   adults, both dietary data and biomarker. Choline

11   intakes are low relative to the AI for most age/sex

12   groups, after young children. Phosphorus intake

13   is low in 9 to 14-year-olds, as well as magnesium.

14   So magnesium is low, relative to the

15   EAR, across most age groups. So our analytic

16   summary so far is that nutrient intakes have not

17   changed considerably since the evaluation.

18   Nutrient intake distributions taken into

19   consideration with biological endpoints and

20   clinical outcomes suggest that vitamin D, calcium,

21   fiber and potassium are underconsumed.

22   Sodium, saturated fat and added sugars

1 are overconsumed for all Americans ages one and

2 older. We're still talking, and that's why we

3 brought this to you today, in terms of the

4 distinction of what is a nutrient of public health

5 concern for some of those remaining nutrients?

6   In addition to those for all age groups,

7 we've looked at this as a life stage kind of

8 approach, and so iron is of particular concern

9 among adolescent and premenopausal females.

10 That's both dietary and biomarker data.

11   Older adults seem to be at risk for low

12 intakes of protein, and I showed you the data on

13 the muscle strength, as well as vitamin B12.

14 Adolescents, there was -- this is what we're

15 calling a constellation of dietary risk.

16   So this age group has the highest

17 prevalence of not meeting recommendations across

18 most nutrients, and particularly adolescent girls.

19 So protein, folate, B6, phosphorous, magnesium and

20 choline.

21   And then young children, as I showed you

22 earlier, one to three, have high intakes of

1   retinol, zinc, selenium and copper, relative to the

2   UL.

3   So our remaining work I talked about a

4   little bit earlier is what is the role of added

5   sugar in meeting food group recommendations,

6   frequency of eating, looking at beverages, and

7   meeting food group and nutrient recommendations,

8   as well as dietary patterns?

9   We already mentioned that we're going

10   to be working more with the B to 24 and Pregnancy

11   and Lactation to identify nutrients of public

12   health concern in those populations.

13   And then finally, we'll end with a few

14   pattern modeling questions. Thank you very much

15   for your time and attention. And I definitely will

16   answer questions, but we also really want to hear

17   from you guys.

18   (Applause.)

19   CHAIR SCHNEEMAN: A long presentation.

20   It was very quick, though. So you've heard some

21   questions from the subcommittee, but I think also

22   you have questions or comments for the

1   subcommittee.

2   MEMBER DONOVAN: So thanks, Regan. I

3   have two questions, and one is related to the kids

4   in the -- of early ages that are in the upper

5   limits.   Do we know what food groups are

6   contributing to the high intakes of the zinc and

7   selenium?

8   MEMBER BAILEY: Yeah. We haven't

9   really looked at it that way. I could guess at what

10   I think those food sources are, but I think that's

11   premature.

12   MEMBER DONOVAN: Okay.

13   MEMBER BAILEY: And then, you know,

14   there's a lot of discussion around are those ULs

15   the right number? So it might be that the diets

16   are okay, and the ULs are often set based on

17   extrapolated data down for children.

18   So that's why we are calling it, you

19   know -- maybe this is a concern. We certainly

20   didn't want to make a statement without talking to

21   you all, but we are really unsure about to do, and

22   this is just from food alone.

1   So when we will look at supplements for

2   nutrients, those prevalences are going to

3   increase.

4   MEMBER DONOVAN: So my second question

5   was related to some of the -- primarily the

6   cardiovascular outcomes, and is there any

7   factoring in of medications that are used to manage

8   hypertension or cholesterol?

9   MEMBER BAILEY: The way the data are

10   collected is -- so particularly, some of the

11   biomarkers -- no. I mean, we know that a lot of

12   people are on statins. These are the prevalence

13   estimates for a national representative sample of

14   adults.

15   So there are people who taking

16   medications for hypertension. There are people

17   who taking medications for various things, but

18   they're in the survey.

19   CHAIR SCHNEEMAN: So Kay, and then

20   Richard --

21   MEMBER MATTES: Sure.

22   CHAIR SCHNEEMAN: -- and then -- and

1   Steve. So Kay?

2   MEMBER DEWEY: Thank you very much.

3   Kay Dewey. So first, I want to just comment that

4   the UL percent is very, very lightly -- it's too

5   low, because we see this problem across the board,

6   you know, in many countries, and so that's just one

7   comment.

8   So I have three questions. The first

9   is when you're looking at inadequate nutrient

10   intakes, we've talked about the fact that people,

11   at least for adults, tend to over -- underreport

12   their energy intake, and so that might make it look

13   like their nutrient intake is too low.

14   And I think you've talked about this,

15   but if you'd answer again whether you're attempting

16   any correction for that, or at least a sensitivity

17   analysis that would let you judge, you know, is it

18   really low, or it's just they're underreporting

19   energy?

20   MEMBER BAILEY: Yeah. We know that

21   there is underreporting of energy, but for

22   nutrients, it's really not well known how

1   differential that is. We only have recovery

2   biomarkers for a few food components, and so we

3   really can't make estimates about what other

4   nutrients are low as a result of energy

5   underreporting.

6   We haven't really talked about

7   sensitivity analysis. I know there's been some

8   work done with the survey before, so we might want

9   to look at -- especially the nutrients that we do

10   agree are a public health concern, maybe we could

11   do a sensitivity analysis, trying to exclude energy

12   underreporters, and see what those prevalence

13   estimates would look like.

14   That's a really good idea.

15   MEMBER DEWEY: Well, you know, I was

16   thinking more along the lines of if we assume that

17   underreporting is not the assumption -- not

18   necessarily a the assumption, but for a sensitivity

19   analysis, if you're assuming that, you can then

20   apply it as a correction factor across the board,

21   just to see which ones would still emerge as being

22   under the EAR, for example.

1   MEMBER BAILEY: Yeah, but people

2   differentially   underreport   specific   food

3   components, like alcohol or sugars, and those

4   aren't things that really would be good nutrient

5   sources anyway, so I don't know that we could have

6   a correction factor.

