Morning Day 1
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Dr. Eve Stoody: We're starting.

Alright, good morning. This is Eve Stoody, and I'm with USDA's Center for Nutrition Policy and Promotion.

Welcome to Meeting 5 of the 2020 Dietary Guidelines Advisory Committee. This is a virtual meeting for members of the committee that is being webcast to the public. For members of the public, you are joining this meeting in listen-only mode. If you have any technology issues, please use the question box to the left on your screen, and this will be the only use for the "Ask a Question" box throughout the meeting.

All 20 members were able to join us remotely for this meeting. We do want to note that we have a few members whose universities and hospitals are engaged in Coronavirus response activities, so there may be times during this meeting where they need to step out from the discussion.

[0:00:58] We have committee members who are joining us from across the country, including Hawaii, California, Texas, Louisiana, Minnesota, Iowa, Illinois, Indiana, North Carolina, New England, and Washington, DC. So, good morning, good very early morning. I think we have people joining us at kind of the range of time zones is over six hours, or is six hours, so very, very early good morning.

As always, we start the meeting by stating the charge to the committee. This committee was established to examine the evidence on specific topics and scientific questions identified by the Departments of Agriculture and Health and Human Services, to develop a report that outlines your science-based review and recommendations to the Departments, and then to submit the report to the Secretaries of USDA and HHS for consideration as the Departments develop the next edition of the *Dietary Guidelines*.

This timeline provides an overview of out steps so far to update the *Dietary Guidelines*.

[0:01:59] As a reminder, we announced the committee in February of 2019, and this is the 5th meeting of the committee.

Meeting 5 will be held today and tomorrow from 9:00 am until 4:30 pm each day. Please note that there are different webcast links for the morning and afternoon sessions each day. The webcast links were sent out through our Listserv and are also available at DietaryGuidelines.gov.

The agenda is also available at DietaryGuidelines.gov, and Dr. Schneeman will provide an overview of the agenda in her remarks.

So, a few notes about future dates of interest.

As we announced at Meeting 4, the committee plans to hold a meeting on its draft scientific report on Monday, May 11th, and they plan to submit their final report to the Departments by the end of May.

To ensure all public comments can be considered by the committee as it develops its report, the ongoing public comment period will close at 11:59 pm Eastern time on Friday, May 1.

[0:02:57] After the committee submits its report to the Departments, UDSA and HHS will post the committee's final report for public comment in the summer of this year.

So, as usual, please sign up for the email updates on these and other announcements at DietaryGuidelines.gov.

And with that, I'd like to turn it over to my colleague, Janet de Jesus, from HHS Office of Disease Prevention and Health Promotion for opening remarks.

Janet de Jesus: Good morning, everyone. Welcome to Meeting 5 of the Dietary Guidelines Advisory Committee. It is my pleasure to introduce Dr. Don Wright, who is the—who serves as the Deputy Assistant Secretary for Health and the Director of Office of Disease Prevention and Health Promotion since January of 2012.

In this capacity, Dr. Wright, leads coordination and policy development for public health and prevention activities within the Office of Assistant Secretary for Health at the Department of Health and Human Services. Dr. Wright provides leadership for Healthy People and oversees the development of evidence-based health policies, such as the *Dietary Guidelines for Americans* and the *Physical Activity Guidelines for Americans*, and a national plan that addresses adverse drug events and healthcare-associated infections.

[0:04:14] So, prior to joining ODPHP, Dr. Wright served in a variety of federal roles in government, and before his government service, he was a dedicated clinician in Central Texas for 15 years.

Dr. Wright has an exciting new opportunity coming up. He will serve as the US Ambassador to Tanzania, so we're very thrilled for him. He's been in intensive training, including learning Swahili, so we're thrilled that he's going to be able to be here today.

So, without further ado, I'll turn it over to Dr. Wright.

Dr. Don Wright: Thank you, Janet, and to all of the committee members, "Asante sana!" in Swahili. Thank you very much for your contributions.

Let me tell you, it's been a honor to be here this morning, to welcome you all to the 5th meeting of the *Dietary Guidelines for America* and the last scheduled in-person meeting that was rescheduled before the committee presents its report to the Secretaries of the USDA and HHS.

[0:05:11] On behalf of the USDA and HHS, I'd like to thank all of you for the experts you've been over the course of this appointment.

After a little more than a year from your first public meeting, we're nearing the finish line for the 2020 Dietary Guidelines Advisory Committee. I know that we've asked a lot of you, particularly in the last 3 months, and we appreciate your commitment to science and public health, and your contributions to this evidence-based, transparent process.

To Dr. Schneeman and Dr. Kleinman, thank you for your leadership as Advisory Committee Chair and Vice-Chair, and all the time you've dedicated to this effort. Between participating on numerous subcommittee calls and responding to a deluge of related emails, I imagine you're due for a well-deserved break once the committee report is submitted in a few months.

[0:06:05] And to the entire committee, I am truly amazed at how much work you've been able to accomplish. You are the first committee we've asked to review the evidence on nutrition across all—across the life stages, including pregnancy, lactation, and the first 2 years of life.

In addition, the body of evidence on the role of nutrition and disease prevention and health promotion has grown exponentially since the last committee submitted its report, and you've done an impressive job of reviewing this unprecedented evidence base while maintaining a rigorous and thorough process.

This was an ambitious ask for the Departments, and we appreciate your enthusiasm in accepting the task.

We look forward to receiving your report, which will include your recommendations for USDA and HHS to use as we develop the *2020-2025 Dietary Guidelines for Americans*.

[0:07:02] We are confident that the rigorous systematic reviews, data analysis, and food pattern modeling that you have completed over the course of your work will provide the evidence base we need to update the *Guidelines*.

I'd like to recognize and thank the talented hardworking staff who've made all this work possible. Federal employees and contractors from both US Department of Agriculture and the US Department of Health and Human Services have worked seamlessly together and are truly dedicated to supporting the Dietary Guidelines Advisory Committee.

To all staff, I'm confident that I speak for leadership from the USDA and HHS when I say we can't thank you enough for your support to this committee and the work that you will continue to do in developing the *Dietary Guidelines for Americans* in the coming months.

I think it's appropriate that this group of nutrition experts is meeting publicly during National Nutrition Month.

[0:08:02] I think as most of you know, yesterday was Registered Dietician/Nutritionist Day, and given that many dieticians are watching, I'd like to recognize and applaud the work these professionals do to improve the health of their patients, clients, and communities.

As you're all well aware, the *Dietary Guidelines* form the basis for federal food and nutrition policy. From an HHS perspective, we use the *Dietary Guidelines* to inform, first and foremost, consumer dietary guidance delivered through our grants and educational materials. We also use them for food assistance programs, like the Older Americans Act Nutrition Program. We use them for national health objectives, such as the Nutrition and Weight Status Objectives in Healthy People, and we use them in nutrition monitoring and research. It's also used in regulation on food labeling and fortification.

My office at HHS also leads the Healthy People Initiative.

[0:09:00] Since 1979, Healthy People has identified science-based national goals and objectives and ambitious yet achievable targets for improving the health of the nation by the close of each decade.

In this way, Healthy People serves as a road map for benchmarking, charting, and assessing the nation's health promotion and disease prevention efforts. The *Dietary Guidelines* help to inform many of the Healthy People nutrition and weight status objectives and targets.

On March 31st of this year, HHS will launch the 5th iteration of the Healthy People Initiative: Healthy People 2030. I encourage you to check out HealthyPeople.gov when we unveil the nutrition and weight status objectives for the decade.

Another HHS office, the Office of Women's Health, is looking forward to the Advisory Committee's science-based recommendations to promote women's health across the life span, but particularly during pregnancy and lactation.

[0:10:01] We know that proper nutrition during the earliest stages of life is critical to support healthy growth and development during childhood and to help promote health and prevent chronic disease through adulthood, as we know that proper nutrition is important to maintaining a healthy pregnancy and keeping moms healthy.

We are confident that your report will enable us to develop *Dietary Guidelines* for these populations and across the life span that are based on the best available scientific evidence and will improve the health of the American people.

Again, I want to thank you for your willingness to serve on this very important Advisory Committee. I know your work will be instrumental in ensuring that a strong scientific foundation underlines the dietary guidance we provide for all Americans across the life span.

And at this point, I will turn it back to Dr. Schneeman.

[0:10:59] ***Dr. Barbara Schneeman:*** Great. Thank you very much, Dr. Wright, and congratulations on your new position. It sounds exciting.

Dr. Don Wright: Thank you.

Dr. Barbara Schneeman: And interesting. So, before going into my formal slides, I do want to express my appreciation to the staff.

We know that the situation has been changing on a regular basis, and all the states that you're coming from, and the ability to meet virtually means we can continue the very hard work that this committee has been putting forward. So, thank you to the staff and thank you for your flexibility in adapting to current reality as it exists.

And also, my appreciation to the committee members who really put in tremendous effort so that we could be ready for this public meeting, and your willingness to be there at all sorts of odd hours of the day so we can have this public meeting.

[0:11:58] So, just to review for you the agenda that we will be going through.

I'm going to just quickly review the subcommittee structure and the approaches used to examine the evidence.

I'll review our meeting purpose and agenda.

And then, some reminders about the public comments, which have been very important to the committee members as they work through their subcommittees.

So, just to remind you that, in order to accomplish work between the public meeting sessions, we've been divided into six subcommittees: Dietary Patters, Pregnancy and Lactation, Birth to 24 Months, Beverages and Added Sugars, Dietary Fats and Seafood, and Frequency of Eating, and then one cross-cutting group that has been looking at the Data Analysis and the Food Pattern Modeling.

So, members of the committee serve on at least two subcommittees, and Dr. Kleinman and I have divided the committees so that we have some cross-representation.

[0:13:05] The subcommittees have been dealing with the questions that came to us from the Departments of Agriculture and Health and Human Services, and we use these approaches to examine the evidence: data analysis, food pattern modeling, and the NESR systematic reviews.

And I'm not going to repeat what I've said in other public meetings about the details of each of these approaches, but certainly, you can find much more detailed information at the website, DietaryGuidelines.gov.

I would note that, while each question or topic has maybe focused on one of these approaches to examine the evidence, as we're now reaching the point where we're developing our conclusions and beginning to look across the topics, there'll be more opportunity for integrating the conclusions from each of these areas into our report as we work toward putting that together to deliver by the end of the month.

[0:14:14] So, today, we'll be focusing on draft conclusion statements, and I do want to emphasize the "draft" word in conclusion statements. These are how we've developed our answers to the questions based on the evidence that is reviewed. They've been drafted by the subcommittees and are being brought to this full committee, so as a full committee, we can discuss and reach agreement at these public meetings, but do keep in mind that any conclusion statement that we show is considered draft until the committee submits its final report to the Secretaries.

So, these are being brought forward for discussion.

[0:15:02] Okay, so for this meeting, our purpose then is to describe the status and provide updates on the work of the committee and discuss our next steps as we finalize our work.

There is an agenda, as Eve pointed out. The agenda is available at DietaryGuidelines.gov.

Both today and tomorrow, we're starting at 9:00 am Eastern time, and our afternoon session will begin at 1:00 pm Eastern time, and as Dr. Stoody already pointed out, I think you have a login for each of those times.

So, and I would note, we will plan on breaks. They're not set for specific times, but we'll take them as they fit within our discussion.

So, for today's agenda, following the opening remarks, we'll move straight into our subcommittee reports, and the plan for today is to focus on the Data Analysis cross-cutting working group, the Birth to 24 Months subcommittee, Pregnancy and Lactation subcommittee, Dietary Patterns Subcommittee, Frequency of Eating.

[0:16:14] And we have been trying to be sensitive to the time differences in terms of when the subcommittees give their report.

So, and for tomorrow's agenda, again, we'll begin at 9:00 am and will continue with the subcommittee reports. So, what we anticipate for tomorrow is, again, from the cross-cutting

working group, the Food Pattern Modeling, but then move to Dietary Fats and Seafood, Beverages and Added Sugars.

Of course, we will have committee discussion as we move through each of those discussions—each of those subcommittee reports, but then hope to have the broader discussion.

[0:16:58] And then, at the end of the day, we'll talk about next steps: the peer review for the committee's systematic reviews and outline of the committee's report and where we are in terms of starting to integrate across the chapters.

And then, closing remarks at the end of the day.

