Morning

https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1317251&tp_key=a06dd93b89

[0:00:10] ***Announcer:*** Good day, everyone, and welcome to the USDA 2020 Dietary Guidelines Advisory Committee Draft Report Meeting. At this time, I would like to turn the conference over to Eve Stoody. Please go ahead.

Dr. Eve Stoody: Good morning. Yes, this is Eve Stoody, and I'm the designated federal officer to the 2020 Dietary Guidelines Advisory Committee.

Welcome to the final meeting of the 2020 committee. Today's meeting will include discussion on the committee's draft scientific report that they will finalize after this meeting and submit to the Secretaries of USDA and HHS at the end of this month.

Similar to the committee's last meeting in March, this meeting is being held by webcast, and members of the public are joining in listen-only mode. I do want to note, though, if you have any technology issues, please let us know using the box on the left of your screen and our tech support will be monitoring the question box.

[0:01:05] All 20 members are able to join us remotely for this meeting. I do want to note that Dr. Jamy Ard, Dr. Tim Naimi, and Dr. Jamie Stang will have periods of time where they are not available, but they will join the discussion as much as possible.

As always, we start the meeting by stating the charge to the committee. This committee was established to examine the evidence for questions on diet and health identified by the Departments of Agriculture and Health and Human Services, to develop a report that outlines their science-based review and advice to the Departments, and 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 meeting was originally scheduled for May 11 with the committee's report requested by the end of May.

[0:01:57] We announced in April that the committee's schedule was extended by 1 month in consideration of new demands due to COVID-19. We do want to note that we appreciate the committee's flexibility as well as the support team in extending the timeline of this process an extra month.

This meeting will be held today from 11:00 a.m. to 7:00 p.m. Eastern Time. I do want to note that there is a different webcast link for the session that starts today at 1:30, or excuse me, 3:30. So, we'll stay here where we are in this webcast link all the way up until about 3:00 p.m., and then we'll hop off for a break, and when you come back for that afternoon session starting at 3:30, you'll be joining using a different link.

Now, you should have received that link when you registered for the meeting, but if you don't have it, you can also find it at DietaryGuidelines.gov.

Dr. Schneeman will provide an overview of the agenda in her remarks but is also available on our website.

[0:02:56] We have members joining us today from across the country, from Boston, Mass to Honolulu, Hawaii. We also have over 1,000 people who have registered to attend the meeting. Thanks for your flexibility in the timing of the meeting today. We shifted the meeting a little later in the day to try to accommodate our members on the West Coast and in Hawaii, and in Hawaii, the current time is 5:00 a.m., but again, you're in Hawaii.

So, good morning to you from wherever you are joining us, and I'm now going to turn the meeting over to the chair of the committee, Dr. Barbara Schneeman.

Dr. Barbara Schneeman: Great. Thank you, Dr. Stoody, and let me add my welcome to this report meeting for the 2020 Dietary Guidelines Advisory Committee.

The purpose of this meeting is to bring work to the full committee for discussion and decisions.

The meeting will begin with, this morning, with updates on the committee's NESR systematic reviews. Most of these systematic reviews have been presented previously.

[0:03:59] We're providing an update from our last public meeting on these particular systematic reviews.

Most of our time today will be spent discussing our draft advisory report. The committee will also discuss findings from Food Pattern Modeling analysis in the context of the relevant chapters when discussing the report.

The committee will finalize our advisory report using the discussion at this meeting and submit our final report to the Secretaries of USDA and HHS at the end of the month.

As a reminder, over the past 15 months of our work, the committee has been reviewing evidence to answer questions on diet and health using one of three approaches – Data Analysis, Food Pattern Modeling, and the NESR Systematic Reviews.

[0:04:57] This slide includes a brief description of each of these approaches, and we thought that would be helpful to review at—to set the stage for today's discussion.

The data analysis is a collection of analyses that use national data sets to help us understand the current health and dietary intake of Americans. These data help make our advice practical, relevant, and achievable.

Food pattern modeling, this analysis helps us understand how changes to the amounts or the types of foods and beverages in a dietary pattern might impact meeting nutrient needs across the US population.

And the NESR systematic reviews are research projects that answer questions on diet and health by searching for, evaluating, and synthesizing all relevant peer-reviewed studies.

And more information is available—more information on these approaches was presented at previous meetings and is available at the DietaryGuidelines.gov website.

[0:06:04] I should note that conclusions are made from each method that is used, but the advice is based on our approach with all three methods.

So, the committee made—in using these methods, the committee made decisions, all decisions required on—to develop the protocols that guided how each approach would be used to examine the evidence for each question, including establishing inclusion and exclusion criteria for the systematic reviews and outlining the requests for food pattern modeling activities.

The USDA and HHS staff provided invaluable support for implementing these approaches, but the conclusions reached are those of the committee.

[0:06:59] The final protocols and draft conclusion statements were posted in May at DietaryGuidelines.gov where they remain available. Please note that all of these conclusion statements are considered draft until the committee's final report is submitted.

So, at Meeting 5, the committee provided an update on our work, including the NESR systematic reviews.

Following Meeting 5, the subcommittees continued to work on their reviews and the NESR systematic reviews completed peer review, a very valuable addition to the process.

And today, we will provide updates on questions with new conclusion statements or when a grade/conclusion has been changed and allow for discussion by the members.

And the members are aware that they've had access to the draft conclusion statements and are currently reviewing the draft report.

[0:08:02] So as such, these updates will be kept brief on each question and—but will be provided—we will provide an opportunity for questions or comments from the committee members.

So, these are the topics that we will be going through for the NESR systematic reviews. I'm not going to read through this whole list. Just know that these are the topics, and we'll highlight which topics are associated with each presenter as we go through the updates from each subcommittee.

So, the first presentation will be given by Dr. Kay Dewey on looking at the—using the Birth to 24 Months subcommittee review and to focus on human milk and/or infant formula and overweight and obesity. So, Dr. Dewey?

[0:08:59] ***Dr. Kathryn Dewey:*** Thank you very much, Barbara. We presented a description of the approach we would use to synthesize this evidence at Meeting 5, so today, we will briefly review that information and present our draft conclusion statements.

Given the abundance of evidence, we examined the most salient public health outcomes, which is overweight or obesity, and we examined outcomes starting at 2 years of age due to uncertainty about how to interpret earlier outcomes.

We augmented our review of the most recent evidence between January 2011 and September 2019 with the review of within-family sibling analyses from January 1980 to September 2019, and these sibling studies helped to overcome residual confounding, which is pervasive in observational research, and it helps to do this because the siblings share genetic and environmental factors.

[0:10:01] To our knowledge, this is a novel contribution to the field.

We specified six exposures of interest that align with some of the first feeding decisions that caregivers make. Almost all of the evidence that met the inclusion criteria pertain to the first two exposures.

For ever versus never consuming human milk, there were 30 articles that presented evidence from 21 independent cohorts including four studies with within-family analyses of siblings.

For the duration of any human milk consumption among infants fed human milk, there were 21 articles that presented evidence from one cluster randomized controlled trial and 18 independent cohorts including four studies with within-family analyses of siblings.

For the remaining exposures numbered three through six, there was little or no evidence, and on the next slide, I'll present our conclusion statements for those exposures with the rest of the presentation devoted to the first two exposures.

[0:11:05] In these conclusion statements, the exposures with scant or no evidence are shown in bold. For the first, there was insufficient evidence, and for the others, there was no evidence, thus, all of these received a grade of "Grade Not Assignable."

Now, I'll give a summary of the evidence synthesis for the first exposure, ever versus never consuming human milk.

The evidence had strong consistency. 14 of the 21 studies found significant associations, and all of them indicated that ever compared with never consuming human milk is associated with a lower risk of overweight or obesity at ages two years and older. One study showed a marginal association in the same direction, and some of the remaining studies were underpowered.

[0:11:59] In five of seven studies that compared different durations of ever with never consuming human milk, for example, less than six months versus never, or greater than or equal to six months versus never. Longer durations were associated with significantly lower risk of overweight and/or obesity, but shorter durations were not.

This suggests that longer durations of human milk consumption, for example, more than six months, are particularly important.

When we look at those four key studies that conducted within-family analyses of siblings, we found that one study reported a significant association in those analyses between ever versus never consuming human milk and the lower odds of overweight or obesity at 9-19 years of age.

The other three studies did not report significant associations, and rather, they tended to find that the significant associations found in the full sample analyses were no longer significant.

[0:13:00] This may be due in part to the much smaller sample size available for the within-family analyses. However, in two studies, it was clear that there was an attenuation of the estimated association that had been seen in the full sample analyses.

And this suggests that some of the associations between never versus ever consuming breast milk and a lower risk of overweight and/or obesity is explained by confounding.

The evidence also had strong precision. Most of the studies were sufficiently powered. I already mentioned that one study reported a marginal association in the same direction. And some of the remaining studies were likely underpowered.

The studies were generally directly aimed at examining this relationship and there was moderate generalizability. 11 of the 21 studies were conducted in the US, and these included samples that were nationally-representative, had racial and ethnic diversity, and included children from families with low income.

[0:14:06] The remaining evidence, which was mostly from Europe, may be less generalizable because the US may have a higher risk of overweight and obesity.

In addition, most of the evidence was in children, with fewer studies examining outcomes in adolescents and adults.

I've already discussed risk of bias with respect to the four studies that conducted within-family analyses. However, these studies were prone to other risks of bias. For example, two of them asked mothers to recall how they fed their offspring during infancy when those offspring were between 4-18 years of age, and in two studies, height and weight were self-reported by some participants or the outcome assessment methods were not described.

[0:14:56] None of the remaining 17 studies controlled for all of the key confounders we identified in our analytical framework. In particular, a few studies controlled for complementary feeding or childhood diet. Because infant feeding can be strongly socially-patterned, this raises a concern about confounding in this body of observational studies.

Our draft conclusion statement is that moderate evidence from observational studies indicates that ever compared with never consuming human milk is associated with a lower risk of overweight and obesity at two years of age and older, particularly if the duration of human milk consumption is six months or longer.

And now, we'll go on to the evidence synthesis for the second exposure, the duration of any human milk consumption among infants fed human milk. And this evidence was inconsistent. Five studies reported significant inverse associations and three studies reported significant positive associations.

[0:16:02] One study reported a significant association in the opposite direction at two and then at six years of age. The remaining 10 studies reported no significant associations with outcomes measured between 2 and 62 years of age.

Four of the five studies reported significant inverse associations between duration and overweight and obesity, and they were conducted in the US, and all three studies reporting significant positive associations were conducted in Europe, and this may explain some of the inconsistencies in the evidence. It's possible that the association between the duration of any human milk consumption and overweight and/or obesity differs between the US and Europe.

For the within-family analyses of siblings, none of the four studies reported significant associations between duration of human milk consumption and this outcome.

[0:17:02] A key study was the large cluster randomized controlled trial called PROBIT, which was conducted in Belarus and randomized hospitals to an intervention to promote breastfeeding duration and exclusivity or to standard of care.

Infants in the intervention group had significantly higher rates of any human milk consumption than infants in the control group at 3, 6, 9, and 12 months of age. However, the intention to treat analyses found a higher risk of overweight and/or obesity in the intervention group compared to the control group at 11.6 and 16 years.

So, this highly-inconsistent evidence also lacks precision.

These studies did tend to be direct.

For generalizability, 7 of 19 studies were conducted in the US and the rest in Europe, including the cluster randomized trial.

[0:18:05] Differences in obesity prevalence across these countries could limit generalizability.

Most of the evidence was for outcomes in children.

And for risk of bias, there were similar strengths and weaknesses as mentioned for the exposure of ever versus never fed human milk.

For our draft conclusion statement for this exposure, is that insufficient evidence is available to determine the relationship between the duration of any human milk consumption among infants fed human milk and overweight and obesity at two years of age and older, and the available evidence was inconsistent. Therefore, the grade was not assignable.

And that's all.

[0:18:56] ***Dr. Ronald Kleinman:*** Thanks very much, Kay. This is Ron Kleinman, and Barbara and I are going to tag team the questions on each of these areas. So, the table is now open for discussion. Are there any questions of Kay about what she's presented?

Okay, I see nothing in the chat, and I hear no questions, so shall we move on?

Dr. Barbara Schneeman: Any comments? Any comments from the—

Dr. Richard Mattes: This is Rick. I'd like to ask one. Is there any thought to why the European and the US studies would vary?

Dr. Kay Dewey: One possibility is that there may be a lower risk of overweight and obesity in Europe, so it's really hard doing the kind of analysis that we did to tease these differences apart. And I think further work would be needed to try to understand if that might be the case.

[0:20:01] ***Dr. Ronald Kleinman:*** Any other comments or questions?

Dr. Rachel Novotny: This is Rachel. Can you hear me? This is Rachel Novotny.

Dr. Ronald Kleinman: Yes. Go ahead.

Dr. Rachel Novotny: I'm not real familiar with Belarus. Would you think that the children might have had a lower baseline underweight status in Belarus, or do you think that—was that well-

controlled for? ***[crosstalk 0:20:49]*** more important to healthy growth there than it might be in some of our other countries?

[0:20:59] ***Dr. Kathryn Dewey:*** Well, ***[indiscernible 0:21:01]*** status was fairly normal in Belarus. There was not a lot of underweight. But with that said, there's probably a lot less overweight at the time the study was conducted than we experience today in the US.

But it's a—it was a relatively healthy population. The rates, for example, of diarrhea and other types of illness were quite low. So, that was not a constraint on growth in that setting.

Dr. Rachel Novotny: Okay, thank you.

Dr. Ronald Kleinman: Any further comments or questions?

Okay.

Dr. Barbara Schneeman: Great. So, I think we can move to the next presentation by Dr. Snetselaar on—from the Dietary Fats and Seafoods subcommittee, and topics include seafood, pregnancy and neurocognitive development, seafood during childhood/adolescence and neurocognitive development, and then the dietary fats and cardiovascular disease. So, Dr. Snetselaar?

[0:22:12] ***Dr. Linda Snetselaar:*** Yes, thank you, Barbara. This initial question was discussed during previous public meetings.

We presented evidence and draft conclusion statements for three seafood reviews, each with multiple conclusion statements.

Since Meeting 5, we updated one conclusion statement related to the question "What is the relationship between seafood consumption during pregnancy and/or lactation and neurocognitive development of the child?"

The conclusion statement presented in March is shown above and the revised conclusion statement with red text indicating the changes is below.

[0:23:00] The revised conclusion statement for the cognitive development domain is:

Moderate evidence indicates that seafood intake during pregnancy is associated favorably with measures of cognitive development in young children, and the grade here is Moderate.

The revision narrows the focus of a conclusion to young children and changes the draft grade from Limited to Moderate because the evidence in young children was more consistently beneficial and is more approximately linked maternal seafood intake during pregnancy.

We also revised two conclusion statements related to the question "What is the relationship between seafood consumption during childhood and adolescence, up to 18 years of age, and neurocognitive development?"

[0:24:04] In this and the next slide, the conclusion statement presented in March is shown above and the modified conclusion statement with red text indicating revisions is below.

The revised conclusion statement for the cognitive development domain is:

Insufficient evidence is available to determine whether there is a favorable relationship between seafood intake during childhood and adolescence and measures of cognitive development in children and adolescent groups. However, no unfavorable relationships were found between seafood consumption during childhood and adolescence and measures of cognitive development. And the grade here is Not Assignable.

[0:24:57] Because the committee's question did not focus on safety, the subcommittee chose to eliminate conclusions specific to detrimental effects and the word association was changed to relationship since results were derived from both randomized controlled trials and prospective cohort studies.

A similar revision was made in the conclusion statement focused on language and communication development, and the revised conclusion is:

Insufficient evidence is available to determine whether there is a favorable relationship between seafood intake during childhood and adolescence and measures of language and communication development in children and adolescent groups. However, no unfavorable relationships were found between seafood consumption during childhood and adolescence and measures of language and communication development.

[0:26:03] And the grade here is Not Assignable.

And again, I want to emphasize the systematic review did not specifically focus on safety.

Since Meeting 5, we added four conclusion statements related to the question "What is the relationship between types of dietary fats consumed and risk of cardiovascular disease?"

Here, the focus was on—excuse me—here, the focus was on endpoint outcomes, and the characteristics of the body of evidence were described at Meeting 5.

There were a total of 94 articles, 90 from 47 different prospective cohort studies, four from three nested case controlled studies that examined types of dietary fat intake during adulthood and CVD endpoint outcomes.

[0:27:05] 16 articles examined omega-6 polyunsaturated fatty acids. In these studies, associations between total omega-6 polyunsaturated fatty acid intake in adults and CVD were predominantly null.

In the few articles that specifically assessed linoleic acid and arachidonic acid separately, beneficial associations were more often observed for linoleic acid compared to arachidonic acid in adults.

11 articles examined dietary cholesterol. Few articles with inconsistent results assessed the independent relationship between dietary cholesterol intake in adults and CVD endpoint outcomes, thereby, further confounding meaningful conclusions.

[0:28:01] Due to the co-occurrence of dietary cholesterol and saturated fat in animal-source foods, this entangling independent association between dietary cholesterol in adults and CVD endpoint outcomes in these observational studies is challenging.

The subcommittee's systematic review on dietary cholesterol found evidence consistent with current dietary guidelines. More details about these studies are provided in chapter 9 of our report.