7   MEMBER DEWEY: Okay. Well, anyway,

8   something to think about. The second the question

9   is regarding the birth weight outcome you reported,

10   and just in terms of low birth weights, I

11   remember -- and maybe I don't remember. But do we

12   have estimates for SGA, LGA, and preterm?

13   MEMBER BAILEY: Yeah. We don't have

14   preterm right now that I have seen, but we do have

15   all the anthropometrics. We can give you guys all

16   that data, probably be a good conversation to have

17   together.

18   MEMBER DEWEY: Yeah. And one of the

19   issues to take into account is the multiple births

20   and trends in those, because those drive a lot of

21   those numbers. And then lastly, there was a slide

22   where you had a bunch of nutrients, and then you

1 crossed them out, and I think it was based on

2 whether there was a biomarker or some other --

3   MEMBER BAILEY: Not whether there was

4 a biomarker --

5   MEMBER DEWEY: Or --

6   MEMBER BAILEY: -- but whether that was

7 linked to low intake. So for example, vitamin E,

8 there is a very prevalence of vitamin E inadequacy

9 if you look at the diet, but when you look at the

10 biomarker, it's less than 1 percent.

11   MEMBER DEWEY: So when it was crossed

12 out, it meant that --

13   MEMBER BAILEY: That it wasn't

14 confirmed with a biomarker or a clinical outcome

15 endpoint.

16   MEMBER DEWEY: But what if there is no

17 biomarker? Was it crossed out?

18   MEMBER BAILEY: No, I don't think so.

19 Like what are you thinking of? We try to be,

20 like -- all the ones that we were -- special case

21 that we wanted to talk about, which if we could pull

22 up that last slide, that might be helpful.

1   But for a lot of those, they do have

2   biomarkers or no clinical endpoint. Like we have

3   vitamin C from the blood, we don't see a lot of

4   scurvy. You know, so that's why that could be

5   crossed out.

6   CHAIR SCHNEEMAN: So can you go

7   backwards --

8   MEMBER BAILEY: I put it at the end, so

9   I was anticipating this. Okay. Perfect.

10   CHAIR SCHNEEMAN: I think she was

11   looking at the table where you listed everything

12   that was --

13   MEMBER BAILEY: That might take a

14   minute.

15   MEMBER DEWEY: Okay. So here's the

16   list, and then if you could explain what were the

17   reasons for crossing the ones that are crossed out?

18   I just didn't -- you went fast.

19   MEMBER BAILEY: Okay. So probably not

20   a nutrient by nutrient, but there was not a

21   biomarker that could confirm low dietary intakes

22   were a problem, and there was not -- it was not

1   related to any clinical or health outcome.

2   MEMBER DEWEY: Okay. So in some

3   cases, there is a biomarker, but it didn't show a

4   problem --

5   MEMBER BAILEY: Right.

6   MEMBER DEWEY: -- but in other cases,

7   there is no biomarker, so we don't know.

8   MEMBER BAILEY: So what are you

9   thinking there's no biomarker?

10   MEMBER DEWEY: Well, I'm just -- well,

11   I --

12   MEMBER BAILEY: Can you go back to the

13   flowchart? There we go. Okay. So we would start

14   with -- there are -- for most things, we have

15   dietary data available. So is that available?

16   Yes.

17   Are the prevalence estimates within the

18   threshold, is it more than 5 percent of the

19   population or any population subgroup that might

20   have a problem? Yes. Then is there a biomarker

21   available? Yes.

22   Is there suggested evidence of a risk

1   supported by a biological or clinical indicator?

2   No. Like, you know, every path on -- you put the

3   nutrient through -- each nutrient through this

4   kind of pathway to see what was available.

5   MEMBER DEWEY: Okay. So the specific

6   question I have is, the arrow that goes from "Are

7   biomarker data available?" And it says, no.

8   MEMBER BAILEY: Uh-huh.

9   MEMBER DEWEY: And it goes to the left

10   and it says "Lack of evidence to be considered a

11   nutrient or food component of public health

12   concern." Are there any nutrients where there is

13   no biomarker?

14   MEMBER BAILEY: Fiber. And it is a

15   nutrient of public health concern, because it's

16   linked to a clinical outcome.

17   MEMBER DEWEY: Okay. So there's

18   only -- yeah. So basically none of them have been

19   excluded on that basis. Okay. Thank you.

20   MEMBER BAILEY: That was a long way

21   around. Sorry. I didn't get that question.

22   CHAIR SCHNEEMAN: No, but --

1   MEMBER BAILEY: But I spent so much

2 time on this, so I just really have to --

3   CHAIR SCHNEEMAN: I know. It's burned

4 into your mind, so you've got to bring us all along.

5   MEMBER BAILEY: And it's the color.

6   CHAIR SCHNEEMAN: So I can -- did you

7 have anything --

8   MEMBER DEWEY: No.

9   CHAIR SCHNEEMAN: Okay. So Rick?

10   MEMBER MATTES: Rick Mattes. I'm not

11 trying to add anything to your plate, but when you

12 look at beverages, will you be looking at them when

13 consumed alone versus with meals? It's a question

14 that comes up quite often, and it's kind of

15 relevant.

16   I mean, beverages serve functions.

17 When they're consumed with a meal, they help you

18 swallow, and it doesn't mean that one has to use

19 a sweetened beverage to accomplish that, but

20 weighing costs and benefits and hydration or not,

21 it is a more complicated question of knowing to what

22 degree beverages alone are contributing energy and

1 nutrients.

2 MEMBER BAILEY: Yeah. We don't have

3 that built into the analytic framework right now,

4 but I think that can be something that we

5 incorporate into the report as a research

6 recommendation --

7 MEMBER MATTES: Yeah.

8 MEMBER BAILEY: -- something that

9 could be looked at.

10 CHAIR SCHNEEMAN: Yeah. Is it

11 available?