So, as mentioned, we are very interested in public comments. At this point, we've received over 40,000 written public comments since March 12, 2019. So, within a year, that's a lot of public comments.

If there are public comments related to the discussion at this particular meeting, we encourage you to submit them to the committee by Friday, March 27th. Again, that's when they'll be most useful to the subcommittees.

In terms of the written public comments, the comment period will close May 1 at 11:59 pm Eastern, on Friday, May 1.

[0:18:02] And our members are reviewing and considering the public comments received, that they're part of the discussion within the subcommittees as the committee goes through how it's looking at the protocols and the nature of the evidence that is—that it's bringing together.

So, those public comments are an important part of what we do.

So, with that, we will be ready to start with our subcommittee reports. And so, yes, and so, Dr. Bailey, are you ready for the sub—the working group report on Data Analysis?

Dr. Regan Bailey: Yes, Dr. Schneeman. Can you hear me okay?

Dr. Barbara Schneeman: Yep, we can hear you fine.

Dr. Regan Bailey: Okay.

Dr. Barbara Schneeman: We're going to go on silent while you do your report.

Dr. Regan Bailey: Okay, great. Good morning, everyone.

[0:18:57] Today, we'll be going over some of the topics we discussed at previous meetings, but specific to the Birth to 24 Months and Pregnancy and Lactation groups. Those are listed here on this slide.

We'll also be talking about the relationship between added sugar and meeting food group and nutrient recommendations, frequency of eating, beverages and meeting food group and nutrient recommendations, as well as alcohol relative to those same end points.

So, in this data presentation, I'll refer to HM infants. This means infants who receive no infant formula, so infants receiving human milk. And we will talk about infants who are receiving infant formula, including mixed-fed infants, as FMF.

So, this was done, mainly, we wanted to look at primary source in 6-12 months of age, and we didn't have the sample size to look at mixed-fed infants, those receiving both breast milk and formula, so those have been—those infants are categorized as FMF.

[0:20:05] So, as has been the case for most of the work that we do, we rely on the National Health and Nutrition Examination Surveys, and similar databases that have been discussed in the past.

New to this presentation are two data sources where we will have information on breastfeeding initiation and duration as well as the timing and introduction of foods and beverages from the survey listed here.

We've gone over the key definitions several times. I just want to point out that we use consistent definitions as the B24 subcommittee, and you have these on the slide deck.

So, the questions now that we will start with – we will go to Birth to 24 Months and examine these four questions together.

[0:21:04] So, in terms of the B24 group, the sample size for each 2-year cycle of NHANES is very small. Ideally, we'd have a lot more data in each survey cycle, but that's not the reality that we have.

So, what we've done for the presentation of data in this age group is combined data from 2007 to 2014 in order to get adequate sample size to be able to stratify FM and a mixed-feeding and formula-feeding infants.

So, the strength of that is that we have the ability to look at those different groups, but there's also a weakness associated with that, because the nature of the food supply is pretty dynamic, and trends in infant feeding practices could have occurred over these time periods, as well as potential lags in the database to reflect the food supplies.

[0:22:07] There's measurement error inherent with all self-reported dietary data.

The extent to which that exists for proxy interviewers, so obviously, the infants aren't reporting for theirselves, so it's generally parents or caregiver. However, this may not be the person who's most familiar with an infant's dietary intake at particular time periods. So, if a child is in someone else's care for the day, that might be a limitation of proxy report.

Also consider that it's difficult to categorize usual intakes, and this is an ongoing research question, especially in this age group, where eating trajectories are quite dynamic and evolving.

And there are a variety of age ranges. So, even within 6-12 months, there's going to be different energy needs for a 6-month-old versus an 11-month-old. So, just keep that in the back of your mind.

[0:23:08] And finally, we, while we did categorize intake into these two groups, they were not specifically compared.

So, I might say something is higher or lower, and I don't want you to assume that means it's statistically different.

So, let's start to first look at and focus on breastfeeding rates and duration, and then timing of complementary foods and beverages.

And we'd like to thank Clea Perrin and her team at CDC for providing this data to us.

So, this is the percent of US infants who were—where breastfeeding was initiated, so about 84 percent. And then, you can see during different time periods, that that decreases to 57 percent at 6 months and 36 percent at 12 months.

[0:24:04] And the exclusive rates at 3 months and 6 months are also presented on this slide.

This slide looked at the same type of data, but it categorizes by race and Hispanic origin. And you'll see that breastfeeding rates appear to be higher for non-Hispanic white and non-Hispanic Asians, both in terms of initiation and at 6 and 12 months.

This is looking at exclusive breastfeeding. And so, just for frame of reference, the Healthy People 2020 goal at 3 months is 46.2 percent. So, Americans are meeting this goal. However, at 6 months, the goal is 25.5 percent, and we're just shy of that at 24.9.

[0:25:02] So, this is a slide showing the timing of introduction of complementary foods. It's generally recommended that that be anywhere between 4 to 6 months, but we do see about 32 percent of infants who are receiving complementary food before 4 months of age.

That seems to differ by the source of whether an infant is consuming human milk only or infant formula. And so, for the purposes of this slide, you can see the mixed-fed group here, which is—so the rest of the stuff will be lumped in with infant formula—but infants receiving infant formula, there's a higher percentage having a complementary food.

[0:25:59] So, we'll next focus on these three bullet points, and I will walk you through the data as to not read the slide to you.

So, this is a slide that is looking at the proportion of reported intake.

So, this compares the percent of a group that is reporting a food, and then under the main food category, there are food subgroups.

So, I pulled a few comparisons out in bold just to show you and to highlight the point that infants who are receiving formula or mixed-fed, there's a higher percent of reported consumption on any given day across most food groups, but then also to note, that within all infants, there's a low prevalence of, for example, dark green leafy vegetables being reported, so that's at 6 percent, less than 1 percent with total fish and seafood, and about 20 percent for eggs.

[0:27:11] So, we'll see some of this food data translated into nutrient data in the upcoming slides.

So, this slide compared the mean amounts consumed by age group to begin to examine what changes occur at what age. So, remember, this is cross-sectional data, so we can't say intakes for a particular child increase this much, but at the population level for the age group, here's the mean amount of these main groups that are being consumed.

And so, that helps us start to get a sense of when shifts are starting to occur and for what types of mean food groups.

[0:27:58] And so, the first column is 6-11 months, then 12-23 months, and then we have older children 2-5 that is further stratified by sex.

So, in terms of the results for infants 6-12 months, as I mentioned, formula and mixed-fed infants get a larger proportion of food groups from baby food than in human milk infants do. 61 percent of added sugars in human milk-fed infants come from the categories milk and dairy, grains, and fruit, whereas the majority of added sugar among those formula and mixed-fed infants comes from snacks and sweets, baby food, and milk and dairy.

In terms of the older age group within B24, so 12-24 months, the food category source of the food is really similar to that of all Americans age 2+, and we pulled out some data on the top sources of added sugar here, but those top three are among the top five in all age groups.

[0:29:14] So, to summarize some of the data here, breastfeeding initiation rates are high, but exclusive breastfeeding past 3 months and any duration past 6 months is below 50 percent, and we looked at some of those differences by race and ethnicity.

Complementary foods are introduced at less than 6 months of age for the majority of infants, and introduction of complementary foods and beverages at less than 4 months is more prevalent among those infants who are receiving formula who are mixed-fed.

We looked at some of the different patterns between human milk, infant formula, and the mixed-fed group in terms of the types of complementary foods and beverages being reported, and in general, mean intake of complementary foods and beverages is higher among formula and the mixed-fed infants, and a greater proportion of complementary foods and beverages come from sources such as baby foods for formula-fed infants when compared to human milk-fed infants.

[0:30:22] And what that translates to in general, and this is an estimate, but around 100 calories difference on average on any given day, higher intakes for formula-fed than human milk-fed infants.

And so, the pattern of food group intake enforces the food groups among 1-year-olds are similar to that of the rest of the population that we looked at for several iterations of the

Dietary Guidelines. There's a notable increase in the intake of added sugars when 1-year-olds are compared to infants that are less than 12 months of age.

[0:31:01] So, this seems to be a real break point in terms of some food sources and food category, but particularly for added sugars.

Moving on next to talk about nutrients of public health concern and current intakes of nutrients.

So, you'll remember that we had talked about nutrients of public health concern in ages 2+ at Meeting 4 and that we will focus on these specific life stages here today.

And again, here is, just as by way of a refresher, and I'll go through this really quickly, because I think you've seen them at least once, but maybe twice now.

When we identify nutrients or food components of public health concern, the goal is always to have more than one measure. So, we would ideally have nutrient data or intake data paired with a biological endpoint or a clinical health outcome.

[0:32:07] We created this decision tree before we got into the data for how we would make decisions on when we didn't have certain data or how we would kind of have a streamlined way to make decisions based on the availability of data and the science behind some of the outcomes or validated intermediary outcomes.

So, quickly, we refereed to an underconsumed or overconsumed nutrient or food component when it's a problem in 5 percent or more of the population or within specific population subgroups.

We also have the term nutrient or food component of public health concern.

[0:33:00] Again, we linked that with some other indicator, such as a biomarker or a clinical health outcome.

And then, we have nutrients or food components that pose special challenges.

And so, the challenge is maybe in identifying risk groups, or for which dietary guidance to meet recommended intake levels is challenging to develop.

Okay, so let's go into a little bit deeper dive here with the data.

The analytical framework, we'll look at the mean nutrient intakes, usual intake distributions, and compare those to the Dietary Reference Intakes.

And just a quick note, that we did present data on 1-year-olds as part of the 1-3-year-old age grouping, which is the basis for the Dietary Reference Intakes.

[0:33:56] So, I'll try to make slides here where we're referring to certain age groups.

So, in this slide, we are looking at infants who are receiving human milk or formula or mixed-fed, and we really focused on the nutrients that had an EAR for this age group.

And that is limited to protein, iron, and zinc. So, without an EAR, it's very hard to make conclusions around the adequacy of dietary intakes.

So, you will see, for all infants on the far right column, the prevalence that are either below the EAR or above the UL, and there is just substantial differences between infants who have human milk or formula-fed infants, especially with regard to iron and protein and zinc.

[0:34:57] And that also translates into the prevalence above the UL for those nutrients for infants who are receiving formula or are mixed-fed.

So, this slide is a little bit complicated, and I'll just take a moment to walk you through it.

The first column is the adequate intake. So, for food components with an adequate intake, that is the Dietary Reference Intake value that is associated with that in the first column.

When the—the next column is the amount that is assumed to be contributed from complementary foods and beverages as outlined in the Dietary Reference Intakes.

And then, in the next three columns, you will see whether or not the intakes are either above those AI assumed to be contributed for all infants, for infants receiving human milk, and for infants receiving formula or are mixed-fed.

[0:36:13] So, the nutrients in green are where infants are receiving more than the expected from complementary foods and beverages, and then that pink or salmon color, it's less than that AI value. And then, the white is pretty close to what the expectations would be.

So, based on this data, for the proposed nutrients of public health concern for infants who are receiving human milk would then include iron, zinc, and protein.

Based on what we call nutrients or food components that pose special challenges, this is for all infants, we characterized potassium, vitamin D, and choline.

[0:37:11] And then, among infants who are receiving formula or mixed-fed, intakes are notably high above the UL for zinc and for retinol.

So, our draft conclusion statement is that complementary foods should be nutrient-dense, especially for sources of dietary components for which potential risk of inadequacy is noted.

So, that was for 6-12 months.

Moving on to infants and toddlers 12-24 months, similar to what we proposed in the last meeting – potassium, fiber, vitamin D, sodium, and added sugars.

Proposed nutrients or food components with special challenges in this age group include choline and linoleic acid.

[0:38:03] And, just noting that in this age group, many 1-year-olds still exceed the recommendations for zinc and for retinol from foods alone.

So, as we mentioned kind of at the start of this, there are many caveats to consider with looking at this age range.

So, at around 12 months, children start to transition. So, the caveat here are we really don't have a lot of the biomarker data available in this age range. We do have serum ferritin concentration, but that is for 1-5-year-olds entirely combined together, and that data says that about 4 percent overall US children 1-5 have potential iron inadequacy based on biomarkers.

[0:39:04] So, in terms of DRIs, there's been a lot of talk about the basis for the DRIs oftentimes are extrapolated down from adult data.