Draft conclusion statements regarding omega-6 polyunsaturated fatty acids and dietary cholesterol are as follows:

Limited evidence suggests that intake of linoleic acid, but not arachidonic acid, during adulthood may be associated with lower risk of cardiovascular disease, including cardiovascular disease mortality.

[0:29:05] And the grade here is Limited.

Insufficient evidence is available from randomized controlled trials to quantify an independent relationship between dietary cholesterol intake in adults and overall risk of cardiovascular disease. The grade here: Not Assignable.

For evidence regarding types of dietary fat consumed during adulthood and CVD intermediate outcomes, there were a total of 97 articles of which 47 were from parallel randomized controlled trials, 46 were from crossover randomized controlled trials, and five were from non-randomized controlled trials.

It's important to note here that one crossover design randomized controlled trial was also analyzed as a parallel design randomized controlled trial.

[0:30:02] Studies were conducted primarily in the US and a variety of countries across Europe.

Participants were predominantly middle-aged or older adults with overweight or obesity.

Studies examined the effects of types of dietary fat by providing foods that varied in fatty acid content.

28 percent of these studies were controlled-feeding trials.

Regarding replacement of saturated fat, over half of articles pertaining to replacement of saturated fat with monounsaturated fat in adults reported a beneficial effect of monounsaturated fat intake on total and LDL cholesterol.

Most articles reported null effects on HDL cholesterol and triglycerides.

[0:30:59] Over half of articles pertaining to replacement of saturated fat with polyunsaturated fat in adults reported a beneficial effect of polyunsaturated fat intake on total and LDL cholesterol.

Most articles reported null effects on HDL cholesterol and triglycerides.

Only two articles examined replacement of saturated fats with carbohydrates in adults, and effects on blood lipids were mixed.

One study replaced saturated fat with refined carbohydrate, whereas the type and source of carbohydrate in the other study was not reported.

This systematic review builds and expands on work from the *2015 Dietary Guidelines for Americans* committee and was broadly consistent with conclusions drawn by the *2015 Dietary Guidelines for Americans* committee.

[0:31:57] The *2020 Dietary Guidelines for Americans* committee concurred with and updated these conclusions regarding replacement of saturated fat with monounsaturated fat, polyunsaturated fat, or carbohydrates.

The conclusion statement for types of dietary fat during adulthood and CVD intermediate outcomes is:

Strong and consistent evidence from randomized controlled trials demonstrates that replacing saturated fatty acids with unsaturated fats, especially polyunsaturated fatty acids, in adults significantly reduces total and LDL cholesterol. Replacing saturated fats with carbohydrates (source not defined) also reduces total and low-density lipoprotein cholesterol but significantly increases triglycerides and reduces high-density lipoprotein cholesterol.

[0:33:02] Since the 2015 Dietary Guidelines Advisory Committee review, evidence remains inadequate to differentiate among sources of carbohydrates and their impact on blood lipids. And here, the grade is strong.

Nine articles examined dietary cholesterol in adults and blood lipids. Most articles reported null effects of dietary cholesterol on adults and specifically focusing on blood lipids.

Among the few articles that found significant results, higher intakes of dietary cholesterol significantly increased or reduced in higher levels total of LDL cholesterol.

In several studies, it was not possible to isolate independent effects of dietary cholesterol and blood lipids due to simultaneous changes in the amount of fat or proportion of different types of fatty acids in the study diet.

[0:34:05] And finally, the conclusion statement for dietary cholesterol during adulthood and CVD intermediate outcomes is:

Limited evidence suggests that lower intake of dietary cholesterol in adults may reduce total and LDL cholesterol. The grade here is limited.

And, that concludes my update.

Dr. Barbara Schneeman: Great. Thank you so much, Linda. And so, it's—we want to see if there's some questions or comments from committee members on the data/NESR reviews?

Any questions? Comments?

[0:34:58] ***Dr. Ronald Kleinman:*** Hey, this is Ron Kleinman. In the previous—could you just go back to the previous slide?

So here, it says that most articles reported null effects and that there were only a few articles that found significant results.

So, I'm wondering why you concluded that, in the following slide, what you did? So, flip to the next slide now.

Dr. Linda Snetselaar: And which slides are you referring to, please?

Dr. Ronald Kleinman: Yeah. So, yeah, so this conclusion is limited evidence suggests that lower intake of dietary cholesterol in adults may reduce total and LDL cholesterol, but in the previous slide, you say that most of the studies actually don't show or reported null effects of dietary cholesterol.

[0:36:08] So, I was just trying to reconcile the conclusion with the slide of the evidence.

Dr. Linda Snetselaar: Okay, and your concern is the term "limited?"

Dr. Ronald Kleinman: Yeah. Yeah. ***[crosstalk 0:36:27]***. It seems just it would probably be that there was little to no effect, or at least an inconsistent effect. And so, limited evidence that there is an effect is inconsistent. But maybe I'm not following it the right way.

Dr. Linda Snetselaar: No, no. And I think in the slides that I will be doing this afternoon, we go into much more detail in terms of the evidence.

[0:37:03] And we actually will be including some information from a study that was done, a longitudinal study that was done for 7.5 years, and we'll be reporting a bit more evidence from that particular study.

And I think that hopefully will answer your question as well.

Dr. Barbara Schneeman: And Dr. Bailey, did you want to comment also?

Dr. Regan Bailey: We also—Ron, this is Regan Bailey. We also built upon the 2015 Dietary Guidelines Advisory Committee, which had a lot more than nine studies available. So, we were building from what had been done previously, and I think that you're right, Linda, when you present all of that totality together, it might make more sense.

[0:37:58] ***Dr. Linda Van Horn:*** And this is Linda Van Horn. Can you hear me?

Dr. Barbara Schneeman: Yes.

Dr. Linda Van Horn: Hi. Just to offer one additional comment on this particular topic, and Linda's absolutely right. We're going to deal with that more directly later. But I think it's probably relevant across all of our different chapters that there is variability across studies.

And sometimes, a study or a paper is especially meaningful because of its magnitude and its sample size and the power calculations that are available. And as Linda pointed out, it was actually 17.5 years of longitudinal follow-up across six different cohorts that provided new data that had yet to be evaluated that was published just recently in 2019.

[0:39:01] So, not only were we building upon the 2015 review, but this additional work that was just recently completed, thankfully during the time of our review, provided this additional very strong research that offered additional detail that had not previously been evaluated.

So, we'll go back into that later, but it just—I think all of our different subcommittees would agree that there are some papers, some studies that simply present the detail and the power calculations that sort of are worthy of additional consideration because of their size.

Dr. Ronald Kleinman: Yeah, that's very helpful. Thank you.

Dr. Linda Snetselaar: Thank you, Regan, and Linda.

Dr. Linda Van Horn: Sure.

[0:40:01] ***Dr. Barbara Schneeman:*** Great. Any other questions or comments?

Ron, do you want to—

Dr. Ronald Kleinman: Oh, sure.

So, our next is Sharon Donovan, and she's going to address the question on maternal diet and food allergy and atopic allergic diseases. Sharon?

Dr. Sharon Donovan: Thank you, Ron. And, good morning, everyone.

So, we presented the search results, evidence, and draft conclusion statements for maternal diet and atopic dermatitis, food allergies, allergic rhinitis, and asthma at Meeting 5, but we did not present all of the evidence and draft conclusion statements for asthma.

Today, we will briefly present the remaining evidence and draft conclusions for maternal diet and asthma.

[0:40:57] 20 articles from two RCTs and nine prospective cohort studies examined the relationship between maternal diet and risk of asthma in a child between 2 and 18 years of age.

Eight prospective cohort studies involving 16 articles examined diet during pregnancy.

Two RCTs and three articles examined diet during both pregnancy and lactation.

And one prospective cohort study, one article, examined diet during lactation alone.

The studies examined maternal dietary patterns and avoidance and/or consumption of cow milk products, eggs, fish, soybean, peanuts, tree nuts, soy—I see soybean is there twice—wheat, and other foods not commonly considered as allergens.

This slide summarizes the evidence synthesis for asthma.

[0:41:56] So, as you can see across the top are the different timing of exposure, so pregnancy alone, pregnancy and lactation, and lactation alone, and in the first column are the various food products.

And as you can see, there was—were only three foods in which we could generate conclusion statements, and they were all limited.

Egg and fish were presented at Meeting 5, and today, I'll be presenting on cow milk products.

Some of the reasons that we weren't able to grade were because of no or insufficient evidence, and some of the reasons for insufficient evidence were that—the very small body of evidence, usually two studies or less, heterogeneity in the findings, serious flaws in the design and conduct of the study, limited generalizability of the findings to the US populations.

And the full conclusion statements can be found on DietaryGuidelines.gov.

[0:43:01] So, the conclusion statement for maternal cow milk products consumption during pregnancy and asthma is that:

Limited evidence suggests that a lower consumption of cow milk products during pregnancy does not reduce the risk of asthma in the child.

So, these findings are consistent with those of the American Academy of Pediatrics and other authoritative bodies that state that current evidence does not support a role for maternal dietary restriction during pregnancy or lactation to reduce the risk of atopic diseases in the child.

So next, I will present the second conclusion statement for today. So, this is related to omega-3 fatty acids from supplements consumed before and during pregnancy and lactation and developmental milestones, including neurocognitive development, in the child.

[0:43:58] So, this is the description of the evidence. There were—as you can see, we looked at a number of outcomes.

So, for cognitive development, there were 18 articles. 5 of the 8 randomized controlled studies found a favorable effect of supplementation with omega-3 fatty acids during pregnancy on at least one outcome measure.

For language, there were 11 articles, motor, eight articles, visual, five articles, and socioemotional development, 11 articles from 9 RCTs.

For this body of evidence, the findings were inconsistent. All studies reported no effect on at least one measure, and the number and direction of statistically significant findings varied across the body of evidence.

For academic performance, there was one RCT.

[0:44:58] For attention-deficit disorder and hyperactivity, there were two articles from one RCT.

And for autism spectrum disorder, there were two articles, one RCT and one prospective cohort study.

This summarizes the studies for exposures during pregnancy and lactation, and lactation alone. So, for pregnancy and lactation, you can see there were five articles for cognitive, one for language, three for motor—whoops, I didn't mean to go forward—and one for socioemotional development, and these were from three RCTs.

So again, there were few studies and inconsistent findings, and all the studies reported no effect on at least one measure, we found that the number and the direction of the findings varied across the body of evidence.

[0:45:58] And for exposure to omega-3 fatty acid supplements during lactation, there was one RCT published with two articles that combined cognitive, language, motor, and visual development.

So, this slide summarizes the evidence.

Again, exposures across the top and the outcomes in the first column.

And as you can see, the committee was only able to grade one conclusion statement, which was related to omega-3 fatty acid supplements during pregnancy on cognitive development in the child.

So, the conclusion is that limited evidence suggests that omega-3 fatty acid supplements consumed during pregnancy may result in favorable cognitive development in the child.

[0:46:56] I can note that these conclusions are similar to that of a recent COPA review and metanalysis by Middleton College, which stated that—very few differences between antenatal omega-3 ***[indiscernible 0:47:06]*** supplementation and no omega-3 were observed in cognition, IQ, vision, and other neurodevelopmental and growth outcomes.

We're not—basically, we do believe that adequate omega-3 is important for brain development in utero. That's not disputed. However, more studies are needed that are adequately powered, but also take into account more of the maternal diet in respect to DHA and its precursors, along with the inherent synthetic capacity to generate LC PUFAs from their precursors.

I believe that is the last statement on that, and I'd be happy to take any questions.

Dr. Ronald Kleinman: Thanks very much, Sharon. So, are there any comments or questions about either of the discussion points that Sharon presented?

[0:48:02] No other comments?

Okay.

Dr. Sharon Donovan: Thank you.

Dr. Barbara Schneeman: Great. Thanks, Sharon. We can move to the Dietary Patterns subcommittee, and Dr. Boushey will talk about dietary patterns and bone health, diets based on macronutrient distribution, several outcomes will be looked at with that. So, Dr. Boushey?

Dr. Carol Boushey: Hi. Thank you, Barbara.

So, at Meeting 5, a draft conclusion statement and grade was presented for dietary patterns in children and bone health.

[0:49:03] Today, we present a draft conclusion statement for the evidence related to bone health and adults.

I have to get used to the clicker.

This systematic review update included seven population cohort studies published between January 2014 and November 2019 that examined dietary patterns in adults and bone health. All studies examined risk of fractures, mainly hip and older adults. The evidence consistently showed that healthier dietary patterns were associated with reduced risk of hip fractures.

[0:50:01] The studies were generalizable, had few risks of bias, and had large analytical sample sizes with a sufficient number of hip fracture cases.

So, the conclusion statement for dietary patterns: adults:

Moderate evidence suggests that a dietary pattern higher in vegetables, fruits, legumes, nuts, low-fat dairy, whole grains, and fish, and lower in processed meats, added sugar, and sugar-sweetened beverages is associated with favorable bone health outcomes in adults, primarily decreased risk of hip fracture. And the grade for adults: moderate.

[0:50:55] Status relative to existing review: This update builds upon the conclusion drawn by the 2015 committee, which determined that limited evidence suggests a relationship between dietary patterns and bone health in adults.

Also at Meeting 5, we did not fully report diets based on macronutrient distributions, and so, that is what we will now provide an update on.

This systematic review included 47 articles that examined diets based on macronutrient distribution in adults.

Most enrolled participants who were overweight or obese or had features of metabolic syndrome.

[0:52:02] The majority of randomized controlled trials reported no significant effects of macronutrient distributions on intermediate cardiovascular disease outcomes, for example, blood pressure.

Many of the prospective cohort studies reported no significant associations between macronutrient distributions compared and risk of cardiovascular disease.

Of those reporting significant associations, the macronutrient distributions compared and the direction of findings on CVD outcomes varied. Limitations include inconsistent magnitude of the effects reported, risk of bias. Macronutrient distributions that associated with favorable CVD outcomes typically came from diets with higher relative to poorer diet quality overall were reported.

[0:53:00] So, our draft conclusion statement: Diets based on macronutrient distribution: Children:

No evidence was available to determine the relationship between diets based on macronutrient distribution consumed in childhood and concurrent or future development of cardiovascular disease.

Diets based on macronutrient distribution: Adults:

Limited evidence suggests non-energy restricted diets based solely on macronutrient distribution with either carbohydrate, fat, and/or protein proportions outside of the Acceptable Macronutrient Distribution Range, are neither beneficial nor detrimental regarding risk of cardiovascular disease in adults primarily among those at high risk, such as those with overweight, obesity, or features of metabolic syndrome.

[0:54:04] So, the grade was Limited, and the children, the grade was Not Assignable.

At Meeting 5, the draft conclusion statement for dietary patterns consumed and risk of type 2 diabetes was not presented in children—was not presented. And so, today, we'll go over that evidence.

This systematic review included 23 articles that examined diets based on macronutrient distribution in adults.

[0:55:00] Although foods or food groups consumed were not reported consistently, studies that did provide that context tended to examine diets with higher amounts of saturated fat, trans fat, and/or animal-based sources of protein and fat, such as processed meat, red meat, butter, and cheese, as well as refined grains, sugar-sweetened beverages, lower-fiber cereals, and bread.

Limitations include studies rarely compared a different distribution of macronutrients within the context of a constant dietary pattern. Studies made several risks of bias—had several risks of bias. Macronutrient differences between exposure groups were limited in magnitude, in a similar direction, for example, all arms below the AMDR, modestly different from the AMDR, or only relevant for a subset of the population.

[0:56:08] So, our conclusion statement: Diets based on macronutrient distribution: Children:

No evidence is available to determine a relationship between diets based on macronutrient distribution consumed during childhood and risk of type 2 diabetes.

Diets based on macronutrient distribution: Adults:

Insufficient evidence is available to determine the relationship between macronutrient distributions with proportions of energy falling outside of the Acceptable Macronutrient Distribution Range for at least one macronutrient and risk of type 2 diabetes due to methodological limitations and inconsistent results.

[0:57:01] So, for children, the grade was Not Assignable. For adults, the grade was Not Assignable.

Next, what is the relationship between dietary patterns consumed and growth, size, body composition, and risk of overweight and obesity? Again, a conclusion statement that we hadn't completely finished during at Meeting 5.

This systematic review included 31 articles that examined diets based on macronutrient distribution in adults.

Several studies included participants with and without overweight, obesity, or features of metabolic syndrome.

[0:58:03] Most of the articles compared macronutrient distributions that generally compared poor-quality diets to higher-quality alternatives.

Limitations were: Studies rarely compared different macronutrient distributions within the context of a constant dietary pattern.

Most of the clinical trials compared diets to a different dietary pattern either prescribed as a study intervention or as usual intakes. Studies had several risks of bias. The differences in macronutrient proportions between exposure groups were either limited in magnitude, of a similar direction relative to the Acceptable Macronutrient Distribution Range, only moderately different from the Acceptable Macronutrient Distribution Range, or only relevant with a limited subset of the study population.

[0:59:02] So, our conclusion statement, our draft conclusion statement: Diets based on macronutrient distribution: Children:

No evidence is available to determine the relationship between diets based on macronutrient distribution consumed during childhood and growth, size, body composition, and risk of overweight or obesity.

Diets based on macronutrient distribution: Adults:

Insufficient evidence is available to determine the relationship between macronutrient distributions with proportions of energy falling outside of the Acceptable Macronutrient Distribution Range for at least one macronutrient and growth, size, body composition, and risk of overweight or obesity due to methodological limitations and inconsistent results.

