

Morning Day 2

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Dr. Eve Stody: Alright, good morning, and welcome to day 2 of Meeting 5 of the 2020 Dietary Guidelines Advisory Committee. Just as a reminder, for those you who were not with us today, this is a virtual meeting for members of the committee that is being webcast to the public.

Please note, similar to yesterday, that there is a different webcast link for the afternoon session today, so make sure to keep that link handy. It is also available at DietaryGuidelines.gov and we'll also remind you at the end of the morning session.

Members of the public are joining the webcast in listen-only mode. We do want to note, though, if you have any technology issues, please use the question box to the left, and that'll be the only use for the "Ask a Question" box throughout this meeting today.

[0:00:56] All 20 members of the committee are trying to join us at some point throughout the discussions today. I will note that we have at least 16 members with us right now. We do have a few members who are needing to hop on and off the discussion due to coronavirus activities within their hospitals and universities, but they are joining as much as they are able.

So, with that, I'm going to turn it over to the chair of the committee, Dr. Barbara Schneeman.

Dr. Barbara Schneeman: Great. Thank you, Eve, and thank you to all the committee members for, again, joining this morning. And I would just, once again, point out that our committee members come from all over the United States, including Hawaii. And so, some of you are here at—we're calling it morning, but it's very early morning, and we appreciate that participation from the Western states.

[0:01:55] So, just to recap the Meeting 5, our purpose, and yesterday's agenda. Our purpose then is to describe the status and provide updates on the work of the committee and discuss next steps as we finalize our work.

And we commented yesterday that between the public meetings, the committee breaks into subcommittees to accomplish the work that can then be brought back to the full committee for discussion.

And in yesterday's discussion, we had updates from the cross-cutting working group on the Data Analysis piece, the Birth to 24 Months subcommittee, the Pregnancy and Lactation

subcommittee, Dietary Patterns, and the Frequency of Eating subcommittee. So, those were part of yesterday's meeting.

And in today's agenda, we will focus on, first, we will have, again, the cross-cutting working group, but this time, focusing on the Food Pattern Modeling, and then, the Dietary Fats and Seafood subcommittee, the Beverages and Added Sugars subcommittee, and then we'll move into a discussion of next steps, which will include the discussion on the peer review of the committee's systematic reviews.

[0:03:17] We have Dr. Klurfeld from ARS to provide information.

And then, we'll be talking more about the outline of the committee's report and where we are with developing that report. And of course, to also stimulate some committee discussion about that report.

So, we're starting now at 9:00 am. We will break for East Coast lunch at some point. And we will begin again at 1:00 Eastern time. We will likely take a break in the morning and take a break in the afternoon, but those times are not fixed, so we—we just go based on how we're moving through the agenda.

[0:04:06] So, and I also want to start our discussion today by, again, reminding the public particularly, about some particular dates of interest. So, if the public has comments related to the discussion at this meeting, they will be most useful to the committee and the subcommittees if they can be submitted by Friday, March 27th.

There is an ongoing written public comment period, which was opened in March of 2019, and that will close May 1st, 11:59 pm May 1st. So, that can be general comments, but again, if it's specific to the discussion at this meeting, we encourage you to get them in by the March 27th.

[0:04:55] There is one more session scheduled for the *Dietary Guidelines*, and that's the meeting on the draft scientific report, which will be held May 11th and will be webcast only.

So, with, with that, and again, let me remind you of the website. It's always important to keep in touch with the website, because the FAQs are updated in terms of providing the public more information, but also, that's where you can find the protocols and information, the status reports on the work of the subcommittees, so it's a very valuable resource, at DietaryGuidelines.gov.

And with that, we can begin our subcommittee reports, and the first one then will be by Jamy Ard, a member of the subcommittee on the cross-cutting working group, and he'll talk about the food pattern modeling and where we are with those conclusions and recommendations.

[0:06:03] Jamy?

Dr. Jamy Ard: Alright, good morning. I hope everybody's doing well this morning. This is report out from our Data Analysis and Food Pattern Modeling Working Group, and Regan Bailey is our fearless leader, and everybody else that you see there on the slide.

So, let me jump right in.

What we'll do this morning is report out on three questions, but most importantly, most of what I'll be talking about are methods and analytic framework plans for addressing these three questions. We will have a few results to present related to how USDA food pattern variations meet nutrient recommendations for each stage of life, but you can expect that we'll have full results and analyses for the three questions in the report presented in May.

[0:07:10] So, what I'll do is walk you through these three questions and the analytic frameworks for each of the questions and talk about some of the methodology within each of the analytic frameworks so that everybody can have a good understanding of what we hope to get from these exercises.

So, let's go to the first question, which is, for 2+, are changes to the USDA food patterns needed based on relationships identified from a systematic review that we're doing in other subcommittees? How well do the USDA food pattern variations meet nutrient recommendations at each stage of life?

[0:07:56] And if nutrient needs are not met, is there evidence to support supplementation and/or consumption of fortified foods to meet nutrient adequacy?

So, the approach to that question is going to be using food pattern modeling.

