Afternoon Day 1
https://youtu.be/fRq_F2me8Tc

Dr. Barbara Schneeman: It's time to get started, and I think they have the YouTube set up. Just a couple of reminders to the committee. A couple of people pointed out that they couldn't hear as well. So, when you're using the microphone, please make sure it's in front of you when you use the microphone just to make sure people can hear the questions. ***[This paragraph was cut off in the edited video]***

And I just want to repeat something I said in my opening remarks, that what you're hearing are summary statements, draft conclusions, and they're being presented here for the full committee consideration in its decision-making process.

And the final decisions are what will be in the report when it's released.

So, I just want to, once again, highlight that what you're hearing about are draft conclusions, summaries of statements. The committees themselves are looking in much more detail at all of the publications that are being presented as part of the evidence portfolio.

So, with that, we're ready to go to our next subcommittee report, and that's the Dietary Fats and Seafood subcommittee, and Dr. Linda Snetselaar is going to give the report to the committee.

[0:00:59] ***Dr. Linda Snetselaar:*** Thank you, Barbara. I want to acknowledge my committee, Drs. Regan Bailey, Juan Sabate, and Linda Van Horn, who is here by phone, and also, our advisory chair rep, Barbara Schneeman.

The NESR, or NESR staff is implementing protocols for the first two dietary questions that you see on this particular slide, and the topics will be addressed in a future Advisory Committee meeting.

We will be presenting a summary of the evidence, draft conclusion statements, and grades on the three seafood questions today. They are in red.

And the remaining questions focus on dietary fats and neurocognitive outcomes, along with dietary fats and cancer.

[0:02:00] As a reminder, we are defining seafood in the following manner. It is marine animals that live in the sea and in freshwater lakes and rivers, and seafood here includes fish and shellfish.

And this particular slide is designed to sort of orient you to the three questions that we will be focusing on today during my presentation. And we're doing this because the first two questions have a lot of similarities and some subtle differences.

The first question is seafood intake during pregnancy or lactation and neurocognitive development of the child.

And the second question is seafood intake during childhood and adolescence and neurocognitive outcomes.

[0:02:59] As you see—as you will see in the upcoming slides, there are many neurocognitive outcomes, and it's easy to get confused between these two questions and the various outcomes on which we are reporting.

Because the neurocognitive outcomes are varied and most studies did not examine all components of the outcomes, we decided to develop separate conclusion statements for each component.

And then, the third question, the seafood question here is looking at seafood intake during childhood and adolescence and cardiovascular disease outcomes.

So, the first question we addressed was "What is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development of the infant?" And we used NESR systematic review to answer this particular question.

[0:04:03] As a refresher, here is the analytic framework we used to approach this question, and we did review this framework in detail during the July Advisory Committee meeting, and in this question, the exposure was assessed in pregnant and lactating women, and the outcome was measured in children birth to 18 years.

This is a reminder of the specific intervention, exposure, and comparators that we focused on, the criteria applied to all of our seafood protocols, and the particular item here to note is that studies must measure seafood consumption. So, biomarkers of seafood intake, which might include fish oil, or omega-3 polyunsaturated fatty acid supplement studies, or studies that evaluated infant formula with added DHA or EPA were not included.

[0:05:13] This flowchart illustrates the literature search and screening results for two systematic review questions related to seafood consumption and neurocognitive outcomes. One question addresses seafood intake during pregnancy and lactation, and the second question, as I've noted before, addresses seafood intake during childhood.

There were 25 studies that were included in this review of seafood consumption during pregnancy and lactation and neurocognitive development of the infant, and that's highlighted in red here.

[0:05:57] As a reminder, we decided to develop separate conclusion statements for each neurocognitive outcome. The outcomes shown in blue here are the ones we presented draft conclusion statements for during the October public meeting, and I'm going to briefly review these draft conclusion statements that have been previously presented.

So, as a review from the October public meeting, our subcommittee found insufficient evidence was available to determine the relationship between seafood intake during

pregnancy and attention deficit disorder, ADD, also attention deficit hyperactivity disorder, ADHD, and autism spectrum disorder-like traits or behaviors, or ASD diagnosis in the child.

[0:06:58] And due to there being no included studies examining the bottom three outcomes, no evidence was available to determine the relationship between seafood intake during pregnancy and academic performance, anxiety, and depression.

The grade was not assignable for all of these outcomes, and that then concludes our review of the statements presented at the last public meeting.

I will now present draft conclusion statements for the developmental domain outcomes for the very same question, "What is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development of the infant?"

Our subcommittee reviewed evidence pertaining to four developmental domains, and they are shown here on this slide, and we then drafted conclusion statements for each.

[0:08:00] This evidence was reported during the last public meeting, but it does bear repeating. No studies that met inclusion criteria assessed the relationship between maternal seafood intake during lactation and neurocognitive outcomes, including developmental domains in the child.

24 articles from 18 prospective cohort studies assessed seafood intake during pregnancy and developmental domain outcomes. These studies were primarily conducted in the US and also in Europe. Maternal seafood exposure was primarily measured using food frequency questionnaires, though the timing, the type, and the amounts of seafood intake were varied.

The categorization of seafood intake also varied across studies, so that one study might look at quintiles, and another study might look at servings per week.

[0:09:06] There was a variety of assessment tools used within each outcome domain.

Now, I will focus on the first domain, developmental domain, cognitive development. There were 20 articles from 15 prospective cohorts which met inclusionary criteria. The majority of the studies detected positive or null associations between seafood intake during pregnancy and cognitive development in children 5 months to 11 years, and then, looking at IQ or composite intelligence measures, that was done in children 4 to 11 years.

Few studies accounted for all of the key confounders, and there was heterogeneity across the studies in seafood intake categories used in analyses and cognitive assessment methods.

[0:10:07] This tended to limit the specificity of the conclusion.

So, our draft conclusion statements are moderate evidence suggests that seafood intake during pregnancy is associated with improvements in cognitive development in the child. The grade here is moderate for specifically pregnancy.

No evidence is available to determine the relationship between seafood intake during lactation and cognitive development in the child, and the grade here is not assignable specifically for lactation.

Next, we looked at the second developmental domain, language and communication development. There were 14 articles from 12 prospective cohorts which met inclusionary criteria.

[0:11:04] The majority of studies detected a beneficial or null association between seafood intake during pregnancy and language development or verbal IQ in children 6 months to 11 years of age.

Few of these studies accounted for key confounders, and there was heterogeneity in maternal seafood intake, such as the timing during pregnancy, the type, and the amount of seafood intake. Seafood categorization at analysis was varied, outcome assessment tools and measurements were varied, and the ages of children at assessment was also varied.

So, our conclusion draft statements are moderate evidence suggests that seafood intake during pregnancy is associated with improvements in language and communication development in the child.

[0:12:07] The grade here is moderate specifically for pregnancy.

No evidence is available to determine the relationship between seafood intake during lactation and language and communication development in the child, so the grade here is not assignable specifically for lactation.

Then, our third developmental domain involved movement and physical development. There were 13 articles from 9 prospective cohorts which met the inclusion criteria. The majority of the studies found either null or beneficial associations between seafood intake during pregnancy and movement and physical development in the child.

Few of the studies accounted for key confounders, and there was heterogeneity in, again, maternal seafood intake, timing, type, and amount, and types of movement and physical development examined were varied.

[0:13:10] The outcome assessment tools were varied, and the ages of children at follow-up was also varied.

Our draft conclusion statement is insufficient evidence is available to determine the relationship between seafood intake during pregnancy and movement and physical development in the child.

No evidence is available to determine the relationship between seafood intake during lactation and movement and physical development in the child, so the grade here is not assignable for pregnancy and lactation.

Now, for the fourth developmental domain, social-emotional and behavioral development. There were 9 articles from 6 prospective cohorts which met the inclusion criteria.

[0:14:02] There were no apparent trends across studies since there were mostly non-significant associations.

There was a concern for risk of bias, which we cared greatly about, and as we're working on these questions, we do focus on this. And this risk of bias was due to few studies accounting for all key confounders, differences in measurement of exposures and outcomes, heavy reliance on parental report for most of the outcomes.

And then, it was difficult to determine the relationship due to heterogeneity in, again, maternal seafood intake, the timing, type, and amount, the ages of the children at follow-up, six months to 13 years, so variable there, and outcome assessment tools varied. The dimension of social-emotional and behavioral development was also varied in these studies.

[0:15:03] Our draft conclusion statement is insufficient evidence is available to determine the relationship between seafood intake during pregnancy and social-emotional and behavioral development in the child.

No evidence is available to determine the relationship between seafood intake during lactation and social-emotional and behavioral development in the child. And the grade here is not assignable for pregnancy and lactation.

Moving on now to question two, this particular question is "What is the relationship between seafood consumption during childhood and adolescence and neurocognitive development?" And we did, again, use NESR systematic review to answer this particular question.

[0:16:00] This is the analytic framework we used to approach this question. This was reviewed in detail during the July Advisory Committee meeting, and in that particular meeting, we discussed the exposure, childhood and adolescence through 18 years of age, and the outcome was measured in individuals 2 years and older.

This flowchart highlights studies which met the inclusion criteria. 13 studies were included in this review of seafood consumption during childhood and adolescence and neurocognitive development.

13 studies from both randomized control trials, RCTs, and prospective cohort studies met inclusion criteria for this review.

[0:17:00] There were 6 articles from 3 randomized control trials. 2 randomized control trials evaluated fish intake in children between the ages of 4 and 6, and the intervention for both the RTCs consisted of fatty fish meals compared to meat meals three times a week for 16 weeks.

The third RCT, the FINS-TEENS study, was conducted with adolescents 14 to 15 years and participants in this particular study consumed fish meals compared to meat meals three times a week for 12 weeks.

Outcomes were assessed before and after the trial, and assessment tools tended to vary.

There were 7 articles from 6 prospective cohort studies which evaluated seafood intake during childhood and neurocognitive development.

[0:18:03] These studies were done in the UK, and Sweden, China, and Canada.

Seafood intake was reported as oily fish or just fish intake, and the majority of studies assessed fish intake using a food frequency questionnaire.

Outcomes were assessed in children 3 to 18 years of age, and there were a variety of assessment tools used.

For this particular question, no prospective cohort study accounted for all key confounders.

Now, I will focus on the evidence which evaluated the developmental domains. The four developmental domains are shown here, along with how many articles evaluated outcomes from these specific domains. A majority of studies were conducted in Northern Europe, particularly in Scandinavian countries.

[0:19:00] For the first developmental domain, cognitive development, there were 7 articles included in our review.

Of these 7, 4 articles were from 3 randomized control trials and 3 articles were from prospective cohort studies.

The 4 articles from the 3 randomized control trials found predominantly null or beneficial affects of seafood compared to meat meals in children 4 to 6 years, and in 4 to 15-year-old adolescents.

There were 3 articles from 3 prospective cohorts, beneficial associations were found between child seafood intake at 9 to 15 years and cognitive development in children 12 to 18 years of age. No association was found between child seafood intake and cognitive development at 3.5 years.

[0:20:03] Our draft conclusion statement then is insufficient evidence is available to determine whether seafood intake during childhood and adolescence is associated with

improvements in cognitive development in children and adolescents, grade not assignable here for specifically improvement.

Then, moderate evidence suggests that seafood intake during childhood and adolescence does not have detrimental impact on cognitive development in children and adolescents, and here, the grade is moderate relative to no detrimental impact.

For the second domain, language and communication development, 5 articles were included, 3 from 2 RCTs, and 2 from prospective cohort studies.

[0:20:59] Evidence from the 2 RCTs found no affect of fish compared to meat meals on language and communication development at 4 to 6 years in primary analysis.

The 2 prospective cohort studies found a positive association between seafood intake during childhood and adolescence and language and communication development and verbal IQ in children 12 to 18 years of age.

Heterogeneity was found in child seafood intake, looking at timing, type, amount, and duration, and the age of children at assessment was variable, and outcome assessment tools were also variable in these studies.

So, our draft conclusion statement here is insufficient evidence is available to determine whether seafood intake during childhood and adolescence is associated with improvements in language and communication development in those children and adolescents, and the grade here is not assignable specifically focusing on improvement.

[0:22:09] Moderate evidence suggests that seafood intake during childhood and adolescence does not have detrimental impacts on language and communication development in children and adolescents. The grade here is moderate for no detrimental impact.

For the third domain, movement and physical development, there were 2 randomized control trials included in our review. Both randomized control trials used the nine hole peg test as the assessment tool in children 4 to 6 years of age, intake of fatty fish meals compared to meat meals had predominantly no effects on manual dexterity and fine motor coordination.

[0:22:59] One study found that fish meals had a beneficial effect on fine manual dexterity and the fine motor coordination only applied in the non-dominant hand.

Due to limited amounts of studies, our draft conclusion statement is insufficient evidence is available to determine the relationship between seafood intake during childhood and movement and physical development in children. The grade here is not assignable.

For the fourth domain then, social-emotional and behavioral development, 3 studies were included in the review, 2 randomized control trials, 1 was conducted in 4 to 6-year-olds, and 1 in 14 to 15-year-olds, and they did not find a significant effect of fish meals compared to meat meals on change in behavioral symptoms in primary analysis.

[0:24:01] In the 1 article from the 1 prospective cohort study, there was a null association between seafood intake at 3 years and social-emotional and behavioral development in children at 4 to 13 years of age.

All of these studies used a strengths and difficulties questionnaire and there was heterogeneity in the ages of the children at intervention and exposure and outcome assessment, and child seafood intake varied in terms of timing, type, amount, and duration.

Our draft conclusion statement is insufficient evidence is available to determine the relationship between seafood intake during childhood and adolescence and social-emotional and behavioral development in children and adolescents, and the grade here is not assignable.

[0:24:58] So, moving on to attention deficit disorder, ADD, and attention deficit hyperactivity disorder, ADHD-like behavior for seafood intake during childhood and adolescence, there were 2 randomized control trials included in our review.

And these studies found fish meals three times a week compared to meat meals had a null effect on ADD/ADHD-like behavior at 4 to 6 years and 14 to 15 years.

It was difficult to determine a relationship due to the inadequate number of studies and outcome assessment relied mostly on parental report.

So, our draft conclusion statement is insufficient evidence is available to determine the relationship between seafood consumption during childhood and adolescence and attention deficit disorder or attention deficit hyperactivity disorder-like traits or behaviors, and the grade here then is not assignable.

[0:26:08] No studies included examined autism spectrum disorder as an outcome. Therefore, our draft conclusion statement is no evidence is available to determine the relationship between seafood intake during childhood and adolescence and autism spectrum disorder-like traits or behaviors or autism spectrum disorder diagnosis, and here, the grade is not assignable.

Moving on to academic performance for seafood intake during childhood and adolescence, there was 1 prospective cohort study included in our review, and this study found a significant positive association between frequency of consumption of meals containing fish at 15 years and higher total school grade at 16 years.