[1:00:01] So, the grade for children: Grade Not Assignable. For adults: Grade Not Assignable.

And now, for the next parts of this report, I'm going to change over to Dr. Steven Heymsfield, and he'll cover the remaining areas of the dietary patterns update.

So, is everything good with the switching over?

Dr. Steven Heymsfield: Sure. Okay, thanks very much, Dr. Boushey. This review will discuss the macronutrient distributions and risk of sarcopenia.

Just a reminder, sarcopenia is a progressive and generalized loss of skeletal muscle mass either alone or in conjunction with either both low muscle strength and low muscle performance.

[1:01:09] And the previous review included four prospective cohort studies.

This specific presentation on macronutrient distributions will focus on two of those four prospective cohort studies.

In both of these studies, the percent of energy from fat was reported as above the AMDR.

And these studies included a number of limitations. The sample sizes were relatively small and had very few cases of sarcopenia. There were also several risks of bias, such as the lack of adjustment for all potential confounders and potential for selection bias due to enrolled participants likely representing healthier individuals.

[1:02:04] The studies were also inconsistent in how dietary intake was assessed and the results were— that were reported.

And that brings us to our conclusion statement that diets based on macronutrient distribution:

There's insufficient evidence available to determine the relationship between diets based on macronutrient distribution and sarcopenia, and therefore, we concluded that grade was Not Assignable.

I'll move on to the next report then, which is dietary patterns and neurocognitive health. And just a reminder, at Meeting 5, a description of the evidence was presented for this question.

[1:02:58] The slides that I'm about to show you present the summary of evidence and draft conclusion statement for dietary patterns and neurocognitive health.

This is an update to an existing systematic review and includes 26 articles, including randomized controlled trials, cohort studies, and nested case controlled studies.

Dietary patterns were examined using various methods. For example, indices or scores, factor or cluster analysis, and a variety of other methods.

And included articles examining dementia, cognitive decline, cognitive impairment, and cognitive function.

The majority of significant findings reported healthier dietary patterns consumed during adulthood were protective in either improving measures of cognitive impairment and/or reducing the risk of cognitive impairment or dementia.

[1:03:59] Studies with non-significant or mixed associations suggest these healthy dietary patterns did not worsen cognition.

Now, there were a number of limitations identified, as shown, including a general lack of randomized controlled trials, risk of bias, and considerable variation across the body of evidence, particularly in the methods used to test and report cognitive impairment.

And that brings us to our conclusion statement, that:

Limited evidence suggests that dietary patterns containing vegetables, fruits, unsaturated vegetable oils, and/or nuts, legumes, and fish or seafood consumed during adulthood were associated with lower risk of age-related cognitive impairment and/or dementia.

We assigned this grade Limited.

[1:04:57] Just as a reminder, this update concurs and builds upon the conclusion drawn by the 2015 committee, which conducted a systematic review that identified 30 articles from a wide range of study designs, using different methods to measure neurocognitive outcomes, but produced relatively consistent findings.

Okay, thanks very much. I'm happy to take any questions.

Dr. Barbara Schneeman: Great. So, if there are any questions for Dr. Boushey and Dr. Heymsfield, or comments?

Any questions or comments?

Okay.

Dr. Carol Boushey: Well, thank you very much.

Dr. Barbara Schneeman: Thank you to both of you for the presentations and the work of the subcommittee.

[1:06:01] ***Dr. Steven Heymsfield:*** Thank you, Barbara.

Dr. Barbara Schneeman: And is Dr. Naimi available? I know we had a bit of time juggle. I just wanted to check if he's available.

Announcer: We do not have Dr. Naimi.

Dr. Barbara Schneeman: Great. Okay, so what we'll do with Dr. Naimi's subcommittee report is, it's an important update on alcohol and all-cause mortality, we'll just move that into the afternoon so that there will be the opportunity to get that update before we go into those specific chapter reviews.

So, I just want to check and make sure, at this point, are there any other comments or questions or things that committee members would like the subcommittees to expand upon or provide more information on, based on these updates?

[1:06:57] Okay. Everyone's good to go. Great.

So, my next is to introduce the outline for the committee's report to set up for the review of the chapters that we'll be spending the rest of our time going through, and just—whoops.

Just to remind you all, this is our organization of the committee's report, which was discussed at Meeting 5, and remains the same.

In today's discussion, we'll be focusing on two sections, which contain the committee's advice to the Departments on the—for the *Dietary Guidelines*.

PART B: INTEGRATING THE EVIDENCE
PART D: THE EVIDENCE ON DIET AND HEALTH

And this section, part D, contains 14 chapters.

[1:07:55] The first chapter discusses dietary intakes through the life course, including discussion about the nutrients of public health concern, and the remaining chapters are organized by life stage – Pregnancy and Lactation, Birth to 24 Months, and Individuals 2 Years and Older.

So, for today's discussion, we'll provide an overview of each chapter, and this is the template for the chapters, with the discussion really focusing on the committee's evidence-based advice to the Departments, which is generally found in the summary section of the respective chapters.

I think it's important to note that the speakers are going to be providing a summary of their chapters, and as you can imagine, there will be many more details in the committee's report, but the presentations will summarize the committee's advice for our discussion today.

[1:08:55] So, in forming this advice, it's important to understand that the committee's have worked across all of the conclusion statements, and noted earlier, that each method results in a conclusion statement, but now, we're looking at the totality of the scientific evidence to develop advice based on the evidence for USDA and HHS to consider as the Departments develop the *2020-2025 Dietary Guidelines*.

So, the chapters are the opportunity to integrate the evidence across these three methods.

So, today's discussion will include presentations for each of the 14 science-based chapters. We'll plan to take some brief breaks between life stages. And we're aiming for a break around 1:00 p.m. and one around 3:00 p.m., but those times may be adjusted based on the presentations. And of course, we plan to adjourn at 7:00 p.m.

[1:10:02] Please note that we will need to move to a new webcast link at 3:30, so one way or another, we will have a break in that time period. Otherwise, all the times are tentative, and we'll just keep adjusting to allow for committee presentation and committee discussions.

So, with that, we will start with the first presentation on current dietary intakes through the life course. Dr. Regan Bailey will be giving that for chapter 1.

Dr. Regan Bailey: Are you ready for me? Okay. Hi, everyone. Can you hear me okay?

Dr. Barbara Schneeman: Yes.

Dr. Regan Bailey: Great. So, this is subcommittee 7, Data Analysis and Food Pattern Modeling, and we had five questions which we've reviewed at each of our meetings.

[1:10:57] So today, I'm just going to provide a really high-level overview of our findings and recommendations.

So, unlike the other subcommittees, where the number of papers reviewed can be counted, our work differed in many ways.

We have several draft conclusion statements for each of the five questions.

We examined more than 150 reports and results from requested data analysis from multiple federal monitoring and surveillance systems.

The dietary data we analyzed or—we didn't analyze it, but we reviewed it, reflects the most current NHANES cycles available, but for certain population subgroups, multiple cycles had to be combined, and this was especially true with the Birth to 24 population subgroup, as well as women who were pregnant and lactating.

All of the data we had available to us were cross-sectional in nature, and also observational. So, it limits our ability to infer causality but does provide a rich description of the American dietary landscape.

[1:11:56] And again, unlike other subcommittees, while we provide conclusion statements for our questions and our responses, these conclusion statements are not graded, but we do take into consideration the strength and limitations of the analysis when making the conclusion statements.

So, as Dr. Schneeman already introduced, one portion of this group is Data Analysis, and I'll be summarizing those for you today.

Most Americans have one or more chronic health conditions that are related to the dietary intake across the life course, including overweight and obesity, heart disease, stroke, type 2 diabetes, hypertension, liver disease, certain types of cancer, dental carries, and metabolic syndrome.

In many instances, overweight and obesity may be the earliest manifestation of energy imbalance and poor nutritional status, and many of the chronic conditions that we examined develop as a consequence of overweight and obesity.

[1:12:56] Given that most Americans are overweight or obese, this is obviously quite concerning.

In general, chronic health conditions have become more prevalent over time and are highest among older adult populations, racial and ethnic minority groups, and those with lower income levels. Racial variation exists for almost all health conditions this committee examined, including during pregnancy.

I'll provide just a few quick examples.

While Asian-Americans have a lower prevalence of most chronic health conditions examined in general, pregnant Asian women have the highest prevalence of gestational diabetes. Low birth weight is highest among non-Hispanic blacks and it is at the highest level in more than 25 years.

Chronic liver disease is highest in American Indians and Alaskan natives and continues to increase over time.

The American dietary landscape has not changed appreciatively over the last decade.

Patterns of food group intake across the life course contribute to higher than recommended intakes of added sugars, sodium, and saturated fats.

[1:14:02] Whole grain intakes remain extremely low across the population.

Intakes of fruits and vegetables are lower than current recommendations, with most Americans consuming less than one cup of whole fruit per day.

Less than half of vegetables are consumed alone or as a distinct raw or cooked portion, meaning that they are largely being consumed when incorporated into another type of food like snack foods or as part of a mixed dish.

In terms of the life stage approach that our group took, I'll first present data on pregnancy and lactation.

While the HEI scores of women who are pregnant or lactating is higher than women of similar ages, many dietary deficits were noted. Very limited biomarker data that is national in scope is available to adequately describe the nutritional status of pregnant, and especially lactating American women.

[1:14:56] Biomarker data suggests that iron and iodine are of concern during pregnancy, and given the severity of neural tube defects, we must remain vigilant on folic acid intakes among reproductive-age females, especially prior to conception and during the first trimester.

Looking now at older infants, we examined food behaviors as well as dietary intakes, and we did this stratified by primary mode of feeding.

The American Academy of Pediatrics recommends introduction of complementary foods and beverages at about six months of age when infants are developmentally ready. Our national data suggests that most infants are introduced to complementary foods and beverages prior to six months of age.

The mode of feeding is also related to the timing of introduction, in that infants receiving infant formula are introduced earlier to complementary foods and beverages, as well as the types and amounts of foods that are reported, as we have discussed at a previous meeting.

[1:16:01] So, in terms of identifying nutrients or food components of public health concern, iron has been identified in infants who are human milk fed. While protein and zinc are also low relative to reference standards in human milk fed infants, the estimates are not supported by biochemical, clinical, or health consequences to date, but should continue to be monitored.

These are the three food components for which we have an EAR value in this life stage. Relative to the adequate intake, older infants have low intakes of potassium, vitamin D, and choline, and those could be enhanced by the inclusion of fruits, vegetable, cheese, yogurt, eggs, and legumes during the transition from milk-based to table food feedings for all infants.

And for infants who are primarily fed infant formula or mixed fed, some infants had dietary intakes of zinc and retinol that were above the upper tolerable intake recommendations.

[1:17:05] So, moving on to toddlers, so during the ages of 12 to 24 months, a rapid devolution occurs in terms of meeting recommendations. This is generally when a child is exposed to foods consumed by parents and caregivers.

During the time between infancy and toddlerhood, large increases in added sugars and saturated fats are observed.

Patterns of food group intakes and sources of food groups among toddlers are similar to that of the US population 2 years and older. This is one of the critical life stage periods that our work has identified.

So, in terms of nutrients of public health concern for this age, low intakes of potassium, fiber, and vitamin D are of concern, as well as high intakes of sodium and added sugar.

Nutrients for which special challenges were identified include choline and linoleic acid.

[1:18:03] These nutrients are under consumed and are found in foods including eggs, nuts, seeds, and meat that are generally not consumed in high amounts by many toddlers. Choline and linoleic acid were low relative to the AI, but we lack biomarker or clinical data to note these food components should be evaluated for public health concern.

So, moving on now to the data that we examined for all Americans 2 and older, which has been the focus of the *Dietary Guidelines for Americans* since their inception.

Here are the data to support my previous statement that the dietary intakes of Americans have not changed much over the previous decade. There's been a change from 56 to 59 in terms of the AGI score. So, not currently, nor have Americans ever had dietary intakes that are aligned with the *Dietary Guidelines*.

[1:19:00] So, many of the same food components of public health concern that have been identified in previous committees remain, including vitamin D, calcium, fiber, and potassium, sodium, saturated fat, and added sugar.

We also noted, in addition to those food components on the previous slide, that the preteen and adolescent age group had a low intake across many different nutrients, so while those nutrients themselves may not be of public health concern individually, it's the constellation of low intakes across many nutrients in this age group that is of concern.

While older adults have a higher HEI score relative to other age groups, additional concerns were observed, including low protein and low intakes of B12 and B6.

[1:20:00] Given that osteoporosis and sarcopenia are so prevalent, developing nutritional strategies to mitigate risk is especially salient, especially among women.

In the next few slides, I will mention research needs and data gaps that we identified in our work.

First, while we took this life stage approach, life stage is not clearly defined at the federal level. The national survey data have different sampling age groups than the Dietary Reference Intake age groups, and terms like child, adolescent, adult, and older adult are inconsistently defined.

For the Birth to 24 Month age group, given that this is the first committee to address this life stage, there will need to be a Healthy Eating Index or other metric to evaluate dietary exposures.

Additionally, for the existing HEI, we need an additional method to examine some of the questions.

[1:20:59] So, for example, one of the questions we were looking at was how much added sugar could be accommodated in the diet? We couldn't look at the Healthy Eating Index scores of people who had high or low added sugar and compare the HEI scores, because added sugars is, of course, a component of that calculation.

Next, we know what most Americans are not doing. They're not following the *Dietary Guidelines*, but we don't know what their patterns are. So, NHANES data used to collect information on self-selected dietary patterns, such as vegetarianism, but that is no longer being conducted, so we largely do not know what patterns currently exist.

Data from the IFIC Food and Health Survey suggests that 43 percent of Americans followed a specific diet or eating pattern in the last year.

So, as I've alluded to ad nauseum throughout this process, the last point I want to make is the absolute lack of data available for certain population subgroups, including Birth to 24 Months, Pregnancy and Lactation, and among some race/ethnic groups.

[1:22:09] Biomarker data that are current and national in scope are needed to adequately describe the nutritional status of Americans, particularly those who are under-represented.

At some times, our committee had to utilize biomarker data from NHANES 2003-2006 in making some of our decisions.

Changing gears completely, but still complaining, certain issues have been included sporadically in the *Dietary Guidelines*, and while not covered by this committee, should be represented in public health messaging.

In some cases, these topics may reflect links related—links to related areas that are relevant to the diet and nutrition, things like food safety, oral health, or physical activity, or in other cases, may reflect nutritional issues that remain of public health importance but don't need additional input from the Advisory Committee because of existing current input from other authoritative sources, so, things like trans fat and reducing sodium intake.

[1:23:15] Identifying such a process would maintain the integrity of the *Dietary Guidelines* while enabling the Advisory Committees to focus its attention on novel topics of the highest priority for scientific review.

I think Dr. Dewey will mention, and we've talked about this before, but we need a database of human milk that is updated. So currently, we have a human milk database that is in Legacy status. Some of the values in that database were derived from a small number of hyper-producers of human milk, while others are estimated from cow's milk.

[1:23:59] I think that we could argue that most lactating women are neither hyper-producers nor cows, so it stands to reason that that should be of highest priority.

And that's a complicated ask because the composition of human milk changes for some nutrients in response to maternal diet and is also variable depending on the age of the infant.

So, it's not an easy challenge to overcome.

And then finally, we really need updated Dietary Reference Intake values, especially for infants and young children, to best characterize potential risks for dietary inadequacy and excess. And as I mentioned, for some infants, ages of infants, there were only three EARs available to make conclusions of whether or not they're at dietary risk.

[1:24:55] And then finally, many Americans may need support and tools and strategies to help manage weight, analyze, and plan their diets. The USDA historically provided Super Tracker, which was used by both the lay public and the research communities, but it has been discontinued. So,

technologies that aid behavior change and menu planning are likely needed to help individuals follow the *Dietary Guidelines*.

So finally, to summarize, diet is a modifiable factor that is critically related to the primary and secondary prevention of most non-communicable diseases and the leading cause of disability and death affecting Americans.

Dietary intake is also an important determinant of body weight and risk of overweight and obesity. Overweight and obesity begin early in life and remain public health problems in all age groups.

So, we know that the diet is quite complex and has implications for the risk of disease both in the moment and later in life, but this is quite difficult to quantify.

[1:26:06] So, in order to both encourage and facilitate healthier diets, the focus should not only be what Americans are eating, but also, the social, economic, and environmental contexts that determine our dietary patterns.

These contexts also drive diet and health disparities that exist in the United States.

In addition to establishing optimal dietary patterns early in life, efforts should continue to ensure energy balance early in life and maintenance of that energy balance over the life course.

We still lack an inherent understanding about how food security status relates to dietary intakes. This was first mentioned by the 2015 Dietary Guidelines Advisory Committee, but still remains largely unknown.

[1:26:57] Future committees may wish to examine optimal nutritional strategies for the prevention of cognitive decline in older adults, as well as osteoporosis and sarcopenia, which I previously mentioned.

And finally, the how of it all. We know what we think Americans should do, what they should eat, how they should exercise, but how do we get people to engage and how do we encourage them to do it?

We need help from behavioral experts and multi-sectorial approaches to solve the complex issue of poor diet quality in America.

Americans need to make shifts in their diet that do not add calories but make substitutions with more nutrient-dense foods and beverages, for the most part.