There's very little experimental data to inform the Dietary Reference Intakes. And so, that one caveat in mind, particular among the UL, because there are such large proportions of infants and young children exceeding the UL from food alone for certain nutrients.

Existing food composition data on human milk are outdated and don't account for known variations that exist for a number of components.

And then, it's always challenging to estimate the volume of human milk that is consumed.

[0:39:58] And so, in NHANES and in most studies, assumptions are made about the volume of human milk that is being consumed.

Okay, so we'll move on now to pregnancy and lactation.

This is a radar plot showing the differences in HEI scores between pregnant women in purple, lactation women in red or maroon, and then similarly-aged women who are not pregnant or lactating in blue.

And you can see straightaway that the HEI scores are notably higher among pregnant and lactating women than their non-pregnant or lactating peers, and this seems to be driven by higher intakes of fruit, greens and beans, whole grains, fatty acids, and seafood and plant proteins, specially seafood and plant proteins in lactating women, combined with lower intakes of refined grains, sodium, and saturated fats.

[0:41:03] So, our draft summary statement is that during pregnancy and lactation, the diet quality of women, as reflected by HEI, is higher than women of the same age range who are not pregnant or lactating.

Moving on to look at the nutrients of public health concern and intakes during pregnancy and lactation, it's a time when many women are using dietary supplements, particularly dietary supplements containing micronutrients.

And on this slide, the prevalence of dietary supplement. So, you can see that 77 percent of pregnant women are taking a supplement.

So, a lot of pregnant women, those in the first trimester, those who are a little bit younger, 20-24, and those who are living in a family of lower income, are less likely to use supplements compared to their counterparts.

[0:42:07] So, this is just a broad summary of energy.

So, energy intakes increase as recommended to meet the demands either for growth or during lactation to produce milk. In general, similar to what we saw from the HEI slides, dietary fiber intakes, while it's still low, is notably higher. So, this is the percent receiving the adequate intake.

And most pregnant and lactating women are within the AMDR for protein, carbohydrate, and for essential fatty acids.

So, this is a really busy slide, but we wanted to be able to provide a comprehensive comparison of how pregnant (in green) and lactating women, what their intakes are relative to the EAR.

[0:43:09] So, remember when we have an EAR, the percent less than the EAR would be considered at-risk for inadequacy.

And so, the first number is from foods alone, and the second number is from total intake inclusive of dietary supplements.

So, you can see the estimates here for the EAR, and then remember, when we have an adequate intake, we can't see anything below that, that risk for inadequacy, we simply can characterize the percent of the population that is above the AI to assume adequacy.

And then, the numbers in purple can be interpreted as intakes that are at risk for potential excess, so above the tolerable intake level or above the CDRR, the Current Disease Risk Reduction. For right now, we only have the DDRR for Sodium.

[0:44:12] And so, with the dietary data and taking into account other things that we know relative to potential biomarkers or health outcomes, we really focused our conclusions and statements around these nutrients that are listed in red, and we'll talk a little bit about supplement use during pregnancy and lactation, but it's very difficult to meet the recommendation for iron without the use of a supplement, but then among supplement users, it really increases the proportion above the UL.

[0:44:56] So, we have biomarker data on non-pregnant non-lactating women of similar ages, but we don't have data specific for pregnancy and lactation. But based on transferrin receptor and serum ferritin, about 20 percent of reproductive-age females in the US have biomarkers indicative of low iron status.

So, we don't have dietary data on iodine in the food databases, given the variable nature of iodine in the soil and differential uses of iodine-containing products or ingredients in the food supply.

So, for example, some salt is iodized, some salt is not iodized.

So, it's really challenging to try to estimate dietary intake, but at the group level, median urinary iodine is a pretty good tool to look at population or a group.

[0:46:03] And so, in terms of US pregnant women, the—regardless of what survey years you use, there's two different survey years presented on this slide, the estimate is close to, but it falls below 150, so below where the World Health Organization cut off for insufficiency.

And based on these two publications, we know that dairy consumption, iodized salt, and supplements, prenatal supplements containing iodine, are factors that are related to increasing iodine status.

Reproductive-age females appear to be adequate from their median urinary iodine concentration, but iodine requirements increase exponentially during pregnancy.

[0:46:57] So, based on that, we have some summary of the data here.

As I said, most pregnant and lactating women are using nutrient-containing products. Supplements decrease the risk of inadequacy, but they also increase the risk of high intakes, especially among users for folic acid and iron.

So, without supplement use, it's very difficult to meet iron recommendations. 95 percent of US women who are not taking a prenatal or dietary supplement containing iron would be at risk.

What's interesting is that iron requirements are much lower in lactation, even lower than reproductive-age females, but many lactating women continue to use prenatal levels of iron.

[0:47:58] So, I'm not going to imagine that you recall the last slide, but their percent above the US is higher than that of pregnancy.

So, it's important to note, too, that pregnant and lactating women don't exceed the UL from food sources alone.

So, based on what I have described here, proposed nutrients of public health concern are similar to those that are carried forward from the 2+ - vitamin D, calcium, fiber, potassium, sodium, saturated fat, and added sugars, with the addition of iron in pregnancy.

We wanted to mention, though, there are some of those food components that pose special challenges, and so, given the importance of iodine for cognitive development of infants in utero, we want to keep a close eye on iodine, but are not elevating it at this point, but we would like to hear your thoughts on it.

[0:49:07] Also, folate, for the first trimester, so folic acid is important for closing the neural tube and is associated with risk of neural tube defects. And so, while biomarker data of non-pregnant and non-lactating women do not indicate issues with folate deficiency, we think it should be kept at a special challenge, particularly in the first trimester.

And then, choline and magnesium have been related to health outcomes in pregnancy, but we only have dietary data, and so, we have, from the dietary data, a high prevalence of potential inadequacy, so characterizing that as a food component that poses special challenge.

[0:50:00] Moving on to the relationship of eating frequency and food group and nutrient recommendations.

So, just a reminder of the analytical framework. We look at the frequency of eating with and without naming occasions in a 24-hour period, as well as the hourly distribution and the percent engaging in self-described meals and snacks, and then, we'll provide some data on meals and snacks including beverage events, and then the proportion of total energy that is kind of—we looked at it based on like late in the day eating, so from 8:00 pm to 11:59 pm, we have some data there.

[0:50:57] And we've talked a bit with the Frequency of Eating committee in our joint calls, but this is going look like an overwhelming slide, but I'll try my best to just go over it really quickly.

So, on average, Americans have 5.7 eating occasions per day. Those eating occasions tend to cluster primarily around noon or evening hours. Most people report 3 or 2 meals, and you can see the estimates in paren there.

So, the first blue box focuses on breakfast. So, 85 percent of Americans report breakfast typically between 7:00 and 9:00 a.m. and provides 18 percent of energy. It's less-frequently consumed by 12-19-year-olds, non-Hispanic black Americans, Americans with lower income,

but more energy is obtained in lower-income groups at breakfast relative to other race/ethnic groups.

[0:52:01] And Hispanic-Americans get more nutrients at breakfast than other race/ethnic groups. This should be interpreted with a little bit of caution, because the Spanish-language equivalent for different meals may influence how breakfast was categorized.

Moving on to lunch, 81 percent report lunch generally between 12:00 and 1:00 pm, provides about a quarter of energy. It's less-frequently consumed by Hispanic and non-Hispanic blacks and lower poverty to income ratio groups, especially among children 2-11, and low poverty/income ratio groups consume less energy and nutrients at lunch than other race/ethnic groups.

And the last spot on the right, 93 percent of Americans report dinner generally between 6:00 and 8:00 pm. Around 32 to 36 percent of energy intakes are obtained at dinner.

[0:53:02] Most protein and energy being consumed is at dinner, and it's less-frequently consumed by 12-19-year-olds, Hispanic and non-Hispanic blacks, and low-income children have higher energy intakes but not necessarily nutrient intakes at dinner.

Down on the bottom, there's other data about things that are labeled as extended consumption. Those tend to happen between 6:00 to 11:00 am, and we've talked about that as potentially being drinking a coffee or tea slowly over time. That tends to be what we think of as extended consumption, but of course, it's not limited to that.

So, most Americans snack, and snacking tends to occur most frequently between lunch and dinner, so between 2:00 to 5:00 or after dinner, so 8:00-10:00.

[0:53:56] And then, alcoholic drinks tend to occur between 8:00 and 10:00 pm.

So, our draft conclusion statement, and again, I show you all this data because I can't show you all the data we have, or we'd be here for months…

Various eating patterns exist in America, and this includes the frequency and timing, and they're shaped by age, race/ethnicity, and income. So, we didn't see many sex or gender differences in the broad brush strokes that I showed you in the last slide.

As I mentioned, snacking is ubiquitous. 93 percent of Americans snack. It provides about 22-23 percent of total energy, and usually 2-3 snacks are reported per day.

In terms of those late-night eating events that we talked about, so after 8:00 pm but before midnight, really associated with alcohol intake in adults, and intakes of added sugar, sodium, saturated fat in both adolescents and adults, so about 25-30 percent of those food components are consumed in those later hours.

[0:55:09] When we compare individuals who report two meals versus three meals, those who report three meals have higher HEIs than those who report two meals, and I think those are transposed on the slide, but it tends to be about 5 points higher.

And then, from this, we really—it's hard to say a lot with the type of data with we have, but every eating occasion is a chance to make nutrient-dense food choices. So, shifts in childhood and adulthood snacks and adolescent eating frequency and timing could help with achieving recommendations.

[0:55:57] And then finally, the last question we'll cover today is "What is the relationship between beverage intakes and achieving food and nutrient recommendations?" and this is just to go over the definitions that we've talked about before, but just a reminder of the types of data that we're looking at.

The analytical framework, again, looking at food group and dietary components per 8 ounce of discrete beverage types, beverage contribution and the percent of energy, nutrients, and food components, food groups, and calories, as well as the consumption or prevalence of fortified beverages and cow's milk and milk substitutes.

And I'll focus mainly, though, on the top part of the slide here, with the box around it.

[0:56:55] So, in this slide, you'll get the percent of infants and toddlers consuming different beverage types, at least once on the first 24-hour recall in What We Eat in America and in NHANES 2007-2016.

So, 27 percent of children 6-11 months report consuming human milk on any given day, and that's how you can put these numbers in.

So, this first column's for 6-11 months, and the second column is 12-23 months.

Now, you can see same thing by type of milk, and then other beverages, even including water here on this slide.

And this slide, we're looking at the mean daily energy intake in selected nutrients from beverages among toddlers and infants. So, you can see the orange line there represents older group in the B24, so 12-24 months, whereas the blue bar is 6 to less than 12 months.

[0:58:03] So, we were able to look at that food category sources of nutrients in plain milk in this age group is the primary source of potassium, calcium, and vitamin D, whereas sweetened beverage is the primary source of added sugars.

We've looked at this slide in at least one other meeting, so this is looking at children from NHANES 2015-'16, and those are subdivided by age groups, 3-5, 6-11, and 12-19. And you can see the percent of energy in certain dietary components that are being consumed from beverages.

So, added sugars are primarily from soft drinks and fruit drinks and represents about 16-28 percent.

[0:58:57] And again, plain milk capturing a primary source of calcium, potassium, and vitamin D in these age groups.

This is looking at adults. This slide is keeping all age groups together here for adults, but it's looking at the differences between males in blue and females in green. And again, the percent of energy in different food components being provided from beverage.

I see the chief difference here in adults is that the primary source of potassium is coffee, which is something we didn't see in children and B24. And this is because coffee is not really the best source of potassium, but it's so frequently consumed that it is the top source of potassium from beverages.

[0:59:55] And so, our draft conclusion statements are beverages are diverse in their contribution to food groups and dietary components. Selection of beverage choice can contribute positively to food groups that are below recommendations and nutrients that are underconsumed, as well as dietary components that exceed recommendations.

So, plain milk, calcium-fortified soy beverage, and 100 percent juice contribute to meeting food group and nutrient recommendations without contributing calories from added sugars, and

coffee, without addition of sugar, is a good source and a notable source of potassium among adults.

And then, this is just the last part of these conclusion statements.

So, beverages contribute added sugars, and this is increased from about 30 percent in young children to 50 percent in adolescents.