So, you'll see this slide several times during our presentation. This is the analytic framework, and I'll just kind of walk you through the basic steps to remind you. You've seen this before.

So, the steps that we will use for updating and developing the patterns related—for food pattern modeling include these five different steps.

So, the first is basically identifying the energy levels, and those levels range from 1,000 kilocalories to 3,200 calories per day, and that covers the majority of the population. And there's 200-calorie increments for those steps in between.

[0:09:00] The second step then is to look at nutrient goals for each level. And within each calorie level, we're looking at things like the macronutrient targets, minerals, vitamins, etcetera.

And then, once those are established, that gets mapped to food grouping, so, our basic food groups in terms of fruits, vegetables, grains, etcetera, dairy.

And once those food groups are established in terms of the amount of foods necessary to meet the calorie targets, then the nutrients obtained from those food groups are calculated.

And so, that then leads to the last step, which allows you to compare the nutrient levels that you've obtained from those food groupings at those calorie targets to establish nutrient goals—to determine nutrient adequacy.

[0:10:01] So, those are the five steps to—that will be used for food pattern modeling process in terms of the analytic framework.

So, the data sources, and again, you'll see this slide a couple of times, this is a reminder, but this is population 2 and older, including women who are pregnant or lactating, and the data sources include USDA Food and Nutrient Database for Dietary Studies, the Food Pattern Equivalent Database, and the National Nutrient Database for Standard Reference, SR28.

So, those are our data sources for the foods and nutrients that we'll be using.

Alright, so let me walk you through a couple of key definitions so we're all on the same page.

[0:10:59] Food groups and subgroups, you've heard TusaRebecca describe this in some detail before. These are just reminders of the five major food groups and some subgroups that are part of that.

And then next, we have nutrient profiles. So, I'll spend a second on this just to make sure everybody understands.

So, nutrient profiles basically is a way of creating a weighted average of nutrient-dense forms of foods. So, a nutrient profile basically says, “How many nutrients do we expect from a representative food in a given food cluster or item cluster?”

So, if we were to take dairy, for example, and say, “We’re going to use milk, yogurt, and cheese as representative, or as foods in that item cluster,” and we know that, on average, someone in my age group eats 50 percent of their dairy as milk, 25 percent as yogurt, and 25 percent as cheese, we would take the nutrients from the representative food of milk, of yogurt, or and cheese, and multiply those nutrients by the percent that they contribute to the overall item cluster.

[0:12:26] And sum those up to get a particular nutrient profile.

And so, someone like TusaRebecca had to do this by hand for each one of these nutrients. So, it’s a lot of work. But she’s got it all figured out.

And there’s a weighted average that then is calculated that considers a range of food choices for Americans in a nutrient-dense form. And so, that nutrient-dense piece is really important, because if you go to the next slide, nutrient-dense foods or representative foods are food items in a cluster that are basically the foods with the least amount of added sugars, sodium, and solid fats.

[0:13:14] So, it’s the most nutrient-dense form of the food with the least amount of added sugar, sodium, and fat in terms of additional non-nutritive energy, so to speak.

That is compared to a typical choice representative food. A typical choice food is something that is most frequently consumed within an item cluster and includes whatever the added sugar, solid fat, and sodium might be.

Now, it’s important to note that a typical choice representative food is not necessarily the worst choice. So, that’s something I think was important to point out, because I think we might assume that a typical choice, given the way we generally eat, is not necessarily the—is usually on some extreme.

[0:14:13] But, for example, for sweets, the typical choice might be an oatmeal cookie, whereas there are plenty of other worse choices, like a fried Oreo, for example.

So, added sugars are sugars that are added during the processing or packaging of foods, and that includes regular sugar, like a bag of sugar, or syrups and honey, concentrated fruit or vegetable juices, in terms of sugars from those sources that are in the excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type.

[0:14:59] Alright, so I think that covers all of our definitions.

So now, let's get back to the analytic framework and kind of walk through the steps for what we're talking about in terms of this particular question. And just to remind you, what we're looking at are changes to the USDA food pattern based on relationships identified in systematic reviews, and then how well do those food pattern variations meet nutrient recommendations for each stage of life? And if nutrient needs are not met, is there evidence to support supplementation or consumption of fortified foods to meet nutrient adequacy?

So, that's what we're going to be focused on right now.

So, stage 1 or step 1 is establishing energy levels, and basically taking the DRI formula to estimate energy requirements for each age/sex group, including women who are pregnant or lactating.

[0:16:05] And as I said before, that leads to 12 energy levels, going from 1,000 calories to 3,200 calories in 200-calorie intervals, and that's intended to cover the majority of the population from 2+.

So, the second step then is establishing nutrient goals, and the nutrient goals for each food intake pattern are age- and sex-specific. And generally, what happens is individuals who are sedentary represent sort of the worst-case scenario, so to speak, in terms of being able to meet those needs that is the lowest energy level.

[0:16:57] And so, in that type of scenario, the lowest energy level is rounded to the nearest calorie pattern, and that's set for the age/sex subgroup and used to evaluate the pattern against nutrient goals.