[0:27:06] However, it's important to keep in mind that it was difficult to determine a conclusion here due to an inadequate number of studies and concern for risk of bias from measurement of exposure and outcome.

So, our draft conclusion statement is insufficient evidence is available to determine the relationship between seafood consumption during adolescence and academic performance in those adolescents, and the grade here is not assignable.

For the outcomes of anxiety and depression for seafood intake during childhood and adolescence, there were 2 prospective cohort studies included in our review. 1 prospective cohort study found a significant positive association between greater fish intake at 10 to 11 years and lower odds of the diagnosis of internalizing disorder that included anxiety or depression at 10 to 14 years.

[0:28:11] And then, 1 prospective study did not find an association between fish intake at 14.5 years and depressive symptoms at 17.5 years.

It's difficult to determine a relationship here due to an inadequate number of studies, inconsistent results, and little information describing exposure.

So, our draft conclusion statement is insufficient evidence is available to determine the relationship between seafood consumption during childhood and adolescence and anxiety and depression in children and adolescents. Grade here is not assignable.

[0:28:59] No included studies examined neurocognitive health in adulthood as an outcome, and therefore, our draft conclusion statement is no evidence is available to determine the relationship between seafood intake during childhood and adolescence and neurocognitive health, which includes cognitive decline, anxiety, and depression in adulthood, and the grade here is not assignable.

That concludes our review of the second seafood question.

And the third seafood question we reviewed was "What is the relationship between seafood consumption during childhood and adolescence and risk of cardiovascular disease?" So, we're moving away from the neurocognitive area. We used NESR systematic review to answer this particular question.

This is the analytic framework we used to approach this particular question.

[0:29:58] This was reviewed in detail during the July Advisory Committee meeting, and in this question, the seafood exposure was assessed in childhood and adolescence through age 18 years of age, and intermediate outcomes were measured in children and adults, while endpoint outcomes were only measured in adults.

This is the flowchart for the literature search and screening results for the third seafood question addressing seafood intake during childhood and adolescence and risk of cardiovascular disease, and there were 4 studies included.

Of the 4 studies included, 2 were randomized control trials. In both randomized control trials, children were 10 to 12 years of age. The first study provided children with school meals, and that included either 100 grams of oily fish or a cheese salad sandwich five times per week for 12 weeks.

[0:31:04] The second randomized control trial provided schoolchildren with 6, 7, or 8 grams of tuna fish, and the intervention frequency, duration, and control conditions in this particular study were not reported.

These studies measured blood pressure and blood lipids.

The other 2 studies included the review—included in the review were prospective cohort studies, and one study assessed fish intake at 10 years using a 7-day food record at baseline, 3, and 6 months, and outcomes were assessed looking at blood pressure and blood lipids.

The other study assessed fish and oily fish intake at 7.5 years. This was done in the late 1930s, and it included a household inventory.

[0:32:00] And those outcomes looked at were stroke mortality and coronary heart disease mortality. And these particular outcomes were measured during 60 years of follow-up.

Results from the few available studies were not consistent. It's difficult to determine a relationship due to an inadequate number of studies and serious methodological limitations of some of the studies.

So, our draft conclusion statement here is insufficient evidence is currently available to accurately determine the relationship between seafood consumption during childhood and adolescence and risk of developing cardiovascular disease. The grade here is not assignable.

We have completed the systematic review of the three seafood questions, and these now will undergo peer review and will begin—we will begin drafting this section of the report.

[0:33:12] Our subcommittee will now move to examining dietary fats with a series of questions related to that topic and we will be starting with relationship between dietary fat and risk of cardiovascular disease.

I want to thank the subcommittee members, and additionally, thank the staff for the huge amount of work that goes into doing these systematic reviews, and thank you all for being here today to listen to what we have synthesized relative to this particular topic. Thank you.

[Applause]

[0:34:00] ***Dr. Barbara Schneeman:*** So, if we could have comments or questions for the subcommittee?

Dr. Kathryn Dewey: So, thank you very much. That was very clear and nicely laid out.

The question has mainly to do with the seafood intake during childhood and adolescence and cognitive development outcome. As I recall, there were three randomized control trials, but the duration of those was 12 or 16 weeks. And so, a question is whether you

think it's plausible that that's long enough to create the kind of tissue changes that one might think would be the link between seafood and something in the brain.

And if it's not long enough, what is the feasibility of adjusting that question with randomized control trials of sufficient duration, and should we then look more carefully at the prospective cohort studies?

[0:35:02] In that situation, I think you said there were 3, and that 2 showed a relationship, and 1 with a younger age group did not.

So, in this situation, the value of prospective cohort studies might be pretty high, and I would like to know what your group felt were the key limitations that led you, I think, to the conclusion of insufficient evidence despite those positive relationships.

Dr. Linda Snetselaar: Yes, I think we did look at type of study, you're right. I do think that in many instances, it—we are coming up with some future direction kinds of things that it would be great to certainly include more prospective studies possibly, but in addition to that, we as a committee have looked at what are some of the concerns that went into looking at prospective studies?

[0:36:06] And in addition, randomized control trials, and do we need additional studies that would focus on more consistency among the assessment, the timing, those things, the duration of a study, those kinds of things?

So, I think everything you're bringing up is 100 percent correct. We looked at this and came to a conclusion. I think that one of the things following a list of our conclusions is to work closely with your committee as well and come up with some final conclusions that would incorporate both ideas from your committee and the work your committee has done along with the work that our committee has been involved in.

[0:36:58] ***Dr. Kathryn Dewey:*** If I could just follow up with that. I don't think you mentioned it, but I did know that you didn't find any studies for exposure from birth to 24 months, and where the outcome was assessed after 24 months of age.

So, we actually don't have anything to say about seafood consumption in the first two years of life and developmental outcomes.

Dr. Linda Snetselaar: So, that may be a future directions piece.

Dr. Kathryn Dewey: Yeah.

Dr. Ronald Kleinman: Linda, that was just great. My question is about, again, neurocognitive outcomes and the positive results of seafood consumption during pregnancy. And I wondered, is there—was there a dose response in those studies, or was that examined, I guess?

And then, a second question was you noted that none of those studies adequately controlled for confounders, and I'm wondering whether the effect diminished significantly when confounders were considered?

[0:38:02] ***Dr. Linda Snetselaar:*** Yes, I think—I remember beginning to talk about this question, and then working very carefully on what should our confounders be, because the more confounders you have, the more likely you are to end up with no results.

And so, I think that's an important question. It was just something that came up again and again in terms of particularly the prospective cohort studies.

And then, what was your first question again? I'm sorry.

Dr. Ronald Kleinman: Whether there's a dose response in consumption of seafood and the outcome. So, as the exposure increased, did any of those studies look at increasing the exposure and the consequences of that to sort of lend more credibility to the intervention?

[0:38:59] ***Dr. Linda Snetselaar:*** Yeah, I think we need more studies that have certainly increased exposure. More specifics on the studies we looked at, I might look to our NESR team to answer that question, but certainly, exposure is incredibly important, and when you look at the amount of seafood in some of the studies, it was incredibly small.

Dr. Barbara Schneeman: So, I think, Joan, were you going to—

Dr. Linda Snetselaar: Go ahead.

Dr. Barbara Schneeman: Joan, were you going to comment? I was just—

Dr. Joan Sabate: In some of the studies, and I don't remember exactly which one of the slides, I mean as far as answering the question of a dose response, I mean there were some studies that it was flat, others that there was a dose response, and others had a U shape. So, the intermediate I mean had some relationship, but the highest amount—I mean lower, back to the no exposure.

[0:40:07] So, in fact, a U shape in some of the—

Dr. Regan Bailey: There's also a lot of variability in some studies reported fish intake in grams, some reported it in servings. And so, it was kind of hard to synthesize how much actually was the exposure.

Dr. Barbara Schneeman: Tim?

Dr. Timothy Naimi: Tim Naimi, Boston University. Linda, that was a really nice presentation, and I guess my question is similar to Ron's and related also to the dose response, but more along the lines of for those ones in which you had exclusively observational studies, and none of them had all of the key confounders, and we know that confounding is likely to bias it in the direction you found. Can you talk about giving it a

moderate evidence grade as opposed to a limited one? I guess that's where I feel a little bit uncomfortable.

[0:41:00] ***Dr. Ronald Kleinman:*** Yeah, I didn't push that far, but that's where I was going as well.

Dr. Linda Snetselaar: I think that's a very good point, and certainly, as we look at these conclusion statements again, these are not carved in stone, as Barbara has been mentioning several times.

And I think as we look at these statements and maybe work with some of the other subcommittees, we may make some changes. So, very good point.

Dr. Regan Bailey: Well, in most of the studies, there was either beneficial association or null association. And so, we really—I think there was one study in one subgroup that there was a detrimental association. So, the vast majority of the literature was either beneficial or null, which is why we went with a moderate, because of all of the consistency in the inconsistency.

Dr. Linda Snetselaar: But those decisions were hard-thought, and we spent a great deal of time thinking about them. So…

[0:42:00] ***Dr. Barbara Schneeman:*** But certainly, part of the point here is from the discussion for the subcommittee to take the information and consider the points being raised, and also, to look where we need cross-talk between the subcommittees.

Dr. Richard Mattes: Rick Mattes. Can you hear me? She couldn't hear me before, so…

Dr. Linda Snetselaar: I can hear you now.

Dr. Richard Mattes: Okay. Two questions that are a big more global. So, your group, I think singularly, reports effects of positive and negative, and in this case, there was no significant effect, which could also be said there's no association, which is the way all the rest of our recommendations seem to read, and I think we should be consistent. Either we're going to say that there's effects this way or that way, or we're just to say there's no association, and not differences between the groups in how we report that.

[0:42:57] ***Dr. Linda Snetselaar:*** Yeah, I think you're 100 percent correct, that we do need to be very consistent across the subcommittees, and I think that process is being thought about and will be in the works soon.

Dr. Richard Mattes: One other, in terms of consistency. So, in at least one other subgroup, where you have—like your question 1, you have all prospective cohort studies. Did you downgrade trials that only had a single estimate of intake at baseline and then track for 10 years and looked at an outcome as opposed to trials that repeated say a food frequency questionnaire or whatever, so you have some sense that that level of exposure was

maintained during that 10-year interval, or was the response on that questionnaire was reliable?

[0:43:56] We've held, in another group, a higher standard, and I'm just wondering how you used that.

Dr. Linda Snetselaar: Good question. Can I refer to Joanne on that?

Joanne Spahn: None of these questions specifically addressed seafood intake during pregnancy and during childhood. So, when we extracted the data, there were maybe a third, or maybe a little less than a third of the studies that measured seafood intake more than once during pregnancy, and then during sea—during childhood, the tables will indicate whether or not there were repeat measures.

Certainly, the RCTs were definitive in a certain period of time. I don't recall the childhood having a lot of repeat measures.

[0:44:56] ***Dr. Richard Mattes:*** Yeah, I would just suggest that when you assign the strength, that be a factor that you put into the consideration.

Dr. Joan Sabate: Joan Sabate. I think this is a good point, but I recall in the discussions, and I think there was no studies that had repeated measures in childhood that I remember on that.

Dr. Barbara Schneeman: Kay?

Dr. Kathryn Dewey: Kay Dewey. I want to follow up on the comment about—I think you mentioned, Rick, the statement that said that moderate evidence suggests that seafood intake during childhood and adolescence does not have detrimental impacts, and that's the one that you thought should say there's no association. Is that the one you were referring to?

Dr. Richard Mattes: There were a couple where there is a report of whatever the evidence is pro and whatever the evidence is negative. In no case was there a significant association in either direction. In some cases, there was insufficient evidence.

[0:45:58] But if there's evidence of no detrimental, is that different from no evidence of an association?

Dr. Kathryn Dewey: Right. And so, I just want to clarify that we're talking about the same conclusion statement.

And I'm not sure if this was explained, but my understanding is that this was driven in part by the concern about mercury exposure and that there is the concern about detrimental effects. Now so, on one hand, I think having a statement about no harm is useful, but on the other hand, the way you approach that question is different than when you're trying to show a relationship in the sense of it being a safety kind of study analysis.

And so, I don't know if the studies looked at it the right way in terms of ruling out harm, which is different from the way you approach it when you're saying that there is benefit.

Dr. Linda Snetselaar: Good point.

Dr. Kathryn Dewey: So, that might be something to look at again.

[0:46:56] If they did it the appropriate way, I think it's important to say that, on which how many did, because if there's a statement possible about no harm, that would be extremely useful.

Dr. Linda Snetselaar: Good point. Thank you.

Dr. Joan Sabate: Again, Joan Sabate. The no harm relates to the cognition, not to any other factors. In other words, we had a series of studies maybe 14 or 15, I don't remember, of which only 2 or 3 seems to have some relationship that was significant, one with a U shape included, but many had basically flat, no relationship.

So, we came to the conclusion that seems there was none that has a detrimental effect as far as cognition. I mean we came to this conclusion, that no harm relates only to cognition, not to any other parameter.

As far as the studies, especially the prospective studies, not all, as a matter of fact, if I remember correctly, many of them were not originally designed to test the fish effect.

[0:48:01] It was mainly to design the harmful effects of mercury. And by the way, in a second publication, I mean there was something as far as the consumption of fish and cognition.

So, we had some of the studies of the prospective studies that were not originally designed for fish intake and cognition.

Dr. Jamy Ard: Jamy Ard. So, just to continue on in terms of ***[indiscernible 0:48:34]*** and how we're describing certain effects. My initial impression, after seeing the words around associated with improvements in etcetera, makes me feel like that's a treatment effect or that something's starting from a deficit.

And I don't know if that is shared by others, but I just wanted to share that in terms of it is not the same to me as something that might say a beneficial effect, or I don't know exactly the other ways that you—these things are quantified in terms of cognition or language and communication, and those types of things.

[0:49:21] But that might be something to think about.

[indiscernible 0:49:24]

Dr. Rachel Novotny: Rachel Novotny. This is a little bit out of place but related to this conversation about language and how we're reporting. It makes me wonder, with most of our questions, whether we don't want to consider both protective effects—at any rate, to consider whether there's another pass at our questions for some of these things.

I'm thinking specifically, which I've been talking to Sharon about, of the upper limit for folic acid, which was not specifically our question, but it feels like we should say something about that.

[0:50:08] So, we might need to take another pass at our studies as well to see if there's something we could legitimately say about that.

So, I think it's a general question for us as to whether we're considered sort of both ends of the spectrum for many of our questions.

Dr. Barbara Schneeman: Other comments or questions?

Great, well—

Dr. Regan Bailey: Linda Van Horn's on the line. I don't know if she—if you want to give her an opportunity, or if she has something to say. Is that possible?

Dr. Barbara Schneeman: Is she on the line?