[1:00:55] And among adults, beverages contribute to nearly 60 percent of added sugars intakes.

The top sources of added sugars are sweetened beverages other than milk and milk substitutes, fruit drinks, sports/energy drinks, smoothies, and coffee and tea, which of course are not naturally sweet, but that is inclusive of sugars that are added to those beverage types.

And then, alcohol. So, this will be the last question, but it's more or less a different part of beverage. So, it has its own protocol due to the unique elements of this question.

For analytic framework, includes looking at the prevalence of alcohol use, binge drinking, and frequent binge drinking, as well as contribution of alcohol to energy, caffeine, and added sugars.

We also examined alcoholic beverages and their contribution to total energy, added sugars, caffeine, and beverage calories.

[1:02:02] I'm getting a warning that's coming up on my computer. Is anyone else seeing that?

Dr. Barbara Schneeman: Yes, I can see it.

Dr. Ronald Kleinman: Yes.

Dr. Regan Bailey: Okay, I clicked it. Can everybody still see these slides?

Dr. Barbara Schneeman: Yes.

Dr. Ronald Kleinman: Yes.

Dr. Regan Bailey: Thanks, you guys. It's like I'm alone, like I'm on an island out here. Well, okay. So, in terms of alcohol use, in 2017, the per capita consumption of alcohol was 2.34 gallons on average per person for Americans age 14 and older.

And just to give some context around that, the Healthy People 2020 objective is 2.1 gallons. So, we're above that recommendations. And 41 states exceed the Healthy People 2020 objective.

[1:02:59] And it really varies by where you are in the country in terms of per capital consumption of alcohol.

So, 17 percent of adults ages 21 to 26, and 65 percent of adults 26 and older have used alcohol in the last month.

About half of alcohol drinkers report binge drinking. So, just as a refresher, binge drinking signs for men is five or more, and for women four or more drinks in one occasion in the last month.

So, alcohol use is lower among older adults, whereas binge drinking can tend to be high among those 21-25. Important to note during ***[indiscernible 1:05:30]*** spring break, I guess.

In terms of some more results, alcohol is reported more frequently between—excuse me, for men than for women on any given day, and a significantly larger proportion of total beverage calories come from alcohol.

[1:04:11] Alcoholic beverages contribute about 4-5 percent total energy intakes.

And then, you can see at the bottom of this slide, the percent of adults who reported this alcohol beverage by specific type, whether that's beer, wine, or spirits.

And then, on the right-hand side, you can see the amounts.

So, men tend to drink beer more often than women, and tend to do so in a higher volume, whereas women have slightly more wine than men, both in terms of amount and percent reported.

And then, for mixed drinks, you can see the data there.

[1:04:57] So, just, I asked the question, this is the total amount of a mixed drink. So, this could be something, a vodka soda. That would be the total volume, not necessary 14 ounces of vodka or other spirits.

So, our draft conclusions around this data are that per capital consumption's gone up. Most adults report consuming alcohol. Among half of drinkers report binge drinking. Alcohol use tends to decrease with age. And reported incidence of alcohol beverages differ by age and by sex. And beyond contributing energy intake, alcoholic beverages contribute little toward meeting food or—food group or nutrient recommendations.

[1:05:56] I thought that was the last question. I'm so sorry. We're going to go on to the last question now, the relationship between added sugar intake and achieving food and nutrient recommendations.

So, we looked at this in terms of usual distribution of added sugars, the percent of the population consuming less than 10 percent, the current recommendations from energy, and then food category source.

So, mean intake of added sugars have decreased significantly over time across all age groups. So, when earlier year's NHANES are compared to a more recent, we see that there is a big decrease from 21 tsp-equivalent to 16 teaspoons-equivalent over time.

Mean intakes of added sugars were lowest for non-Hispanic Asians, but similar across other race/ethic groups.

[1:07:00] And you can see the mean intakes of added sugars in teaspoon-equivalents by race and ethnicity here. So, when I mentioned that non-Hispanic Asians, they're about 9.6 teaspoon-equivalents compared to other race/ethnic groups, which are more similar.

Mean intakes of added sugar is similar across income groups, so hovering around 16 percent.

This slide shows you that nearly 70 percent of added sugars come from five categories, and we've talked about this before, but just by way of refresher, those top 5 categories are sweetened beverages, desserts and sweet snacks, coffee and tea, because of their addition, candy and sugar, and breakfast and cereal bars.

[1:07:55] And so, the top are the actual percent of total added sugars by age group, and then also, provided here, we used a life stage approach in some of our previous meetings, we tend to see,

in the blue bar, sugar-sweetened beverages, these tend to increase and are highest in these age groups, and then tend to decrease again.

So, you can look at those five categories in terms of how they shift with different age groups.

So, our draft conclusion statements are that added sugars have significantly decreased over time, but still remain quite high across all populations that I've mentioned, and we've talked about the source of added sugars and that most added sugars are coming from the five food categories specifically.

And while breakfast cereals and bars are a top source of whole grains, they also contribute added sugar.

[1:09:04] Similarly, with coffee, it seems to be a good source of potassium among adults, but with the addition, is also contributing added sugar.

So, choices with no amounts of added sugar could be made within categories to still help consumers meet the recommendation for those food groups and nutrients that we know are low.

And I think it stands to reason that added sugar intakes could be greatly reduced by decreasing those certain food groups that we talked about contribute the most, the sweetened beverages, desserts, and sweet snacks and candies, and then by potentially having lower-sugar options for coffee, tea, and breakfast cereals and bars.

And now, I promise I'm done.

[1:09:56] So, this is just a slide showing the members of the committee, which is a great privilege of mine to work with these amazing people, both the members of the group as well as the support staff. So, thank you.

And since I'm the first, I have no idea of how to take questions. But I'd be happy to take them.

Dr. Barbara Schneeman: Right. So, yeah, thank you very much, Regan. That was a very thorough presentation, lots of data to look at that and consider.

So, I'm going just sort of have people chime in if they have questions. You can always alert, send me a note if you're having trouble getting questions raised.

I'd also remind you, please be sure to state your name, since we won't have your picture on the screen.

So, we're open.

Dr. Richard Mattes: This is Rick Mattes. Regan, I have a question.

[1:10:57] In the data on formula and mixed-feeding diet, if I remember correctly, you said that those in that category had about 100 kcal greater energy intake per day. They also had higher protein, iron, and zinc.

Is the contribution of protein, iron, zinc in proportion to that 100 kcals, or disproportionate? I'm trying to sort of gauge whether smart decisions are being made there or poor decisions are made there.

Dr. Regan Bailey: You know, that's really something we should follow up on. It seems to be that they're consuming more of everything, so I don't know if there's relative to those specific nutrients or food components, but we can certainly look at that.

Dr. Kathryn Dewey: This is Kay. Can I—can you hear me?

Dr. Regan Bailey: Yes.

[1:11:57] ***Dr. Kathryn Dewey:*** Oh, good. I just wanted to comment that the main reason for the difference in iron and zinc intake, and potentially some of the protein, is that those are total intakes including feeding formula, and the formula is fortified by iron and zinc.

So, it's not necessarily coming from the complementary food portion. And I think what was presented there, the primary difference was just the amount coming from complementary foods and beverages, not from the predominant milk source. Is that right, Regan?

Dr. Regan Bailey: Yeah, yeah. And I think he was asking specifically about those complementary foods. So, within those complementary foods, what are the relative contributions to zinc and iron, and protein, which we haven't looked at those.

Dr. Kathryn Dewey: Right. But you also showed that the kind of quality issues of those complementary foods and beverages were, if anything, a little lower in the formula and mixed-fed infants than in human milk-fed infants.

[1:13:02] ***Dr. Regan Bailey:*** Yeah.

Dr. Kathryn Dewey: So, they're probably not richer in most nutrients. So, that probably does not count for the difference in total iron and zinc consumption.

Dr. Regan Bailey: Yes.

Dr. Richard Mattes: Yeah, so if that's the case, then this is another example of smarter choices being made for those complementary foods.

Dr. Regan Bailey: Absolutely.

Dr. Richard Mattes: Improved diet quality. Yeah.

Dr. Kathryn Dewey: Right. But most of that issue will be in the human milk-fed infants who have much higher risk of inadequate iron, zinc, and protein. So, that was shown in the slides, and that's one of the things we'll be addressing in the ***[indiscernible 1:13:49]***

Dr. Regan Bailey: Yeah, and how to make the most nutrient-dense choices in complementary foods and beverages.

[1:13:58] And this data showed were not inclusive of dietary supplements, but supplement use, particularly for iron and zinc, for example, are really low. So, that's another option for obtaining nutrients for those who may be at risk.

Dr. Kathryn Dewey: Following that logic, Regan, I wonder if you could show again, the slide that shows the food groups for Birth-24 or 6-12 months in particular, which was divided by human milk-fed and formula and mixed-fed?

Dr. Regan Bailey: Yeah, I'm trying to do that. Actually, you know, you have the power to do that, too. Is this the slide you mean?

[1:14:57] ***Dr. Kathryn Dewey:*** No, that's the nutrients. I'm thinking of the foods.

Dr. Regan Bailey: So, if you—

Dr. Kathryn Dewey: I remember where you pointed out—

Dr. Regan Bailey: Not that one?

Dr. Kathryn Dewey: The one before that, I believe. Yeah, there we go. Okay.

So, if you look at the meat line, the beef, veal, pork, etcetera, they'll all infants, and only 14 percent met that in a given day. So, the human milk-fed group is even lower. It's 7 percent, and then 16 percent for the formula/mixed-fed group.

So, you know, just by that we have to think hard about the recommended complementary foods that would meet things like iron and zinc, in particularly the human milk-fed group.

Dr. Regan Bailey: Yeah, without exceeding the formula group. We know from some of the data we worked on through FITS, that baby food and iron-fortified infant cereals have gone down over time, but iron sources in particular, and zinc, particularly for the human milk infants.

[1:16:11] ***Dr. Kathryn Dewey:*** Right.

Dr. Richard Mattes: This is Richard Mattes again. Can I shift—go ahead and finish, Kay.

Dr. Kathryn Dewey: Oh, no, I'm done.

Dr. Richard Mattes: Oh, okay. I was going to change topic to the alcohol data, and you made the point that alcohol contributes a substantial amount of energy. It doesn't itself contribute any nutrients.

But can you comment on the degree to which alcohol consumption is associated with other food patterns, and as a result, in looking at the diet in sort of totality, poses a different level of risk?

[1:17:05] For example, I have an idea, yeah, but does alcohol drinking promote the choice of foods that are high in sodium? So, even though it's not a source of sodium, it's actually associated with a higher-sodium diet. That's just a guess. I don't know.

Dr. Regan Bailey: Yeah, and you're on the line, if what I say is wrong, if you have anything to add. We haven't looked at that specifically, but you're right. We know that 25 to 30 percent of sodium and added sugars are being consumed at the same—in the same timetable, from 8:00 to 12:00. Now, we can't make any causal statements, people who are drinking alcohol are—they're consuming more sodium or added sugar, but it seems like most of those things are occurring at the same time.

So, we haven't specifically looked at it, but we can kind of skirt around it a little bit.

[1:18:00] ***Dr. Richard Mattes:*** Yeah, I would chime in that I agree with Regan. We didn't really look at that. I think there's also a lot of differences in the consumption patterns of people who consume different beverages types, but we don't think that, to my knowledge, that it's an association and not a cause-related.

Dr. Jamy Ard: This is Jamy. So, Rick, I mean brings up another point that I think we pick up on in the dietary patterns discussion, because we had a lot of conversation about that in the subcommittee yesterday regarding what the associated with alcohol intake, especially in dietary patterns that may call out the use of or inclusion of moderate amount of alcohol versus not including that in certain dietary patterns, and the implication of that.

[1:18:58] So, I don't know that we came to a clear sort of conclusion, but it's something that I think will come up again in the discussion later on around dietary patterns.

Dr. Barbara Schneeman: So, Regan, this is Barbara, and I'm going to go back to the sort of patterns over the life stage, and I appreciate your caveat that we don't really have a way to look at a change in the individual, namely the data gives us the data at the population level, but it seems like the data that we have could suggest that, if a pattern is established early, that it's at a population level anyway, it may be carrying over into later life stages. Is that fair to say?