12 MEMBER BAILEY: Every eating occasion

13 is recorded as a separate eating occasion. So you

14 could do it that way. So if someone just reports

15 a beverage, you could separate that out with the

16 NHANES data.

17 CHAIR SCHNEEMAN: Dr. Heymsfield?

18 MEMBER HEYMSFIELD: How was strength

19 measured?

20 MEMBER BAILEY: With hand grip.

21 MEMBER HEYMSFIELD: Hand grip?

22 MEMBER BAILEY: Yeah.

1   MEMBER HEYMSFIELD: Because what

2 caught my eye was the Asians have highest

3 prevalence of low strength, and you use that

4 measure for a sarcopenia diagnosis, and strength

5 is related to body size. I wondered if adjustments

6 were made for body size?

7   MEMBER BAILEY: No. These -- what we

8 presented today are just prevalence estimates. At

9 some point, they were age-adjusted when I specified

10 that for things that -- like cancer, but we haven't

11 done it like that for the muscle data, but that's

12 a good idea.

13   So that does bring up the point about

14 protein, and it's low in older adults. There's a

15 rather high prevalence of low muscle strength.

16 How do you feel about that in terms of would that

17 rise to the level of something you would consider

18 to be a public health concern?

19   I'm not putting you on the spot --

20   MEMBER HEYMSFIELD: Yeah.

21   MEMBER BAILEY: -- specifically, but I

22 mean, that --

1   MEMBER HEYMSFIELD: I'm not sure I know

2   the answer.

3   MEMBER BAILEY: You can just say,

4   tangerine. You know, that's an option for you.

5   MEMBER HEYMSFIELD: Yeah. Just work

6   with NHANES data a lot and am very interested in

7   sarcopenia, and I think the body size is a very

8   important covariant in that analysis, so I think

9   before you make any conclusions about Asians

10   being -- lacking strength, you need to really

11   adjust for body size in some way.

12   I'm not sure how, but --

13   MEMBER TAVERAS: In the same vein of

14   not wanting to add anything to this long list, but

15   there are two things that I was going to ask about.

16   One was, you talked about obesity in the adults but

17   not in children, and I think there are really good

18   definitions and NHANES, I think, now is reporting

19   on severe obesity in children.

20   So I would ask if that is available and

21   going to be included?

22   MEMBER BAILEY: So Jamy did some

1   follow-up on body composition data. Do you recall

2   if those numbers --

3   MEMBER ARD: I am sure they're probably

4   there, severe obesity for children. So I think

5   that should be included. Yes.

6   MEMBER TAVERAS: And along those same

7   lines with an increase in severe obesity, we're

8   starting to see nonalcoholic liver disease in

9   children, and it's not one of the outcomes, so --

10   MEMBER BAILEY: That wasn't measured.

11   MEMBER TAVERAS: It wasn't?

12   MEMBER BAILEY: Children -- but we

13   talked a lot of about that. We really know that

14   that's an issue, and we wish we had more data to

15   address that.

16   MEMBER NAIMI: Yeah.   If

17   I -- that's -- some of the elevated ALTs and ASTs

18   in adults are accounted for by fatty liver, by

19   alcohol as well as by hepatitis C, but there's no

20   way to tease those apart. And the AST/ALT for kids

21   B-

22   (Off-mic comments.)

1   MEMBER MAYER-DAVIS: Yeah. So again,

2   speaking of adding things, so you mentioned that

3   HEI was available for the cycle of NHANES data that

4   you are using, but not other indices related to

5   dietary patterns, and not wanting to, you know,

6   steal any thunder from my colleague here to my left,

7   you know, a variety of dietary patterns, you know,

8   are -- you   know   demonstrate   some   really

9   interesting findings.

10   So I don't know how impossible is it to

11 look at other types of indices related to dietary

12 patterns beyond the HEI?

13   MEMBER BAILEY: Yeah. I agree with

14 you. I think that there are a lot of different

15 dietary patterns, but when we really looked at this

16 data, it boiled down to five food groups that were

17 contributing almost half or more energy.

18   So I think what we're looking at is an

19 American pattern. I think there's variations in

20 there. But from the 2015 to 2020 extensive work

21 on dietary patterns, they recommended only indexes

22 and scores be applied to characterize dietary

1   patterns because, after a cluster analysis, were

2   subject to too many decisions, and couldn't be

3   reproduced across cohorts.

4   MEMBER MAYER-DAVIS: Right.

5   MEMBER BAILEY: And so --

6   MEMBER MAYER-DAVIS: So I was thinking

7   more specifically about Mediterranean diet, for

8   example, or DASH as another example.

9   MEMBER BAILEY: Well --

10   MEMBER MAYER-DAVIS: And I completely

11   agree with you --

12   MEMBER BAILEY: So the National Cancer

13   Institute has a dietary patterns methods

14   project --

15   MEMBER MAYER-DAVIS: Yes.

16   MEMBER BAILEY: -- and they use all the

17   different scores, and there's a very high

18   congruency between the HEI and the Mediterranean

19   score and the DASH index. I'm not saying there's

20   perfect agreement, but they're pretty robust.

21   MEMBER BOUSHEY: Want me to back you up

22   on that?

1   MEMBER BAILEY: Sure do.

2   MEMBER BOUSHEY: Yeah. That's what I

3   was going to say. I mean -- and the other issue

4   is creating those dietary patterns, you know, for

5   individual food items is actually a little -- it

6   is more challenging, not that it wouldn't be a

7   wonderful thing to do.

8   It's just that it would be a large

9   investment of time on your part, and we do know with

10   the adult data from the dietary patterns methods

11   project, but they are -- they all come out very

12   similarly.

13   MEMBER BAILEY: But I really do hear

14   your point, Beth --

15   MEMBER BOUSHEY: Yeah.

16   MEMBER BAILEY: -- and you know, we

17   know what they're not doing. They're not doing

18   this, but we don't know what they are doing, and

19   I think it could be a research recommendation that

20   future committees walk in the door with knowing

21   what the existing patterns are that are different

22   than just HEI. That would be very helpful.