Dr. Regan Bailey: Because she's on the committee. I just didn't—we didn't talk about it before, so…

Dr. Barbara Schneeman: Is she—oh, she's mainly listening.

[0:50:59] So, she'll let us know. Yeah. No, and I think these are all useful comments for the subcommittee to take back and look at, and also working with the staff to make sure we do have consistency across the subcommittees.

So, I think then we'll move to our next subcommittee report, which is the Beverages and Added Sugars subcommittee, and Dr. Mayer-Davis will do that report.

Dr. Elizabeth Mayer-Davis: Thank you very much. So, first, I do want to recognize the great work of the committee, Drs. Leidy, Mattes, Naimi, and Novotny, to say nothing of—oh, thank you for that, yeah, yeah—and Schneeman, and of course, the NESR staff that just continues to amaze us every day.

Alright, so let's see.

[0:52:00] I'm clicking the clicker but see myself instead of a slide. That's not really what I want to see actually.

So, let's see. What do I need to do here?

Oh, and that's way farther than I need to be. Let's see. There was some sort of funny delay.

Dr. Barbara Schneeman: Yeah, there you go.

Dr. Elizabeth Mayer-Davis: Alright, here we go. So, let me just overview what we will go over in this session today. This is just a brief summary of the questions that we are addressing in this particular committee: questions related to non-alcoholic beverages, added sugars, and alcohol.

So, we have completed our work towards our draft conclusions for birth weight standardized for gestational age and sex as an outcome related to non-alcoholic beverages.

Under way are a set of questions related to various non-alcoholic beverages in relation to growth, size, body composition, and risk of overweight and obesity, for which, there's been a screening of some 17,000 terrifying articles and 214 articles identified to be included for that set of questions with 70 articles currently under review for the subset of questions that are focused on milk.

[0:53:24] I won't be presenting details on that particular piece today, because that is—we are in the midst of that effort.

Also underway are questions related to added sugars and risk of cardiovascular disease. Screening is underway relatively early on for that, with 5,000 articles screened.

Coming up next are questions related to added sugars and risk of type 2 diabetes, and also, outcomes of growth, size, body composition, and risk of overweight and obesity.

[0:53:59] We are also working on the question related to alcohol and all-cause mortality, and I will be presenting some more information about that today, as well as presenting information about non-alcoholic beverages and birth weight.

So, that's the overview.

So now, we will focus on this particular question that you see here on the screen, "What is the relationship between beverage consumption during pregnancy and birth weight standardized for gestational age and sex?" And this is approached via the NESR systematic review process.

This is our analytic framework, and I do want to take a moment on this, because there are actually quite a large number of decisions embedded in this analytic framework that took a fair amount of time to sort through and that follow for much of our work for a range of questions.

So, you'll see, in terms of intervention and exposure, we've set out these various subtypes of beverages, and you can see the list here.

[0:55:07] We've shown this before. That's the same list that we've had.

The comparator is something that I want to highlight, because that does impact on the studies that we review. So, for our comparator, we're looking at differences in amount of the same beverage consumed, which could include no consumption of a particular beverage, or versions of the beverage diluted with water.

We also consider as a comparator a given beverage versus a solid form of that same food, broadly speaking, a given beverage versus water, and then specifically, we are looking at sugar-sweetened beverages compared to low- or no-calorie sweetened beverages, and we're looking at dairy milk with different amounts of fat.

So, this provides the scope really of what we're doing.

[0:55:58] Otherwise, if you just had beverages with no clarity with regard to comparator, you would not be able to go through this in any kind of coherent manner.

So, then for outcomes for this particular question, we're looking at birth weight. That could be presented in a continuous fashion or in categories, small for gestational age or large for gestational age, or birth weight for length.

The population then for exposure would be women either before or during pregnancy.

And then the outcome, the infants at birth.

You'll see key confounders here, child sex and gestational age, maternal age, race, ethnicity, SES, and a variety of additional confounders listed there.

Other factors that are considered, total energy intake. That definitely becomes important in a good amount of this work. And then, a variety of other variables related to other components of diet, as well as parity medications and supplement use.

[0:57:00] So, for the question here related to beverages during pregnancy and birth weight, these were the numbers of studies.

We started out with some 7,600, and that got pared down through screening of titles, abstracts, and then full text relative to our criteria, and the articles that emerged then for complete review are 19 in number to be included in our systematic review.

So, this is a table that we've shown before, just showing how we're sort of categorizing beverages so that we can go through this work systematically. What you see highlighted are the types of beverages for which there was a literature available for us to look at, so milk, low and no calorie sweetened beverages, sugar-sweetened beverages, coffee and tea, and plain water are the relevant categories.

[0:58:04] And we'll start here with sugar-sweetened beverages and low- or no-calorie sweetened beverages. Now for this particular segment of the presentation, our subcommittee opted to provide more detail here than we will subsequently, and the reason that we're doing that is that we wanted to make sure that it was clear to all of you really what's the—what is the way in which we're proceeding with this work? How are we looking at the data? What does this really look like? So, we're giving a little bit more specifics here just for that purpose of providing that kind of an example.

So, starting again here, beverages during pregnancy and birth weight, with these exposures. There were 7 studies all of which were prospective cohort studies.

[0:58:59] And in terms of the exposures across those studies, three of them examined sugar-sweetened beverages independently, two of the studies examined low- or no-calorie sweetened beverages independently, and then two of them had a combined category of sugar-sweetened beverages and low- or no-calorie sweetened beverage intake.

The outcomes included continuous birth weight, and categorical, small for gestational age, large for gestational age.

Whoops, there we go.

So, this is an example of three studies, and one of the various types of summary tables that we look at, where you can see, for each study, the sample size, the country where the study was conducted, the exposure and the comparator for the first study, sugar-sweetened beverage, estimated intake, and servings per week assessed in the second or third trimester by validated food frequency representing current intake.

[1:00:06] And you can see, glancing through here, there is variability across studies in terms of how the exposure was measured, the timing of the measurement as well. And then, the outcomes and whether or not the outcome of birth weight was adjusted for gestational age and/or sex or not.

I need to take a moment for a glass of water here. Excuse me. Sorry about that.

And for these studies, TEI, we're looking for adjustment for total energy intake. You can see the first couple did not address this at all, but the last adjusted via a step-wise process. And then, you see participant characteristics here.

[1:00:58] Just to give you sort of a glimpse at what's considered here. I'm not walking through all this detail. Don't worry. That would be not good.

But this just shows sort of a couple of reminder columns about the study, and then the actual results for continuous birth weight and for categorical birth weight with some color-coding to identify where statistically significant findings were available.

[unrelated – coughing and asking for cough drop 1:01:25-1:02:29]

So, back to pregnancy and birth weight, looking at sugar-sweetened beverages only, those three studies. So here, we found mixed findings. ***[sidebar 1:02:41]*** So, very mixed findings.

So, in one study, it was found greater intake of sugar-sweetened beverages was related to higher birth weight. Another study found the opposite.

[1:02:58] And then, the third study, the relationship was not statistically significant. And none of these particular studies used the same categorical outcome, so there wasn't a way to compare across.

This is a view of risk of bias. Many of the presentations have mentioned an evaluation of risk of bias, and there is this specific tool that's used that considers confounding. Confounding is based on the specific key confounders listed in the analytic framework, in this case, as I showed at the beginning, and those risk of bias is then classified as low, moderate, serious, or critical.

And then as well, selection of participants, classification of exposures, deviation from intended exposures, missing data, outcome measurement, and selection of the reported result from the paper as a whole, and the most common risk for bias in this particular set, inadequate adjustment for key confounders and inadequate description or definition of the exposures.

[1:04:08] So then, moving towards the literature that focused on low- and no-calorie sweetened beverages or the combination of those plus sugar-sweetened beverages, two studies examined the low-and no-calorie sweetened beverages independently. One of those studies reported greater intake was related to lower birth weight, and another study, relationship that was found not statistically significant, and neither of those studies examined categorical birth weight outcomes.

There were two studies that combined those categories of beverages, sugar-sweetened and low- and no-calorie sweetened beverages, and for those, one study reported a greater combined intake in relation to lower birth weight.

[1:04:59] Another study reported greater intake related to higher risk of small for gestational age. And then, the third study reporting a relationship between combined intake and small for gestational age that was not statistically significant.

So, our conclusion then for this particular question is here. Insufficient evidence is available to determine the relationship between consumption of sugar-sweetened beverages or low- and no-calorie sweetened beverages during pregnancy and birth weight outcomes, so the grade is not assignable.

Moving then to the question of beverages during pregnancy and birth weight, focusing now on dairy milk, there were 6 studies that assessed dairy milk intake, one RCT and then five prospective cohort studies.

And the exposure was commercially-available dairy milk of varying fat and sweetener content.

[1:06:00] The outcomes here were five studies that assessed continuous birth weight and three studies that assessed categorical birth weight outcomes.

In terms of findings, four studies found greater milk intake related to higher birth weight. One study found lower milk intake related to higher birth weight.

With the outcome SGA, one study found greater dairy milk intake related to lower risk of SGA. Another study found the relationship to be not statistically significant.

A study that looked at large for gestational age did not find a statistically significant association.

And then, a study that looked at low birth weight, greater milk intake was related to lower risk.

The conclusion statement here was that there was insufficient evidence available to determine the relationship between consumption of dairy milk during pregnancy and birth weight outcomes, with the grade not assignable.

[1:07:01] And I'll just fill in here a little bit, and I'm not showing all the details of those studies reviewed, but the risk of bias was considerable across studies, primarily due to concerns with adjustment for key confounders, particularly total energy intake, and also, very little evidence or no evidence, and certainly not consistent evidence with regard to dose response.

So, that was a little bit of some background that led us to this particular conclusion.

Turning then to tea as the beverage of interest, there were 8 studies that assessed tea intake. All of these were prospective cohort studies. Most of the studies combined tea into a single exposure variable, although some looked at some specific types of tea, oolong, black, green tea, and three of the studies specifically looked at caffeinated tea versus tea that is without caffeine.

[1:08:07] Six of the studies assessed birth weight in a continuous fashion. Eight studies looked at categories of birth weight outcomes.

And in terms of findings, three of the studies reported greater intake of tea related to lower birth weight. Three studies showed relationship with birth weight that was not statistically significant.

In terms of SGA, three studies showed a relationship to be not statistically significant, while two studies showed greater tea intake in relation to higher risk of SGA.

In terms of low birth weight as an outcome, three studies showed a relationship that was not statistically significant.

And for large for gestational age, one study showed highest intake level was related to higher risk for LGA.

[1:08:56] And so, a conclusion here was also insufficient evidence is available to determine the relationship between consumption of tea during pregnancy and birth weight outcomes, grade not assignable.

Moving then to coffee. There were 7 studies that assessed coffee intake in relation to birth weight, and again, these were all prospective cohort studies.

The exposure generally was average coffee intake. Three out of those studies examined caffeinated coffee specifically.

Five studies assessed continuous birth weight, six assessed categorical birth weight outcomes.

From three of those studies, greater coffee intake was related to lower birth weight. In two studies, relationship with birth weight was not significant.

For SGA, in two studies, greater coffee intake was associated with higher risk, and in two studies, the relationship was not significant.

[1:10:00] Low birth weight, similarly, two studies, relationship was not significant. One study, greater coffee intake was associated with higher risk.

In terms of our conclusion statement, insufficient evidence is available to determine the relationship between consumption of coffee during pregnancy and birth weight outcomes, grade not assignable for coffee.

And again, in terms of risk of bias, there were considerable concerns with regard to adjustment for key confounders, particularly energy intake, and also, the difficulty of this issue of coffee versus caffeine, that may or may not be important. So, we just—there was overall, again, simply insufficient evidence. Grade not assignable.

Plain water. Again, this is intake during pregnancy with respect to the outcome of birth weight.

[1:11:00] So, there were 2 studies that assessed plain water intake, both of which were prospective cohort studies.

The studies looked at tap and bottled water and did not include flavored, carbonated, or fortified water by way of how the exposure was specified.

Outcomes, again, two studies assessed continuous birth weight and two assessed categorical birth weight outcomes.

In terms of findings, for two studies, the relationship with birth weight was not significant. And two studies found the relationship to not be significant for the outcomes categorical of small for gestational age or low birth weight.

So again, conclusion. Insufficient evidence is available to determine the relationship between consumption of plain water during pregnancy and birth weight outcomes. Grade not assignable.

[1:11:56] So, I've mentioned some of these, but just in summary, across this literature with regard to beverage consumption during pregnancy and birth weight, there were quite a few of these studies where the attrition was greater than 25 percent, which is—provides a risk of bias in terms of selection.

Total energy intake was considered in some studies, but many studies was not considered. Some of the samples had poor generalizability with respect to lower socioeconomic status and minority populations.

In terms of concerns regarding exposure, variation in fat or sweetener levels in these different beverages, that information was generally not available. I mentioned a moment ago that about half of the tea and coffee evidence examined only caffeinated versions or the difference wasn't clear between the caffeinated and un-caffeinated. There were a lot of issues regarding exposure definitions and assessment methods and timing of the assessment of intake of those beverages during pregnancy.

[1:13:04] Birth weight, and I hadn't mentioned this and should have highlighted this probably a little bit more, it definitely contributed to some of these conclusions, birth weight was inconsistently adjusted for gestational age and sex, and actually, our original question specified birth weight for gestational age and sex. Many studies adjusted for one but not the other. Some adjusted for neither.

Again, inconsistency in the outcomes assessed and definitions used. And for some of the studies, where there was a statistically significant result, the effect size in some cases was quite small with a practical or clinical significance that was unclear.

So, moving now to alcohol as an exposure, we are working on the question of "What is the relationship between alcohol consumption and all-cause mortality?"

[1:14:03] And again, this is via the NESR systematic review process. We do have a new protocol compared to what we've discussed about before that's posted on DietaryGuidelines.gov, and we'll talk about it here, but it is posted as well.

So first, in terms of definition, for this question of all-cause mortality in relation to alcohol consumption, all-cause mortality is defined as the total number of deaths from any and all causes during a specified time period, and this does not include then studies of cause-

specific mortality, in other words, total number of deaths from a specific cause, CVD, cancer, or otherwise. So, that's the outcome, all-cause mortality.

So, this is the analytic framework, and this, the alcohol field is one that has a number of unique characteristics that we really thought through carefully with regard to establishing our analytic framework, and so, I wanted to highlight a number of things here.

[1:15:08] In terms of our intervention and exposure, the primary exposure is average consumption of alcoholic beverages as well as the pattern of consumption of alcoholic beverages, meaning for example, number of drinks per drinking day or drinks per drinking occasion.

In terms of comparator, the comparator would be different average alcohol consumption or different pattern of alcohol consumption among current drinkers as the primary comparator. A secondary comparator would be intake compared to never drinkers. And you'll notice that former drinkers are not shown here because there's a whole variety of reasons that people are former drinkers, such that that group as a comparator would not be appropriate.