[1:20:03] ***Dr. Regan Bailey:*** Yeah. I think with those caveats, it's pretty fair to say. So, when we look at the top contributors to energy, and different things.

So, this was the energy slide. They're pretty stable at 2 and above, and I think what will be interesting to see how these patterns emerge in that 1-2-year age, because that's really where I think patterns are established and are pretty dynamic. So, I agree.

Dr. Barbara Schneeman: I saw it on the presentation.

[1:20:56] ***Dr. Regan Bailey:*** So, any other questions?

Dr. Barbara Schneeman: Any other questions?

Dr. Linda Van Horn: I'm Linda. Can you hear me?

Dr. Regan Bailey: Oh yeah. Hi, Linda.

Dr. Linda Van Horn: Hi. Sorry, it's hard to know who can hear what. I, again, thank you for the excellent and thorough review, and I'm also kind of going back to what Barbara was saying with the interest in racial/ethic differences in breastfeeding behavior, and thinking about one of the slides that you were showing some of those differences – initiation and duration, and seeing especially that the Asian population continued to have exclusive breastfeeding pretty much longer than anyone else.

[1:21:57] And also, going—thinking about the questions that were related to introduction of complementary food groups before 4 months. One of the things that was interesting, when you start to think about this, is we're looking at these data without recognizing perhaps a contribution to growth and development and weight gain and things of that sort.

And those children that introduce complementary—are introduced to complementary foods earlier, the potential tendency to eat more calories is potentially initiated at that point, that those extra 100 calories could in fact be excessive in some cases, at that early age.

[1:22:53] So, it will be interesting to follow or figure out, over time, whether those recommendations have made, historically, to continue breastfeeding as long as possible, do in fact ultimately impact growth and development of the child and prevention or advance of pediatric obesity.

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

Dr. Linda Van Horn: Because I'll just continue that for a second, I was struck with the topic of protein foods and human milk versus formula-fed infants, and looking at that category in particular, and wondering, again, is it that, or—certainly, they're undereating what's recommended, but in the long run, we don't know, at that point, the size or age of that child, and then whether in fact, or smaller infants, that could be part of really what's contributing to this.

[1:24:06] ***Dr. Regan Bailey:*** Yeah, yeah. That's a good point.

Dr. Kathryn Dewey: This is Kay Dewey again. I still haven't had a chance to say that the difference in energy intake between human milk-fed and formula or mixed-fed infants is not only in the forthcoming complementary foods and beverages, but there also tends to be differences in intake from the milk source.

So, to the higher intakes, again, of formula-fed infants. So, the difference in total energy intake between those groups is actually quite large.

Dr. Regan Bailey: It's both.

Dr. Kathryn Dewey: Yeah, it's both. And there's some debate about whether protein content of infant formula may be partly driving that. So, there's a lot of physiological/biological reasons why it might be driving appetite.

[1:25:02] So yeah, there's a lot of uncertainty, but that's one other factor seems to be.

Dr. Linda Van Horn: That's wonderful. I think that's what's especially exciting to talk about initiating these rounded dietary guidelines, starting at birth, because we'll finally have a chance to look over the life course of diet intake and how early introduction of food, etcetera, really makes a difference ultimately with data backing, that's great.

Dr. Kathryn Dewey: Yeah, I want to point out also, that in the previous meeting, we reported on some of the results regarding the review of timing of introduction of complementary foods, and there is some evidence that introduction before 4 months may be related to a higher risk of overweight later.

[1:26:00] ***Dr. Linda Van Horn:*** Yeah, right. Right.

Dr. Regan Bailey: And I was surprised to see, this is Regan, that 30 percent were receiving foods before 4 months of age.

Dr. Linda Van Horn: Yeah, that's a little troubling.

Dr. Kathryn Dewey: Yeah.

Dr. Barbara Schneeman: So, any other comments or questions at this point?

Okay, I'm going to suggest we take a brief break now, about 15 minutes. And I just would remind all of our committee members, do not exit from the webinar, and probably it's preferable if you keep your phone on mute. We do not want to lose you.

So, please, let's go ahead and take a break until about 20 'till, and then we'll get started again.

Dr. Regan Bailey: Okay, thank you.

[1:27:01] ***Dr. Barbara Schneeman:*** Thank you again, Regan.

Dr. Regan Bailey: Thanks, Barbara.

[Break 1:27:07-1:41:16]

Dr. Barbara Schneeman: Hello, this is Barbara, and I hope everyone is back on the call. I would say if not, their blame is their own.

Dr. Regan Bailey: This is Regan. I'm here.

Dr. Barbara Schneeman: Okay. Great. So, we're ready to move to our next subcommittee report, which is going to be the Birth-24 Months subcommittee report, Dr. Dewey. So, Kay, are you ready to go?

Dr. Kathryn Dewey: Yes, I am. Thanks, Barbara.

Dr. Barbara Schneeman: Great.

[1:41:56] ***Dr. Kathryn Dewey:*** So, everyone should be able to see the slides, and I'd like to begin by thanking the members of the subcommittee who are listed here, and also, all of the staff, who have been doing an amazing job at helping us through the many systematic reviews that we've been conducting.

At the last public meeting, we presented eight different topics and conclusion statements, which was a marathon. We won't have quite so many today, so you can rest easy, and I will not be repeating those.

So today, we'll be discussing three questions that are listed here – Nutrients from supplements or fortified foods and growth, size, and body composition, Nutrients from supplements or

fortified foods and bone health, and Human milk and infant formula and growth, size, and body composition.

The first systematic review that I'll present today is addressing the question, "What is the relationship between specific nutrients from supplements and/or fortified foods consumed during infancy and toddlerhood and growth, size, and body composition?"

[1:43:09] At the last public meeting, we explained that the specific nutrient chose for this particular question was iron, and that we would focus on iron from supplements, not from fortified foods, because iron supplements are recommended for breastfed infants in the US by the AAP.

We did not address iron from fortified foods within this systematic review because systematic reviews on complementary foods, which we presented at the last meeting, included iron-fortified foods.

Therefore, the refined question that we addressed is "What is the relationship between iron from supplements consumed during infancy and toddlerhood and growth, size, and body composition?"

[1:43:58] This is an important question. Some infants actually become iron-deficient before 6 months of age. That is related to their body stores of iron at birth, and that tends to be related to their gestational age, birth weight, and whether delayed cord-clamping occurred.

Because there's a risk of iron deficiency, even before 6 months, the current statement from the American Academy of Pediatrics is to provide iron supplements to breastfed infants at 4 months of age until appropriate iron-containing complementary foods are introduced into the diet.

But iron is one of those nutrients that's a double-edged sword. If you need it, it's important to have enough. If you are iron-replete, excess iron may actually be harmful.

So, it is important to understand, what are the consequences of giving iron supplements to breastfed infants?

[1:45:03] So, here's the analytical framework for the refined question. We were interested in consumption of iron from supplements during the first 24 months of life compared to consumption of iron at a different dosage or frequency from supplements or compared to iron from fortified foods.

And on the right are the outcomes of interest, which included measures of growth, size, and body composition at any age.

This is the flowchart for this search. You can see the numbers of titles screened and abstracts and full texts screened. That ended up resulting in 8 articles from the electronic search and another 2 from the manual search. So, in total, there were 10 articles that we were able to look at.

[1:45:58] Those 10 articles were published between 2002 and 2016, and they were mostly randomized control trials. Most of the evidence was in infants. There was only one study in toddlers. And the studies focused on infants fed human milk.

The interventions and comparators fell into three categories: iron from supplements compared to no iron, and that included studies that had a control group given nothing or given a placebo.

Number two was iron from supplements compared with a different amount of iron from supplements, and that included studies that gave iron at a different dosage or for a different duration.

And the third was iron from supplements compared with iron from iron-fortified foods.

And the outcomes fell into two categories. Sorry, I did not mean to do that.

[1:46:59] Growth or attained size at the time of follow-up.

Now, I want to note that before summarizing the synthesis of the evidence, there were a few studies that reported attained size at follow-up between groups that differed in size at baseline or that didn't report or didn't control for baseline size, and because of that, we did not think about those studies very much further than that in our synthesis, because we were not able to interpret their results.

So, when we examined the evidence comparing iron from supplements with no iron, the evidence was consistent in that no studies reported greater growth in infants given iron supplements.

[1:47:58] Three of the five studies reported significantly slower growth in infants given iron supplements. And two studies did not report a significant difference.

And we noted some possible explanations for these inconsistencies.

First, the population examined by one study in particular, which was conducted in rural China, seemed to have a higher risk of iron deficiency based on a comparison of the average hemoglobin and serum ferritin concentrations of the control or placebo groups at the end of the study. And this study found no significant differences in growth.

Secondly, the studies differed in the extent to which the infants were supplemented with iron-fortified infant formula or iron-rich foods, which may have obscured any effects of iron supplementation on growth.

[1:48:56] And lastly, the timing of the iron supplementation differed among studies. Of the three studies that began iron supplementation by 6 weeks of age, two of the three did not report significant differences in growth between intervention groups, and the third reported significant differences among female but not male infants.

On the other hand, both of the studies that began iron supplementation at about 4 months of age showed significant group differences in growth, and that was slower in the group given iron supplements.

So, this is the next set of questions with different comparisons.

The first one is iron from supplements versus different dosages of iron from supplements. There were three studies in this particular comparison. We couldn't compare them because of heterogeneity in design.

[1:50:00] One of them reported significantly slower growth in infants given iron supplements for a longer duration versus a shorter duration. One study did not report differences in growth between infants given iron supplements at different dosages. And one study, which is the only one in toddlers, did not report significant differences in attained size between toddlers given iron with different dosages.

And then, for the bottom section, which was the comparison of iron from supplements versus iron from fortified foods, there were two studies, and again, they were hetero—there was a lot of heterogeneity, so we couldn't directly compare them.

One study reported significantly-greater growth in infants given the same dosage of iron from supplements compared with iron-fortified infant formula.

[1:50:58] And one study did not report significant differences in growth or attained size in infants given similar dosages of iron from supplements compared with iron-fortified infant cereal.

So, our evidence synthesis resulted in this first conclusion statement. Moderate evidence indicates that human milk-fed infants who are supplemented with iron do not have greater growth and may have slower growth than human milk-fed infants not supplements with iron, and we graded the evidence underlying this conclusion statement as moderate.

The second part of the conclusion statement reflects the gaps in the evidence for the other comparisons. There was insufficient evidence available to determine the relationship between iron from supplements consumed during infancy and body composition during infancy, or in the second bullet, any measure of growth, size, or body composition after 12 months of age.

[1:52:12] And then, the third bullet, the effect of iron supplementation after 12 months of age on the outcomes of interest. And so, the grade was not assignable for these particular questions.

The second systematic review that I'll present today is "What is the relationship between specific nutrients from supplements and/or fortified foods consumed during infancy and toddlerhood and bone health?"

At the last public meeting, we explained that the specific nutrient we chose for this question was vitamin D and that we would focus on vitamin D from supplements due to the current US recommendations for vitamin D supplementation for breastfed infants.

[1:53:00] We did not address vitamin D from fortified foods within this systematic review. Again, because the systematic reviews on complementary foods, which we presented at the last meeting, included fortified foods.

So, the refined question for this review was "What is the relationship between vitamin D from supplements consumed during infancy and toddlerhood and bone health?"

This is the analytical framework for our refined question. We were interested in consumption of vitamin D from supplements during the first 24 months of life compared to consumption of vitamin D at a different dosage or frequency from supplements or compared to vitamin D from fortified foods.

And on the right, the outcomes of interest were measures of bone mass, biomarkers of bone metabolism, Ricketts, and fracture through adolescence.

[1:54:01] So, this is the flowchart for this search. Quite a number of titles were screened. That resulted in 453 abstracts and 39 full texts screened, but most of those were excluded for a number of reasons. And we ended with 5 articles from the electronic database search and 1 from a manual search, for a total of 6 articles.

Those 6 articles were published between 2010 and 2018. They were all randomized control trials. There were 5 studies in total, but those 2 articles were from the same randomized control trial. And all of these focused on infants fed human milk.

[1:54:57] The interventions and comparators fell into three categories: 400 international units per day versus higher dosages, 400 international units per day versus a lower dosage, and 200 IU per day for different durations compared to placebo.