The committee also recommends that the next iteration of the *Dietary Guidelines* provide very specific messaging to consumers around beverage intake with a focus on sweetened beverages and alcohol.

[1:28:05] So, I'd like to thank the subcommittee members as well as the outstanding federal staff who supported this work. Chapter 1 culminated to a 98-page document that further expounds on this very high-level presentation that I gave today.

So, thank you very much for your time and attention.

Dr. Barbara Schneeman: Great. Thank you very much, Regan. So, are there questions or comments from the committee members?

Dr. Richard Mattes: This is Rick. Regan, could you comment, the analysis that was done was very much nutrient or food component oriented, but there are other patterns that one could consider, cultural patterns, temporal patterns, and so on. Can you comment on the level of priority you think future committees should place on other dimensions of patterns?

[1:28:57] ***Dr. Regan Bailey:*** Yeah, I think from some of the work on your Frequency of Eating committee, there's not a lot that is known in terms of when people are eating, intermittent fasting, time-restricted eating. The ways that the data are captured in a 24-hour recall, we can't always make such inferences.

So, I think we might have to build new tools into a 24-hour recall to get at some of those kinds of issues.

I think our primary focus really needs to be behavioral, I think, and structural. There's a lot of barriers and I think the focus has to be on how to support and enable people to make better choices, and oftentimes, they're not choices, they're just issues of access.

[1:30:01] So, I'm not sure that I answered your question exactly, but…

Dr. Richard Mattes: Yeah, I think that's relevant, very relevant. Thanks.

Dr. Barbara Schneeman: Other questions or comments?

Dr. Carol Boushey: Hi, Regan. This is Carol Boushey speaking, and I really appreciate this insert that your group did with Super Tracker. Interestingly enough, it's one of the—a big feedback that I have received from a number of people, and we don't—and what happens, because it was from the government, people really thought that it was for them and that they used it as a really credible source.

[1:30:56] So, that was—I appreciate that you brought that up in your group.

Dr. Regan Bailey: Thanks.

[crosstalk 1:31:06]

Dr. Linda Van Horn: This is Linda Van Horn. Oh, sorry, go ahead.

Dr. Regan Bailey: No, please go.

Dr. Linda Van Horn: I would just like to echo what Carol said.

I too, I have had many people express some disappointment of not having access to a simple diet assessment tracking tool. And I think, especially even starting as young as childhood, the ability for Americans to truly have the chance to monitor what they're eating, and we're all aware of apps that exist now that try to do that.

But if there was a universally-available simple tracking tool that would help people to adhere to the recommendations that we're making, and also provide potentially additional data to help monitor what people are eating.

[1:32:11] That could go a long way as far as improving adherence to the recommendations in a manner that was more standardizable and consistent to allow future Dietary Guidelines committees to look at both sides of these questions.

Dr. Regan Bailey: I agree. Thank you.

Dr. Barbara Schneeman: So, I'm going to go ahead and, I think we have one more presentation that we'd like to do before the break, but do we have Sharon Donovan's slides?

Dr. Sharon Donovan: Yes, I'm ready.

[1:32:58] ***Dr. Barbara Schneeman:*** Okay, great. I think if we can do that before the break, it'll help with the timing. So…

Dr. Sharon Donovan: Okay, perfect.

Okay, well thank you very much. It's my pleasure. I'll be presenting two chapters which are new to the *Dietary Guidelines* process. The first will be Pregnancy, and then I'll be presenting on Lactation as well.

This is the subcommittee members for the Pregnancy and Lactation committee, but the evidence that I'll be summarizing today was generated by Pregnancy and Lactation, Beverages and Added Sugars, Dietary Fats and Seafood, and Frequency of Eating.

So, I just want to set a little bit of the stage, and a comment that we have in the report is that we oftentimes think about pregnancy as a 40-week distinct period of time, but I think as we look at a life span approach for the *Dietary Guidelines*, it's becoming quite clear that a woman's nutritional and health status prior to pregnancy influences outcomes, how well that pregnancy proceeds influences not only the child's health, but lactation and subsequent pregnancies and longer-term health.

[1:34:13] So, I think that the concept of pregnancy and lactation should really be considered within the life span, and we should really be considering the health of the mother prior to, during, and after pregnancy.

So, the other thing to keep in mind is that pregnancy induces physiological and metabolic changes and that these can predispose some women to developing life-threatening conditions such as gestational diabetes and hypertensive disorders, and that these can also then predispose the mother to developing diabetes and hypertension later in life.

We also know that excessive gestational weight gain, so outside of the IOM recommendations, is relatively common, particularly in women with a high pre-pregnancy BMI, and that the retention of that excess body weight postpartum places that woman at higher risk for chronic diseases and subsequent pregnancies later in life.

[1:35:11] So, from the infant perspective, putting this within those first 1,000 days of developmental origin, we now know that those in utero and early life exposures are critically important for developing metabolic—risk of metabolic diseases and neurodegenerative disorders.

So, really focusing on the mother's health beginning at conception, continuing through the second year of life, it's critical to ensuring this optimal physical, social, and psycho-motor growth and development.

And again, as Barbara mentioned at the beginning, this is really the first edition of the *Dietary Guidelines* that's taking that life span approach, and with the pregnancy and lactation, and then the B-24, we're really encompassing those first 1,000 days of life.

[1:36:04] So, the previous, the 2015 Dietary Guidelines committee, included some discussion of nutrients of public health concern, but pregnant and lactating women were considered in the over age 2, but this is really the first time that we're really taking a deeper dive into specific relationships between food and beverage patterns and micronutrients during pregnancy and both maternal and fetal outcomes that affect large groups of women and their children.

So, we had 11 questions that we addressed, and as I mentioned, these were addressed by several different subcommittees. So, consistent with the *Dietary Guidelines*, there was a large focus on dietary patterns.

[1:36:58] So, we looked at dietary patterns during pregnancy and the risk of gestational diabetes, hypertensive disorders during pregnancy, gestational weight gain.

We also looked at frequency of eating on gestational weight gain and dietary patterns on gestational age at birth.

We then also looked at the relationship between dietary patterns consumed during pregnancy on birth weight, beverage consumption on birth weight, and then looking at maternal diet during pregnancy and the child's risk of food allergies and atopic diseases, including atopic dermatitis, allergic rhinitis, and asthma, examined seafood consumption and neurocognitive development in the child, which was presented earlier today.

And then, we also looked at omega-3 fatty acids from supplements on neurodevelopmental outcomes in the child.

[1:37:59] And then, we were able to examine also folic acid from supplements on a number of different outcomes, including maternal micronutrient status, gestational diabetes, hypertensive disorders, human milk composition, and neurocognitive development in the child.

So, I would like to mention that four of the systematic reviews included in this body of evidence, which examined the impact of dietary patterns during pregnancy on maternal and birth outcomes, were undertaken by the USDA and HHS as part of the Pregnancy and B-24 Project.

These were published in the American Journal of Clinical Nutrition in 2019 and were adopted by the 2020 guidelines committee.

We also, the remaining questions were answered by new systematic reviews.

[1:38:59] So, we generated 65 draft conclusions across the 11 questions.

There were over 160 articles representing over 110 studies in the new systematic reviews, and 51 articles representing 38 studies in existing reviews.

We were able to make conclusion statements graded from Strong to Grade Not Assignable, but I want to point out that we were unable to grade the evidence for most. Almost 70 percent of the conclusion statements were due to insufficient evidence, and I will give you a heads up that this is even worse for lactation.

So, I think as Regan mentioned, about not having good surveillance data in pregnant and lactating and B-24, the evidence base for us to draft our best conclusions also requires much additional research, and we've noted those gaps and made suggestions in the report.

[1:39:58] So, since we had so many questions, I just wanted to quickly, over the next three slides, just remind you of what the questions were and what were our summary conclusions.

So, for dietary patterns and GDM, we were able to have a grade of Limited for dietary patterns before pregnancy and risk of GDM.

We looked at dietary patterns and hypertensive disorders. We were able to have a grade of limited for diet before and during pregnancy, but only in healthy white women, not in other races and ethnicities.

And for dietary patterns during pregnancy and gestational weight gain, there was a grade of Limited for during pregnancy.

I wanted to point out, for question 4, which is the frequency of eating.

There was no evidence available for dietary patterns before and during pregnancy and gestational age at birth.

[1:41:00] During pregnancy, there was limited data for improvement.

And then, looking at these last two, the dietary patterns and birth weight, we were unable to make a conclusion.

And beverage consumption, there was insufficient evidence for any of the beverages.

So, this basically are all of the atopic outcomes that we looked at maternal diet, and you can review the various dietary patterns as well as milk products, but what I want to mention is that, for all of these, all of the evidence showed no relationship or no reduction in risk. So, there was no evidence to suggest that maternal consumption of any of these dietary components increased the risk of these atopic diseases in the offspring.

So, as I mentioned earlier, this is consistent with the American Academy of Pediatrics and other bodies, which suggest that women who are pregnant consume healthy varied diets and not restrict their intake of specific foods.

[1:42:04] In terms of seafood consumption, there was favorable for—during pregnancy for cognitive development, and also, language and communication. This was Moderate, and this was Limited.

Omega-3 supplements during pregnancy, again, favorable for cognitive development with a Limited.

And then, among the four outcomes we looked at for folic acid supplementation, this was really our only strong conclusion, that maternal folate supplementation improved maternal folate status, which, as Regan mentioned, may be important for prevention of neural tube defects, and that for hypertensive disorders, we found limited evidence that, if the folic acid supplement is consumed early in pregnancy by high-risk women, that it would reduce the risk. There was no benefit for low-risk women.

[1:42:59] So, turning to summarizing the data, we found that certain dietary patterns were associated with a modest risk reduction for excessive gestational weight gain, gestational diabetes, hypertensive disorders, and pre-term birth.

So again, these are all very important outcomes for maternal and child health.

It's also important to note that the components of these dietary patterns align with dietary patterns associated with lower overall chronic risk in women who are not pregnant and lactation.

So again, looking at this life cycle approach that potentially the recommendations we're making of women of reproductive age would be consistent during pregnancy as well.

So, this shows the dietary—the foods that higher consumption of these foods within the dietary patterns reduced the risk, and these are the foods that lower consumption of these within the dietary patterns reduced the risk.

[1:44:01] So again, if you're consuming higher levels of these, they're not beneficial.

So, really, the take-home message is, if you look across, there's quite a bit of consistency with fruit and vegetable consumptions, whole grains, nuts, legumes and seed, fish, and then also, pretty good consistency here.

So, I think that, within a dietary pattern approach, we can think about advice that could potentially reduce the risk of many very serious adverse outcomes of pregnancy.

I just wanted to mention frequency of eating, because that is something where there was no evidence, but we know the frequency of eating is an important component of dietary patterns, and there is some guidance from the IOM recommending that pregnant women eat three meals and two or more snacks a day, again, to try to ensure that they're consuming extra nutrients, but also, by minimizing gastrointestinal complaints.

[1:45:02] Also, some of the existing literature suggests that eating patterns do change during pregnancy, moving from main meal-focused patterns to more snack-dominant patterns by the third trimester.

But we really need more evidence to determine what's the impact of these changes in frequency of eating and meal patterns on outcomes?

And we also would add beverages as well because there was insufficient evidence to determine that, but we know that beverages also an important component of dietary patterns.

So, we—another summary, the evidence reviewed reinforces the importance of nutrition for women of reproductive age and women who are pregnant for optimal maternal and fetal outcomes.

And looking at chapter 14, so the food pattern modeling, what—

[1:45:59] Basically, each of the three patterns that are described in that chapter, the Healthy US-Style, Healthy Vegetarian, or Healthy Mediterranean-Style, is expected to meet the nutrient needs of women who are pregnant, with the possible exception of choline, iron, vitamin D, and vitamin E.

And again, you can see that choline, vitamin D, and vitamin E are kind of oftentimes identified across the life span as nutrients that are being under consumed.

Again, during pregnancy, the RDA for iron increases from 9 to 27 milligrams per day. So, women really need to make very careful choices, or may require iron supplementation to meet the iron needs, but we believe that, with education, that much of the iron needs during pregnancy could be met with diet.

Also, that folic acid supplementation, our systematic review confirmed that that improves maternal folate status and may reduce the risk of hypertensive disorders in at-risk women.

[1:47:10] But as noted by Regan, that really, a lot of the protection for neural tube defects and hypertensive disorders was early in pregnancy, and the neural tube closes within the first 28 days of gestation prior to the time that many women don't even know that they're pregnant.

So, looking at a life cycle approach, we would really recommend that women of reproductive age who are planning to become pregnant ensure that their folic acid status is sufficient.

So, moving on to the draft strategy.

So, we've done this in two ways. The first seven are strategies for women of reproductive age, and then we have several strategies directed to the agencies.

[1:47:57] So, the first is to encourage women to achieve a healthy weight before pregnancy and strive for gestational weight gain within the 2009 IOM recommendations, and that increased energy needs during pregnancy can best be met by consumption of a varied nutrient-dense diet.

Encouraging women before and during pregnancy to choose dietary patterns that are higher in the foods that we were able to show or are lower in the foods that we showed through systematic reviews, were associated with reduced risk of gestational diabetes and hypertension, excessive gestational weight gain, and preterm birth.

Again, encouraging women to consume foods and beverages that are good sources of potential shortfall nutrients identified in chapter 1, as Regan just presented. So, education of women who are pregnant to follow healthier dietary patterns can help to meet many of these nutrient gaps.

[1:49:02] Also, encouraging women to not avoid potentially allergenic foods during pregnancy unless it's medically warranted to protect the mother's health.

And also, encouraging women who are pregnant to consume seafood in accordance with recommendations of the *2015-2020 Dietary Guidelines*.

So, we found that seafood was part of a healthy dietary pattern, and so, we are encouraging or supporting the recommendation, and this recommendation is at least 8 to up to 12 ounces of a variety of seafood per week, but choices that are low in methyl mercury.

We also encourage women who are or may become pregnant to follow the *2015-2020 Dietary Guidelines* to avoid alcohol during pregnancy, particularly during the first few months, could result in negative behavior and neurological consequences.

[1:50:04] No safe level of alcohol consumption during pregnancy has been established.

And also, encouraging women who are pregnant to select foods in accordance with food safety recommendations outlined in previous reports of the *Dietary Guidelines*. This would include avoiding unpasteurized milk and soft cheeses, undercooked meats, and eliminating processed meats. Many of these are to avoid exposure to listeria.

But now, we have a couple of recommendations for the federal programs. The first is we support the efforts by federal programs, particularly the WIC program, Special Supplemental Nutrition Program for Women, Infants, and Children, and encourage pregnant women to take advantage of available nutrition counseling services.

[1:50:59] As noted by Regan, we support further development of surveillance systems and databases that report dietary and beverage intakes, but also, consider the context in which people are eating, which is important across the life span, but as I noted, because we know that women during pregnancy do change their patterns, that we should collect data that's rich in terms of not only when, but all of the eating occasions that are going on.

So, that is the end of the recommendations that we have for this report, so I'd be happy to take any questions.

Dr. Richard Mattes: Hey, Sharon. This is Rick. I have a question. Could you add some clarity on how refined grains were defined? It's a diverse group, and it has some staple foods, like breads and pastas, which frequently are enriched, and so, could contribute to nutrients of concern, but it also, it's my understanding, is that it includes things like donuts and cakes and cookies and so on.

[1:52:14] ***Dr. Sharon Donovan:*** Right.

Dr. Richard Mattes: Do you think that there is a need to differentiate within that group when looking for associations with health outcomes, or are you comfortable lumping all of those kinds of foods, sort of staple foods and the indulgent foods together?

Dr. Sharon Donovan: Right. That's a really excellent point. And so, that came from one of the pre-existing reviews. But I think that it would really be warranted to separate those, because there are a lot of fortified grains that are actually really important for helping pregnant and lactating women to meet folate requirements.

[1:52:57] So, I think that somehow getting a handle on refined flour that may be fortified, and I know that this could be captured through the surveillance systems, but I can't speak to specifically—we know that categories of foods that are considered whole grain versus refined grains, but that was a systematic review that we adopted that was a prior from the Pregnancy and B24.

But I think that your point is very well-taken.

Dr. Jamie Stang: Sharon, can you hear me?

Dr. Sharon Donovan: Yes.

Dr. Jamie Stang: This is Jamie Stang, and I was on that tech committee. And what I would say is I totally agree that it would—that there's a need to differentiate between the different types of refined grains. In that case, what happened is we—whatever was reported in the literature, and they generally just reported refined grains as a category.

[1:54:00] Most of the, if any, of the studies actually defined—included what was in there gave specifics.

So, we kind of had to go with what was reported by the research. But I think that's an important point that, when people publish research, it's really important to define what they're considering a refined grain.

Because otherwise, we're just using a term that could mean a lot of different things.

Dr. Barbara Schneeman: I think that's come out in other discussions as well. That's a good point.

Dr. Carol Boushey: This is Carol Boushey. And fantastic, fantastic presentation. Thank you so much. And there are parts of it that sort of followed up with Regan's, and this disparities in access to food.

And I realize we do have these federal programs that allow access to some high-quality food, the SNAP program, and the WIC program.

[1:55:07] And so, we really want to make sure that we support these programs and even—they're not enough even.

But that's one mechanism that we have and want to make—ensure that that mechanism stays in strong shape to help with these issues about diet, quality diet.