[1:15:59] So, primary and secondary comparators here are important to note.

The population, we're focusing primarily on adults 21 years and older, which means that if there are studies that are primarily adults but happen to include some individuals younger than the drinking age, that's fine, but we're not looking at studies that would be specifically focused on underage drinking.

And then outcome, all-cause mortality already discussed. And so, this again, primarily adults 21 years and older.

Now, in terms of key confounders, we're looking at sex, age, race, ethnicity, some marker of SES we considered to be quite important in this work, as well as consideration of eating pattern or diet quality, physical activity, and smoking. These are our key confounders.

In addition, as a key confounder for average consumption exposure, pattern of consumption would be considered important.

[1:17:02] And then, on the flip side of that, for pattern of consumption as the exposure, average consumption would be important to consider.

In addition, other factors to be considered, total energy intake, ideally without the alcohol, and then, age distribution of the study sample, anthropometric measurements, hypertension, blood pressure, diabetes, glucose, lipids, medications, as well as family history of chronic disease, and beverage type.

So, we started with the standard criteria for study design, publication status, language, country, and health status of participants. It was discussed earlier.

And a little bit more detail here again, because of this particular topic of alcohol, I already mentioned the exposure.

[1:17:58] And so, it's important in terms of inclusion criteria, that the exposure is that which we've defined. Information on type of beverage will be collected if available, but we don't exclude a study if that's not available, it's just good if we can have it.

And again, in terms of exclusion criteria, data on non-drinker groups, where never and former are combined, say in an observational study, would actually be excluded just because of the potential problems and bias with combining and including the former drinker group along with the never drinker group. So, the never drinker group is a secondary comparator, but a study would be excluded if the study includes former drinkers.

And the comparator, I've already focused on that, so don't need to repeat that.

And again, in terms of exclusion criteria, with regard to the comparator, again, the former drinker issue needs to be considered and that would be excluded if there was a study where the comparison with never and former drinkers was combined.

[1:19:13] In terms of the dates here, we include studies from January 2000 to now, January of 2020, and exclude articles published prior to January 2000. And again, I already mentioned about the age of participants.

So, you saw from a couple of the earlier examples, for this particular subcommittee, the numbers of studies is very high. And so, we have had to really think about prioritizing our remaining work.

And what we're doing is with regard to added sugars and health outcomes for cardiovascular disease, we are approaching that, building on the 2015 NESR systematic review.

[1:20:05] In terms of type 2 diabetes, we'll be building on the 2015 Advisory Committee report, as well as for growth, size, body composition, and risk of overweight and obesity, again, building on the 2015 work.

For alcohol and health outcomes, we are prioritizing all-cause mortality as the first outcome to be examined. I just discussed about that, work under way, and as time allows, we will move then to address as outcomes, CVD, cancer, neurocognitive health, as well as growth, size, and body composition.

So, that's where we are. Again, thanking the members of the subcommittee as well as the support staff, doing wonderful work to help us out.

Open to questions.

Dr. Barbara Schneeman: Great. Thank you.

[Applause]

[1:21:04] ***Dr. Barbara Schneeman:*** So, questions and comments for this subcommittee?

Yeah, Ron?

Dr. Ronald Kleinman: Yeah, Beth, that was a great presentation. This is a minor comment, and you alluded to it. It has to do with the outcome of birth weight. And you mentioned the small effect size, and whether these were biologically significant. So, I wonder if it's worth just noting that when you say higher birth weight in some of the studies to either parentheses or something (within normal reference values) or something to indicate that these are still normal children and ***[indiscernible 1:21:44]***

Dr. Elizabeth Mayer-Davis: Correct, and that is the case. So, yes, that's a good comment. So, in the report, it will be important to provide that framework. Yeah, thank you for that comment, yeah.

Kay?

[1:21:59] ***Dr. Kathryn Dewey:*** Yeah, Kay Dewey. With regard to the dairy milk and birth weight analyses, one of them was I think four out of the five studies that looked at birth weight showed a positive relationship, and one didn't.

I was wondering what the sample sizes were for all of those.

And I know that you gave the conclusion statement as insufficient evidence. I'm just curious about sort of the choice between limited and insufficient. I know in our subcommittee, sometimes when most of the studies are going in a certain direction, we might have chosen limited, and this one seems to be a case where that might be the situation.

I know you mentioned some important limitations, but one of them you mentioned was adjusting for total energy intake, and I feel that that's one that is one of those gray areas, because it could be on the causal pathway, so it's a little bit different than a regular confounder.

[1:23:00] And so, I wondered if you could speak to that particular analysis and conclusion.

Dr. Elizabeth Mayer-Davis: Yeah, yeah. So, that, first of all, it was the case that, for those four studies, there were concerns in terms of risk of bias and accounting for key confounders was one of the primary concerns.

Total energy intake was a concern, and the role of total energy in this kind of situation is always a question. Whether you consider that to be part of a causal pathway or not could be debated for hours. So, I appreciate that concern.

One of the problems with that literature also had to do with dose response. So, for example, I'm recalling now, although the NESR team will recall better, but I recall now at

least one of the studies where there was a significant effect. There was no evidence for dose response.

[1:23:59] So, there was quartiles, so any quartile compared to the first, once you got to the second quartile, that was it, flat thereafter.

So, that's just an example of another one of the several problems across that literature. But I appreciate that, and one of the reasons that I could answer the question with that level of detail in terms of that one study is because I looked at that myself again, and I said, "Now, let me make sure I'll remember why we made that decision." So, that was a great, great comment.

And I'm looking over here to Brittany. I don't know if you want to add to that. That would be helpful, too.

Brittany James Kingshipp: Sure, ***[indiscernible 1:24:37]***. So, I was also just glancing at the milk literature to see the sample size question, and it ranges from the mid kind of 100s up to about 3,000, depending on which cohort they were looking at.

And so, there were concerns about the things Beth has noted. Also, as was noted kind of across this body of evidence, that body of evidence had multiple studies with very high attrition rates.

[1:25:00] And so, that combined with inconsistency and whether birth weight was adjusted for gestational age and sex or not, it was roughly half the studies did, half did not.

The same was true with total energy intake. So, what we did was look at total energy intake kind of beyond the scale of the regular confounder so that we were interested, if they did adjust for it, that's answering one question, and if they did not, it's answering another question, both of which we are interested in.

And so, it wasn't necessarily that they got penalized if they did not, they just got treated differently in interpreting the findings. And so, because that was also done inconsistently in that body of evidence, all of those inconsistencies kind of snowballed to the point that no clear even limited conclusion could be drawn.

Dr. Kathryn Dewey: Thanks.

Dr. Elizabeth Mayer-Davis: Any other questions?

[1:25:58] ***Dr. Barbara Schneeman:*** Okay, I'm seeing none. I suggest we take a break right now. And just in case you have fallen asleep, I hope you're awake now.

Female: No need for coffee now.

Dr. Barbara Schneeman: So, I would suggest, if you could please be back at about—by a quarter 'till, that would be great.

[Break 1:26:29-1:44:55]

Dr. Barbara Schneeman: So, we're now ready for our last subcommittee report.

[1:45:02] So, we're now ready for our last subcommittee report of the day.

Is it—no, it's working now.

So, and that will be the Data Analysis and Food Pattern Modeling, the cross-cutting working group, and so, Dr. Regan Bailey will be giving that subcommittee report. Okay.

Dr. Regan Bailey: And it's my great pleasure to do so and represent the people on the committee, and Jamy Ard, Jamie Stang, Tim Naimi, and Teresa Davis, and supported by Dr. TusaRebecca Pannucci.

Wow, I look tired. It's a very strange thing to see your face that big.

So today, we will be presenting very summary types of statements, draft conclusions of summaries of so much data.

[1:46:03] So, in your committees, I'm hearing a constant theme of "We have insufficient evidence." Subcommittee 7 has nothing but evidence. We have so much data and we can't—we will share it all with you in the report, but what I'd like to attempt to do is to show you some of the highlights, the top-level kind of findings today and where we're thinking.

So, you'll see those.

And then, the remaining work we have to do is we have to work within our committee with the B24 as well as the Pregnancy and Lactation committee to refine some of those questions as they relate to food and nutrient intakes and nutrients of public health concern.

And then, the last part, of course, our subcommittee is responsible for the food pattern modeling. That will be informed by the evidence that you all have from your committees.

So today, we will focus primarily on Americans 2 years and older, so infants and toddlers, the B24, and pregnant and lactating women aren't going to be the focus of the data I'm presenting today.

[1:47:06] So, all of the data that we will be talking about, we have as age groups, by sex, by race, ethnicity, and socioeconomic status, and again, I can't show you all those, but I'm going to give you some high-level takeaways.

And just a reminder of the analytic framework. So, we're using, for the dietary intakes, the NHANES What We Eat in America. At this point, the data I'm presenting today are

just from foods and beverages. So, the nutrient intake data are not inclusive of dietary supplements at this point.

We'll be presenting data on chronic diseases from these sources, and again, this is all posted online, and we've gone over it, but just to have it fresh in mind.

So, the first question that we will be presenting evidence on is to "Describe and evaluate current intakes of food groups and nutrients."

[1:47:59] And so, we'll go through these at a pretty high level.

So, for fruit, the top contributors to fruit are whole fruit, 100 percent fruit juice, and sweetened beverages, and then in bold, I have the intakes, the mean or average intakes for Americans 2 and older, so about 1 cup equivalent per day of fruit.

For vegetables, vegetables are primarily being consumed as part of burgers and sandwiches and mixed dishes. So, less than 50 percent of the vegetables that are being consumed are discrete vegetables. And if there's one thing you're going to hear me say today again, over and over, is burgers and sandwiches, okay? So, that's something that really will come through in this data, and that is kind of reflective of the American dietary pattern.

Dairy. So, most dairy intake, about 1 ½ cups per day on average, coming from fluid milk and cheese.

[1:48:59] Fluid milk intake decreases with age. And over time, since 2007-8, total dairy intake has decreased in the United States.

Whole grains is coming primarily through breakfast cereals and bars. So, we have seen increases in whole grain intake across time, but only 2 percent of Americans are currently meeting whole grain recommendations.

And then, protein foods, primarily coming from animal-based sources. In general, it's adequate for most Americans, except for females ages 12 to 19 and 70 years and older, with about 5.8 ounce equivalents per day.

The majority of the American population for all groups examined are exceeding recommended energy intake from solid fats and added sugars. The main source of solid fats is? Burgers & sandwiches, desserts and sweet snacks.

[1:49:57] And then, in children less than 11 years of age, high-fat dairy is also a significant source of solid fat.

So, the main source of added sugar is sweetened beverages, desserts & sweet snacks, and coffee & tea.

And so, I use the ampersand to keep food groups together. I don't generally like the ampersand, but just for clarity. So, burgers & sandwiches together, desserts & sweet snacks together, coffee & tea together.

So, our draft conclusion statement is that for Americans ages 2 and older, intakes of fruits, vegetables, dairy, and whole grains are generally below recommended amounts and have not changed over time. Intake of total grains and total protein generally meet recommended amounts.

Okay, for ages 1 and older, because the food group we're looking at compliance with previous Dietary Guidelines. When we're looking at nutrients, we're looking at 1 and older, because the Dietary Reference Intake age groupings are 1 to 3. So, sometimes you'll see 2+, 1+, so just for some clarity there.

[1:51:01] So, 90 percent of children and 58 percent of males, 67 percent of females have carbohydrate intakes within the AMDR.

Across all age groups, protein intake is within the AMDR. Protein also has an EAR, and I mentioned that older adults and teenage females have intakes that are below the EAR.

So, the proportion of the population with fat within the AMDR is around 60 percent for children and 50 percent for adults.

And for all ages, sodium, saturated fat, and added sugars are overconsumed.

In terms of nutrients that are under-consumed, we have several, including vitamins A, C, D, E, K, calcium, magnesium, fiber, choline, and potassium. In addition to those, other population groups have nutrients or food components that are under-consumed.

And so, we're going to focus on these a little bit more when we do the last question, question five, on nutrients of public health concern.

[1:52:03] So, keep these in your mind. We're going to come back to them.

And then, in young children, retinol, zinc, copper, and selenium are overconsumed relative to the upper level.

So, moving on to dietary patterns and beverage consumption. Just a reminder, the analytical framework, at this point, we have the average HEI, total and component scores, but we are waiting for the distribution of those scores. So, we'll be looking at that as well as food category contributions to total energy intake.

And so, though we're talking about dietary patterns, just a reminder that we don't have self-reported patterns of intake. So, we're looking at reported intakes relative to the HEI, not necessarily able to categorize patterns as vegetarian or Mediterranean, okay?

So, for children and adults, we will look at beverage intake data in the following ways, and we've talked about this, by the population groups, mean intakes, and the percent of energy and nutrients coming from beverages, as well as calories.

[1:53:08] Just a reminder of the definitions of the beverage categories that we'll be talking about today. We've seen these before.

Okay, you've seen this slide before. Out of 100 points, the American diet is currently at a score of 59, and what's encouraging is that it has increased slightly over the last decade, from 56 to 59, and we do see age differences. So, young children 2 to 5 and adults over the age of 65 tend to have higher scores than all other age groups.

So, this might look complicated, but let's walk through it.

So, of all of the ways that the 100 points are divided are around the edge of the spiderweb here.

[1:54:03] So, if you start with total fruits and start going clockwise, you get higher points for more compliance, whereas if you went counterclockwise from total fruits, lower intakes are associated with a higher point score.

So, in the ideal spiderweb, I don't know what these are actually called, but—what is it called?

Dr. Richard Mattes: Radar plot.

Dr. Regan Bailey: Radar plot, okay. In an ideal radar plot, you would have the whole—if you had a score of 100, it would be all around the outside.

So, in this slide, we can see some differences among race/ethnic groups.

So, non-Hispanic Asians have the highest HEI score, and those are represented with the color red on the radar plot, and you'll see differences in—within certain food categories. For example, look at greens and beans, how more compliant that race/ethnic group is with the recommendations.

[1:55:01] Non-Hispanic blacks have the lowest HEI score relative to the other groups.

So, our draft conclusion one, from some of that data, is that while average diet quality has slightly improved, scores are not necessarily consistent with the current recommendations, and we do see differences with sex, age, race/ethnicity, and income, though the differences are generally small.

This is where the food categories that are contributing to energy, and the—I'm just going to take a second to walk through these, because I know we've looked at them before, but just to remind you.

So, the first bar is for all Americans 2 and older. All the different colors represent the top 10 food categories. And one thing that's surprisingly consistent is those categories do not change. What changes is the proportion by age group.

[1:56:06] So, these are food category sources. You can see that for children 2 to 5, there is less proportion from burgers and sandwiches than, say in adulthood.