So, please note that 400 international units per day is the RDA for infants from birth to 12 months, and the AAP recommends that infants who are breastfed or partially breastfed should receive a supplement at that dose unless the lactating mother is taking supplements in the amount of about 6,000 IU per day.

The outcomes for this review fell into three categories: bone mass, biomarkers of bone metabolism, and Ricketts.

[1:55:55] So, for the first comparator, 400 international units per day compared to higher dosages, there was inconsistent evidence regarding bone mass. One of the four studies reported positive relationship between the dose of vitamin D and bone mass outcomes, but one of the four studies reported significant inverse relationships between vitamin D dose and bone mass outcomes, and the other two studies did not report significant relationships between the vitamin D dose and bone mass outcomes.

On the bottom, we have the evidence regarding the biomarkers of bone metabolism, and that evidence was consistent. There were three studies, and all three did not report any significant relationships between vitamin D dosage and biomarkers of bone metabolism.

[1:56:56] The next contrast was 400 international units per day compared to lower dosages, and in this case, there was only one study, and that study did not report a significant relationship between vitamin D dose and either bone mass or the biomarkers of bone metabolism.

And the last comparison was 200 IU per day for different durations compared to placebo, and there was only one study. This did not report any relationship between the duration of vitamin D supplementation compared with placebo and the biomarkers of bone metabolism or Ricketts.

So, the conclusion statement from the first part of this review was that limited evidence suggests that there is no relationship between consumption of 400 IU per day of vitamin D under 12 months of age compared with higher dosages of up to 1,600 IU per day and biomarkers of bone metabolism followed up to 36 months of age and we graded this evidence as limited.

[1:58:13] I'd like to note that the literature search date range began in the year 2000. So, evidence related to the recommendation underlying 400 international units per day may predate our search. So, this statement only refers to comparing 400 to higher dosages.

The other note is that high doses of vitamin D in lactating mothers and whether that's related to bone health in their infants was outside of the scope of our systematic review.

[1:58:55] For the other comparisons that I mentioned, the conclusion statement is that insufficient evidence is available to determine the relationship between 400 IU per day of vitamin D from supplements compared with higher dosages and bone mass, Ricketts, or fracture, and also for 400 IU per day of vitamin D per day from supplements compared with no vitamin D from supplements or lower dosages of vitamin D from supplements or vitamin D from fortified foods and bone mass, biomarkers of bone metabolism, Ricketts, or fracture, so the grade was not assignable for these two conclusions.

And the same caveats apply here in terms of the literature search, date range, and the fact that dosing mothers with vitamin D was outside of the scope of our review.

[1:59:55] So, the last systematic review that I'll discuss today is "What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and growth, size, and body composition?"

At the last public meeting, we explained that differences in growth and size between infants fed human milk and infant formula are already well-established but that the associations between infant feeding and body composition, including obesity, are less clear.

So, we refined our question, which is shown here, to say, "What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and body composition, including obesity?"

Here is our refined analytical framework.

[2:00:57] We divided the duration, frequency, and volume of exclusive human milk and/or infant formula consumption into a series of six comparisons that align with the first feeding decisions that caregivers make, and that includes whether or not to feed human milk, and then for caregivers who decide to feed human milk, how long to feed human milk at all, and then how long to feed human milk exclusively.

You'll note that we examined exclusive human milk consumption prior to the introduction of infant formula only, and that was to avoid overlap with the other review presented at the last public meeting that examined the timing of introduction of complementary foods and beverages.

And then, for caregivers who decide to supplement human milk with infant formula, we wanted to examine the intensity of proportion or amount of human milk that is fed and whether caregivers are feeding one or both substances during a single feeding session with the thought that feeding both human milk and infant formula during one feeding session may be topping off and may represent overfeeding.

[2:02:18] And finally, for caregivers feeding human milk at the breast and by bottle, we wanted to examine the intensity of proportion or amount of human milk fed at the breast versus at the bottle.

And on the right, you can see that our refined list of outcomes includes an intermediate outcome, which is rapid weight gain from birth to 24 months, as well as the endpoint outcomes related to body composition, BMI, BMIz score, weight for length, overweight, and obesity at any age.

[2:03:01] Now, in looking at all of the papers that were screened for that review, and given the time frame for completing our review, we have some updated criteria for what we will be able to examine.

And the first of those is that we've decided to examine the most recent evidence from our literature search, which is from the years 2011 up to September of 2019.

And we've also decided to examine within-family analyses of siblings from the entire literature search date range of January 1980 to the present. And what that means is that these studies are able to compare siblings within the same family who were fed differently, either mostly breastfed or not, for example, or siblings with different outcomes, in other words, they became overweight or not, and then the study looks back at how they were fed as infants.

[2:04:15] And this is a very useful strategy to control for confounding by many different potential variables.

If someone is typing, so if you could please mute, that would be helpful. Thanks.

This flowchart shows the literature search and the screening results. We used two different literature searches, which are noted with the letters A and B in the flowchart.

Literature search A was from the Pregnancy and Birth to 24 Months Project, which used a search date range of January 1980 to March 2016.

[2:05:03] And that literature search was very large, because it was intended to find studies for several questions related to human milk and infant formula, so you can see that there were 31,335 abstracts screened for that.

Literature search B was smaller, because it was intended to capture just the literature published in the last 3 years, and that was around 2,000 abstracts.

You can see that, ultimately, down at the bottom, 81 articles were identified that met the inclusion criteria for the question about human milk and infant formula and body composition, including obesity.

So, this slide gives you a snapshot of the evidence available.

[2:05:59] On the left column, you can see the six exposures that I described on the analytical framework, and across the top, you can see the age groupings based on the outcome measurement, so between the birth and 24 months, 2-5 years, 6-11 years, 12-19, and then 20+. And those are age groupings used in the NHANES.

So, you can see that the majority of the evidence addressed ever versus never consuming human milk or the duration of any human milk with the outcomes that we are interested in over those age intervals.

For the remaining topics, down below, you can see very, very few studies. So, they will not be the focus of our evidence synthesis, and clearly, those will be research recommendations that we will be sure to include to address these gaps in the evidence.

[2:07:10] Now, almost all of the evidence for this question was observational studies, and that's not surprising given that, ethically, it's very difficult to do a randomized trial in which you randomly assign infants to be fed human milk or not.

The notable exception is the trial called the PROBIT trial, Promotion of Breastfeeding Intervention Trial, which is a cluster randomized trial of an intervention to promote the duration and exclusivity of human milk consumption, so not a randomized control trial of breastfeeding per se, but of an intervention to promote breastfeeding.

[2:07:55] Now, there were 24 articles from 17 independent US cohorts, as well as studies from several other countries that we identified in this search, and the outcomes fell into four major categories: overweight and obesity, BMI, BMIz score, and weight for length as continuous measures, and trajectories, for example, rapid infant weight gain or BMI trajectories, and body composition.

Now there's quite a lot of evidence to cope with for this, and given the abundance of evidence, we decided to start with the most salient public health outcome of that list, which is overweight and obesity, and we are still in the middle of reviewing that evidence.

We're starting with examining outcomes that are from 2 years of age and older because of uncertainty about how to interpret earlier outcomes.

[2:09:02] We know that in the first 2 years of life, the infant's overweight status or body composition is very dynamic and not necessarily predictive of overweight risk later in life, but after 2 years of age, that is more predictive.

In addition to looking at these studies in the way that we've described, we, as I mentioned, we will augment our review of this most recent evidence with a review of the Living Family Sibling Analyses over the entire search range, and these studies, as I said, help to overcome residual confounding, which is pervasive in the observational research on this question because of sibling's shared genetic and environmental factors.

[2:09:54] And to our knowledge, this will be a novel contribution to the field, so we're quite enthusiastic about tackling the question this way.

And that is the end of my formal presentation. Again, I'd like to thank all of the members of the subcommittee and the fantastic support staff for their assistance.

So, I'm available for questions.

Dr. Regan Bailey: Kay, this is Regan. Well, do you know what the doses of iron supplements were?

Dr. Kathryn Dewey: Yes. I can quickly tell you that they varied. For example, one of the US studies gave 7.5 milligrams of iron from 4-9 months of age. Another one gave 1 milligram per kilogram of body weight per day from 4-9 months.

[2:11:06] And the one in rural China gave 1 milligram per kilogram of body weight per day. So, those are the types of dosages, for the most part.

Dr. Regan Bailey: Thanks.

Dr. Kathryn Dewey: Sure.

Dr. Ronald Kleinman: Kay, it might be worth just commenting, again, on these iron studies, on the—on the actual weights of these infants. Because I think they didn't fall out of—outside of reference standards, so they were lower, but still within normal reference standards. Is that right?

Dr. Kathryn Dewey: The average weights and lengths of the infants would have, yes, fallen within reference ranges. I can't say that each individual baby would have done that.

[2:12:04] So, we're looking at the averages.

And in terms of the—yeah, the magnitude of the differences varied from study to study, and these are generally were pretty short intervals. For example, a 5-month study period. So, they need to be interpreted in terms of what that might or might not mean, which is hard to say.

Dr. Ronald Kleinman: Yeah, thank you.

Dr. Kathryn Dewey: Sure.

Dr. Barbara Schneeman: Do we have other comments or questions from the group? Thank you, Kay, for really great presentation of where your subcommittee is.

[2:13:01] And I know there's going to be a lot of interest in the work that you're finishing up now.

And if there are no additional questions for Kay and this subgroup, we could move to our next subcommittee report.

Dr. Sharon Donovan: I can—I'm happy to do that, if we're ready.

Dr. Barbara Schneeman: So, why don't we go ahead? And then, there may be more questions evolving as the discussion goes on. Thanks, Sharon.

Dr. Sharon Donovan: Okay.

Dr. Barbara Schneeman: So, the next presentation—let me just say, the next presentation then will be Sharon Donovan, the subcommittee is Pregnancy and Lactation.

[2:14:03] ***Dr. Sharon Donovan:*** Okay. Well, good morning, everyone. This is Sharon Donovan, and I'm happy to present on behalf of our committee. And today, I will be discussing the evidence synthesis, grading, and conclusion statements for four reviews, and the summary of the evidence for one review.

This slide and the next slide summarize the questions that the Pregnancy and Lactation subcommittee will be addressing. The font that is grayed out are ones that were presented in the January meeting. And today, I will be discussing the relationship between dietary patterns, gestational weight gain, postpartum weight loss, and neurocognitive development of the infant.

I will also discuss the relationship between maternal diet—whoops—and food allergies and atopic diseases in the offspring.

[2:15:09] Lastly, I will—this slide's separate, just summarize the questions related to nutrients from supplements and fortified foods. Again, the questions in gray were presented in January and October, and today, we will be presenting just the evidence for omega-3 and neurocognitive development of the offspring, and we still need to grade those final statements.

So, moving to the first question, which was "What is the relationship between dietary patterns consumed during pregnancy and gestational weight gain?"

[2:16:00] This shows the analytical framework. Again, we followed the intervention and exposure and comparator of similar questions related to dietary patterns. The population was women during pregnancy, healthy or at risk for chronic disease.

We defined gestational weight gain as the change in maternal body weight from baseline, which could be before or during pregnancy, depending on the study, to a later time point during pregnancy and/or right before delivery.

Weight gain was also assessed in relationship to weight gain recommendations based on pre-pregnancy BMI, and again, the population was women during pregnancy.

And our key confounders are summarized below, and those are fairly consistent with the—actually, this should have been updated.

[2:17:00] This key confounder is not—we noticed was not correct. So, I have—I'm sorry that didn't get posted.

The key confounders that we have are age, race/ethnicity, socioeconomic status, physical activity, pre-pregnancy BMI, smoking, history or diagnosis of gestational diabetes or gestational hypertension, and parity. And those will be corrected on the final slide that will be posted. Again, I apologize for that.

This shows the flow diagram for the literature search and the screening results. I will note that we did a combined search for the impact of dietary patterns consumed during pregnancy and lactation on both gestational weight gain and postpartum weight loss, which I will present next.

[2:18:03] For gestational weight gain, we started with a little over 11,000 articles and ended up with 25 that met our inclusion criteria. Of those, four were RCTs, and there were 9 prospective cohort studies, which contributed 21 total articles.

This slide gives an overview of the evidence, and as you can see, there was a wide range in the numbers of participants per study, a low of 35 to a little over 66,000. Studies were conducted across the world, including eight in the US.