Dr. Sharon Donovan: Right. So, we need to have accessibility and affordability.

But I think, in looking at the evidence, it's quite clear that, I think we can develop educational messages to women about components of a healthy diet that actually can affect a number of outcomes that we really are trying to reduce the incidence in the US of during pregnancy.

[1:56:00] So, I think that part is helpful, that we don't have to have a lot of special different diets, that there's many components that are protective across many of the outcomes we looked at.

Dr. Barbara Schneeman: Other—

Dr. Linda Van Horn: Hi. Just one more. This is Linda Van Horn, and I agree, this is just so exciting to introduce this whole topic into the—this set of *Dietary Guidelines*, and with great expectations for things to come.

And one of those that I hope we would address in the future, because I think, as we have tackled this idea about diet over the life course, beginning, potentially, at the time of conception, these questions that were addressed, of course, are primarily related to pregnancy, lactation, etcetera.

[1:57:09] But as we begin to recognize that some of these dietary patterns, especially as they relate to adverse pregnancy outcomes such as gestational diabetes or gestational hypertension, etcetera, are now becoming clearly associated with future risk for cardiovascular disease in that woman, in that mother.

And so, that further contributes the thought that, if we are able to identify dietary patterns that would reduce these risks during pregnancy, they could have ultimate benefit for long-term health across the life course for—certainly for women.

[1:57:59] And so, going forward, being able to identify and connect these dietary patterns during pregnancy with adverse pregnancy outcomes and future risk, and ways to offer preventative strategies, I think will become increasingly interesting and potentially useful for a long-term prevention.

Dr. Sharon Donovan: Yeah. Yeah, I agree. There's a lot of evidence that's accumulating out there of even—like you mentioned starting at conception, but we certainly know that pre-conceptional health and dietary intake, and even in some of our systematic reviews.

So, there's a number of interventions now that are aiming at trying to improve the maternal health and body weight prior to conception.

And so, I do think that this is really an exciting research area, and I hope that, by the next edition, that we'll have a lot of new exciting evidence that we can examine that show the links really across the life span.

[1:59:06] ***Dr. Linda Van Horn:*** Right, right. I agree.

Dr. Ronald Kleinman: So, should we take a break here? Or go on?

Dr. Barbara Schneeman: Yes, I—I think we can go ahead and take a break here between. Maybe come back at around 1:30, give people a chance to refresh their tea or coffee or whatever time zone they're in.

Dr. Ronald Kleinman: Sounds great.

Dr. Barbara Schneeman: Yeah.

Dr. Ronald Kleinman: Sharon, you really took the floor, you really did a beautiful job with that.

Dr. Sharon Donovan: Thank you.

[Break 1:59:50- 2:26:57]

[2:26:57] ***Announcer:*** And you are live.

Dr. Ronald Kleinman: That's great. Thank you very much, and Sharon Donovan is going to continue now, discussing diet and health relationships, and now she's going to focus on food, beverage, and nutrient composition during lactation. Sharon?

Dr. Sharon Donovan: Thank you, Ron. So again, this was undertaken by the Pregnancy and Lactation subcommittee, with some questions also being examined by Dietary Fats and Seafood and the Frequency of Eating subcommittees.

So, just as with pregnancy, when we consider nutrition during lactation, we're considering both the health of the mother and the child.

And nutrient requirements during lactation are intended to support the nutritional needs of the mother, but also to provide additional amounts of energy and nutrients associated with the increased metabolic demand for milk synthesis as well as the secretion of nutrients into human milk.

[2:27:57] For many nutrients, the requirements during lactation differ from those during pregnancy. They're very distinct physiological states. So, women who are lactating should adapt their dietary choices and supplement use to meet the needs of lactation.

It's important to note that about 70 percent of women who are lactating use dietary supplements, which is higher than non-pregnant/non-lactating women, but about 50 percent of them continue to use prenatal supplements during lactation. So, that's something we'll address later on.

Also, you think about pregnancy, there's changes that are made during pregnancy to prepare for lactation. One of that is the deposition of body fats.

And so, energy requirements for lactation take into account mobilization of some of those maternal fat stores, which could then potentially assist women in postpartum weight loss.

Also, concentrations of some of the micronutrients, but not all, in human milk are correlated with the maternal nutrient status.

[2:29:03] And so, they can be also affected by diet and supplement use.

And when we think about human milk though, and Kay will touch on this as well, but human milk not only contains the nutrients that the infant requires, but many bioactive substances that can support optimal growth, development, but also influence neurocognitive and immune development in the risk of atopic diseases.

So again, for the first time, the *2020-2025 Dietary Guidelines* are specifically focusing on guidelines for women who are lactating. Previous committees have provided some guidance.

And we re-examined questions related to seafood consumption and omega-3 fatty acid supplements, which were addressed by previous committees, but really focused on a lot of new relationships, with a focus, again, on dietary patterns during lactation.

[2:30:03] So, we had a total of eight questions, and this is the first four.

So, we looked at dietary patterns, postpartum weight loss, frequency of eating and postpartum weight loss, dietary patterns and human milk composition and quantity, and we found no evidence on quantity, so we focused on composition.

We also looked at the relationship between maternal diet during lactation and child food allergies and atopic outcomes.

Then, we had three questions that focused on various exposures and neural development in the child.

So, the first is dietary patterns consumed by the mother during lactation, seafood consumption during lactation, and omega-3 fatty acid supplements during lactation.

We also examined folic acid supplements on three outcomes, maternal micronutrient status, human milk composition, and the child neurodevelopmental outcomes.

[2:31:04] So, all of these questions were answered by new NESR systematic reviews.

So, more than 30 articles, representing 25 studies, were included in 6 of the 8 NESR reviews, so no studies were identified that met the inclusion criteria for questions 5 and 6, which were dietary patterns and neurocognitive development and seafood consumption and neurocognitive development.

It's really important to note, though, that the subcommittee, we were only able to grade—we were unable to grade 33 of the 37 conclusion statements.

So, 89 percent of our conclusion statements were insufficient or no evidence.

So, there are clearly notable gaps, and we really encourage an active body of research to help to inform some of these gaps and to guide future *Dietary Guidelines*.

[2:32:02] So, to just quickly review the key science, we really were only able to grade evidence for two questions.

So, the first was the relationship between dietary patterns consumed during lactation and human milk composition and quantity. We were only able to grade evidence related to fats, so:

Limited evidence suggests that maternal consumption of diets higher in fat, so greater than 35 percent, and lower in carbohydrate during lactation is related to higher total fat content in milk collected in the maternal postprandial period.

So, this was very specific to the timing of milk collection.

There's also limited evidence to suggest that certain maternal dietary patterns during lactation, including diets based on macronutrient distributions, are related to relative proportions of

saturated fat and monounsaturated fat in human milk and polyunsaturated fats in human milk collected in the postprandial period.

[2:33:05] And part of these differences in these fatty acids are related to the difference between which fatty acids are actually synthesized within the mammary gland, which are the saturated/monounsaturated versus the polyunsaturated, which more closely reflects maternal diet.

So then, the other question that we were able to form conclusion statements was related to folic acid supplements and fortified foods. So, again, we found no evidence for fortified foods, so we were only able to have conclusions with supplements.

We were able to conclude that moderate evidence indicates folic acid supplements consumed during lactation are positively-associated with red blood cell folate and may be positively-associated with serum and plasma folate.

[2:33:58] So again, this is consistent with what we found during pregnancy for folic acid supplementation and maternal status.

Moderate evidence indicates that folic acid supplements consumed during lactation do not influence folate levels in human milk. And again, this is consistent with the evidence, although folate is a water-soluble vitamin, the levels in the maternal diet do not seem to influence the concentrations in human milk.

So, we were unable to draw conclusions regarding maternal dietary patterns or frequency of eating during lactation and postpartum weight loss.

We also, no conclusions regarding maternal dietary patterns and human milk composition, other than total fat and fatty acids.

And no conclusions regarding maternal dietary patterns, seafood, omega-3, or folic acid supplementation on neurocognitive outcomes in the child could be drawn due to lack of evidence.

[2:34:58] So, the quandary here, so we did find, with pregnancy, that certain dietary patterns were protective. We also found that many of those components aligned with dietary patterns associated with lower chronic disease in women who were not pregnant or lactating.

So, these, again, supports relatively consistent dietary patterns associated with healthy outcomes in women of reproductive age.

Therefore, and it's shown in chapter 14, that the three food patterns, the Healthy US, Healthy Vegetarian, and Healthy Mediterranean-Style, will—are expected to meet the nutrient needs for women who are lactating, with the possible exception of vitamin A, choline, D, and E.

So, if you were here during the pregnancy, choline, vitamin D, and vitamin E are consistent.

[2:35:56] During pregnancy, it was—iron was not met by the dietary patterns, and for lactating women, it's vitamin A.

So, while we were unable to throw—show through systematic reviews, relationships, we believe that it's still prudent to recommend that women who are lactating continue to consume healthy dietary patterns consistent with benefits during pregnancy and for non-pregnant and non-lactating women, which should meet most of their nutrient needs.

Again, despite the lack of evidence to determine the relationship between seafood consumption during lactation and neurocognitive outcomes in the child, we believe that seafood choices are still important components of a healthy dietary pattern for women who are not pregnant and lactating, as well as those who are pregnant.

Additionally, seafood may increase the DHA content of human milk and provides other shortfall nutrients for women who are lactating.

[2:36:57] So, that leads us to our recommendations. So, we have strategies for women who are lactating, and then several for the agencies.

So, the first is basically to encourage women who are lactating to consume a wide variety of foods that are consistent with dietary patterns described in chapter 14.

Encourage consumption of foods and beverages that are good source of the potential shortfall nutrients identified in chapter 1, as well as those that I just mentioned, that may not meet the requirements on these three patterns described in chapter 14.

So, for example, choline was both a shortfall nutrient as well as may not be met by these dietary patterns for lactating women. Therefore, we believe that they should follow the dietary

patterns but may need some selective education/nutrition education on different food sources to emphasize to meet some of these shortfall nutrients.

[2:38:00] We encourage women to discontinue the use of prenatal supplements during lactation unless they're medically indicated. These supplements are usually formulated to meet the high iron requirements of pregnant women.

As I mentioned before, pregnant women have an iron requirement of 27 milligrams per day versus 9 for non-pregnant women, and the iron requirement during lactation drops back down. So, if they continue to take the prenatal supplements, they are at risk of exceeding the upper limit for iron intake during lactation.

We encourage women not to avoid potential allergenic foods. There was no evidence that that reduced atopic outcomes in the infants. Again, unless medically indicated for the mother's health. For example, if she has an existing food allergy, then obviously, it's prudent for her to avoid those foods.

[2:39:01] And then, these are basically recommendations where we're continuing to recommend from the *2015 Dietary Guidelines*, which is that women who are breastfeeding should consult their health provider regarding alcohol consumption, and also, to consult a healthcare provider about advice concerning caffeine consumption. We did not specifically review this evidence, but we think it's prudent to carry those over.

Again, we encourage women who are breastfeeding to consume seafood in accordance with the recommendations of the *2015-2020 Dietary Guidelines*, which again, is 8-12 ounces of a variety of seafood per week, with choices that are lower in methyl mercury.

And the last is really kind of going back to this life cycle approach in terms of body weight, and so, encouraging women to maintain a healthy pre-pregnancy weight, achieve appropriate weight gain during pregnancy, initiate and maintain breastfeeding throughout the child's infancy, which can potentially help with postpartum weight loss, and then to return to a healthy weight during the postpartum period if possible.

[2:40:16] Again, we did not review evidence regarding relationships between maternal BMI or gestational weight gain through lactation success, however, there's other evidence in the literature that shows a high pre-pregnancy BMI and excess gestational weight gain are risk factors for suboptimal breastfeeding outcomes.

So, we have now three recommendations to—we support, we should say, the recommendations for federal programs. Again, going back to WIC, just as in pregnancy, we encourage women who are lactating to take advantage of available nutrition counseling services.

[2:40:55] We also have some recommendations around policy systems and environmental change strategies, and competitive pricing of healthy food and beverage choices, so that women of all economic strata can afford them. Again, looking at the healthy foods and beverages in pantries and other food assistance programs. So, I think this touches on what we were discussing previously in terms of access.

Given the documented health benefits to the mother and the infant, we support broad implementation of federal programs that promote, protect, and support breastfeeding.

And we also, just as with pregnancy, support the development of surveillance systems and databases to report food and beverage intakes, and this ideally should represent diverse subgroups of women, include effects of food security and economic status, and include food and beverage consumption and supplement data to show how fortified foods and supplemental sources of nutrients contribute.

[2:41:58] As I mentioned, in all of our searches on fortified foods and supplements, there was no evidence for fortified foods. So—and I think as Rick brought up, there are many components of the food supply that are fortified with micronutrients, so are important for pregnant and lactating women.

So, just a final point, that again, despite the importance of the questions examined in this chapter, the available evidence for most questions was insufficient. So, 89 percent of our 37 conclusion statements were no or insufficient evidence.

So, many questions remain to be answered. Content and pattern of the diet of women during lactation, the influence of postpartum weight loss, human milk composition and quantity, and child outcomes are just a few, as well as other questions that the committee was not asked to address. And these will be outlined in the report.

[2:43:01] So, thank you.

Dr. Ronald Kleinman: Well, that was amazing. Thank you very much for going through all of that so quickly, and we will hold on, on questions, and move on to Kay's presentation, and then we can have questions at the end of that.

So, with that, Kay Dewey is going to talk about diet and health relationships birth to age 24 months, and she has four chapters to go through. Kay?

Dr. Kathryn Dewey: Thanks, Ron. And thanks, Sharon. Yeah, this is a bit of a marathon here, so I hope everybody can hang in there. I'm going to go pretty quickly through chapters 4, 5, and 6, because those conclusions statements have been presented previously, and I'll spend more time on chapter 7, which is new.

But I do want to thank all the members of the subcommittee. We've worked very hard at creating what I'm about to show you, and as well, all of the staff involved.

[2:44:04] So, for the first chapter, I'll talk about chapter 4. We had four outcome domains that we examined with respect to the duration, frequency, and volume of exclusive human milk or infant formula consumption, and those were overweight and obesity, long-term health outcomes, nutrient status, and food allergies and atopic allergic diseases.

So, even though there's only those four questions, there were many, many more sub-questions, because there were six different human milk or infant formula exposures that are lined up on that left-hand column in terms of ever versus never, the duration of any human milk, the duration of exclusive human milk consumption, the intensity of human milk feeding in mixed feeding, breast versus bottle-feeding in those that feed human milk, and a question about topping up within a feed or within a feeding episode.

[2:45:02] So, the blue dots, of which there are 58, represent the topics that we examined for these questions, these exposures, and all of the different sub-outcomes that were included.

The questions on overweight and obesity and nutrient status were answered using new NESR systematic reviews. And just earlier this morning, I talked about the conclusion statements for overweight and obesity.

The questions on long-term health and food allergies and atopic diseases were answered using existing NESR systematic reviews from the Pregnancy and Birth to 24 Months Project, which was published in 2019.

And actually, the purpose of that project was to conduct these reviews that would contribute to the evidence base going into these new *Dietary Guidelines*.

[2:45:56] So, in terms of what we covered, over 200 articles were included in the NESR systematic reviews, and over 150 from the existing reviews, and over 60 from the new reviews.

The conclusion statements were graded from Moderate to Grade Not Assignable.

And most of the evidence compared infants who ever consumed human milk with infants who never did so, or infants who consumed human milk for different durations.

Most of the evidence measured outcomes during childhood.

Most of it was observational studies, but there was that one exception of a cluster randomized controlled trial, the Promotion of Breastfeeding intervention trial, that provided evidence for overweight and obesity, atopic disease, and long-term health outcomes.

And in a nutshell, human milk consumption was sometimes associated with a beneficial outcome for overweight and obesity, asthma, and type 1 diabetes, and was sometimes not associated with an outcome, for example, atopic dermatitis, but in no case was consuming human milk associated with an adverse outcome.

[2:47:04] So, instead of going through all the conclusion statements again, I'm going to just summarize our key findings here, and to show you that for ever versus never being fed human milk, that was related to a lower risk of overweight or obesity, type 1 diabetes, and asthma.

A longer duration of human milk feeding was related to a lower risk of type 1 diabetes and asthma.

And a lower duration of exclusive human milk feeding was related to a lower risk of type 1 diabetes.

Most of these were graded as Moderate, the exceptions being type 1 diabetes for ever versus never being fed human milk, which was graded Limited, and for the duration of exclusive human milk feeding with type 1 diabetes.

[2:48:00] Now, we talked this morning about the evidence for the relationship between ever versus never and risk of child overweight and obesity, but what I want to go through now is a little

discussion about how difficult it is to actually draw conclusions from that in terms of causality, and this is because of the risk of confounding in observational studies and the limitations of the sibling-pair studies.

But I can say that other systematic reviews and meta-analyses have generally come to similar conclusions.

There was an umbrella review, for example, in 2016, that estimated a reduction of about 13 percent from the high-quality studies, but even then, they couldn't completely rule out residual confounding.

And in terms of the duration of breastfeeding, they did indicate that a very short duration seems to be having a lesser protective effect than breastfeeding of longer duration with respect to overweight and obesity.

[2:49:01] Now, there are a number of potential biological mechanisms that could underly this relationship. For example, a rapid weight gain during infancy is consistently related to subsequent risk of overweight or obesity, and it's well-documented that rapid weight gain is more likely among formula-fed infants.