And we'll come back and look at some of those when we look at how patterns track across life, but just to give you a sense of food category source of energy for this context right now.

So, our second draft conclusion is that foods and beverages consumed via mixed dishes, such as sandwiches, casseroles, and pizza, sweets & snacks, and beverages, contribute about 50 to 60 percent of total energy intake.

Food subcategory source contributions to energy vary by all of the population demographics that we've talked about, but for the total population, about 5 subcategories make up most of the energy, and that's?

[1:57:02] Burgers & sandwiches, desserts & sweet snacks, rice, pasta, and grain-based mixed dishes, sweetened beverages, and chips, crackers, and savory snacks.

So, this is looking at where beverages are contributing to energy intakes. So, in general, about 15 percent of energy comes from beverages, and this is specifically among 2- to 19-year-olds.

So, beverages contribute about 40 percent or more of added sugar in 2- to 19-year-olds. The percent of added sugar from beverages significantly increases with age. And so, when milk is decreasing, it tends to be replaced with sweetened beverages.

But all is not lost in the beverage category. For 40 percent of vitamin C and D, and more than 20 percent of carbohydrates, calcium, potassium, and magnesium are coming from beverages, mainly milk and 100 percent fruit juice.

[1:58:06] And not surprisingly, more than 80 percent of caffeine comes from beverages.

This is looking at adults. So, this is a pie chart showing of all of the beverage's calories, where they—what specific foods they are coming from, and the three top sources are sweetened beverages, alcohol, and coffee and tea. And what's interesting here is there are sex differences. So, males have more energy intake in terms of beverage calories from alcohol, whereas women are more likely to have coffee and tea calories.

Which brings me to conclusion number three. Calories from total beverage account to 15 to 18 percent of total energy for Americans.

[1:58:58] Fluid milk as a beverage decreases starting in early childhood and intake of sweetened beverages increases. And beverages account for 40 to 50 percent of added sugars

in the diet, and alcoholic beverages contribute 21 among females and 31 percent among males of total beverage calories.

Okay, we are probably only about 20 percent of the way through with my slides, so I just want to give you like some context. Just take a deep breath. We're going to do this. Okay.

So, this question asks about how patterns track across life stages, and ideally, to answer this type of question, we'd have longitudinal data. What we have is cross-sectional data, so we can look at different age groups and try to get some trends and some patterns, but we can't necessarily say how they track within and individual or within populations or subgroups.

[1:59:58] So, we will use this analytic framework, again, looking at food category source, means, beverage contributions, as well as HEI scores across different life stages for 2 and above.

This radar plot shows you how diet quality and different components of the HEI changes by age. So, remember, I said the youngest children and older adults have the highest diet quality. When we put the 2 and 19-year-olds together in blue, that kind of changes the story a little bit, but nevertheless, you can see that older adults have a higher HEI score in what foods are represented in the diets of older adults, so, things like total vegetables, green beans, seafood, and plant proteins, as well as fruit, refined grains, and lower added sugars.

[2:00:57] So, as we talked about before, so once children begin to age, their milk intake goes down, and so, the scores on the dairy component, you can see that clearly from this plot.

So, this is going to be the start of a marathon of slides that look exactly like this, but the title is going to change, and the colors are not always consistent. So, if you want me to stop and you want to look at them in a little bit more detail, our safe word in our subcommittee is tangerine, so if you want me to stop, just say, "Tangerine," and I'll know it's time to stop.

Okay, so this is looking at energy. You've already seen this one, so we won't spend too much time here.

But next, looking at vegetables and how those change with different age groups. So, the green is represented by vegetables, including beans and peas that are not starchy. As I mentioned earlier, less than 50 percent of our vegetables are consumed as a vegetable alone.

[2:02:01] Chips, crackers, and savory snacks and pizza are a larger source of vegetables for children than for adults or older adults, and mean vegetable intakes tend to increase with age.

Looking at fruit, you can see, as I told you earlier, that primarily coming from whole fruit, but it does decrease after the age of 5, and then pretty much levels off and stays about the same after the age of 5, and 100 percent fruit juice decreases after adolescence.

This is looking at whole grain intake, and we talked about the mean intake earlier, but chips, crackers, and savory snacks as a source of whole grains decreases, and yeast, bread, and tortillas increases as a source of whole grains among individuals in older age groups. So, you can just see kind of some of the patterns.

[2:02:57] The number one contributors generally stay the same, but the proportions change with different age groups.

So, going on to dairy. There is a food category source shift from higher fat among young children to burgers and sandwiches among young and middle-aged adults, and older adults, desserts and sweets and snacks are really a large contributing source to dairy.

This is looking at protein foods. So, mean total protein is generally within recommended ranges. We talked about those groups that it's not. For older children and younger adults, burgers and sandwiches is the main food category source, and mixed dishes contribute a smaller proportion of protein to the intakes of older adults.

Looking at added sugars, mean added sugar intake is highest in adolescence and early adulthood. The food category sources here change across the life course.

[2:03:57] So, desserts and sweet snacks are a large contributor for both young children and older adults, whereas in the—in between those two age groups, it's really sweetened beverages, so from 6 to 50, and for adults, coffee and tea are also a source of added sugar.

These are—coffee and tea are not naturally containing these, so this is inclusive of the addition. So, I should have made that point earlier.

This is looking at calcium. This slide is set up in just the same way. So, high-fat milk and yogurt is the largest contributor among young children, and it shifts to burgers and sandwiches for adolescents and adults, and water makes up a large contributor among adults to calcium intakes.

This is looking at potassium. So, milk and yogurt is a large contributor for young children, and that shifts to? Burgers and sandwiches. Thank you, somebody's awake, alright.

[2:04:58] And then, coffee and tea and vegetables in adulthood as a large contributor.

This is looking at sodium, and as we mentioned earlier, it's overconsumed across all life stages, and this is primarily coming from? Burgers and sandwiches, and that's pretty consistent across most age groups.

This is looking at vitamin D. And remember, I'm only showing you the highlight reel, okay? So, you can imagine how much data we've been looking at. So, vitamin D is under-

consumed across all life stages. Again, children are getting vitamin D, similarly to calcium, from high-fat/low-fat dairy and milk, and in adults, it's burgers and sandwiches.

So, this is our draft conclusion statement. There's general consistencies in diet quality seen across life stages. Diet quality is better among young children and older adults, but even still, still does not align with existing guidance.

[2:06:00] Food category sources of food groups and nutrients differ across life stages, in particular, intakes of milk and yogurt after early childhood decrease, and intakes of added sugar from beverages increase.

Fruit and vegetable intake declines through adolescence and adulthood and then increases among older adults. Intakes of burgers and sandwiches contribute to most food groups, nutrients, and food components, which fall outside of recommended ranges.

So, burgers and sandwiches help contribute to under-consumed nutrients because they're so ubiquitously consumed, but they also, at the same time, contribute to those nutrients and food components that we want to limit, such as sodium and saturated fat.

Deep breath. Okay.

So, for the prevalence of nutrition-related chronic conditions, we have, as I mentioned earlier, several data sources. What I'm going to do here is a word that I learned yesterday called "bookend."

[2:07:00] So, I'm going to tell you the conclusion, and then I'm going to show you the data, and then we'll revisit the conclusion as a group to get some input. Because there is a lot of information I'm going to give to you and distilling it into a couple sentences is very complicated, so we'd really love to hear the committee's feedback on what you think are the most salient points to include in this section.

So, we are looking at this with a life stage approach, and the colors are simply there to show you that there are certain things, like body composition, that we will be looking at in most age groups, cardiovascular endpoints.

So, we'll start with young children. We only have two outcomes in young children.

We have body composition. So, more US children under the age of 24 months are overweight, about 9 percent then underweight based on weight for recumbent length. The prevalence of low birth weight and very low birth weight are 8.3 and 1.4 percent respectively.

[2:08:00] Non-Hispanic black mothers have the highest prevalence of low birth weight babies, and this has increased over time.

We have a different age group for allergies. So, based on proxy report, the prevalence of food allergy is 6.6 percent. So, this is not clinically confirmed data. I felt strange using the word self-report, because it was birth to 4, and I'm just imagining like a little baby trying to

tell you. Anyway. So, proxy report. There's obvious limitations with that kind of data. It's not clinically confirmed.

So, looking at the data that we have available in children in the following categories.

The prevalence of overweight is about 17 percent, obesity 18.5 percent, and underweight 3 percent.

The prevalence of underweight is higher in boys than girls and increases with age. However, the prevalence of underweight has decreased over time.

[2:09:00] The prevalence of obesity is higher in boys than girls. It increases with age and has increased since 2007 and 2008.

Among girls, the race/ethnic group with the highest prevalence of obesity is non-Hispanic black, whereas among boys, the highest prevalence is in Hispanic and Mexican-Americans.

The prevalence of obesity is lowest among children whose head of household has a college degree or higher.

So, our draft conclusion for CVD intermediate outcomes. The prevalence of hypertension is 4 percent and is higher in males, non-Hispanic blacks, 18-19-year-olds, and those with obesity relative to their peer counterparts.

The prevalence of high LDL is 5 percent, and the prevalence of low HDL is 15.5 percent.

The prevalence of high LDL is higher in non-Hispanic whites and Hispanic and Mexican-Americans, and you can see the percentages there, when compared with non-Hispanic black and Asian youth.

[2:10:01] The prevalence of low HDL cholesterol is higher in males, non-Hispanic whites, and youths with obesity.

So, for each chronic health condition we've examined in children, the highest prevalence is among those with obesity.

We have one cancer outcome, and that is leukemia, and you can see the incidence and mortality rate, both of which are higher among boys than girls. And so, this is inclusive of birth to 19 years of age from the SEER data.

In terms of diabetes and pre-diabetes, we have data on 12-19-year-olds, and the prevalence of those combined is 23 percent. This is coming from NHANES data.

Dental carries. So, first, looking at 2-19-year-olds, the prevalence is about 46 percent, and then untreated dental carries is about 13 percent.

[2:10:59] So, and this tends to be associated with age. Again, this is cross-sectional data, so we can't say the prevalence of carries increases with age, but the age groups and the prevalence track in the same way.

Hispanic youths have the highest prevalence of dental carries, but non-Hispanic blacks have the highest prevalence of untreated dental carries.

The prevalence of both carries and untreated carries is lower among families with a higher income, and there has been a slight downward trend over time for the prevalence of total and untreated dental carries.

Moving on to adults. The overall prevalence of underweight among adults is 1.5 percent. The prevalence of overweight and obesity and severe obesity are highlighted there in parentheses. The prevalence of overweight has decreased, while the prevalence of obesity and severe obesity has increased.

[2:11:56] And the prevalence of obesity and severe obesity is higher in women than it is in men.

Mean body weight, waist circumference, and BMI have increased over time. Adults 40-59 have the highest prevalence of obesity.

Hispanic and Mexican-Americans have the highest prevalence among men, and among women, it's non-Hispanic black women.

Looking at the data, the overall presence of dental carries among adults age 20-64 is 90 percent, and 96 percent among adults ages 65 and older. Women have a slightly higher prevalence than men among 20-64-year-olds, but the prevalence converges after the age of 65. Non-Hispanic blacks have the highest prevalence of untreated dental carries. And the overall prevalence of complete tooth loss is 2 percent in 20-64 but increases to 17 percent among those age 65 and older.

So, looking at cardiovascular intermediate and outcomes.

[2:13:00] High cholesterol among adults is 12 percent. Low HDL, 18 percent. Hypertension, 29 percent. Coronary heart disease, 6 percent. And stroke, around 3 percent.

So, when we talk about adults in general, we're talking about 19 and older, but some of the data come from different surveys, so that is why we have 18 and 19 for some of these age groups here.

The prevalence of high cholesterol and low HDL has decreased since 2007-8. Women have a higher prevalence of high cholesterol. Men have a higher prevalence of hypertension, low HDL, CHD, and stroke.

Adults 40 to 59 have the highest prevalence of total cholesterol and low HDL. However, adults ages 65 and over have the highest prevalence of hypertension, CHD, and stroke.

So, some more key findings here. Non-Hispanic whites have the highest prevalence of high cholesterol among women. However, Hispanics have the highest prevalence of high total cholesterol among men.

[2:14:01] Hispanics have the highest prevalence of low HDL for both men and women. Non-Hispanic blacks have the highest prevalence of hypertension and stroke. American Indian and Alaska natives have the highest prevalence of coronary heart disease.

The prevalence of hypertension, coronary heart disease, and stroke are lower among those with higher education levels, and those with a college degree tend to have the lowest prevalence of these cardiovascular outcomes.

In terms of diabetes and metabolic syndrome, diabetes is prevalent in about 14 percent of US adults, pre-diabetes 34 percent, and metabolic syndrome almost 35 percent. So, men have a higher prevalence of diabetes and pre-diabetes, but there's no differences for metabolic syndrome.

So, the prevalence of diabetes and metabolic syndrome is higher among older age groups. In fact, 52 percent of older adults have metabolic syndrome.

[2:15:00] The prevalence of diabetes is higher among those with higher BMIs, and Hispanic and Mexican-Americans have the highest prevalence of diabetes and metabolic syndrome

In terms of chronic liver disease, we have two different measures. First is self-report, which is about 2 percent, but then looking at ALT and AST, ALT is elevated in about 10 percent and AST in 16 percent of US adults.

Hispanics have a higher prevalence of liver disease, high ALT, and high AST when compared with non-Hispanics. American Indian and Alaska natives have the highest prevalence of liver disease. Men and women have the prevalence, and mortality rates differ. So, men have a higher mortality rate than women, and mortality rates have increased over time, particularly in men, and then men age 55-64 have the highest mortality rate from chronic liver disease.

[2:16:02] So, these are a different data source, so this is from the National Vital Statistics System.

These are the age-adjusted prevalence rates for chronic liver disease and cirrhosis, and you can see that they have increased since 2006 to 2016 in every age group except for males 45-54, and men 55-64 have the highest mortality rate from chronic liver disease, and the lowest rate is among females 25-34.

Moving on to cancer, so the cancer with the highest incidence rate among females is breast cancer, followed by male prostate cancer. Age group and cancer type with the highest incident rate is prostate for men among ages 65 and older.

[2:16:55] Mortality rate is highest for lung and bronchus cancer, and the age group with the highest mortality rate from that cancer is among older adults, so 65 and older. Men have a higher incidence and mortality rates than women across all shared cancer types, and the incidence and mortality rates for every cancer type are highest among individuals 65 and older.

So, we'll talk last in this section about pregnant women. We're just going to talk about gestational diabetes today, because the 2018 pregnancy-induced hypertension data is just coming into our emails now, so we'll hold off on that until next time and just focus on gestational diabetes right now.

Total prevalence, about 6 percent. It is higher in women who are older than 40. There's some race/ethnic differences, so non-Hispanic Asians, 11 percent have gestational diabetes, also very high in American Indian and Alaska natives, and native Hawaiians and Pacific Islanders.