1   MEMBER MAYER-DAVIS: Yeah. Because

2   there are established approaches to these scores,

3   some of which are more common in the literature,

4   but some are, you know, fairly obscure.

5   MEMBER BAILEY: Uh-huh.

6   MEMBER MAYER-DAVIS: So -- yeah.

7   MEMBER BOUSHEY: I wanted to give you

8   a shout-out, a team shout-out. Your screener that

9   you developed addressed one of the very comments

10   that have come from the National Academy of

11   Sciences report, so you have a lot to be proud of.

12   That really answered a big question, that you have

13   a method now of looking at these nutrients of

14   concern. So I really have to give you a shout-out.

15   MEMBER BAILEY: We really took that

16   report to heart when we were developing this, but

17   what we realized is that system works nutrient by

18   nutrient, but it failed us when we came across the

19   adolescent females, because we were like this is

20   how we're going to say something is a food component

21   of concern.

22   And then we were like wait a minute. We

1 have this high-risk -- what we consider to be a

2 high-risk group, but -- so nothing is perfect, but

3 we thank you very much.

4 CHAIR SCHNEEMAN: Actually, related to

5 that topic -- and first of all, let me remind the

6 Committee that the subcommittee has also asked for

7 your input on presenting the conclusions around the

8 chronic health conditions.

9 And if you'd recall -- and you can look

10 back at your slides -- but there's a general

11 statement, and then Regan went through a lot of very

12 specific data. And so part of the question that

13 is being asked is, how do we represent -- well, how

14 do we find a balance in representing that? Do we

15 do just a general statement and then each one

16 separately? Or do we need an overall conclusion

17 statement?

18 And then the other that I think we have

19 gotten some discussion is looking at these

20 nutrients of public health concern.

21 And I'm going to ask you about

22 potassium, because I know that potassium was below

1 the AI across the food groups, but we also have the

2 new DRI report which did not give us a chronic

3 disease reference value for potassium.

4 And so maybe just -- some of you in the

5 subcommittee are thinking about potassium as a

6 nutrient of public health concern.

7 MEMBER BAILEY: Yeah. As you know,

8 the DRI was recently updated, and we talked about

9 this. Jamy, if you want to -- can you summarize

10 what we said in our small group meeting yesterday

11 about potassium from -- Jamy was on the committee.

12 MEMBER ARD: Sure. So the issues with

13 potassium, from a clinical standpoint -- yes,

14 there are no issues with people coming into primary

15 care and emergency rooms with rampant hypokalemia.

16 So that's not an issue.

17 I think the main potential chronic

18 disease risk related to lower potassium intake is

19 related to cardiovascular disease, and in

20 particular, hypertension, and some of the sequelae

21 of that.

22 So you know that there's a relationship

1   between higher potassium intake and lower

2   prevalence of high blood pressure. We know that

3   there are differences in subpopulations in terms

4   of potassium intake and some of those differences

5   maybe explain some disparities in outcomes and

6   health outcomes.

7   So   for   minority   populations,

8   African-Americans in particular, you see higher

9   prevalence of hypertension, lower intake of

10   potassium in that group. And we also know that

11   potassium has a blunting effect in terms of the

12   hypertensive effect of sodium.

13   So in populations where potassium

14   intake is higher, even for a higher sodium intake,

15   you see a less robust response in terms of blood

16   pressure.

17   So I think part of the discussion we had

18   yesterday was there could be an argument made that

19   potassium intake is part of the public health

20   concern group, even though we don't have some of

21   the, you know, sort of classical direct links; you

22   have more indirect ones, per se.

1 But there is a body of evidence that

2 supports the idea that higher potassium intakes may

3 actually have an impact at the population level.

4 So I think that, you know, summarizes the points

5 in the discussion.

6 MEMBER BAZZANO: Lydia Bazzano. So I

7 would second what Jamy just said, Dr. Ard, and also

8 in terms of nutrients of concern, I know Steve can

9 speak -- I know you all did not specifically say

10 protein in older adults, but I think, you know,

11 given the levels that -- the prevalence that we're

12 seeing, I think they probably should be concerned.

13 MEMBER DEWEY: Kay Dewey. I have

14 another question. I think the list of nutrients

15 where you were examining whether they were of

16 public health concern did not include fats, and is

17 there a reason for that?

18 MEMBER BAILEY: Yes. We hadn't looked

19 at that data specifically, but you've reminded me

20 that we really need to do that. So we looked at

21 saturated fats, but we didn't look at other fatty

22 acids so we should absolutely do that. Thank you.

1   CHAIR SCHNEEMAN: Any comments, any

2   questions?

3   Regan, do you want to put that draft

4   conclusion statement up, and let's see if

5   there's -- ah. Great.

6   So I guess the question, though, is are

7   we comfortable with this general statement,

8   knowing that the report itself will go through some

9   of the details that Regan has presented?

10   And again, it's still a draft,

11   so there's still some tweaking that probably needs

12   to be done.

13   MEMBER ARD: So the alternative to that

14   statement is something that then calls out some

15   specific chronic diseases that, you know, may be

16   of more interest or more concern.

17   So as an example, we had nominated

18   something like dental caries and metabolic

19   syndrome and diabetes as being really concerning,

20   as well as increasing rates of mortality related

21   to chronic liver disease.

22   So these were things that were, you

1 know, somewhat striking for us as we reviewed the

2 data, but they were, you know, our perspective.

3 And so I guess the question is, do we just leave

4 this very general and be very generic and point out,

5 you know, things that we all know?

6 Chronic disease is increasing and the

7 disparities, and you know, it's worse in some

8 subgroups compared to others, and we could stop

9 there.