This may be partly due to a difference in infant self-regulation of energy intake, which may differ between breast-and formula-fed infants for a variety of reasons.

One thing that's been examined is the protein intake among formula-fed infants, which is speculated to drive hormonal differences that may stimulate greater weight gain and fat deposition.

And there are some randomized controlled trials of reduced protein formulas that have demonstrated less-rapid infant weight gain and reduced obesity at school age, although the precise mechanisms for this are not yet clear.

[2:50:01] In addition, the concentrations of free amino acids in human milk compared to formula also may be important. We know that free glutamate is high in human milk and it is a key signal for satiation.

One experimental study looked at this question and actually found a significant difference in early rapid weight gain when glutamate content was higher.

In addition, there's the possibility of overfeeding of formula-fed infants. We know that feeding by bottle may make it more difficult for the infant to communicate satiety signals and the caregiver may urge the infant to finish the bottle so as to avoid wastage.

These sometimes differences in the dietic approach of caregivers and infants during feeding may have longer-term implications for programming of appetite regulation.

[2:50:58] So, moving on to type 1 diabetes. The prevalence of this is relatively low, but small increases in the risk for this outcome may have important public health implications.

The autoimmune destruction of insulin-producing beta cells in the pancreas that results in type 1 diabetes occurs in genetically-susceptible individuals but is likely triggered by environmental agents early in life.

So, that's why it's possible that infant feeding could be playing a role. And the potential biological mechanisms for a protective effect of breastfeeding are probably linked to differences in composition of human milk compared to infant formula.

There are numerous biologically-active components in human milk, and they may play a role in reducing gut permeability and early enterovirus infections and in promoting a healthier infant gut microbiota.

[2:51:56] For asthma, the conclusion we reached that human milk is related to reduced risk of asthma is supported by previous meta-analyses. I won't go through all the numbers shown here. I just want to point out that in children with an atopic first-degree relative, the odds ratio was—is quite dramatic, 0.52, whereas in those without a family history, it was not significant.

So, for this outcome, potential biological mechanisms are that breastfeeding is associated with a reduced number of respiratory tract infections in infancy.

Exclusive breastfeeding may be beneficial for lung function. There's some good evidence on that front.

And breastfeeding may mediate these effects through protecting the lungs from viral infections or by promoting maturation of the infant immune system and microbiome.

[2:52:57] So, in terms of what kinds of evidence we were able to look at, our reviews were limited to selected outcomes, as you've seen here, and we were not asked to review some other types of

outcomes. For example, we did not include child infectious diseases, cancer, mortality, or development, nor any of the maternal outcomes that may be related to the initiation or duration of lactation, including a reduced risk of breast, ovarian, and endometrial cancers, hypertension and cardiovascular disease, non-alcoholic fatty liver disease, and type 2 diabetes.

So, the feeding recommendations that are developed should ideally take all of these into account.

With that said, the evidence that we did review is consistent with existing recommendations for breastfeeding in the US and globally, including many other high-income countries, which generally advise exclusive breastfeeding until about age six months, with continued breastfeeding thereafter, together with appropriate complementary feeding, until at least 12 months or 24 months of age.

[2:54:13] However, the current breastfeeding rates in the US indicate considerable room for improvement.

This slide illustrates how the breastfeeding rates currently compare to the 2020 Healthy People goals. And the good news is that the rates generally have achieved those goals. Initiation of breastfeeding is almost 84 percent, which is up from 76.7 percent in 2010, and exceeds the 2020 goal.

By six months, 57 percent are breastfeeding, which is up from about 47 percent in 2010 and slightly below the 2020 goal of 60.6 percent.

[2:54:56] And by 12 months, 36 percent are breastfeeding, which is up from about 25 percent in 2010, and slightly above the 2020 goal of 34 percent.

Exclusive breastfeeding rates at three and six months are very close to the goals, with about half exclusively breastfed at three months, which is up from 37 percent in 2010, and 25 percent at six months, up from 17 percent in 2010.

However, this still means that 75 percent of infants in the US are not exclusively breastfed or exclusively fed human milk during the first six months, as recommended. And the prevalence of mixed breast and formula feeding, which is not shown here, is quite high.

At six months, for example, 32 percent of infants received human milk supplemented with infant formula, and 43 percent received no human milk at all.

Therefore, the committee supports two recommendations.

[2:55:59] The first is to encourage exclusive breastfeeding, ideally for the first six months of life, with continued breastfeeding through the first year of life or longer, as desired by the mother and infant, and to encourage the broader implementation of policies and programs that promote, protect, and support breastfeeding to benefit both the health of the mother and the infant.

And with that, I'd like to, again, thank the support staff for this and ask if there are any short questions on this chapter before I move on to chapter 5.

Is anybody there?

Dr. Ronald Kleinman: Yes.

Dr. Kathryn Dewey: Okay. Thank you. Alright, well I'll take silence as affirmative. Okay.

[2:56:56] So, just in order to move along and get through this as quickly as possible, I'll get started with chapter 5, and this dealt with complementary feeding, or foods and beverages consumed during infancy and toddlerhood.

And for this set of questions, we had both the timing and the type of complementary feeding with respect to five types of outcomes, growth, size, and body composition, development, nutrient status, bone health, and food allergies and atopic allergic diseases.

The first five questions were answered using existing NESR systematic reviews from the Pregnancy and Birth to 24 Months Project published in 2019 as we already mentioned.

Question 6 was the relationship between added sugars consumption and risk of cardiovascular disease.

[2:57:57] Number 7 was types of dietary fats and cardiovascular disease.

And number 8 was seafood consumption and risk of cardiovascular disease and neurocognitive development.

Those three questions were part of the new NESR systematic reviews conducted by other subcommittees – Beverages and Added Sugars subcommittee and the Dietary Fats and Seafood subcommittee.

For these reviews, over 230 articles were included.

And the conclusion statements were graded from Strong to Grade Not Assignable.

Most of the articles were from the 10 existing NESR systematic reviews that examined the timing of introduction and/or the types and amounts of complementary foods and beverages consumed and various health outcomes.

In the new systematic reviews, there was one article on added sugars and cardiovascular disease, three on types of dietary fats and cardiovascular disease, and no studies on seafood consumption and either cardiovascular disease or neurocognitive development.

[2:59:10] So, we had very little evidence on those.

Most of the evidence measured outcomes during childhood, and most of it was from observational studies, although many reviews also included some randomized controlled trials.

I'll start with the issue of timing of complementary food and beverage introduction, and the evidence suggests that complementary foods and beverages should not be introduced to infants before four months of age.

This is consistent with a recent meta-analysis indicating that introducing such foods before four months was associated with an increased rate of overweight and obesity at 2-12 years.

[2:59:58] Complementary food and beverage introduction at age 4-5 months versus 6 months does not offer long-term advantages or disadvantages with regard to growth, size, body composition, overweight or obesity, iron status, or risk of food allergy, atopic dermatitis, eczema, or asthma during childhood.

And formula-fed infants may be at particular risk of excess energy intake when complementary foods and beverages are introduced early, as they appear to exhibit less self-regulation of energy intake than is observed among breastfed infants.

With regard to the types and amounts of complementary foods and beverages and growth, size, and body composition, we found that these outcomes were generally unrelated to intakes of meat, cereals, or foods that differed in fat content or composition, and this is consistent with the conclusions of a recent umbrella review.

[3:01:00] It did not find associations between certain types of complementary foods and subsequent growth or body composition outcomes. That review also found no relationship between total fat or polyunsaturated fatty acid intake and these outcomes.

However, the consumption of sugar-sweetened beverages does appear to be related to an increased risk of obesity in childhood, although the evidence for that is quite limited.

And juice intake appears to be positively-associated with infant weight for length and child BMIZ scores.

But again, the evidence is limited, and most studies did not specify the type or percentage of fruit in the juice.

With regard to iron status, this was our strong conclusion statement, showing that iron-rich or iron-fortified complementary foods and beverages, for example, meats and iron-fortified cereals, can help maintain adequate iron stores or prevent iron deficiency during the first year of life among infants with insufficient iron stores or breastfed infants who are not receiving adequate iron from another source that, for example, might be fortified.

[3:02:22] The benefit of those types of iron-rich or iron-fortified foods for infants who have sufficient iron stores, for example, those that are consuming iron-fortified infant formula, would be less evident.

And these conclusions are consistent with the recommendations of numerous authoritative organizations regarding the need for an adequate source of dietary iron after six months when iron stores at birth may become depleted.

[3:02:57] And that's quite critical because iron is particularly important for normal neurological development and immune function.

For zinc status, there is some evidence that complementary foods and beverages with substantial zinc can support zinc status during the first year of life, particularly among breastfed infants who are not receiving adequate zinc from another source.

And again, the benefit is less evident for infants who are consuming a fortified infant formula.

The reason for this is that zinc concentration in human milk declines sharply during lactation, and by six months, zinc intake from human milk is a very small proportion of the estimated requirements.

For that reason, both iron and zinc are considered problem nutrients, and this is true globally, for breastfed infants at 6-12 months. For example, the nutrient density per 100 calories of food required for breastfed infants at 6-9 months of age are nine times higher for iron and four times higher for zinc compared to the nutrient density required for an adult male.

[3:04:08] In terms of fatty acid status, we found moderate evidence indicating that complementary foods and beverages with differing fatty acid profiles, particularly the long-chain polyunsaturated fatty acids, can influence the child's status.

So, particular attention to the fat content and composition of such foods is needed because polyunsaturated fatty acids are key nutrients for brain development, which is most rapid from conception to age 24 months.

In terms of food allergies and atopic allergic diseases, atopic disease are actually relatively common in the US, and infancy may be a critical period for development of tolerance to food antigens.

[3:04:57] There's strong evidence that introducing peanut in the first year of life may reduce the risk of food allergy to peanuts. The evidence is strongest for infants with highest risk, but also applicable to others.

And these conclusions are consistent with other reviews. For example, a meta-analysis indicated that introducing peanuts in the first year of life was associated with a 71 percent reduced risk of peanut allergy.

And for that reason, the AAP now endorses introduction to peanut in the first year of life.

In addition, introducing egg in the first year of life may be beneficial.

There's less strong evidence on early introduction of other foods that contain common dietary antigens and prevention of allergies or atopic disease. However, the AAP states that there's no

evidence that delaying the introduction of such foods, for example, eggs and fish, beyond 4-6 months prevents atopic disease.

[3:06:04] So, in terms of our advice, we have a recommendation around timing of introduction that states that complementary foods and beverages should not be introduced to infants before 4 months of age, and introduction at age 4-5 months as compared to 6 months does not offer long-term advantages or disadvantages with regard to the outcomes that we reviewed.

Now, for infant feeding guidelines from other sources, for example, in high-income countries, they are consistent with this.

They generally recommend that such foods should be introduced at about or around six months, although some recommend an age range of 4-6 months.

And these types of recommendations should ideally take into account the benefits and risks related to all relevant outcomes.

[3:06:57] And our reviews did not include some of those outcomes, for example, infant infectious diseases and maternal outcomes that may be related to the duration of exclusive breastfeeding, and for that reason, the age of introduction of complementary foods and beverages.

With regard to the types and amounts of complementary foods and beverages, we recommend to provide foods that are rich in iron and zinc, either intrinsically, such as meats, or due to fortification, particularly during the second six months of life among breastfed infants.

And secondly, to provide complementary foods and beverages that contain adequate amounts of polyunsaturated fatty acids, given their critical role in brain development and the link between dietary intake and the child's fatty acid status.

Although human milk is an important source of key fatty acids, milk concentrations are influenced by maternal dietary intake. Thus, both the mother and the child should consume diets that are adequate in these nutrients.

[3:08:00] With respect to consistency, guidelines from several high-income countries also emphasize the need for foods rich in iron and zinc, with some recommending that these be the first complementary foods introduced, and Canadian authorities emphasize that higher-fat

complementary foods and beverages that are nutrient-rich are key complements of a healthy diet under two years of age.

With regard to food allergy and atopic diseases, the recommendation is to introduce peanut and egg in the first year of life after complementary foods and beverages are introduced.

And for other types of food allergy, the evidence for protective effects is less clear but we found no evidence that avoiding such foods in the first year of life is beneficial with regard to preventing food allergies or other atopic or allergic diseases.

[3:08:56] And recent guidelines from high-income countries are generally consistent in recommending that introduction of such foods should not be delayed beyond the first year of life.

In addition, we recommend to avoid consumption of sugar-sweetened beverages by children younger than age two years.

The evidence for avoiding or limiting juice intake under age two years is less clear.

The consensus is really quite widespread among authoritative bodies in high-income countries that sugar-sweetened beverages should not be consumed by children under two for several reasons.

First is that the energy from such beverages may displace energy from nutritious complementary foods and beverages, leading to nutrient gaps.

The second is that their consumption is related to the risk of child overweight.

And thirdly, the intake of such beverages in early life may set the stage for greater intake of sugar-sweetened beverages later on.

[3:09:57] I'd like to mention that there was a consensus statement quite recently from four organizations in the US recommending that juice not be given in the first year of life and that no more than four ounces per day of 100 percent fruit juice should be consumed at ages 1-3 years. Although we didn't have enough evidence to reach that conclusion, I wanted to let you know about that statement.

In terms of future DGAC topics, we want to stress that our committee was asked to address several questions related to what to feed infants and young children.

And these represent only a portion of all the feeding questions that are relevant for infants and toddlers.

So, questions of how to feed were not among the topics selected to be addressed by our committee, but they are of critical importance with regard to building healthy eating habits that can be maintained throughout life.

[3:10:59] So, these key issues should be taken up by the next DGAC.

And again, thanks to the staff, who were fantastic in helping put this all together. And I think there's time for a few questions if there are any.

Dr. Richard Mattes: This is Rick. I have two questions, one for Sharon and one for you, Kay.

Sharon, you identified three specific diets that were consistent with meeting nutrient goals, and I have no issue with that except recognizing that food availability is an issue and that cultural food patterns are important to recognize if we want people to actually follow a diet.

Are you concerned that, by labeling diets, we elevate them to a point that people think they have to follow that specific diet, when in fact, their local foods could just as well meet goals just by different combinations?

[3:12:10] So, rather than listing diets by names, we list the characteristics that should be emulated.

So, that's my question for Sharon.

And then, for Kay, you were very clear that you didn't answer all relevant questions for all the nutrients, and I'm wondering about the iron recommendation. As you pointed out, there is a literature on iron supplementation and risk of infection. Does that cause you to be a little more tempered in the recommendation for iron fortification when we didn't examine that question?

Dr. Kathryn Dewey: If I could answer that one first, it's real quick. We did examine that question, and that's in the next chapter 6 report that I'm getting to.

Dr. Richard Mattes: Oh, sorry. Okay, okay.

[3:12:57] ***Dr. Sharon Donovan:*** Yes, and then in terms of the diets, those are basically the names of the diets that are just dietary patterns, I should say, described in chapter 14 of the report. So, I did not name those. Those were part of the modeling with—where to show, if you followed those components, then you would be able to meet nearly—so we don't need a special diet for pregnant or lactating women. They should be able to eat a similar diet as non-pregnant/non-lactating women. They just need to—they need to make maybe some different food choices that are higher.

And so, maybe, I don't know, Regan, if you want to comment on that?

Dr. Regan Bailey: Yeah, I think these are more just used to describe the combinations of the food groups, and we'll have a whole presentation on the USDA food patterns.

[3:13:57] But there's a Healthy US-Style, a Vegetarian-Style, and a Mediterranean-Style. And that's exactly what they are. They are styles. They are words that describe these various combinations, but they are not prescriptive in nature.

And I'm uncertain, and I'd love ideas for how we would refer to these to the lay public if not to describe them in this way.

Dr. Richard Mattes: No, that would take me a little time to think about. But what you're describing is what I would hope the outcome would be, that they are just exemplars of patterns of food combinations that work rather than being specific sort of prescriptive ways, and listing only three of them gives the impression that these are the ways you have, these are your options.

[3:14:56] So, as long as we're real clear that they're just examples, I'm feeling better about it.

Dr. Regan Bailey: Yeah, and we only provide the examples really at the main food group level. Individuals can customize, like for example, vegetables. There's a recommendation for a specific cup equivalent of a vegetable, but that can be met through any combination of different categories of vegetables. I have a whole bunch of slides on that.

Dr. Barbara Schneeman: Yeah, I'm going to suggest we hold that discussion to chapter 14, and maybe, if there are any other questions for Kay, let her proceed with her other chapters?

Dr. Kathryn Dewey: Okay, thanks very much. Okay, can someone put chapter 6 up?

[3:15:59] Alright, great. This was, I've been told, the shortest chapter in the report. But it doesn't mean it was not a lot of work.

So, we examined nutrients from dietary supplements and growth, size, and body composition, and the relationship between vitamin D from supplements and bone health.

And both of these were answered using new reviews.

There were 16 articles altogether.

We graded the conclusion statements from Moderate to Grade Not Assignable.

And most of the evidence here was actually randomized controlled trials.

For the iron question, all the evidence focused on growth or size, not body composition, and it was in infants and toddlers and not older ages.

For vitamin D, most of the evidence focused on bone mass and biomarkers of bone metabolism, not rickets or fracture, and it was in infants and toddlers and not older ages.