[2:18:01] The prevalence remains relatively stable across educational status, but among those with obesity, particularly class 3 obesity, the prevalence is 14 percent.

So, older adults. We have two outcomes here, muscle strength and osteoporosis and bone health.

So, 19 percent of older adults have reduced muscle strength. This is data coming from NHANES. And there's really an increase with age. So, 48.6 percent of adults over the age of 80 have reduced muscle strength. So, the age-adjusted prevalence is not different between men and women. It's about 19 percent. And similarly, when we're older than 80, it's slightly higher in women than men, but not substantially different, so 49 versus 47.

Non-Hispanic Asians have the highest age-adjusted prevalence rate, followed by Hispanics, and then non-Hispanic blacks have a prevalence that is about 19 percent, and then non-Hispanic whites about 18 percent.

[2:19:09] In terms of osteoporosis, it's estimated that about 11 percent of adults over the age of 50 have osteoporosis, and about 45 percent have low bone mass. And as we know, women are disproportionately affected by both osteoporosis and low bone mass, and that's amplified here in the last bullet point.

So, again, given all of the complexity of the data that we showed you, it was very hard to come to a conclusion statement, so this is a work in progress, and we really want it to be informed by you, but we kind of started with this large umbrella to try to be inclusive of all the things that we found, but we'd like to drill down and have some more specific conclusions.

[2:19:59] Okay, we are on the last question.

Evaluate nutrients of public health concern.

So, we've talked a lot about intakes of food groups, shortfall nutrients, and this will be our last question. So, a nutrient of public health concern, we have tried to use the terminology food component, because there's things that we're talking about that aren't essentially nutrients. So, if you are confused, that is why. The question is written for nutrients, but we are trying to use food components.

So, we developed this flowchart ahead of time before we looked at the data to make decisions. So, sometimes we had dietary data available, sometimes we have biomarkers, sometimes we have clinical outcomes. So, we had a decision tree in place before we looked at the data to try to be as transparent as possible, and I don't expect you to read that because it's very small, but it'll be in the report.

So, we first started by casting a wide net.

[2:21:01] We defined under-consumed or overconsumed when a food component was not within the range of 5 percent or higher relative to a Dietary Reference Intake or a quantitative authoritative recommendation, such as a previous *Dietary Guideline* recommendation for saturated fat, similarly, for overconsumed.

Then, those are elevated to a nutrient or food component of potential public health concern when supporting data through biomarkers, functional indicators, that these low intakes or high intakes are directly related to a health condition.

Then, we are proposing this category called nutrient or food component that poses special challenges.

[2:21:55] This was a term that was used by the 2005 committee to identify food components for which *Dietary Guidelines* to meet recommendations was challenging, but we've extended this to also include nutrients or food components that pose special challenges in identifying at-risk groups, and I'll show you what I mean in the next couple of slides.

So, casting our wide net of 5 percent for under-consumed nutrients, there were a number of nutrients that were either in the population or in specific subgroups denoted with an asterix, that were not well-aligned with recommendations, either the EAR or the AI.

So, when we next evaluated whether there was a biomarker or a clinical endpoint that we could tie low intakes to, we were able to eliminate several nutrients, and those that are listed in bold have previously been linked to a health outcome or a biomarker, whereas we still have a few that are listed there in red that are special challenges.

[2:23:02] In terms of overconsumption, we've already talked about sodium, saturated fat, and added sugars, but compared to the UL, young children are exceeding the UL for retinol, zinc, selenium, and copper, and you can see those prevalence estimates in the

parentheses there, ranging from about 6 percent for copper to 50 percent for zinc and selenium.

So, then we come to these food components that pose special challenges, and this is where we could also use some of the committee feedback and guidance. So, I mentioned that protein was under-consumed in adolescent and older females, vitamin B12 might be of concern in older adults, both dietary data and biomarker, choline intakes are low relative to the AI for most age/sex groups after young children, phosphorus intake is low in 9-14-year-olds, as well as magnesium.

[2:24:00] So, magnesium is low relative to the EAR across most age groups.

So, our analytic summary so far is that nutrient intakes have not changed considerably since the last evaluation. Nutrient intake distributions, taken into consideration with biological endpoints and clinical outcomes, suggests that vitamin D, calcium, fiber, and potassium are under-consumed. Sodium, saturated fat, and added sugars are over-consumed for all Americans ages 1 and older.

We're still talking, and that's why we brought this to you today. In terms of the distinction of what is a nutrient of public health concern for some of those remaining nutrients?

In addition to those for all age groups, we've looked at this as a life stage kind of approach. And so, iron is of particular concern among adolescent and premenopausal females, that's both dietary and biomarker data.

[2:25:00] Older adults seem to be at risk for low intakes of protein, and I showed you the data on the muscle strength, as well as vitamin B12.

Adolescents, there was—this is what we're calling a constellation of dietary risk. So, this age group has the highest prevalence of not meeting recommendations across most nutrients, and particularly adolescent girls. So, protein, folate, B6, phosphorus, magnesium, and choline.

And then, young children, as I showed you earlier, 1-3 have high intakes of retinol, zinc, selenium, and copper relative to the UL.

So, our remaining work, I talked about a little bit earlier, is what is the role of added sugar in meeting food group recommendations, frequency of eating, looking at beverages and meeting food group and nutrient recommendations, as well as dietary patterns.

[2:25:57] We already mentioned that we're going to be working more with the B-24 and Pregnancy and Lactation to identify nutrients of public health concern in those populations.

And then finally, we'll end with the food pattern modeling questions.

So, thank you very much for your time and attention, and I definitely will answer questions, but we also really want to hear from you guys.

[Applause]

Dr. Barbara Schneeman: A lot of information very quickly. So, you've heard some questions from the subcommittee, but I think also if there are questions or comments for the subcommittee, that would be useful at this point.

Dr. Sharon Donovan: So, thanks, Regan. I have two questions. One is related to the kids, the early ages that are in the upper limits. Do we know what food groups are contributing to the high intakes, particularly for zinc and selenium?

[2:27:01] Dr. Regan Bailey: Yeah, we haven't really looked at it that way. I could guess at what I think those food sources are, but I think that's something we can consider.

Dr. Sharon Donovan: Okay.

Dr. Regan Bailey: And then, there's a lot of discussion around are those ULs the right number. So, it might be that the diets are okay and that the ULs are often set based on extrapolated data down for children. So, that's why we are calling it maybe this is of concern. We certainly didn't want to dismiss it without talking to you all, but we are really unsure about what to do, and this is just from foods alone. So, when we will look at supplemental nutrients, those prevalence estimates are going to increase.

Dr. Sharon Donovan: So, my second question was related to some of the primarily the cardiovascular outcomes. And is there any factoring in of medications that are used to manage hypertension or cholesterol?

[2:28:02] Dr. Regan Bailey: The way that the data are collected is—

Dr. Barbara Schneeman: Please make sure that you're—

Dr. Regan Bailey: Oh, sorry.

So, particularly some of the biomarkers, no. I mean we know that a lot of people are on statins. These are the prevalence estimates for nationally-representative sample of adults. So, there are people who are taking medications for hypertension, there are people who are taking medications for various things, but they're in the survey.

Dr. Barbara Schneeman: So, I have Kay, and then Rick, I think you're—

Dr. Richard Mattes: Sure.

Dr. Barbara Schneeman: And then, and Steve?

Dr. Steven Heymsfield: Yeah.

Dr. Barbara Schneeman: Okay. So, Kay?

Dr. Kathryn Dewey: Thank you very much. Kay Dewey. So, first I want to just comment that the UL for zinc is very, very likely an overestimate. Is that right? Underestimate. No, it's too low. Because we see this problem across the board, in many countries, and so, that's just one comment.

So, I have three questions.

[2:29:01] The first is, when you're looking at inadequate nutrient intakes, we've talked about the fact that people, at least for adults, tend to over—under-report their energy intake.

And so, that might make it look like they're nutrient intake is too low. And I think we've talked about this, but if you could answer it again, whether you're attempting any correction for that, or at least a sensitivity analysis that would let you judge is it really low or are they just underreporting energy?

Dr. Regan Bailey: Yeah, we know that there is underreporting of energy, but for nutrients, it's really not well-known how differential that is. We only have recovery biomarkers for a few food components. And so, we really can't make estimates about what other nutrients are low as a result of energy underreporting.

We haven't really talked about sensitivity analysis. I know there's been some work done with the survey before.

[2:29:58] So, we might want to look at, especially the nutrients that we do agree are of public health concern, maybe we could do a sensitivity analysis trying to exclude energy under-reporters and seeing what those prevalence estimates would look like. That's a really good idea.

Dr. Kathryn Dewey: Well, I was thinking more along the lines of if we assume that underreporting is not differential, which is not necessarily a safe assumption, but for a sensitivity analysis, if you assume that, you can then apply just a correction factor across the board, just to see which ones would still emerge as being under the EAR, for example.

Dr. Regan Bailey: Yeah, but people differentially underreport specific food components, like alcohol, or sugars, and those aren't things that really would be good nutrient sources anyway. So, I don't know that we could have a correction factor.

Dr. Kathryn Dewey: Okay. Well, anyway, something to think about.

The second question is regarding the birth weight outcome.

[2:30:56] You reported it just in terms of low birth weight, I remember, and maybe high birth weight? I can't remember. But do we have estimates for SGA, LGA, and preterm?

Dr. Regan Bailey: Yeah, we don't have preterm right now that I have seen, but we do have all of the anthropometrics. We can give you guys all that data. It would probably be a good conversation to have together.

Dr. Kathryn Dewey: Yeah. And one of the issues to take into account is the multiple births and the trends in those, because those drive a lot of those numbers.

Dr. Regan Bailey: That's a good point.

Dr. Kathryn Dewey: And then, lastly, there was a slide where you had a bunch of nutrients, and then you crossed them out, and I think it was based on whether there was a biomarker or some other—

Dr. Regan Bailey: Not whether there was a biomarker, but whether that was linked to low intake. So, for example, vitamin E, there's a very high prevalence of vitamin E inadequacy if you look at the diet, but when you look at the biomarker, it's less than 1 percent.

Dr. Kathryn Dewey: So, when it was crossed out, it meant that—

Dr. Regan Bailey: It wasn't confirmed with a biomarker or a clinical outpoint—endpoint.

[2:32:00] Dr. Kathryn Dewey: But what if there is no biomarker? Was it crossed out?

Dr. Regan Bailey: I don't think so. Like what are you thinking of? We tried to be like all of the ones that we were special case that we wanted to talk about, which if you could pull up that last slide, that might be helpful.

But for a lot of them, we do have biomarkers or no clinical endpoint. Like we have vitamin C from the blood. We don't see a lot of scurvy. So, that's why that could be crossed out.

Dr. Barbara Schneeman: So, can you—

Dr. Kathryn Dewey: I think if—

Dr. Barbara Schneeman: I think you need to go back. Backwards, yeah.

Dr. Regan Bailey: I put it at the end because I was anticipating this. Oh no, it went one more. Okay, perfect.

Dr. Barbara Schneeman: I think she was looking at the table where you listed everything that was—

Dr. Regan Bailey: That might take a minute and a lot of—

Dr. Barbara Schneeman: There you go.

Dr. Regan Bailey: Oh!

[2:32:58] ***Dr. Kathryn Dewey:*** Okay, so here's the list, and then if you could just explain what were the reasons for crossing out the ones that are crossed out? I just didn't—it went fast.

Dr. Regan Bailey: Okay. So, probably not a nutrient-by-nutrient, but there was not a biomarker that could confirm low dietary intakes were a problem, and there was not—it was not related to any clinical or health outcome.

Dr. Kathryn Dewey: Okay, so in some cases, there is a biomarker, but it didn't show a problem?

Dr. Regan Bailey: Like vitamin E.

Dr. Kathryn Dewey: And in other cases, there is no biomarker, so you don't know?

Dr. Regan Bailey: So, what are you thinking there's no biomarker for?

Dr. Kathryn Dewey: Just, well I—

Dr. Barbara Schneeman: Maybe go back to the flowchart. Oh, yeah.

Dr. Joan Sabate: Yeah, make it work fast.

Dr. Regan Bailey: Okay, so we would start with, for most things, we have dietary data available. So, is that available? Yes. Are the prevalence estimates within the threshold?

[2:34:00] Is it more than 5 percent of the population or any population subgroup that might have a problem? Yes. Then, is there a biomarker available? Yes. Is there suggestive evidence of a risk supported by a biological or clinical indicator? No.

Like kind of every path on—we put the nutrient through, each nutrient through this kind of pathway to see what was available.

Dr. Kathryn Dewey: Okay, so the specific question I have is the arrow that goes from "Are biomarker data available?" and it says, "No," and it goes to the left from where I'm looking, and it says, "Lack of evidence to be considered in nutrient or food component of public health concern." Are there any nutrients where—

Dr. Regan Bailey: Fiber.

Dr. Kathryn Dewey: —there is no biomarker?

Dr. Regan Bailey: Fiber. And it is a nutrient of public health concern because it's linked to a clinical outcome.

Dr. Kathryn Dewey: Okay, so there's only—yeah, so basically, none of them have been excluded on that basis?

Dr. Regan Bailey: Uh-uh.

Dr. Kathryn Dewey: Okay, thank you.

Dr. Regan Bailey: That was a long way around.

[2:35:01] ***Dr. Barbara Schneeman:*** Oh, but we love the flowchart.

Dr. Regan Bailey: I'm sorry. I didn't get that question. But I spent so much time on this, so I was just really happy—

Dr. Steven Heymsfield: She was very happy to show you the flowchart.

Dr. Barbara Schneeman: It's burned into your mind, and so, you've got to bring us all along.

Dr. Regan Bailey: And it's the color.

Dr. Barbara Schneeman: So, I think—did you have anything else?

Dr. Kathryn Dewey: No, I'm fine.

Dr. Barbara Schneeman: Okay. So, Rick is next.

Dr. Richard Mattes: I sure—Rick Mattes. I'm not trying to add anything to your plate. But when you look at beverages, will you be looking at them when consumed alone versus with meals? It's a question that comes up quite often, and it's kind of relevant. I mean beverages serve functions when they're consumed with a meal. They help you swallow. It doesn't mean that one has to use a sweetened beverage to accomplish that. But weight cost and benefits and hydration and not, it's a more complicated question.

[2:36:00] And knowing to what degree beverages alone are contributing energy and nutrients would—

Dr. Regan Bailey: Yeah, we don't have that built into the analytical framework right now, but I think that can be something that we incorporate in the report as a research recommendation. It's something that could be looked at.

[indiscernible 2:36:19]

Dr. Barbara Schneeman: Yeah, is it available?