10 Or we could, you know, incorporate or

11 call out things that we think are, you know,

12 particularly concerning, either across life stages

13 or related to other things that, you know, would

14 be relevant for some of the questions that other

15 subcommittees are dealing with, or related to

16 things that we think are relevant, you know, with

17 regard to where particular recommendations might

18 go or be needed for emphasis?

19 MEMBER DEWEY: Kay Dewey. So one

20 thought is to at least highlight in some way the

21 outcomes that are being examined in some of the

22 literature   reviews   that   the   different

1   subcommittees are doing.

2   So the certain cardiovascular disease

3   outcomes are part of several of those, and also

4   growth, size, and body composition, so overweight

5   and obesity. All those come to my mind as

6   deserving to be highlighted, because we are going

7   to talk about whether diet is related to them.

8   MEMBER NOVOTNY: Just in general, I

9   would like us to think about what to do with weight

10   status or overweight/obesity. I see it's kind of

11   listed as a -- almost like a demographic, and

12   whether it goes along with health condition or

13   whether we have to like call it out as an

14   intermediary, metabolic syndrome was mentioned in

15   your review. It's closer to the diet than the

16   pathway of many of the conditions. So just to -- I

17   think we should think about where that goes and

18   follow it.

19   MEMBER TAVERAS: I wonder also if you

20   can group them in that way, that some of these are

21   obesity-related and make the summary a little

22   more -- that the cluster is associated with

1 obesity?

2   MEMBER DONOVAN: Yeah. I'm sort

3 of -- I'm just struggling on whether this is

4 appropriate or how to say it, but I guess when I

5 was looking at your comments and you were talking

6 about racial/ethnic differences, that to me, it

7 seems like we also need to include socioeconomic

8 status and potential health care coverage, because

9 I don't think it's just genetics.

10   Right? And that was kind of led to my

11 respect of the genetic components, but we also

12 disparities in prevention, and I think these

13 differences are because people who have health

14 insurance are getting their medications and

15 they're getting earlier screening of prediabetes

16 and they're getting a lot more prevention, and diet

17 intervenes with that, but it's, you know, a broader

18 issue, and it's quite beyond the scope of dietary

19 guidelines.

20   But this aspect of, you know -- to give

21 you more work, if we could look at things

22 beyond -- you know, other demographics in terms of

1   SES   or   health   care   or   SNAP   utilization

2   or -- because to me, that leads directly to

3   potential application of dietary guidelines in

4   nutrition programs.

5   MEMBER BAILEY: Many of our protocols

6   have food security --

7   MEMBER DONOVAN: Yeah.

8   MEMBER BAILEY: -- included --

9   MEMBER DONOVAN: Right.

10   MEMBER BAILEY: -- to try to get --

11   MEMBER DONOVAN: Right.

12   MEMBER   BAILEY: --   a

13   different -- other than just, you know, how much

14   money does your family have? How is that money

15   distributed towards nutrition specifically? So

16   that's ---

17   MEMBER DONOVAN: That would be great.

18   MEMBER BAILEY: -- yeah.

19   MEMBER MAYER-DAVIS: Just looking at

20   this statement, I very much appreciate Rachel's

21   comment -- this is Beth Mayer-Davis -- to pull out

22   obesity,   and   then   frame   obesity-related

1 conditions.

2 I think that's part of calling out and

3 being more specific. Thinking back to Jamy's

4 comment, particularly about, you know, some of the

5 areas that, you know, maybe are not above the radar

6 right at this moment, you know, like increasing

7 mortality related to liver disease, like dental

8 caries.

9 So seeing those data, we're not

10 necessary surprised, but it's not necessarily what

11 would have been front-of-mind, and so you know, I

12 think that was really a good comment. So I think

13 taking opportunity to be a little bit more specific

14 here, in that regard.

15 And then my second part of this comment

16 has to do with being more explicit about health

17 equity and inequity, because that's really, you

18 know, what we're talking about.

19 And I think that's really important as

20 we think about the Dietary Guidelines with respect

21 to informing federal food policy, which is about

22 food security, access, all those kinds of things.

1   So I'd like to, you know, see that aspect of health

2   equity brought out as well.

3   CHAIR SCHNEEMAN: So we're reaching

4   the end of our allotted time, but one of the things

5   that Dr. Kleinman and I have been talking about is,

6   as one of the chapters, it's important for us to

7   start integrating the work of all the subcommittees

8   and where do we come to after addressing all of

9   these questions.

10   And so I'd like to just finish the

11   meeting by maybe going around if we had any

12   particular thoughts about that issue, or kind of

13   what Regan was asking the Committee about. It's

14   an opportunity for you to get some final comments

15   for today, based on what we've been hearing.

16   And are you beginning to see some things

17   that sort of emerge to top priority from the work

18   that your subcommittees are doing? So it's always

19   tough to figure out who goes first. I'm going to

20   pick on Kay.

21   MEMBER DEWEY: Well, I mean, the

22   challenge that we have is integrating across the

1 B to 24 age group, because this is the first time

2 that recommendations for this age group are going

3 to be this report, and as you all know, we have

4 multiple outcomes for the same exposure, and so we

5 haven't yet talked about how to integrate across

6 those.

7 Yeah. Well, one thing I do want to

8 repeat that I said at the last meeting, to make sure

9 everyone is aware, that we are only looking at a

10 subset of all the different types of eating advice

11 that might be given for this age group, and in

12 particular, we're focusing on the what to feed and

13 not the how to feed.

14 So a general question then is, how far

15 do we go in even talking about the ones where we

16 have not done systematic reviews. And so any

17 advice I throw back to you that the overall

18 Committee would like to give us on how that gets

19 approached would be very helpful.

20 MEMBER DONOVAN: I mean, I've just been

21 seeing -- we haven't really had the opportunity to

22 speak in terms of Regan's committee on intakes and

1   the prevalence of things like gestational diabetes

2   and all of those.