[2:18:56] Most of the participants were between the ages of 18 and 45. The majority were white, or the race/ethnicity was not reported. And most were mid- to high-socioeconomic status.

There was also a lot of different ways of dietary patterns were assessed based on indices or scores, factor analysis, or principle component analysis, interventions with experimental diets, reduced rank regression, and macronutrient proportions.

And I will note that, because of when this search was done, we did include macronutrient proportions rather than just looking at other sort of known dietary patterns or reported dietary patterns.

We, as noted, there were several different ways gestational weight gain was reported, so adequacy, total weight, gestational weight gain, the rate of gestational weight gain, gestational weight gain for a specified time period or trimester.

[2:20:04] So, as you can see, it's a very complicated data set.

There were three—so this is the summary of the data for the RCTs. Three RCTs assessed the effect of the Mediterranean diet. Two of the three showed that the intervention group had a significantly lower gestational weight gain compared to the control group.

The third RCT showed that women assigned to a Mediterranean diet with extra virgin olive oil tended to have lower weight gain until the second trimester but not for the full duration of the pregnancy, not total gestational weight gain.

Some of the limitations were researchers were not blinded. In some cases, the outcome assessment methods were unclear.

[2:20:58] Deviations from intended interventions. No preregistration data analysis plan. And limited consistency, directness, precision, and generalizability.

For the prospective cohort studies, 13 of 19 showed an association between maternal dietary patterns and gestational weight gain. We categorized the results in several different ways. Greater adherence to a dietary pattern identified as beneficial by the study was associated with lower gestational weight gain for six studies. Greater adherence to a dietary pattern identified as detrimental by the study was associated with a higher gestational weight gain.

The third: greater adherence to a beneficial dietary pattern, which could include DASH, or DASH/OMNI, or Mediterranean diet, or Healthy Eating Index, was associated with a higher gestational weight gain.

[2:22:01] And the last: a greater adherence to dietary patterns derived by reduced rank regression was associated with higher gestational weight gain.

Again, these were prospective cohort studies. We identified a number of limitations in these studies. Therefore, our draft conclusion statement for this body of evidence is that limited evidence suggests that certain dietary patterns during pregnancy are associated with a lower risk of excessive gestational weight gain during pregnancy. These patterns are higher in vegetables, fruits, nuts, legumes, and fish, lower in added sugar and red and processed meats.

We also wanted to note that there were—we also looked at whole grains and dairy, but the results were mixed, and therefore, we removed that from our conclusion statement.

[2:23:01] And overall, we considered the—we graded this as limited.

I want to note that not all of these foods were part of the same patterns. This was generally a conclusion of foods that were commonly found in patterns that were associated with lower gestational weight gain.

So, the next question that we addressed was "What was the relationship between dietary patterns consumed during lactation and postpartum weight loss?"

Again, our analytical framework, similar intervention/comparators, our population, and for both the intervention and the endpoints are now women during lactation.

Again, we looked at change in weight from baseline in postpartum to a later time during the postpartum period, and we also looked at postpartum weight retention if gestational weight gain is controlled for.

[2:24:06] So, this is the key confounders for this search. So, we looked also, keeping in mind pre-pregnancy BMI and gestational weight gain, and breastfeeding practices, both duration and exclusivity.

Again, as I noted, this was a combined search. Sorry. And we only found one paper that addressed the question of "What is the relationship between dietary patterns consumed during lactation and postpartum weight loss?"

This was a randomized control trial. The study was conducted in the US with 129 participants. They were all lactating ***[indiscernible 2:24:55]***.

Okay, somebody needs to mute themselves, whose coughing.

[2:25:00] They were predominantly non-Hispanic white and well-educated.

The interventions was a Mediterranean diet versus the USDA My Pyramid diet. Was initiated at around 17 ½ weeks postpartum. And the duration was 4 months.

And they reported postpartum weight loss as the weight change from baseline to 4 months, so at the beginning of the initiation.

So, the summary of this evidence is basically there were no statistically significant differences in postpartum weight loss between the two groups, so, the group on the Mediterranean-style diet versus the My Pyramid diet.

Some notable limitations. Obviously, lack of blinding of participants and investigators. There was a relatively high attrition rate. There were some issues with implementing the intervention and concerns about adherence.

[2:25:59] Therefore, we concluded that there's currently insufficient evidence available to determine the relationship between dietary patterns consumed during pregnancy and lactation and postpartum weight loss, and we did not assign a grade.

So, the next question was "What was the relationship between dietary patterns consumed during lactation by the mother and developmental milestones, including neurocognitive development of the offspring?"

So, our analytical framework is shown here. Again, we're looking at adherence to a dietary pattern versus a different dietary pattern or level.

The outcomes were consistent with what we have used in previous searches, looking at developmental outcomes.

[2:27:03] So, these included milestones of achievement, and cognitive, language, motor, movement, physical, socioemotional. We also assessed whether studies that reported academic performance, ADD/ADHD, anxiety, depression, and autism.

So, the population was birth through 2-18 years of age.

Again, some of the standard key confounders. When we were—we're assessing neurocognitive outcomes. They have been consistently including maternal substance abuse, family history or diagnosis of neurocognitive disorders, and also, complementary feeding as other factors to be considered.

So, this shows the flow.

[2:27:57] So, you see there were 30—a little over 3,000 titles screened, of which no articles met the inclusion criteria.

Therefore, we concluded that no evidence is available to determine the relationship between maternal dietary patterns consumed during lactation and developmental outcomes on neurocognitive development, and we're unable then to assign a grade.

So, now I'm going to launch into the largest part of our presentation today, which is "What is the relationship between maternal dietary intake during pregnancy and lactation and the risk of infant and child food allergies and atopic allergic diseases?"

So, again, we were looking at dietary intake of foods or food groups compared to no food or a different amount of dietary intake of the same food or food groups.

[2:29:02] Women during pregnancy are the population.

For the comparator and intervention, so we looked at food allergies, food sensitization, allergic rhinitis, atopic dermatitis, and basically, from birth to 18 years of age.

For the outcome of asthma, we focused on just children and adolescents 2-18 years of age, since it's difficult to diagnose asthma under 2 years of age.

So, some of the—okay, somebody needs to mute their phone. There's a lot of background.

So, in terms of the key confounders, we included family history of atopic allergic diseases, mode of delivery, breastfeeding practices, timing of introduction of complementary foods and beverages, types of complementary foods and beverages, also urban/rural environment.

[2:30:05] So, these are factors that have been associated with increasing the risk of food allergies and atopic allergic disease in other studies.

We also included—sorry—animals, pets, farming exposure.

And again, other factors to consider, probably most pertinent, indoor/outdoor environment.

So, we did a search, one combined search for all of the outcomes, which resulted in 39 papers that met our criteria.

I'm still hearing somebody turning papers or something, so please verify that your phone is muted.

Of those 39 articles, there were 6 RCTs, providing 8 articles, 1 non-randomized control trial, and 14 prospective cohort studies, producing—providing 31 articles.

[2:31:09] So, this is a description of the evidence overall. The studies ranged from 62 to nearly 62,000. They were conducted across the world: Japan, UK, the US, Denmark, etcetera. The maternal mothers, average age was approximately 30 years of age, majority white and/or race/ethnicity not reported, mid- to high-socioeconomic status.

So, the various interventions were food or beverage consumption level, predominantly from the prospective cohorts, avoidance diets, or dietary pattern adherence.

[2:32:03] These are the outcomes, and we are—we reviewed the evidence for each of these outcomes separately, and therefore, have a number of statements or draft conclusions that we've reviewed and graded, so I will be going through each of these separately.

So, the next few slides will review the evidence for atopic dermatitis.

So, we divided this up by pregnancy, pregnancy and lactation, or lactation alone as the period of time for the maternal diet, and then within that, we've separated it out by categories.

So, the first category showed that there was no association found between consumption or restriction and the risk of atopic dermatitis or eczema.

[2:33:04] So, this was observed for cow milk products in 6 of 7 studies, egg in all 4 studies, peanut both studies, soybean, and dietary patterns.

We also found some studies which reported a higher consumption of foods was associated with a reduced risk of atopic dermatitis, and this was, again, you can see, not quite as consistent as this category, but we observed that for studies investigating yogurt, fish, wheat, vegetables, and fruits.

And finally, there was 1 study showing that higher consumption was associated with increased risk, and this was shown for 1 of 4 prospective cohorts for meat.

[2:33:59] For pregnancy and—for exposures during pregnancy and lactation, there was no relationship between restriction of cow's milk products and eggs and the risk of atopic dermatitis.

For 1 non-randomized control trial and 2 RCTs showed that restriction of cow milk products reduced the risk of atopic dermatitis and eczema.

And there was 1 RCT looking at this intake—restriction during lactation alone, and it found that, for cow milk products, restriction reduced the risk of atopic dermatitis and eczema.

So, now, I'm going to go through a number of draft conclusion statements and grades for relationships between various foods or food products and atopic dermatitis.

[2:34:59] So, moderate evidence suggests that lower or restricted consumption of cow milk products during pregnancy does not reduce the risk of atopic dermatitis in the offspring, and we graded this as moderate.

We felt there was insufficient evidence is available to determine the relationship between restricted consumption of cow's milk products during both pregnancy and lactation or lactation alone on the risk of atopic dermatitis and eczema, mainly due to the low numbers of studies, and so, grade not assignable.

Next, for egg, we—our draft conclusion is that moderate evidence suggests that lower or restricted consumption of egg during pregnancy or during both pregnancy and lactation does not reduce the risk of atopic dermatitis and eczema in the offspring, so moderate grade.

[2:36:00] For fish, limited evidence suggests that maternal fish consumption during pregnancy does not increase the risk of atopic dermatitis in the offspring, limited grade.

For tree nuts and seeds, there was no evidence available to determine the relationship between maternal tree nut and seed consumption during pregnancy and the risk of atopic dermatitis and eczema in the offspring, so grade not assignable.

In terms of dietary patterns, there's limited evidence suggesting that dietary patterns during pregnancy are not associated with the risk of atopic dermatitis and eczema, and there were 6 studies in this, and none of them showed a relationship, but again, there were concerns about the quality of the studies, which resulted in a limited conclusion and grade.

[2:37:04] So, this is basically a conclusion statement that's summarizing a number of foods. So, insufficient evidence is available to determine the relationship between maternal consumption of peanuts, soybeans, wheat and cereal, meat, vegetables, fruit, yogurt, and probiotic milk products during pregnancy and the risk of atopic dermatitis and eczema, a grade not assignable.

This is during lactation. So, we found no evidence was available to determine the relationship between eggs, fish, peanuts, tree nuts and seeds, soybeans, wheat/cereal, meat, vegetables, fruits, dietary patterns, yogurt, and probiotic milk products during lactation and the risk of atopic dermatitis, grade not assignable.

[2:37:55] So now, we're turning to the next outcome, which is food allergy. And let me just look at my notes. Unfortunately, we don't get to see our notes when we're doing this.

So, for food allergy, we had a total of 7 studies that met our inclusion criteria. They were conducted either during pregnancy or pregnancy and lactation. There were no studies conducted during lactation alone.

So, for pregnancy, there was no association between the consumption and risk of food allergies for cow milk products, egg, soy, and wheat.

Higher consumption of peanut was associated with a reduced risk of food allergy.

And again, no association between restriction of cow milk products and risk of food allergy in the offspring.

[2:39:01] So, our draft conclusion statements for maternal soybean consumption and food allergy, limited evidence suggests no relationship between maternal soybean consumption during pregnancy and the risk of food allergy, with a grade of limited.

Of cow milk products, there's insufficient evidence is available to determine the relationship between lower or restricted consumption of cow milk during pregnancy alone or during both pregnancy and lactation and the risk of food allergy, so grade not assignable.

For—this is a category that we're calling foods not commonly considered to be allergens but were evaluated in some studies.

[2:39:57] So, for the first, we found that no evidence was available to determine the relationship between maternal consumption of foods not commonly considered allergens during pregnancy and the risk of food allergy in the offspring, and there's insufficient evidence available to determine the relationship between maternal consumption of these foods during lactation and food allergies, so for both draft conclusion statements, there's grade not assignable.

And the conclusion statement for the specific foods, insufficient evidence is available to determine the relationship between maternal consumption of peanuts, eggs, wheat during pregnancy and the risk of food allergy, and again, this—although there was one study with peanuts, it was a single study. Therefore, we felt that there was insufficient evidence, and grade not assignable.