Dr. Regan Bailey: Every eating occasion is recorded as a separate eating occasion. So, you could do it that way. So, if someone just reports a beverage, you could separate that out with the NHANES data.

Dr. Barbara Schneeman: Are you done?

Okay, Steve?

Dr. Steven Heymsfield: Regan, how is strength measured?

Dr. Regan Bailey: With hand grip.

Dr. Steven Heymsfield: Hand grip?

Dr. Regan Bailey: Yeah.

Dr. Steven Heymsfield: Because what caught my eye was the Asians has the highest prevalence of low strength, and we use that measure for sarcopenia diagnosis, and strength's related to body size. I wondered if adjustments were made for body size.

[2:36:59] ***Dr. Regan Bailey:*** No. These—what we presented today is—are just prevalence estimates. At some point, they were age-adjusted when I specified that for things that—like cancer. But we haven't done it like that for the muscle data, but that's a good idea.

So, that does bring up the point about protein. It's low in older adults. There's a rather high prevalence of low muscle strength. How do you feel about that in terms of—would that rise to the level of something you would consider to be of public health concern?

I don't want to put you on the spot specifically, but I mean that is—

Dr. Steven Heymsfield: I'm not sure I know the answer.

Dr. Regan Bailey: You can just say "tangerine." That's an option for you.

Dr. Steven Heymsfield: Yeah, I just work with the NHANES data a lot, and I'm very interested in sarcopenia. And I think body size is a very important covariant in that analysis.

[2:37:57] So, I think before you make inclusions about Asians being a lack of strength, you need to really adjust for body size in some way. I'm not sure how, but you—but something, yeah.

Dr. Elsie Taveras: In the same vein of not wanting to add anything more to this—

Dr. Regan Bailey: But yet, you all do.

Dr. Elsie Taveras: But there are two things I was going to ask about. One was you talked about obesity in the adults but not in children. And I think there are really good definitions in NHANES. I think now is reporting on severe obesity in children. So, I would ask if that is available and can be included.

Dr. Regan Bailey: So, Jamy and Tim really summarized the body composition data. Do you recall if those categories were—

Female: Do I do that one too?

Dr. Jamy Ard: It's okay. Yeah. I am sure that they're probably there.

[2:39:01] Severe obesity for children. So, I think that should be included, yes.

Dr. Elsie Taveras: And along those same lines with the increase in severe obesity, we're starting to see non-alcoholic fatty liver disease in children, and it's not one of the outcomes?

Dr. Regan Bailey: Yeah, that wasn't measured—

Dr. Elsie Taveras: It wasn't? Okay.

Dr. Regan Bailey: —in children. But we talked a lot about that. We really know that that's an issue, and we wish we had more data to address that.

Dr. Timothy Naimi: Yeah, in fact, that's some of the elevated ALTs and ASTs in adults are as accounted for by fatty liver, as well as by alcohol, as well as hepatic disease, particularly hepatitis C. But there's no way to tease those apart. And then, the AST/ALT data, there's none for kids, yeah.

[2:39:58] ***Dr. Elizabeth Mayer-Davis:*** I had a question. Yeah.

Regan, so speaking of adding things, so you mentioned that HEI was available for the cycle of NHANES data that you are using, but not other indices related to dietary patterns, and not wanting to steal any thunder from my colleague here to my left, a variety of dietary patterns are demonstrating some really interesting findings.

So, I don't know how impossible is it to look at other types of indices related to dietary patterns beyond the HEI?

Dr. Regan Bailey: Yeah, and I agree with you. I think that there are a lot of different dietary patterns, but when you really look at this data, it boiled down to five food groups that were contributing almost half or more energy.

[2:41:00] So, I think what we're looking at is an American pattern. I think there's variations in there.

But from the 2015-2020 extensive work on dietary patterns, they recommended only indexes and scores be applied to characterize dietary patterns because factor and cluster analysis were subject to too many decisions and couldn't be reproduced across cohorts. And so, we—

Dr. Elizabeth Mayer-Davis: Right. So, I was more thinking specifically of Mediterranean diet, for example, or DASH as another example, and I completely agree with the issues around cluster and factor analysis.

Dr. Regan Bailey: So, the National Cancer Institute has a Dietary Patterns Methods project, and they use all the different scores, and there's a very high congruence between the HEI and the Mediterranean score and the DASH index. I'm not saying there's perfect agreement, but they're pretty robust.

[2:41:59] Dr. Carol Boushey: Do you want me to back you up on that?

Dr. Elizabeth Mayer-Davis: Sure do.

Dr. Carol Boushey: Yeah, that's what I was going to say. I mean and the other issue is creating those dietary patterns for individual food items is actually a little chal—it is more challenging, not that it wouldn't be a wonderful thing to do.

It's just that it would be a large investment of time on your part, and we do know from the adult data, from the Dietary Patterns Methods project, that they are—they all come out very similarly.

Dr. Regan Bailey: But I really do hear your point, Beth. We know what they're not doing. They're not doing this. But we don't know what they are doing. And I think it could be a research recommendation that future committees walk in the door with knowing what the existing patterns are that are different than just HEI. That would be very helpful.

Dr. Elizabeth Mayer-Davis: Yeah, because there are established approaches to these scores, some of which are more common in the literature than others, but some that are fairly prominent. So, yeah.

[2:43:06] Dr. Regan Bailey: Absolutely.

Dr. Carol Boushey: I want to give you a shoutout, the team a shoutout. Your screener that you developed addressed one of the very comments that had come from the National Academy of Sciences report. So, you have a lot to be proud of. That really answered a bit question that you have a method now of looking at these nutrients of concern, so I really have to give you a shoutout.

Dr. Regan Bailey: Yeah, we really took that report to heart when we were developing this, but what we realized is that that system works nutrient by nutrient, but it failed us when we came across the adolescent females, because we were like "This is how we're going

to say something is a food component of concern," and then we were like "Wait a minute. We have this high risk, what we would consider to be a high-risk group that—"

[2:43:59] So nothing is perfect, but we thank you very much for your comments.

Dr. Barbara Schneeman: Actually, related to that topic, and first of all, let me remind the committee that this subcommittee has also asked for your input on presenting the conclusions around the chronic health conditions. And if you recall, and you can look back at your slides, but there's a general statement, and then Regan went through a lot of very specific data.

And so, part of the question that is being asked is how do we represent—how do we find the balance in representing that? Do we just do a general statement, and then each one separately, or do we need an overall conclusion statement?

And then, the other that I think we have gotten some discussion, is looking at these nutrients of public health concern.

[2:44:56] And I'm going to ask you about potassium, because I know that potassium is below the AI across the food groups, but we also have the new DRI report, which did not give us a chronic disease reference value for potassium.

And so, maybe just some of the subcommittee's thinking about potassium as a nutrient of public health concern.

Dr. Regan Bailey: Yeah, as you know, the DRI was recently updated, and we talked about this. Jamy, if you want to—can you summarize what you said in our small group meeting yesterday about potassium? Jamy was on the committee for—

Dr. Jamy Ard: Sure. So, the issues with potassium, from a clinical standpoint, yes, there are no issues with people coming into primary care or emergency rooms with rampant hypokalemia. So, that's not an issue.

[2:45:59] I think that the main potential chronic disease risk related to lower potassium intake is related to cardiovascular disease, and in particular, hypertension, and some of the sequela of that.

So, we know that there's relationship between higher potassium intake and lower prevalence of high blood pressure. We know that there are differences in subpopulations in terms of potassium intake, and some of those differences maybe explain some disparities in outcomes, in health outcomes.

So, for minority populations, African-Americans in particular, you see higher prevalence of hypertension, lower intake of potassium in that group.

And we also know that potassium has a blunting effect in terms of the hypertensive effect of sodium. So, in populations where potassium intake is higher, even for a higher sodium intake, you see a less robust response in terms of sodium—in terms of blood pressure.

[2:47:06] So, I think part of the discussion we had yesterday was there could be an argument made that potassium intake is part of the public health concern group, even though you don't have some of the sort of classical direct links, you have more indirect links, per se.

But there is a body of evidence that supports the idea that higher potassium intakes may actually have an impact at the population level.

So, I think that was summarized as the points in discussion.

Dr. Lydia Bazzano: Lydia Bazzano. So, I would second what Jamy just said, Dr. Ard, and also, in terms of nutrients of concern, I know Steve, Dr. Heymsfield, did not specifically say protein in older adults, but I think given the levels of prevalence that you're seeing, it probably should be concern.

[2:48:15] ***Dr. Kathryn Dewey:*** Kay Dewey. I have another question. I think the list of nutrients where you were examining whether they were of public health concern did not include omega-3 fats, and is there a reason for that?

Dr. Regan Bailey: Yeah, we hadn't looked at that data specifically, but you remind me that we really need to do that.

Dr. Kathryn Dewey: Okay.

Dr. Regan Bailey: Yeah, we looked at saturated fats, but we didn't look at other fatty acids. So, we should absolutely do that.

Dr. Kathryn Dewey: Because there's an AI for that?

Dr. Regan Bailey: Yeah. Thank you.

[2:48:59] ***Dr. Barbara Schneeman:*** Other comments or questions?

Regan, do you want to put that draft conclusion statement up and just see if there's—

Yeah, great.

So, I guess the question really is are we comfortable with this general statement, knowing that the report itself will go through some of the detail that Regan has presented? And again, it's still draft, so there's still some tweaking that probably needs to be done. But I'm just interested.

Dr. Jamy Ard: So, the alternative to that statement is something that then calls out some specific chronic diseases of maybe more interest or more concern.

[2:49:59] So, as an example, we had nominated something like dental carries, and metabolic syndrome, and diabetes as being really concerning, as well as increasing rates of mortality related to chronic liver disease.

So, these were things that were somewhat striking for us as we reviewed the data, but they were our perspectives.

And so, I guess the question is, we could just leave this very general and be very generic and point out things that I think we all know, chronic disease is increasing, and there are disparities, and it's worse in some subgroups compared to others, and we could stop there, or we could incorporate or call out things that we think are particularly concerning either across life stages or related to other themes that would be relevant for some of the questions that other subcommittees are dealing with, or related to things that we think are relevant with regards to where particular recommendations might go or be needed for emphasis.

[2:51:18] ***Dr. Kathryn Dewey:*** This is Kay Dewey. So, one thought is to at least highlight in some way the outcomes that are being examined in some of the literature reviews that the different subcommittees are doing. So, for certain cardiovascular disease outcomes are part of several of those. And also, growth, size, and body composition, so overweight and obesity are the ones that come to my mind as deserving to be highlighted, because we are going to talk about whether diet is related to them.

[2:51:59] ***Dr. Rachel Novotny:*** Yeah, I guess just in general, try—would like us to think about what to do with weight status or overweight/obesity. I see it's kind of listed as almost like a demographic, and whether it goes more on the health condition or whether we actually call it out as an intermediary.

Metabolic syndrome was mentioned in your review. It's closer to the diet in the pathway of many of the conditions. So, just to—I think we should think about where that goes and probably call it out. Yeah.

Dr. Elsie Taveras: I wonder also if you can group them in that way, that some of these are obesity-related, and make the summary a little more—that the cluster is associated with obesity-related conditions.

[2:53:00] ***Dr. Richard Mattes:*** Every one of those I think is related to that. It's one just big fat cluster.

Dr. Barbara Schneeman: Sharon?

Dr. Sharon Donovan: Yeah, I'm sort of I guess struggling on whether this is appropriate, or how to say it, but I guess when I was looking at your comments and you were talking about racial and ethnic differences, to me, it seems like we also need to include socioeconomic status and potential healthcare coverage, because I don't think it's just genetics, right?

And that was kind of what led to—I mean there's likely genetic components, but we also have disparities in prevention, and I think these differences are because people who have health insurance are getting their medications and they're getting earlier screening of pre-diabetes, and they're getting a lot more prevention.

And diet intervenes with that, but it's a broader issue, and it's likely beyond the scope of *Dietary Guidelines*, but this aspect of—to give you more work—if we could look at things beyond—other demographics in terms of SES or healthcare, or SNAP utilization.

[2:54:15] Because to me, then that leads directly to potential applications of *Dietary Guidelines* in nutrition programs.

Dr. Regan Bailey: Many of our protocols have food security—

Dr. Sharon Donovan: Yeah, food security.

Dr. Regan Bailey: —included to try to get a different—other than just how much money does your family have, how is that money distributed towards nutrition-specific things?

Dr. Sharon Donovan: That would be great.

Dr. Elizabeth Mayer-Davis: Just looking at this statement, I very much appreciate Rachel's comment, and this is Beth Mayer-Davis, to pull out obesity, and then adding to Elsie's, to frame obesity-related conditions.

[2:54:59] I think that's part of calling out and being more specific, thinking back to Jamy's comment, particularly about some of the areas that maybe are not above the radar right at this moment, like increasing mortality related to liver disease, like dental carries.

So, seeing those data, we're not necessarily surprised, but it's not necessarily what would have been front of mind. And so, I think that was really a good comment. So, I think taking opportunity to be a little bit more specific here in that regard.

And then my sort of second part of this comment has to do with being more explicit about health equity and inequity, because that's really what we're talking about, and I think that's really important as we think about the *Dietary Guidelines* with respect to informing federal food policy, issues about food security, access, those kinds of things.

[2:55:56] So, I'd like to see that aspect of equity brought out as well.

Dr. Barbara Schneeman: So, we're reaching the end of our allotted time, but one of the things that Dr. Kleinman and I have been talking about is, in one of the chapters, it's important for us to start integrating the work of all the subcommittees, and where do we come to after addressing all these questions?

And so, I'd like to just finish the meeting by maybe going around, if you have any particular thoughts about that issue, or some of what Regan was asking the committee about, just it's an opportunity for you to give some final comments for today based on what we've been hearing. And are you beginning to see some things that sort of emerged to top priority from the work that your subcommittees are doing?

[2:57:03] So, it's always tough to figure out who goes first. I'm going to pick on Kay.

Dr. Kathryn Dewey: Wow. Well, I mean the challenge that we have is integrating across the B-24 age group, because this is the first time that recommendations for this age group are going to be in this report. And as you all know, we have multiple outcomes for the same exposure. And so, we haven't yet talked about how to integrate across those.

Yeah, well, one thing that I do want to repeat that I said at the last meeting, and to make sure everyone's aware, is that we're only looking at a subset of all the different types of feeding advice that might be given for this age group, and in particular, we're focusing on the what to feed and not the how to feed.

[2:58:06] So, a general question then is how far do we go at even talking about the ones where we have not done systematic reviews? And so, any advice, I'll throw it back to you, that the overall committee would like to give us on how that gets approached would be very helpful.

Dr. Sharon Donovan: Well, I mean I've just been seeing we haven't really had the opportunity yet to speak in terms of Regan's committee on intakes and the prevalence of things like gestational diabetes and all of those, so I think that will be important to start to integrate.