3   So I think that will be important to

4   start to integrate, and you know, and while

5   pregnancy and lactation has been a component of

6   previous Dietary Guidelines, I think pulling out,

7   you know, this sort of special life stage, as we're

8   taking that life stage approach and thinking not

9   only about improvements for maternal health,

10   because we certainly know that women with

11   gestational diabetes are at higher risk for type

12   2 diabetes later.

13   So again, we haven't really had a lot

14   of time to think about that, I think, in terms of

15   integrating the data in terms of whether pregnant

16   or lactating women are actually consuming and

17   what are the incidence of these health conditions?

18   But I think what we have seen, you know,

19   from both in B-24 and Pregnancy and Lactation, we

20   have a lot of inability to draw conclusions because

21   the data sets -- the data is just not there.

22   So clearly, as we move forward -- and

1 there was a comment earlier about research needs.

2 And we'll have very long lists of research needs,

3 and so that's -- again, I think at the end, we'll

4 be able to make some conclusions, but

5 unfortunately, I don't think very many of them will

6 be strong, but we'll have lots of recommendations.

7 MEMBER BAILEY: I really like the life

8 stage approach that we're taking, and it's very

9 clear for B to 24 and Pregnancy and Lactation.

10 They have specific working groups. It's been less

11 clear to me how to handle the other life stages.

12 And so integrating all the information

13 from the different life stages is going to be a

14 little bit more challenging, but I think really,

15 really important.

16 And then the other thing that really

17 stuck out to me in going through all of the data

18 that we did is that foods and nutrients are

19 inextricably linked, when you see that the food

20 changes over time, and we see that mirrored with

21 nutrients. And I feel it's very important that we

22 meet people where they are in terms of

1   recommendations. So people are consuming a lot

2   of --

3   MEMBER DONOVAN: Burgers and

4   sandwiches.

5   (General laughter.)

6   MEMBER BAILEY: So we have to give them

7   tools and strategies to do that in a better way,

8   not just, you know, you need to eat more of this,

9   eat less of that. But giving them real strategies

10   for success, I think, will be something that is

11   important, at least from my perspective.

12   MEMBER NOVOTNY: What I'm thinking

13   about is really integration and just trying how to

14   weave this in a useful way, like a sentence, but

15   I think the problem is this last point about

16   socioeconomic   status   and   the --   I   know

17   socioeconomic status has been in our models as a

18   variable to consider, but given the potential use

19   of our findings, I'm wondering whether we should

20   be looking at the different subgroups in order to

21   inform policy, and indeed, whether there should

22   have been other kinds of variables in our models

1   that might have helped us, like food security or

2   something about health utilization.

3   I'm   not   sure   also   about   the

4   race/ethnicity route, whether that's going to be

5   the most helpful way to go about it, but that's what

6   I'm thinking about.

7   MEMBER STANG: I would follow up

8   with -- I think we've talked about the life span,

9   but also thinking about the life course approach.

10   So the fact -- when we were looking at the data

11   yesterday, we saw these adolescent females with

12   this constellation of poor nutrition, and I'm

13   thinking, these are our future mothers.

14   And so there's this whole circular

15   piece that what's important during pregnancy and

16   lactation informs what happens to the children,

17   which then grow up to be mothers themselves or

18   fathers.

19   And so somehow to weave that piece

20   throughout   the   report   that   there's   this

21   generational piece that I think often we miss

22   because of the way that data is collected or

1 reported, but it has a lot of contextual

2 implications for the recommendations we make.

3   MEMBER TAVERAS: I was thinking, I

4 guess, three things.

5   One, Sharon mentioned, it's

6 discouraging to see so much insufficient evidence

7 and inability to make conclusions from very little,

8 in some cases, data that is out there and results.

9   And I think that's going to be really

10 important as we summarize, because I think there

11 is quite a bit of attention on what is going to

12 emerge from here, and I think we'll have to be

13 careful with how do we frame this in a way that sets

14 up the next Dietary Guidelines or the next

15 Committee on what were some of these research

16 recommendations, and where we might be able to

17 contribute for research purposes for the next

18 round?

19   I'm struck, Reagan, with the

20 conversation we just had about so many of these

21 chronic diseases are obesity-related and the

22 increase in trends and the prevalence of obesity,

1   and I think that's important.

2   I think we have to call it out. Even

3   if all the chronic diseases, cancer, CVD, if they

4   all cluster around obesity, I think that it is going

5   to be important that we really drive that home,

6   because in our subcommittee and in many others,

7   growth size and body composition is something we're

8   paying close attention to.

9   And then the only other thing that I

10   found interesting is there is a big drop-off -- and

11   maybe because I am a pediatrician and I think a lot

12   about the child diet, but there are some really

13   interesting patterns from two to five to six and

14   older that seems to be this critical point where

15   so many of the other patterns that you showed are

16   deteriorating and decreasing.

17   And I wonder if there's a way -- as we

18   talk also about life course and life stage, if we

19   can point out some areas of opportunity in either

20   these critical periods or setting staff to work

21   with people and populations in those critical

22   periods, that there might be more room for

1   influencing diet in those settings and age groups.

2   MEMBER DONOVAN: I think -- I looked at

3   that too as kind of the child care to school, and

4   there's different policies in school lunch and in

5   CACP, and so I think that's a really smart

6   observation.

7   MEMBER MATTES: Yeah. I don't want to

8   just be redundant, but to amplify the importance

9   of paying attention in our discussion sections

10   about future directions, that this is so

11   disheartening.

12   We spent so much time building these

13   models, to find the greatest science, and we're all

14   ending up with science that isn't answering the

15   questions, and so it's vital that we encourage

16   future researchers to design their trials so that

17   we can get to the bottom of all this.

18   The only other thing that I felt

19   compelled to comment on, but nobody anywhere has

20   talked about food palatability. I mean, there are

21   certainly issues and disparity issues and so on

22   with regard to access and so on, but the primary

1   reason that we pick one thing over another is

2   because we like one thing more than another, and

3   so I hope we don't lose sight of that, and somehow

4   we can leave this in, that we have to pay attention

5   to that component of food.