[3:17:05] Just by way of some background, the AAP, in 2010, recommended iron supplementation for breastfed infants from 4 months until iron-containing complementary foods are introduced.

However, other authoritative organizations since then have recommended against routining supplementation of breastfed infants and instead recommend supplementation for high-risk groups or those with a diagnosis of iron deficiency, and some also note the importance of delayed umbilical cord clamping, which can have a strong effect on the iron stores shortly after birth.

Iron is one of those nutrients that can be considered a double-edged sword. It's very important to prevent anemia and support development, and supplementation can be highly beneficial for iron-deficient infants.

[3:17:59] However, excess iron intake among iron-replete infants may be harmful.

In our review, we found no positive effects and possibly negative effects on growth when iron supplements were given to breastfed infants younger than age 9 months compared with infants not given iron or given a placebo.

And these potentially adverse effects of iron supplements on growth under 2 years of age are consistent with other findings, for example, a meta-analysis of children from 4-24 months from both high-income and lower-income countries in which infants and children randomized to receive iron supplements had less length gain and weight gain than those who did not receive iron.

And there are several potential mechanisms by which iron may adversely affect growth among iron-replete children, including increased gastrointestinal illness, impaired zinc or copper status, pro-oxidative or pro-inflammatory effects, and disturbances in the gut microbiota.

[3:19:04] One important finding is that, before 6 months of age, iron homeostasis appears to be either absent or limited, such that supplemental iron is likely to be absorbed even if the infant is iron-replete.

After 6 months, infants appear to be able to down-regulate iron absorption appropriately.

So, our summary is that routine iron supplementation of all breastfed infants may not be advisable.

An alternative could be to screen for iron deficiency among higher-risk infants under 6 months and provide iron supplements only to those with iron deficiency.

After 6 months, other sources of iron can be provided, such as iron-rich or iron-fortified complementary foods, so iron supplementation is generally not needed.

[3:19:57] Moving along to vitamin D deficiency, this is most likely in those living at high latitudes with dark skin and/or with inadequate sunlight exposure.

The adequate intake for infants is 400 IU per day and, at 1+ years, it's 600.

The average human milk vitamin D concentration is only 20 IU. So, it's much lower than the AI.

While maternal high-dose vitamin D supplementation may increase human milk concentration, but the risks and benefits of that approach have not been fully evaluated.

And it's in large part for that reason that the AAP recommends vitamin D supplements for breastfed infants, and I have the full quote here, I won't read it, just to say that they do

mention the possibility that a lactating woman taking high-dose vitamin D has higher milk levels, but for breastfed and partially breastfed infants, they do recommend 400 IU of vitamin D per day.

[3:21:07] So, in our review, we looked at studies that were conducted since 2000, and the existing recommendations regarding vitamin D supplementation during infancy are based on the evidence compiled largely before 2000.

What we did review indicated that doses higher than 400 IU per day do not seem to result in any differences in biomarkers of bone metabolism compared to 400 IU per day.

So, we concluded that, at this time, the evidence does not provide a basis for recommending vitamin D supplementation above 400 IU.

[3:22:00] And that is all I have for chapter 6. If there aren't burning questions, I can move right on to chapter 7, which is—will have a lot more for everyone to digest.

Alright, well, I think everyone involved in chapter 7 can testify to the challenges that we encountered in attempting, for the very first time, to develop food-based dietary food patterns for this age group.

So, I'm going to go into a fair bit of explanation of what we did and what we learned from that process.

The questions were:

Can USDA food patterns be established based on the relationships identified in the systematic reviews?

And if so, how well do these variations meet nutrient recommendations for infants and toddlers?

[3:23:02] And if nutrient needs are not met, is there evidence to support supplementation and/or consumption of fortified foods to meet nutrient adequacy?

I'd like to start by mentioning that this period from birth to 24 months is characterized by major changes in feeding patterns and dietary intake.

Exclusive breastfeeding is recommended for about 6 months, and for infants not fed human milk or are mixed-fed, commercial infant formula is generally recommended until 12 months.

Around 6 months of age is the transition from sole consumption of human milk and/or infant formula to a varied diet that includes nutrient-rich complementary foods and beverages.

So, based on those assumptions, the committee decided that USDA food patterns are not necessary for infants younger than age 6 months, and we began the food pattern modeling work at age 6 months.

[3:24:00] One important consideration in looking at possible food patterns is the primary milk source consumed by the infant, and that's because human milk differs from infant formula in nutrient composition, bioavailability of nutrients, and the presence of bioactive substances.

In addition, the composition of human milk changes over time and in response to maternal diet.

So, the energy and the nutrients that are needed from complementary foods and beverages vary by infant milk source.

Well, I'll start with how we approached the age range from 6-12 months, and our first goal was to find combinations of complementary foods and beverages to meet nutrient needs of infants whose milk source is human milk, in other words, no infant formula, and we made that as the first goal because infant formula is fortified, so the intakes of certain key nutrients are considerably higher than is the case for a human milk-fed infant.

[3:25:05] But then, we went ahead and estimated the expected nutrient intakes of infants fed infant formula if they were to consume the same types and combinations of complementary foods and beverages.

Now, I want to note that the provision of key nutrients is only one of the ways in which human milk influences infant health and development. There are many health benefits of breastfeeding for the mother as well as the child, as we have mentioned. The food pattern modeling results that we'll show you for infants should not be interpreted as an evaluation of the value of human milk compared to infant formula.

They are intended to demonstrate the ways that nutritional goals can be met through these foods that take into account the milk source in the child's diet.

For 12-24 months, the food pattern modeling was conducted separately from what we had done at 6-12 months, and that's because there are RDA values for most nutrients for ages 12 months and older, but only for three at 6-12 months.

[3:26:12] Infant formula is not recommended after 12 months.

And most infants in the US no longer receive human milk after age 12 months.

So, the situation is quite different than it is at 6-12 months.

Now, I want to say a word about the role of complementary feeding, because it's not just a source for nutrients.

Complementary feeding is important for many other things. For example, introducing food types and textures can be beneficial for developing manual dexterity and other aspects of motor development, supporting the development of appropriate feeding and eating behaviors, and reducing the risk of food allergies.

And furthermore, implementing responsive feeding practices and the modeling of healthy eating behaviors, and bonding through food and mealtimes are very important aspects of complementary feeding.

[3:27:06] Food pattern modeling focuses on nutrient intake, and it is not designed to address these other important aspects of complementary feeding.

The methods for this were all based on the food pattern modeling approach and the analytical framework and food modeling process in general was presented at the March meeting.

I'm going to briefly go through the steps for this age range, because there are a few differences.

Our first step for establishing energy levels, we relied on the DRI formulas for estimated energy requirements that take into account the energy deposition for the growing child.

Then, we determined the appropriate energy levels of reach age/sex group.

[3:27:56] And we chose five energy levels from 600 to 1,000 calories at 100-calorie step intervals to cover the energy needs for the majority of infants and toddlers.

The second step is to establish nutritional goals. This was done based on the age/sex groups and for the nutrients that are shown here.

Other goals could include potential recommendations of the 2020 committee, as you'll hear in a few minutes.

The third step is to establish the food groupings and the food group amounts, and this was informed by the existing food groups and subgroups in the USDA food patterns for ages 2 years and older.

What we did was to create options with different proportions of energy from human milk or infant formula, and thereby, calculate the remaining energy for complementary foods and beverages.

To do this, energy from human milk was modeled at three levels, at low, average, and high, based on empirical data and applied to each of three age intervals.

[3:29:06] The energy from infant formula was also modeled at three levels but only applied to two of those age intervals.

This table shows the energy from human milk at those three levels, high, average, and low, at each time period, and the consequent amount of energy available for complementary foods and beverages.

So, just to illustrate, at 600 calories in total, human milk may range from a high of 600, meaning all of that in the earliest age range and at high intake levels, down to 240 calories at the lower human milk level at 9-12 months.

And as a result, the calories available for complementary foods and beverages range from none to 360.

[3:30:01] And just to illustrate, at 800 calories, the amount coming from human milk could be all of it down to a low of 160 calories from human milk, and the amount for complementary foods and beverages ranges from 0 up to 640.

So, this is just to illustrate to you that we had a very wide range of calories within which we were attempting to fit the foods and beverages that would meet all nutrient needs, and I will tell you that is quite a task.

We started by taking the 1,000-calorie level pattern established in the existing pattern and then, when total energy was to be less than that amount, the amount of each food group were decreased such that the food group density in the pattern remained similar to the food group density of the 1,000-calorie pattern.

[3:30:59] So basically, extrapolating downward, but keeping things proportional.

And then, we had to modify the combinations of complementary foods and beverages in order to reach all or most of the specified nutrient goals.

In order to ***[no audio 3:31:17- 3:35:03]***

Dr. Barbara Schneeman: —this all sound very logical. It's complicated. I know it is. I was on that discussion. So, you're doing a great job at communicating it.

Dr. Kathryn Dewey: Yeah, I think I finally understand. It helps to write the chapter and make the slides to get it all in your head.

Announcer: I think you're back alive.

Dr. Kathryn Dewey: Great. I'm going to go back. Is this the right place to start over?

Dr. Barbara Schneeman: Go back one slide. Okay, yeah.

Dr. Kathryn Dewey: Okay, so this is just to say we evaluated the nutrient level in each exercise against the goals, which were generally at least 90 percent of the RDA or the AI, and then if those goals were not met, we reevaluated and adjusted to the best of our ability.

[3:36:05] So, this slide illustrates some of the steps we took in the modeling for infants and human milk from 6-12 months.

And as I was saying, in the first step, with food groups amounts in proportion to the amounts in the 1,000-calorie pattern, there were many nutrient gaps. They were low in iron, as we expected, but also many other nutrients.

The iron content of this first step was far below the RDA of 11 milligrams, and the zinc content also tended to be below the RDA.

So, in the second step, we replaced 56 calories of grains with an equivalent amount from fortified infant cereal, which is half an ounce equivalent per day, and that allowed us to increase the iron content to about 8-9 milligrams at 6-9 months and 8-11 at 9-12.

[3:37:01] This was still lower than our goal for most energy levels and human milk proportion options, but it was much closer, and the zinc content was adequate.

So, the third step was then to examine how much energy remained for other complementary foods and beverages after including the fortified infant cereal.

And this slide illustrates how much that represents. I'm not going to go through all the details, but it has the three levels of human milk intake, we have the energy from all complementary foods and beverages, and then we subtract the infant cereal to give us the remaining amount, which is shown in the red bar.

And that is shown to be between 0 at 6-9 up to 224, and then from 124 to 484 at 9-12 months, and then from about 300 up to 740 at the second year of life.

[3:38:02] So again, a huge range in calories to work with for the other complementary foods and beverages.

So, in the final step, we examined how those calories could be allocated across the food groups and subgroups to move closer to adequacy for several nutrients in particular, iron, zinc, potassium, and choline.

So, one of the other things that we did was to set up a minimum amount of seafood, eggs, and nuts at this age in accordance with the recommendations to introduce these foods during this age period.

We also set a maximum for dairy, given that infants at this age are receiving human milk or infant formula.

And then, the remaining nutrient gaps were filled to the extent possible by prioritizing protein foods, particularly meat, because of the relatively high content and bioavailability of iron and zinc in red meats in particular.

[3:39:06] So, this table illustrates the approximate amounts of the food groups and subgroups in example combinations of complementary foods and beverages for ages 6-12 months. You'll notice that it is not called a USDA food pattern, and that's because we don't think it's quite ready for that label. This is simply some examples that came pretty close to meeting the nutrient goals.

And you'll see, if you look at the amounts, that they're pretty small, because at 6-9 months, babies are just not eating very much, but it does include the fortified infant cereal, as I mentioned, and it includes some protein foods and fruits, vegetables, and a very small amount of dairy.

The weekly amounts are also shown here in ranges just to illustrate what we think can fit into the calories.

[3:40:02] At 9-12 months, it's still a fairly small amount of food but slightly larger for all of these food groups than it is at 6-9 months.

What I can tell you is that there still were some gaps in the nutrients in these example combinations. So, for example, potassium falls short, which is true for many other age groups, and therefore, choosing potassium-rich fruits and vegetables, as well as whole grain products, which are generally higher in both potassium and iron than refined grains, is a good idea.

There's no energy remaining for added sugars at all, and very, very few calories available for oils or solid fats.

So, in terms of what the infants fed infant formula would then be consuming, we replaced, in the combinations I just showed you, we replaced human milk with infant formula, and because these models included both fortified cereal as well as infant formula, there were very few shortfall nutrients except for vitamin D and omega-3 fatty acids at some energy levels.

[3:41:19] However, there is the potential for excess intakes of certain nutrients, in particular, iron, which reaches almost two times the RDA at 9-12 months, although none of the estimates exceeded the UL of 40, and for zinc, which was generally somewhere between 200 and 340 percent of the RDA.

And all of those for zinc exceed the UL, which is only 5 milligrams, although I should say that UL has been challenged as being too low.

[3:41:56] But I can say that formula-fed infants don't need the extra iron and zinc from fortified infant cereal if the formula intake is above a certain level, and therefore, they could substitute other grain products, preferably whole grain, for the 0.5 ounces equivalent of fortified infant cereal.

So, these are the draft conclusion statements based on the 6-12 months modeling work.

We were not able to establish a recommended food pattern at this age because of uncertainty about nutrient requirements and challenges in meeting the RDA for iron in particular through complementary foods and beverages.

However, examples of potential combinations of complementary foods and beverages that come close to meeting almost all nutrient recommendations are described for a variety of scenarios that differ in the proportion of energy coming from human milk or infant formula.

[3:42:56] The example combinations that I just showed you support the consumption of fortified infant foods to meet nutrient adequacy for infants whose milk source is human milk.

And formula-fed infants who also consume iron-fortified infant cereals may consume pretty high levels for iron at this age, as I mentioned already.

So, further work is needed to determine the feasibility of meeting all nutrient recommendations for infants fed human milk at 6-12 months from diets that do not include any fortified foods.

With the exception of vitamin D, supplementation should not be necessary if fortified foods with appropriate levels of fortification are included for infants whose milk source is human milk, and I already went over with you the vitamin D supplementation guidance that's already present for infants.

[3:43:58] So, moving on to 12-24 months, we started with toddlers that were fed neither human milk nor infant formula.

And the first step, again, was to set up a model that included the food group amounts in proportion to the amounts in the 1,000-calorie pattern for older children.

And the subsequent steps were designed to fill the nutrient gaps that were evident in those first step models, for example, for iron and calcium.

And again, we set seafood at a certain minimum per week, and we also increased whole grains to achieve potassium, and oils to achieve omega-3 and omega-6 fatty acids.

This table shows the amounts in the food groups and subgroups in the Healthy US-Style pattern that we developed for these toddlers. So, I'm going to briefly run through what it shows.

[3:44:59] We have, with 1,000 calories on the left and 700 at the right, somewhere between ½ and 1 cup equivalent of fruit, 0.65 to 1 cup of vegetables, with a variety of different types of vegetables. Should note that the numbers in that portion are per week, not per day.

For grains, it ranges from 1.75 to 3 ounce equivalents per day with a vast majority coming from whole grains. We really had to pump that up in order to achieve some of the nutrients we were aiming for.

And the protein foods as a whole are 2 ounce equivalents per day and distributed in amounts per week with a pretty strong emphasis on meats and poultry, again, for the iron and zinc content, with some eggs, some seafood, nuts, seeds, and soy, and 1.66 to 2 cups per day of dairy, and 9-13 grams per day of oil.

[3:46:09] Now, for that pattern, I can show you the nutrient levels and how they compare to the AI or RDA. I'll just highlight a few.

The percent of calories from protein range from 18-23 percent, which is fairly high, and fat ranged from 32 to 35 percent.

There were some nutrients that fell short of 90 percent of the AI or RDA that are shown here in the red. This was mostly at the 700-calorie level, where the amount of energy for complementary foods and beverages is very small, and they were all between 84 and 88 percent, but for potassium, vitamin E, and vitamin D, we had shortfalls across most of the energy levels.

[3:47:03] Next, I'll turn my attention to toddlers fed human milk in the second year of life.

We started with the same first step and had to make adjustments to the protein foods, similar to what we had done for infants at 9-12 months, to increase both iron and calcium.

We also had to make adjustments to the vegetable subgroups in order to try to get as much of those nutrients into the pattern as possible, and this resulted in a decrease in the starchy vegetables compared to other patterns.

And we refined—reduced the refined grains to about ¼ cup per day, ¼ cup equivalent, and adjusted dairy to allow for some energy for oils.

Despite all those steps, we still had nutrient shortfalls for several nutrients, but I will still show you what we came up with.

[3:48:02] And again, these are example combinations, because we do not feel ready to label these as actual formal food patterns, given how far we were able to get, but what you can see is that, at 12-24 months.

Can people still hear me? I have a funny sound coming through.

Dr. Regan Bailey: Yes.

Dr. Kathryn Dewey: Okay.

Dr. Regan Bailey: I can hear you.

Dr. Kathryn Dewey: Good, good. Alright.

So, you can see that the amounts of fruits, somewhere between 1/3 and 3/4 of a cup, 2/3 of a cup of vegetables, changes in the weekly—sorry, distribution across the subgroups of vegetables for the weekly amounts, total grains of about 1 1/4 to 2 1/4, and pretty high levels of total protein foods with a distribution across all of those subgroups, a wide range in dairy, because of the differences in calories available, and then 2-11 grams of fat.