[2:40:59] There was no evidence available to determine relationship of maternal consumption of fish or tree nuts and seeds during pregnancy or during lactation and food allergy in the offspring, and no evidence to determine the relationship between maternal consumption of cow milk products, eggs, peanuts, soybean, and wheat during lactation on risk of food allergy.

So basically, there's kind of a dearth of studies looking at maternal food consumption or avoidance during lactation on the offspring, and it's actually consistent with recommendations, but it doesn't provide evidence for us to be able to evaluate.

So now, we're turning to the topic of allergic rhinitis.

[2:42:00] We had a total of 17 studies that met the inclusion criteria. There was studies conducted during pregnancy and pregnancy and lactation. During pregnancy, there was no association between the consumption or restriction of the following foods and the risk of allergic rhinitis in the child, so these are cow milk products, both fermented or non-fermented, egg, tree nut, soybean, wheat, or overall dietary patterns, so no association.

There was some studies, 1 of 2 prospective cohorts in each of these categories that showed higher consumption of either fish or peanut was associated with reduced risk of food—I'm sorry, this should say allergic rhinitis, not food allergy in the offspring.

[2:43:05] And then, for pregnancy and lactation, there was no association between the restriction of cow milk products and risk of allergic rhinitis.

So, the draft conclusion statement for cow milk products and allergic rhinitis is that there's insufficient evidence available to determine the relationship between consumption of cow's milk products, fermented or non-fermented, during pregnancy alone or during both pregnancy and lactation, on the risk of allergic rhinitis, so grade not assignable.

For egg, there's moderate evidence suggests that a lower or restricted consumption of egg during pregnancy does not reduce the risk of rhinitis, allergic rhinitis, with a grade of moderate.

[2:43:58] For seeds, there was no evidence available to determine the relationship between maternal seed consumption during pregnancy or during lactation on the risk of allergic rhinitis, grade not assignable.

In terms of dietary patterns, there was limited evidence suggests that dietary patterns during pregnancy are not associated with the risk of allergic rhinitis in the offspring, with a grade of limited.

And this is a statement that encompasses a number of foods where there was insufficient evidence to determine the relationship between maternal consumption of fish, peanuts, tree nuts, soybeans, wheat, and foods not commonly considered to be allergens during pregnancy and the risk of allergic rhinitis, grade not assignable.

[2:44:57] And for lactation, again, no evidence was available to determine the relationship between maternal consumption of these foods, as well as dietary patterns during lactation and the risk of allergic rhinitis in the offspring, so grade not assignable.

So now, turning to asthma. We found that there were—we call these would be only children age 2 and above, and we found the total of 21 studies that met the inclusion criteria. Currently, we only have draft conclusion statements and grading for 2 of these, and the rest, we have draft conclusion statements, but we have not yet finished grading those, so those will not be presented today.

[2:45:55] So, during pregnancy, there was no association between consumption, restriction of egg and risk of asthma, and for fish, higher consumption was associated with a reduced risk for asthma in 1 of 3 prospective cohort studies.

So, the draft conclusion statements, limited evidence suggests no relationship with maternal consumption of egg during pregnancy and the risk of asthma in the offspring, a grade of limited.

And no evidence is available to determine the relationship between maternal egg consumption during lactation and the risk of asthma in the offspring, grade not assignable.

And for fish, again, limited evidence suggests no relationship between maternal fish consumption during pregnancy and risk of asthma in the offspring, grade of limited.

[2:46:57] And no evidence is available to determine the relationship between maternal fish consumption during lactation and risk of asthma, so grade not assignable.

So, that summarizes all of where we are to date with looking at the relationship between maternal dietary consumption during pregnancy and/or lactation on these allergy and atopic outcomes in the offspring.

So, the last question that I'm going to be presenting today, which we—I'll just be presenting the evidence. We are in the process of drafting the conclusion statements. But this question was related—was "What is the relationship between omega-3 fatty acids from supplements and/or fortified foods consumed before and during pregnancy and lactation and neuro-developmental milestones, including neurocognitive development in the offspring?"

[2:48:03] And I will note that when the subcommittee met in Houston, we discussed this, and we decided to focus our efforts and our search on looking at omega-3 fatty acids from supplements, because the fats and seafood committee had evaluated the effect of omega-3s from fish from the diet on these outcomes in the infants.

And we also thought that there was a larger body of evidence with supplements, and that the risk for overconsumption of omega-3 fatty acids could be more likely from supplements.

So, this shows the analytical framework. So again, we're looking at exposure to omega-3 fatty acids from dietary supplements, which could include multi-nutrient supplements, and then the dietary—the comparator was a different level of supplements.

[2:49:12] So here, we looked at women who could be consuming this before pregnancy, but also during pregnancy and/or during lactation. They could be healthy or at risk for chronic disease.

And again, our outcomes were the same as we've used previously for developmental milestones and neurocognitive development, and we looked from birth to 18 years of age.

So, some of the key factors included, as a confounder, we included fish and other seafood consumption, breastfeeding practices, gestational age, child sex, parity, etcetera.

[2:49:55] We put under other factors to consider: maternal substance use, family history or diagnosis of neurocognitive disorders and complementary feeding.

This shows the flow chart. So, the initial titles screened were nearly 1,400. We ended up with 34 articles that met the inclusion criteria.

So, these 34 articles came from 14 randomized control trials, which produced 33 of the articles, and one prospective cohort. Therefore, we feel that this was actually a fairly strong data set, because it's predominantly including RCTs.

So, of these articles, many were conducted in Australia, but also the US, Mexico, Denmark, Germany, Hungary, Spain, The Netherlands, Canada, and Iran.

[2:51:03] The RCTs included an omega-3 supplement versus placebo. The prospective cohort study, the average supplemental omega-3 dose was 100 milligrams per day. There was various timing of the interventions during pregnancy. The 8 RCTs, the 1 prospective cohort, during lactation or during pregnancy and lactation.

And so, we are just getting—evaluating this evidence. Our goal is to complete this within the next week. But there's quite a bit of evidence here for us to evaluate, grade, and produce draft conclusion statements.

We also have a number of outcomes. So, cognitive, visual, language, motor, socioemotional, ADHD and ASD.

[2:52:01] So, our next steps to finish off our charge for this committee is to—we need to still grade the remaining draft conclusion statements on maternal diet and asthma. As I mentioned, we've only done egg and fish right now. And to draft the conclusion statements and grade the evidence for omega-3 supplementation during lactation and pregnancy and lactation and neurocognitive development.

I think that was my last slide. So again, really thanking the subcommittee members for all of their hard work, and particularly, the support staff. From the time between our meeting in Houston and this meeting was exceedingly short. And there was, as you can see, a lot of evidence for us to get through. So, I guess I'm very thankful for everybody putting in long days and pulling this evidence together.

[2:53:05] I'm happy there—to take questions.

Dr. Barbara Schneeman: Thank you so much, Sharon. I think my mind was starting to spin when I start thinking of all the papers that have been collected and screened and looked at. It's a tremendous amount of work to go into our report.

I had a couple of questions, and I'll let others join in as well.

I know that you used, when you talked about dietary patterns, you used that in sort of generic way, where you had draft conclusion statements. Was there a specific type of dietary pattern that was looked at, or is there a way of characterizing, or will you be able to characterize it in the report?

Dr. Sharon Donovan: Yeah, I think the only place that we really looked at the dietary patterns was with the gestational weight gain.

[2:54:01] And the way that—I don't think there was really sufficient evidence for us to say a DASH diet, or a specific diet, or a proportion.

So, I was going to go back. As you can see, we basically made a general statement at this point about the dietary patterns are patterns of consumption that focus on these—let me see. That should be here, very close to here.

Higher in vegetables, fruits, nuts, legumes, and fish. So, as I stated, this—there wasn't one study necessarily that looked at all of these things, but as we looked at the studies that may have been focusing on a specific food or a pattern, that these were the ones that came out as being associated with a lower risk of excessive gestational weight gain.

[2:55:02] And a pattern that had more sugar and red and processed meats were more associated with a higher risk of excessive gestational weight gain.

Dr. Barbara Schneeman: So, I thought you referred to dietary patterns in the—when you were talking about the food allergy and some of the atopic dermatitis, and that's where it seemed—basically you were saying you didn't really find that there was one specific pattern you could pull out?

Dr. Sharon Donovan: Yeah. So, like I said, there were 6 studies, I'm looking at that in my—that was in atopic dermatitis, which was really the main one that we were able to look at dietary patterns. I have in my notes the different patterns.

[2:55:57] But there were—most of this was from prospective cohort studies, where they gathered information about dietary intake, sometimes through food frequencies or interviews, and then they assigned a dietary pattern, which could be very different. In the Japanese diet versus Chinese diet.

And so, but the bottom line is none of them showed any association. So, based on the fact that these were sort of retrospective, they weren't RCT studies, and that they were pretty consistent in not showing an association, I think is why we didn't go into more depth about that. But if that's something that we can certainly consider in writing the report.

Dr. Barbara Schneeman: Okay, yeah, just to make it clear what was looked at.

And then, I also had a question where you're looking at the omega-3, where you're including multiple nutrient supplements.

[2:57:05] Now, are you looking for ones where it could be multi-nutrient, but you still have some control as to with or without omega-3? I just—

Dr. Sharon Donovan: Right, or a different level.

Dr. Barbara Schneeman: Oh, okay. So, you're still trying to control for the omega-3 content?

Dr. Sharon Donovan: Yes.

Dr. Barbara Schneeman: Okay.

Dr. Sharon Donovan: Right, so there would be a different level too, so maybe no omega-3s, but they're receiving other multi-nutrient supplements, or they may be exposed to a different level of supplement.

Dr. Barbara Schneeman: Okay.

Dr. Sharon Donovan: Yeah, there's—I'll try to recall the details of these studies, but there's so many of them that I may not be able to remember all the details of the studies. So, I will probably not may—I will not be able to remember all the details of the studies.

[2:58:07] ***Dr. Barbara Schneeman:*** Yeah, it's a lot, a lot to be looking at.

So, other questions or comments before we break for lunch?

Dr. Richard Mattes: This is Rick. I'd just ask a general question. In trying to identify a relationship between any kind of specific food, or even food group, and an outcome, seems problematic, because any one food contributes so little to the total diet.

What is your sense of just that approach to trying to answer questions here?

[2:58:55] ***Dr. Sharon Donovan:*** Well, that's a good point, and I'll also open it to other committee members to comment. I mean basically, the literature that we had to evaluate was, in general, trying to focus on a specific food group, and I should have mentioned before that most of the RCTs were also conducted in higher-risk groups.

And so, we will be incorporating that into the report.

So, a lot of the RCTs may have been a family where there was a sibling or a parent with—that had a history of atopic diseases, and so, that's why they were specifically going in and intervening with the avoidance of a food.

So, I think I get your point, but I think the mechanism here with the allergies is not that "Well, oh, eggs are only providing 2 percent of our calories," as much as for somebody who's sensitive, even a very small exposure could be important.

[2:59:57] So, again, we had the evidence that we had, which, in many cases, were looking at specific RCTs where they were avoiding that food for the specific purpose of trying to reduce the risk of that offspring developing it, or they were in a prospective cohort, looking at the relationship between that child getting a cow milk allergy and their overall food intake.

So, did that kind of answer your question?

Dr. Richard Mattes: Yeah, yeah, I think. Good point that, in this instance, where it may be very small exposures can have more marked effects makes this different from other outcomes, where it's more a factor of quantity consumed that may be playing a role. Yeah, well-put. I get it, yep.

[3:00:57] ***Dr. Barbara Schneeman:*** Other questions or comments?

So, at this point, we can go to our break that we have scheduled for lunch. Sorry it's lunch East Coast time. What can I say? Hey, I lived in California for many years. I know what happens.

And I would remind you that, for the afternoon, you will have a different login, and that's true for people both signing into the webinar as well as our committee members. And so, be sure you're using that Thursday pm or Thursday afternoon login when we come back.

And we will reconvene at 1:00 pm, so that's when we're scheduled to start again.

And we'll I guess virtually see all of you at that point.

Group: Thank you.

Female: Have a good lunch. Bye.

Dr. Barbara Schneeman: Yeah, bye.