6   MEMBER BAZZANO: So I like the life

7   course approach and the life stages approach that

8   we're taking, and I do think, you know, that it's

9   important to distinguish the different periods

10   because nutrition is different and the needs are

11   different in different periods of time, and

12   specifically I think in the older adults, you know,

13   we need to think about that as well, that so far,

14   we're kind of all lumped in as adults. So you know

15   I think that might be a particular group with

16   particular outcomes to be focused on.

17   And then the other thing I wanted to

18   mention was also kind of along the lines of what

19   Richard, Dr. Mattes just mentioned, that the data

20   that we have, all of these studies, we've been

21   reviewing a lot, a tremendous amount of studies,

22   most of which are not actually designed to study

1 what we're trying to use them to -- the question

2 that we're trying to use them to answer.

3 So that's a different issue, but it does

4 get to the importance of research for the specific

5 questions that we want to answer.

6 MEMBER SABATÉ: I agree with many of

7 the things that has been said, and I think on the

8 last presentation, I think it struck me that the

9 way that the menu must be -- almost everything is

10 concentrated in sandwiches and burgers.

11 So it's culprit of many things, but also

12 an opportunity. And I think that changes in social

13 trends from different perspectives, not only from

14 food, but also from the perspectives of

15 sustainability and taste. I think this is an

16 opportunity to try to improve the health of

17 Americans, but also tackle other social issues that

18 are concern to today's society.

19 MEMBER LEIDY: I'm not sure if I can add

20 too much to the conversation when we get around to

21 this point, but there's just a couple of things that

22 have come to mind. You know, I think we've all said

1   it.

2   It's surprising right now when you see

3   that there's just a lot of limited evidence, and

4   the evidence that exists seems to be from cohort

5   studies, when we only say we use randomized trials,

6   and I feel like now that kind of just goes to the

7   wayside, because we know we need them.

8   It's that next step of how do you make

9   that happen, you know, from a funding standpoint

10   of getting that out. But I still think that's a

11   vital part of trying to answer some of the questions

12   that we have.

13   So it was more of a surprise. Maybe

14   we'll all sandbagging writing waiting till the end,

15   until March, when all the data come out. I don't

16   think that's the case, but it would be nice if it

17   was. An unrelated issue -- when I look at the food

18   patterns and I think I talked to Regan at lunch a

19   little bit about the different food groups, and I'm

20   struck by the fact that even when we look at whole

21   grains and whether there's an increase in whole

22   grain consumption, we also see that a lot of whole

1 grains that are -- whether they're recommended or

2 they're either in schools or what-not, also have

3 an added sugar component to them.

4   And you know, we'll look at

5 interventions, at least from -- you know, if

6 they're doing added sugars or whatnot, but I think

7 that's just a point that I don't -- we kind of

8 missed that.

9   We look at the food groups and we see

10 where they're coming from, but I'm not sure if we

11 can then tie that fact into a health outcome to say,

12 you know, whole grains may be beneficial, but as

13 an example.

14   But if they're, you know, including

15 added sugars, then a lot of those maybe potential

16 health benefits go away, and I don't know -- we

17 probably may not be the group to do that, but it's

18 just something that, even looking at the food

19 groups, if we could really separate them out based

20 on some of the other food components that are part

21 of that, and whether that's dietary patterning, I'm

22 not sure that where that fits. It's just something

1 that I always see when we look at the different food

2 groups, that other components, other nutrients

3 with some of the other healthier food items, and

4 it's just hard to tease that out.

5   And then just a last point. You know,

6 when we look at the different life stages, and

7 adolescents, particularly females, are, you know,

8 the group of interest from a nutrient standpoint,

9 we also -- I know at least from the literature that

10 there are very few studies in that population.

11   So they kind of go hand in hand. You

12 see the nutrition issues, but they're not always

13 linked with some of the other health outcomes

14 usually for compliance or attrition with that

15 population. But I think that's a really big area

16 for future recommendations.

17   MEMBER ARD: So I think we have not

18 gotten to the dietary patterns section yet, but if

19 I would say something that integrates what we're

20 talking about, I think tomorrow we should hopefully

21 be able to have more discussion about the sort of

22 idea of dietary patterns, when they -- you know,

1   sort of concept that we can double-down on, and that

2   was brought forth in the previous Guidelines.

3   And I think it speaks to several things,

4   you know, what Heather just talked about and what

5   Regan talked about, where nutrients are not

6   consumed in isolation, and foods are not consumed

7   in isolation, when I have my burger and sandwich,

8   I'm also going to have my starchy potatoes, and my,

9   you know, sugar-sweetened beverage.

10   Right? You know these things travel

11   together in the American pattern, and we need to

12   acknowledge the idea that across life stages and

13   in the life cycle, these patterns tend to change,

14   and even from, you know, the use of complementary

15   foods, and how, you know, we feed infants -- those

16   things are starting to develop early. And so if we

17   could think about that idea of how we help inform

18   people around those, you know, concepts of foods

19   traveling together.

20   And then I also think, you know, with

21   regards to the idea of calling out obesity, that's

22   very important, but we haven't really talked about

1   energy intake.

2   And so at some point, we've got to deal

3   with that piece of, you know, how we integrate that

4   into all of what we're talking about, because I

5   think at the end of the day, quality matters, foods

6   matter, nutrients matter. But energy is very

7   important.

8   MEMBER DAVIS: I think it's very

9   important that our report is looking at life stage,

10   and this will be the first time that we've ever

11   looked at it from birth all the way up to the elderly

12   population, and I think our doing it that way,

13   presenting our report by life stage, is more useful

14   for the end user, for the public.

15   And indeed I think we can look at

16   certain things that we've seen in dietary intake

17   of the trends over the last few years. For

18   example, there's been a slight increase in whole

19   grains. Although whole grain intake is fairly

20   low, there's been a slight increase, and is this

21   because the Dietary Guidelines have reported this,

22   and then I think industry may be reacting to this,

1 so they're putting more whole grains into, for

2 example, breakfast cereals and bars, and so forth.