And while pregnancy and lactation has been a component of previous *Dietary Guidelines*, I think pulling out this sort of special life stage, if we're taking that life stage approach, and I'm thinking not only about improvements for the maternal health, because we certainly know that women with gestational diabetes are at higher risk for type 2 diabetes later.

[2:59:17] So, again, haven't really had a lot of time to think about it, but I think in terms of integrating the data, in terms of what are pregnant and lactating women actually consuming, and what are—what's the incidence of these health conditions?

But I think what we have seen from both in B24 and Pregnancy and Lactation, we have a lot of inability to draw conclusions because the data sets, the data's just not there. So, clearly, as we move forward, and there was a comment earlier about research needs, and we'll have very long lists of research needs.

[2:59:59] And so, again, I think at the end, we'll be able to make some conclusions, but unfortunately, I don't think very many of them will be strong, but we'll have lots of recommendations.

Dr. Regan Bailey: I really like the life stage approach that we're taking, and it's very clear for B-24 and Pregnancy and Lactation. They have specific working groups. It's been less clear to me how to handle the other life stages. And so, integrating all the information from the different life stages is going to be a little bit more challenging, but I think really, really important.

And then, the other thing that really stuck out to me, in going through all of the data that we did, is that foods and nutrients are inextricably linked. When you see that the food changes over time, we see that mirrored with nutrients.

And I feel it's very important that we meet people where they are in terms of recommendations.

[3:00:59] So, people are consuming a lot of burgers and sandwiches. So, we have to give them tools and strategies to do that in a better way, not just "You need to eat more of this, eat more of—less of that," but giving them real strategies for success, I think, will be something that's important at least from my perspective.

Dr. Barbara Schneeman: Tim? It's your turn.

Dr. Rachel Novotny: What I'm thinking about is really integration and just trying to think of how to weave this in a useful way to make sense. But I think probably the newest thought around that is this last point about socioeconomic status and the—I know socioeconomic status has been in our models as a variable to consider.

[3:02:08] But given the potential use of our findings, I'm wondering whether we should pay more attention to that in looking at different subgroups in order to inform policy, and indeed, whether there should have been other kinds of variables in our models that might have helped us, like food security, or something about health utilization.

I'm not sure also about the race/ethnicity route and whether that's going to be the most helpful way to go about it, but anyone think—that's what I'm thinking about right now, yeah.

Dr. Jamie Stang: I would follow up with I think we've talked about the life span, but also thinking about a life course approach. So, the fact, when we were looking at the data yesterday and we saw these adolescent females with this constellation of poor nutrition, and I'm thinking "These are our future mothers."

[3:03:06] And so, there's this whole circular piece that what's important during pregnancy and lactation informs what happens to the children, which then grow up to be mothers themselves, or fathers. And so, somehow, to weave that piece throughout the report, that there's this generational piece that I think often we miss because of the way that data is collected or reported, but it has a lot of contextual implications for the recommendations we make.

Dr. Elsie Taveras: I was thinking I guess three things. One, Sharon mentioned. It's discouraging to see so much insufficient evidence and inability to make conclusions from the very little, in some cases, data that is out there and results.

[3:04:00] And I think that's going to be really important as we summarize, because I think there's quite a bit of attention on what is going to emerge from here, and I think we'll have to be careful with how do we frame this in a way that sets up the next *Dietary Guidelines* or the next committee on what were some of these research recommendations and where we might be able to contribute for research purposes for the next round.

I'm struck, Regan, with the conversation we just had about so many of these chronic diseases are obesity-related, and the increasing trends in the prevalence of obesity. And I think, I think that's important. I think we have to call it out, even if all of the chronic diseases, cancer, CVD, if they all cluster around obesity, I think it is going to be important that we really drive that home.

[3:04:58] Because in our subcommittee, and in many other, growth, size, and body composition is something we're going to—we're paying close attention to.

And then, the only other thing that I found interesting is there is a big drop-off. Maybe it's because I am a pediatrician and I think a lot about child diet, but there's some really interesting patterns, from 2-5, to 6 and over, that seems to be this critical point where so many of the patterns that you showed are deteriorating and decreasing.

And I wonder if there is a way, as we talk also about life course and life stage, if we can point out some areas of opportunity in either these critical periods or settings that work with people and populations in those critical periods, that they might be—there might be more room for influencing diet in those setting and age groups.

[3:06:00] ***Dr. Sharon Donovan:*** Yeah, I think that—I looked at that too as like kind of that childcare to school, and there's different policies in school lunches and CACP.

And so, I think that that's a really interesting observation as well.

Dr. Barbara Schneeman: So, I want to just keep going around.

Dr. Richard Mattes: Okay. Yeah, I don't want to just be redundant, but to amplify the importance of paying attention in our discussion sections about future directions, that this is so disheartening. We spent so much time building these models to find the greatest science, and we're all ending up with science that isn't answering the questions. And so, it's just vital that we encourage future researchers to design their trials so that we can get to the bottom of all this.

[3:06:56] The only other thing that I just feel compelled to comment on, nobody anywhere has talked about food palatability. I mean there are certainly issues, the disparity issues and so on, with regard to access and so on, but the primary reason that we pick one thing over another is because we like one thing more than another.

And so, I hope we don't lose sight of that, and somehow, we can weave this in that we have to pay attention to that, that component of food.

Dr. Barbara Schneeman: So, Lydia?

Dr. Lydia Bazzano: So, I like the life course approach and the life stages approach that we're taking, and I do think that it is important to distinguish the different periods, because nutrition is different, and the needs are different in different periods of time.

And specifically, I think in older adults, we need to think about that as well.

[3:08:02] So far, we're all kind of all lumped in as adults. So, I think that might be another particular group with particular outcomes to be focused on.

And then, the other thing I wanted to mention was also kind of along the lines of Richard, Dr. Mattes, just mentioned. The data that we have, all of these studies, we've been reviewing a lot, a tremendous amount of studies, most of which are not actually designed to study what we're trying to use them to—the question that we're trying to use them to answer. So, that's a different issue, but it does get to the importance of research for the specific questions that we want to answer.

[3:08:59] ***Dr. Barbara Schneeman:*** Joan?

Dr. Joan Sabate: I would say I agree with many of the things that have been said, and I think that on the last presentation, I mean it struck me that the way many of us eat, and almost everything is concentrated in sandwiches and burgers. So, is the culprit of many things, but also an opportunity.

And I think the changes in social trends from different perspectives, not only from foods, but also from perspectives of sustainability, and taste, and I think this is an opportunity to try to improve the health of Americans, but also tackle other social issues that are of concern to today's society.

[3:10:06] ***Dr. Heather Leidy:*** This is Heather Leidy. I'm not sure if I can add too much to the conversation when we get around to this point, but just a couple things that have come to mind. I think we've all said it, is it is surprising right now when you see that there's just a lot of limited evidence, and the evidence that exists seems to be from cohort studies.

And we always say we need long-term intervention-based trials, and I feel like now that kind of just goes to the wayside because we know we need them, it's that next step of how to do you make that happen from a funding standpoint and getting that out?

But I still think that's a vital part of trying to answer some of the questions that we have. It was more of a surprise. Maybe we're all sandbagging, ready and waiting until the end, until March, where all the data come out. I don't think that's the case, but it would be nice if that was.

An unrelated issue is I look at the food patterns, and I think I talked to Regan at lunch a little bit about the different food groups.

[3:10:59] I'm struck by the fact that when you look at whole grains and whether there's an increase in whole grain consumption, we also see that a lot of whole grains that are—whether they're recommended or they're in schools and whatnot, also have an added sugar component to that.

And we'll look at interventions, at least from—if we're doing added sugars or whatnot, but I think that's just a point that I don't—we kind of missed that. We look at the food groups and we see where they're coming from, but I'm not sure if you can then tie that back into a health outcome to say, "Whole grains may be beneficial, but as an example…"

But if they're included with added sugars, then a lot of those maybe potential health benefits go away, and I don't know if we—we're probably maybe not the group to do that. It's just something that, even looking at the food groups, if you could really separate them out based on some of the other food components that are part of that, and whether that's dietary patterning or not, I'm not sure where that fits.

It's just something I always see when you look at the different foods is there's other components or other nutrients with some of the other healthier food items, and it's just hard to tease that out.

[3:11:59] And then, just a last point. When we look at the different life stages, and adolescents, particularly females, are a group of interest from a nutrient standpoint, we know—I also know at least from the literature, there's very little—very few studies in that population.

So, they kind of go hand in hand, that you see the nutrition issues, but they are not always linked with some of the other health outcomes, usually for compliance or attrition, with that population, but I think that's a really good area for future recommendations.

Dr. Barbara Schneeman: Jamy?

Dr. Jamy Ard: So, I think we have not gotten to the dietary patterns section yet, but if I would say something that integrates what we're talking about, I think tomorrow, we should hopefully be able to have more discussion about the sort of idea of dietary patterns being a sort of concept that we can double down on, and that was brought forward from the previous guidelines.

[3:13:04] And I think it speaks to several things.

What Heather just talked about, and what Regan talked about, where nutrients are not consumed in isolation, and foods are not consumed in isolation. When I have my burger and sandwich, I'm going to also have my starchy potatoes and my sugar-sweetened beverage, right? I mean those things travel together in American pattern, and we need to—we need to

acknowledge the idea that across life stages and in the life cycle, these patterns tend to change. And even from the use of complementary foods and how we feed infants, those things are starting to develop early.

And so, if we could think about that idea and how we help inform people around those concepts of foods travel together.

[3:14:07] And then, I also think with regard to the idea of calling out obesity, I think that's very important, but we haven't really talked about energy intake. And so, at some point, we've got to deal with that piece of how we integrate that into all of what we're talking about, because I think, at the end of the day, quality matters, foods matter, nutrients matter, but energy is very important.

Dr. Teresa Davis: I think it's very important that our report is looking at life stage, and this will be the first time that we've ever looked at from birth all the way up to the elderly population.

[3:14:58] And I think by doing it that way, by presenting our report by life stage, it's more useful for the end user, for the public.

And indeed, I think we can look at certain things that we've seen in dietary intake, of the trends over the last few years. For example, there's been a slight increase in whole grains, although the low grain intake is very low, but there's been a slight increase. And it is this because the *Dietary Guidelines* have reported this, and then the food industry may be reacting to this, so they're putting more whole grains into, for example, breakfast cereals and bars and so forth.

So, I think our report is quite important in informing the public, but also industry that feeds the public.

[3:15:56] ***Dr. Steven Heymsfield:*** Tomorrow, I'll give the report for the Frequency of Eating committee, and it's a very important front-end part of our report is what you're going to generate from this NHANES data.

So, I'm really looking forward to what that will be, because from what we've found so far, there are huge gaps in the literature, and we've spent a lot of time trying to define what we mean by frequency of eating, and ingestive event, and so on. So, it'd be very good for you to work with us, so we make sure we have the same definition of frequency of eating, yeah.

Dr. Linda Snetselaar: I also think that what we're doing in this committee in terms of looking at younger age groups is incredibly important, and much of what has come up through this committee is the idea that we want to be consistent, we want to be sure that we're working together as subcommittees.

[3:16:58] And particularly as we focus on these younger age groups, being very careful to ensure that we have conclusion statements and then grading that is very consistent across committees, I think is very important.

Dr. Elizabeth Mayer-Davis: This is Beth Mayer-Davis. I just wanted to note that, to some extent, by design, some of the questions that we've addressed have had quite small numbers of studies that sort of made it all the way through, but to some extent, that was by design so that we would get our systems in place and make sure that we were proceeding in an appropriate fashion.

So, I can at least tell you that for Beverages and Added Sugars, some of the questions to come have much larger bodies of evidence. So, it will not all be three studies here or four studies there. For better or for worse, right?

[3:17:53] So, again, not wanting to steal the thunder from Carol's report on Dietary Patterns, that subcommittee talked a lot yesterday, and it is relevant, I think at this point, Jamy alluded to this a little bit as well, I think by way of integration across subcommittees, having a framework of thinking about dietary patterns and what we've been thinking about by way of hierarchy of dietary patterns, foods, and nutrients, I think that will help with some cohesion, including how we integrate across subcommittees.

So, for example, thinking about the Beverages and Added Sugars committee, thinking about Seafood and Fats, and how those components come into play with the dietary; patterns. So, I think that will be an important aspect that will help us in terms of integration.

Dr. Carol Boushey: I could say, "Wow, everyone said it." But I have a list here. And actually, it's a list that supports things that have really been said.

[3:18:57] And as Steve and Beth, Beth is working on this beverage guidelines, I thought going through and describing all those beverages, that was like doing minor surgery.

We really have an issue with vernacular, and a lot of it is driven by popular words, but I think we do need to spend—concentrate a bit on how we can make sure that what we're doing now will be repeatable, that we use language that does describe what people are eating and the activities, and part of the challenge of this is think about your beverages 20 years ago. We only had like one soda that you could select.

So really, we're facing a new world where we get really new foods almost every year. And so, that's a burden on our committee, and we have to somehow think of how to make all that make sense and to be able to bring it all together, because this idea of Kay's, we do need —Kay said we need to put together all of our work across all of our groups, and I thought that was a great suggestion.

[3:20:14] And Rick, about your palatability, I think it's surprising that burgers and sandwiches are so high, and yet, we have this low whole grains. It just doesn't make sense, does it? So, we really have a lot to do to make these guidelines exciting, that people want to follow them, that people see them as something "Hey, I'd like to do that."

But and I'm not sure that we can do that, but let's try to think that we can. Thank you,

Dr. Barbara Schneeman: So, I'm going to give you the last comment.

[3:20:57] ***Dr. Ronald Kleinman:*** So, I think that we've worked very hard to describe the food patterns, or consumption patterns at all of the different life stages that we've talked about, but one way to integrate this is to talk about how these patterns change over time.

And we've also examined health consequences at these various life stages of the foods that are being consumed, and that's another opportunity for integration if we look at cognition, cardiovascular disease, and the vari—hypertension and the various other outcomes and look to see how these relationships change over time as well.

So, I think I liked what—I like what everybody had to say. Jamie mentioned the generational aspect of this, and I think we need to weave that into that conversation about change over time.

[3:22:02] And then, I think it's really important that we couch all of this as—food as one of the social determinants, but there are others.

And to the degree that we can link food consumption patterns, at least to some sense of economic status, that will help us a lot in completing this story and bringing it together so that we demonstrate where the real opportunity here exists. So, that's—I'll stop there.

Dr. Barbara Schneeman: Great. Well, these comments are very helpful. I've been scribbling notes here.

So, I think at this point, we're adjourned for today. I'm looking at Eve. Do we need to highlight anything?

[3:22:55] So, again, we will reconvene tomorrow morning at 9:00. We have several more subcommittee reports to go through, and then we will have the period for public comment, which I'm looking forward to.

So, I hope you all have a good evening. Thank you.