[3:49:10] So, moving on, the next thing we tackled was a vegetarian diet for toddlers, and I need to emphasize that this is a lacto-Ovo vegetarian diet, and this is for toddlers fed neither human milk nor infant formula.

We started with the Healthy Vegetarian-Style pattern at the 1,000-calorie level for older groups.

And there were several nutrient shortfalls when we had that first step, so we then went on to adjust it.

We included three eggs per week to achieve choline.

We shifted the grains to emphasize whole grains.

And we ended up with the pattern shown here. Again, I'll run through it pretty quickly.

[3:50:01] It's similar in terms of fruits and vegetables to the Healthy US-Style pattern for non-vegetarians, and again, with a distribution across those subgroups of vegetables, but it has more legumes than the other pattern.

For grains, very similar in terms of total grains, a very strong emphasis on whole grains in order to meet the nutrient needs.

And protein foods, in terms of 1 ounce equivalent per day, and that's provided by eggs, nuts, seeds, and soy, and dairy.

And then, a small amount of oils.

For this pattern, it's similar in many ways to the Healthy US-Style, but it's a little bit lower in protein, 16-18 percent.

[3:50:59] Calories from fat ranges from 33 to 36 percent. And there are, again, a few shortfall notes here for the 700-calorie level in particular, and for potassium, vitamin E, and vitamin D again.

So, draft conclusion statements for this age group are that, for toddlers fed neither human milk nor infant formula, we developed a food pattern that is consistent with the proportions of food groups and subgroups recommended for children 2 years and older.

It requires careful choices of foods and beverages but does not require inclusion of fortified products specifically formulated for infants or toddlers to meet the nutrient recommendations.

For toddlers who receive at least 20 percent of total energy from human milk, we were not able to establish a recommended food pattern because of uncertainty about nutrient requirements for this age range and challenges meeting the RDAs.

[3:52:07] However, we do show examples of potential combinations that come close to meeting all nutrient recommendations.

For toddlers fed a lacto-Ovo vegetarian diet and fed neither human milk nor infant formula, we developed a Healthy Vegetarian pattern that includes regular consumption of eggs, dairy products, and soy, and nuts or seeds, in addition to the other food groups.

This also requires very careful choices of foods and beverages but does not require inclusion of fortified products.

For both of the age intervals from 6 all the way to 24 months, we have another conclusion statement regarding added sugars, and that is that the combinations of foods needed to achieve recommended intakes of key nutrients leave virtually no remaining dietary energy for added sugars apart from the very small amounts already inherent in the foods used in modeling.

[3:53:10] I just want to say a few more things to discuss what we learned.

The first is that it is very challenging to develop recommended food patterns for this age group because the nutrient needs are high relative to energy requirements and the amounts of food consumed are very low, especially at the younger ages.

We opted to start with modeling the contributions of food groups in proportion to the 1,000-calorie pattern for the older groups with adaptations to correspond to the nutrient needs of this age range.

And this has the advantage of developing patterns that are feasible with respect to the types of foods consumed in the US and that become consistent with the patterns recommended for older age groups by the time we reach 24 months.

[3:54:03] ***yu*** However, the results do not necessarily represent the optimal combinations of foods and beverages for meeting nutritional goals, which actually requires a different modeling approach, and there are pros and cons to doing it differently.

The strengths of the approach we took is that it modeled various scenarios regarding the potential contribution from human milk or infant formula, and in general, the USDA food patterns provide examples of amounts of food groups and subgroups to consume, but they

don't dictate the specific types of foods, and this flexibility allows for foods to be tailored to an individual's needs and preferences, the cultural preferences, and cost considerations.

There are some limitations of what we had to work with. There is uncertainty regarding the nutrient composition of human milk, as was already mentioned, and the nutritional goals in the models for 6-12 months are based mainly on adequate intake values because the RDAs are available only for protein, iron, and zinc.

[3:55:07] I want to say a few words about iron because it is a key nutrient at 6-12 months, and it was the most limiting nutrient for the infants fed human milk.

We couldn't meet the RDA without including iron-fortified infant foods. I should mention that those sorts of foods have been an important strategy for reducing iron deficiency in the US for several decades. But fortified infant foods are not necessarily the only way for infants fed human milk to achieve the RDA for iron.

Red meat is a good source of iron, and heme iron is better absorbed, but obtaining the required amounts solely from red meat, if we don't count liver, may not be feasible. If you put liver in the equation, you can get there, but it's not that widely consumed.

[3:55:55] So, further work is needed to estimate the quantities of animal-sourced foods that would be needed by infants fed human milk to support adequate iron status without fortified foods.

On the other side, infants fed infant formula have the potential for excessive intakes of iron, as I've mentioned.

And this is because the iron content of formulas that are most commonly used in the US is relatively high, and it's about 40 times the iron content of human milk. So, there is a huge difference.

I'd like to say a couple words about potassium. It was challenging to meet the AI for potassium in all of the models.

I should say that there are uncertainties regarding the AI values, but nonetheless, choosing potassium-rich foods is important at these ages.

And so, iodine, we could not predict iodine intakes because the food composition data are not available. But in situations in which neither the mother nor the infant consumes iodized salt or obtains adequate iodine from other sources, the iodine intakes of infants could be deficient.

[3:57:01] And this is important, because the underconsumption of iodine during infancy has some important potential consequences for brain development, especially if maternal intake was also low during pregnancy.

So, we have some conclusions. I won't read all of these because I've already mentioned that for infants aged 6-12 months, we were not able to come up with a recommended food pattern, so we do think some additional work is needed.

Tools such as linear programming and taking into account differences in iron bioavailability in different sources would be very helpful.

We did learn of the importance of prioritizing certain food groups, for example, certain animal source foods are very important sources of key shortfall nutrients, not just iron and zinc, but choline and long-chain polyunsaturated fatty acids.

[3:57:56] Fortified infant cereals can contribute a substantial amount of some of these nutrients, but we still need to pay attention to some of these other food sources to provide all the critical nutrients.

By contrast, the dairy products are probably less crucial at this age than other types of animal-source foods at 6-12 months, because infants are still receiving human milk or infant formula and dairy products tend to have low amounts of iron.

Prioritizing fruits and vegetables is another key element. They're very important, not only for the nutrients they provide, but also to foster acceptance of such healthy foods.

And in addition, the introduction of peanut products and egg in the first year of life is advised to build tolerance to food antigens and to provide good sources of fatty acids and choline.

Moving on to 12-24 months, we were able to establish a food pattern for toddlers fed neither human milk nor infant formula, and this has a wide variety of different sources of foods.

[3:59:05] Again, the key aspect include emphasizing potassium-rich fruits and vegetables, prioritizing seafood, making whole grains a predominant type, and choosing oils over solid fats.

In these patterns, energy from oils is fairly minimal and there's no energy remaining for added sugars.

This figure illustrates the amounts in the recommended intakes in that pattern for the toddlers, which is in the black bars that have the headers and footers on them.

And then, the 5th to 95th percentile of the intakes that we actually have from intake data for this age range from 12-24 months.

And what this illustrates is that, for some of the food groups, like for fruits and for vegetables, the intakes are not that far away from the recommended intakes.

[4:00:05] In the case of fruits actually, it's fine. For vegetables, the recommendations are at the high end. But for the—and for total grains, the intakes are quite high, but for whole grains, the intakes are below the entire range of recommended intakes for both males and females, whereas the refined grain intakes are well above the recommended intakes.

So, that shift is a critical one.

Total protein foods are actually within the intake range and the recommendations for dairy foods also are there.

So, we do think that there is a certain amount of feasibility in the patterns that we were able to develop for the toddlers.

For toddlers fed human milk at 12-24 months, we had a much harder time, but we are able to provide some examples of potential combinations of foods and recommend additional work.

[4:01:08] And this needs to take into account mineral bioavailability, not just for iron, but for the other minerals, like calcium, under various conditions.

And again, as I mentioned, we did come up with a pattern for a lacto-Ovo vegetarian diet, and we do want to emphasize, however, that because of concerns about iron bioavailability in the vegetarian pattern, that we recommend further modeling work that takes that into account.

And again, very careful choices are needed within the vegetarian pattern. It is not a vegan diet. It includes substantial amounts of egg and dairy, and without supplemental fortified products, it is not possible to meet all nutrient goals with a vegan diet at this age.

[4:02:02] We want to emphasize that these findings are not intended to provide a combination of complementary foods and beverages, or a food pattern that's right for every infant or toddler, because children develop at different rates, and many different circumstances influence their feeding needs and decisions.

So, toddlers that have relatively low energy intakes may actually benefit from food combinations that resemble those for the older infants, and then with a gradual shift to the patterns that we've just presented for 12-24 months.

The general principle is to view this period as a continuous transition from diets that are appropriate for infants to diets that resemble family food patterns, and we have a beautiful slide, thanks to TusaRebecca, that illustrates the kind of transitions that we are coming up with.

[4:02:58] These are based on the Healthy US pattern for the toddlers that are not fed a human milk or infant formula, just illustrating what happens at the different calorie levels. Basically, relative amounts of these food groups as children eat more and get older.

We start with relatively small amounts of fruits and vegetables and then expand over time.

The same is true for grains, but what you'll notice is that the whole grains are a much larger proportion of the total in those lower calorie levels. And finally, you get to 2 years and beyond, then there's a greater flexibility.

The protein foods, you'll notice a pretty wide band for the meats and poultry, that purple band. It's actually not small at the youngest or the smallest calorie levels, it's pretty substantial. It's pretty stable in terms of total protein foods until 2 years, and then it goes up a bit.

[4:03:57] Dairy foods are pretty sizable all the way through, expanding a bit.

And then, a very small amount of oils is possible, and getting higher as calorie level goes up.

We're going to do a little more work on this, but this is our attempt at visualizing this transition.

So, in terms of recommendations, we have several as advice for caregivers.

Provide a variety of animal-sourced foods, fruits and vegetables, nuts and seeds, and whole grain products beginning at 6-12 months and continuing thereafter, to provide key nutrients, foster acceptance of a variety of nutritious foods, and build healthy dietary habits.

For infants fed human milk at 6-12 months, consider providing iron-fortified infant cereals or similar products to ensure adequate iron intake.

Provide good sources of omega-3 and omega-6 fatty acids, such as seafood, beginning in infancy, with the standard advice about trying to choose types of seafood that limit exposure to methyl mercury.

[4:05:08] Introduce peanut products and egg between 6 and 12 months, again, using forms of peanuts that don't present a choking risk. The evidence regarding the other potentially allergenic foods in the first year of life is limited, but there is no reason to avoid them.

For toddlers 12-24 months whose diets do not include meat, poultry, or seafood, provide eggs and dairy products on a regular basis, along with the other food groups.

Avoid foods and beverages with added sugars during the first 2 years of life. And for several reasons, which I've already explained, and I won't need to again. But very important to emphasize that this is a period when food preferences and patterns are beginning to form, and so, limiting the consumption of foods that contain added sugars while encouraging nutrient-dense foods, is a really critical step at this age.

[4:06:08] And we have a couple of recommendations for the federal agencies.

One is to develop communication and dissemination strategies that effectively address common misconceptions about diets for infants and children in this age group.

The importance of carefully choosing these foods may not be fully appreciated by the public. For example, there's a rhyme that says, "Food before one is just for fun," and that implies that the only goal during infancy is fostering pleasant feeding experiences, that the nutritional contribution of such foods is not critical.

That's really not true. And so, a more appropriate message is that "every bite counts," which emphasizes the nutrients of concern, while also conveying the need to make eating enjoyable and the importance of responsive feeding practices.

[4:07:02] We also recommend considering strategies to assist caregivers and program managers to use the information about the combinations and patterns described in this chapter. In particular, how to operationalize providing the amounts that are listed.

This information is provided by energy level, but the energy intake of an infant or a toddler is generally unknown by caregivers.

And with that, I have finished explaining to you how we came up with food patterns for this age group, and I very much welcome your questions and discussion.

Dr. Regan Bailey: I think we need a round of applause, Kay. That was really tremendous. Thank you.

Dr. Rachel Novotny: Yay. Are we doing discussion or are we taking a break first?

[4:07:59] ***Dr. Barbara Schneeman:*** Yeah, let's go ahead and do the discussion before we take the break, because we'll—we have a little bit of time past 3:30 that we can still use the bridge that we're on.

Dr. Rachel Novotny: This is Rachel Novotny. Great to have this piece in the *Dietary Guidelines*. Thanks to all who contributed.

I have a very specific question. I wondered, Kay, if you or your group was able to quantify in any way the contribution of potential, at least, contribution of sunlight to the vitamin D needs?

Is that something you could speak to?

Dr. Kathryn Dewey: No, we didn't really do that. It's my understanding that the DRIs make a certain assumption about sunlight exposure, but I don't know what that is for this age group. And so, I think further work might be needed on that.

[4:09:03] First of all, making sure that it would be a safe level of exposure, and then understanding what that might mean. Certainly, at the lower latitudes, like Hawaii, where you live.

Dr. Rachel Novotny: Right. Alright, thank you.

Dr. Joan Sabate: Joan Sabate here. I want to congratulate you, Kay, and your group, for such meticulous and comprehensive work.

I think that is excellent.

I'm not a specialist in this area, on this age group, but I'm a little bit confused by, I would say, contradictory viewpoints or arguments on what site, I mean the excessive intake of iron may not be the best.

[4:10:05] And on the other side, I mean the original schematic way of meeting the demands, I mean that, in some situations, especially when there is too much red meat, I mean we are having up to 200 percent of the requirement.

I don't know if this is the best way to approach it or there are other ways, as you presented in subsequent slides, that reducing the amount of red meat or not even including red it, I mean it probably overall better.

Dr. Kathryn Dewey: So, let me just respond to this saying, first of all, that there may be a difference in how iron from supplements is handled compared to iron coming from a food source, and the caution that we raised in chapter 6 about iron supplements was specific to that form, and in particular was of concern for infants younger than 6 months who were not yet regulating absorption of iron.

[4:11:15] So, that's where I think I am personally the most concerned.

In terms of after 6 months, what we showed is that formula-fed infants who are already getting substantial iron from formula, who then receive an iron-fortified cereal, might be reaching up to two times the RDA.

And for that reason, we actually don't recommend that they get a fortified cereal on top of the formula.

But if you just give them some meat and not fortified cereal, they wouldn't be anywhere close to 200 percent of the RDA. So, that would not worry me.

For the human milk-fed infants and toddlers, that red meat is actually a very important source of iron because it's absorbed much better, and even if you stacked the deck as high as possible

on the red meat, you're nowhere near exceeding the iron RDA at either 6-12 months or 12-24 months.

[4:12:17] So, I think, although older individuals may be more worried about too much iron, and particularly males who are not menstruating, I don't think this is the same kind of thing that we're worried about for children under 2.

Dr. Joan Sabate: Okay, thank you.

Dr. Linda Van Horn: Just out of curiosity, this is Linda Van Horn, I know that in vegetarians, I believe, iron absorption is greater than in omnivores, depending on the source, and I'm just curious if you came across any data suggesting that children of vegetarians likewise have an added or accelerated absorption or enhanced absorption of any exposure to dietary iron?

[4:13:18] I know that was an interesting question of research, but I don't know where that has gone and if there are further data to support either way what happens.

Dr. Kathryn Dewey: Well, I would expect that if vegetarians are absorbing more iron, it might be because they're slightly iron deficient or their iron stores are depleted, and that would upregulate iron absorption. We know that that happens.

So, I don't think it's inherent in what they're eating, it's inherent in what their body is sensing in terms of iron adequacy.

[4:13:57] The same would be true for an infant or a toddler who is becoming iron deficient. Their iron absorption would be upregulated.

And so, that's why we often have so much uncertainty about how to model iron requirements, iron absorption, and risk of inadequacy.

For example, just the iron absorption from human milk has been estimated to range between, let's say 16 percent up to 56 percent. So, and that's probably because the infants themselves differ so much in their own iron status. Yeah.

So, it's a very complicated scenario.

Dr. Linda Van Horn: Yeah, but also of interest in terms of maternal/fetal relationships in terms of diet and absorption and nutrients.

Dr. Kathryn Dewey: That's right, yes, yes.

[4:14:57] ***Dr. Barbara Schneeman:*** Are there other questions or comments? And keep in mind that we have chapters 4, 5, 6, and 7, although certainly, the work done on chapter 7 is huge.

Well, I think if there are no more questions or comments, I'm just checking to see, if there are no more questions or comments, now might be a good time to break so that we can switch to the new webcast link.

[4:16:01] Is that—

Dr. Sharon Donovan: So, what time do you want us to restart? Still at 3:30?

Dr. Barbara Schneeman: I think we need to have—can we take a 20-minute break? Would that work for folks?

Dr. Sharon Donovan: That works for me.

Dr. Kathryn Dewey: Yes, that works.

Dr. Linda Van Horn: Yeah, that sounds good.

Dr. Barbara Schneeman: Okay, so at 3:40. And so, when we come back, we'll start with chapter 8. So, 3:40, great.

Dr. Linda Van Horn: And now, are we supposed to sign off and reenter, or is that later?

Dr. Joan Sabate: Yes.

[crosstalk 4:16:47]

Dr. Rachel Novotny: Do we stay on this line or just a new web line?

Announcer: It's on the web. This is the operator. Leave your phones on here but you can change on the web now. Let me put music on for your audience.