3 So I think, you know, our report is

4 quite important in informing the public, but also

5 industry that feeds the public.

6 MEMBER HEYMSFIELD: Tomorrow, I'll

7 give the report from the Frequency of Eating

8 subcommittee, and I think that's a very important

9 front-end part of our report, is what you going to

10 generate from NHANES data. So I'm really looking

11 forward to what that will be, because from what

12 we've found so far, there's huge gaps in

13 literature, and we spent a lot of time trying to

14 define what we mean by frequency of eating and

15 digestion and so on.

16 So it would be very good for you to work

17 with us so we make sure we have the same definition

18 of frequency of eating.

19 MEMBER SNETSELAAR: I also think that

20 what we're doing in this Committee in terms of

21 looking at younger age groups is incredibly

22 important, and much of what has come up through this

1   Committee is the idea that we want to be consistent.

2   We want to be sure that we're working

3   together as subcommittees, and particularly, as we

4   focus on these younger age groups, being very

5   careful to ensure that we have conclusion

6   statements and then grading that it is very

7   consistent across committees I think is very

8   important.

9   MEMBER MAYER-DAVIS: This is Beth

10   Mayer-Davis. Just wanted to note that to some

11   extent by design some of the questions that we've

12   addressed have had quite small numbers of studies

13   that sort of made it all through.

14   But to some extent, that was by design

15   so that we would get our systems in place, and made

16   sure that we were proceeding, you know, in

17   appropriate fashion.

18   So I can at least tell you that, for

19   Beverages and Added Sugars, some of the questions

20   to come have much larger bodies of evidence, so they

21   will not all be three studies here or four studies

22   there, for better or for worse. Right?

1   So you know, again, not wanting again

2   to steal the thunder from Carol's report on dietary

3   patterns, you know, that subcommittee talked about

4   yesterday, and it is relevant, I think, at this

5   point.

6   Jamy alluded to this a little bit as

7   well. I think by way of integration across

8   subcommittees, having a framework of thinking

9   about dietary patterns and what we've been thinking

10   about by way of hierarchy of dietary patterns,

11   foods and nutrients, I think that will help with

12   some cohesion, including how we integrate across

13   subcommittees, you know, so for example, thinking

14   about the Beverages and Added Sugars committee.

15   Thinking about seafood and fats, and how, you know,

16   those elements come into play with the dietary

17   patterns.

18   So I think that will be an important

19   aspect that will help us in terms of integration.

20   MEMBER BOUSHEY: I could say wow

21   everyone said it. But no I have a list, and actually

22   it's a list that supports things that have really

1 been said, and I -- Steven, Beth -- you know, Beth

2 is working on this beverage guidelines.

3 I thought going through and describing

4 all those beverages, that's like doing minor

5 surgery. We really have an issue with vernacular,

6 and a lot of it is driven by popular words, but I

7 think we do need to concentrate a bit on how we can

8 make sure that what we're doing now will be

9 repeatable, that we use language that does describe

10 what people are eating and the activities.

11 And part of the challenge of this is

12 think about your beverages. Twenty years ago, we

13 only had like one soda that you could select. You

14 know, so really, we're facing a new world where we

15 get really new foods, you know, almost every year.

16 And so that's a burden on our Committee,

17 and we have to somehow think of how to make all that

18 make sense and to be able to bring it all together,

19 because this idea of Kay's -- you know, really we

20 do need -- Kay said we need to put together all of

21 our work across all of our groups.

22 And I thought that was a great

1   suggestion. And, Rick, about your palatability,

2   I think it's surprising that burgers and sandwiches

3   are so high, and yet we have, you know, this low

4   whole grains. It just doesn't make sense, does it?

5   So we really have a lot to do to make

6   these guidelines exciting, that people want to

7   follow them, that people see them as

8   something -- hey, I'd like to do that, but -- and

9   I'm not sure that we can do that, but let's try to

10   think that we can.

11   Thank you.

12   CHAIR SCHNEEMAN: So I'm going to give

13   you the last comment.

14   VICE CHAIR KLEINMAN: So I think that

15   we've worked very hard to describe the food

16   patterns or consumption patterns at all of the

17   different life stages that we've talked about.

18   But one way to integrate this is to talk

19   about how these patterns change over time, and

20   we've also examined health consequences at these

21   various life stages of the foods that are being

22   consumed, and that's another opportunity for

1 integration, if we look at cognition,

2 cardiovascular disease, and hypertension and the

3 various other outcomes, and look to see how these

4 relationships change over time as well.

5   So I think -- I liked what everybody had

6 to say. Jamy mentioned the generational aspect of

7 this, and I think we need to weave that into that

8 conversation about change over time.

9   And then I think it's really important

10 that we couch all of this as food as one of the

11 social determinants, but there are others, and to

12 the degree that we can link food consumption

13 patterns at least to some sense of economic status,

14 that will help us a lot in completing the story and

15 bringing it together so that we demonstrate where

16 the real opportunity here exists.

17   And I'll stop there.

18   CHAIR SCHNEEMAN: Well, these comments

19 are very helpful; I have been scribbling notes

20 here.

21   So I think at this point we're adjourned

22 for today. I'm looking at Eve. Do we need to

1 highlight anything?

2 So again, we will reconvene tomorrow

3 morning at nine o'clock. We have several more

4 subcommittee reports to go through, and then we

5 will have the period for public comment, which I'm

6 looking forward to.

7 So I hope you all have a good evening.

8 Thank you.

9 (Whereupon, at 4:28 p.m., the meeting

10 was adjourned, to reconvene at 9:00 a.m., Friday,

11 January 24, 2020.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Public Meeting

Before: 2020 Dietary Guidelines Advisory Committee

Date: 01-23-20

Place: Houston, Texas

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

_____
Court Reporter