And so, then goal was set for three macronutrients – fatty acids, cholesterol, vitamins, minerals, and fiber, based on the DRIs that were produced between '97 and 2018.

And so, the food patterns are designed for individuals, and so, the goals are the RDA amount, and when an RDA is not available, AI is used.

So, the third step then is to establish food groupings and amounts.

[0:17:56] And so, for this work, the initial updates will use the USDA food pattern established from the last *Dietary Guidelines*, but we might expect, in terms of additional testing or other updates, work that's coming out of the Dietary Patterns subcommittee, or other subcommittees, might inform additional patterns that would be tested to create different food groupings and food groups in several compositions for those respective patterns.

So, the next step is to then determine the nutrient profiles. And so, as we remember, nutrient profiles are basically that weighted average of contribution of different nutrients from foods within a given item cluster.

[0:18:55] And that weighted average is based on the percent of the food items in that cluster, in terms of how they're consumed by specific age/sex subgroups.

So, this is important, because the intake of certain foods varies by age/sex subgroup, and the—it's important to note that the nutrient-dense representative food doesn't change. So, for milk, that will always be skim milk. But the proportion of energy that people consume will vary, the proportion of energy they consume from the milk subgroup will vary based on age.

And this graphic here is just an example of that.

So, for example, in the burnt orange here, at 59 percent, is the group of individuals who are 4-18 years old, and you can see that they're consuming a higher proportion of their dairy as milk compared to, say, individuals who are 19-70, and then that goes back up, or it's higher, I should say it's higher for individuals who are 71+ compared to individuals in the middle category who are 19-70.

[0:20:27] So, for each one of those age subgroups, age/sex subgroups, you would vary the contribution of calories and nutrients from those different food items in the item cluster.

So, what that means then, it leads to a different nutrient profile specific to each life stage, and here is an example.

[0:20:58] Again, if we are staying with the dairy group, you can see that, in the 4-18-year-olds, 82 calories are coming from the dairy group for a cup equivalent, essentially.

And then—I'm sorry, not a cup equivalent, just 82 calories are coming from the dairy group for that nutrient profile, whereas for 71-year-olds, it's 99 calories.

And you see the variations in the amount of things like potassium, vitamin E, vitamin D, and saturated fats is a result of differences in those intakes.

So, if you recall, individuals who were 71 were consuming more of their dairy as either milk or yogurt and slightly lower on cheese.

[0:22:01] And so, that translates into a higher potassium intake and slightly more vitamin A, and a little bit lower than the overall population in terms of saturated fat.

So, those differences in proportions of intake then have an impact on the anticipated nutrient amounts for the dairy food groups based on the stage of life.

Alright, so step 5 then is evaluating the nutrient level in each pattern against a nutrient goal. So now, we've established the nutrient intake profiles, then it's comparing those nutrient levels to what you want to actually accomplish based on the dietary pattern.

[0:22:58] And so, in this particular example, we're using the *Dietary Guidelines* USDA food patterns from 2015-2020. And so, we know that, when we look at that particular pattern, that meets most of the goals for nutrients for most people.

And step 6 would be to go back then and say, for anywhere—any place where you don't see achievement of the nutrient goals, what types of changes can be made, and modifications can be made to get to the potential—get to the goal?

And so, any food group amounts could be modified or adjusted to achieve all the most of the established goals.

[0:23:59] So, let me take you through a few of the analytic results related to nutrient profiles, just to give you a sense of what those look like in terms of comparing previous goals or previous years to current year, and this is draft.

So, analytic results here show that, for 2+, differences in energy estimates coming from the various food groups, you can see the difference in the column to the right there. And again, these are calories.

And you'll see that for fruit, that's a small increase in calories, and there's small changes within other subgroups for vegetables.

[0:24:57] For meat, for example, part of that decrease for meats might be because there—or is because there's a leaner ground beef available that now has a new code and is added to that subgroup. And so, that decreases the calories in terms of its contribution for protein foods by 5 ½ calories.

And you see dairy has increase in terms of its calories by about 8 calories, and that's a result of a new food code from, say Greek yogurt that is a little bit more energy-dense than other varieties, and the proportion of intake of Greek yogurt has gone up.

So, these nutrient profiles are shifting over time as a result of things like introduction of new foods in the food supply, as well as changes in consumption pattern.

[0:26:00] Additional results, so if we were to look at these relative to the life stage, what we see is that there's some differences, again, and this goes back to differences by consumption pattern across the different life stages, and you can see the contribution of energy from the different subgroups or food groups and subgroups about—for 4-18, 19-70, 71+.

So, when we look at that step 5 of evaluating the nutrient level against nutrient goals, as I mentioned before, in the general nutrient profile, or the life stage-specific profile, the Healthy USDA-style pattern meets the RDA or AI for the majority of nutrient goals, and it stays within the upper limits, or stages and limits for the UL and the Chronic Disease Risk Reduction for most nutrients as well.

[0:27:16] There are some notable exceptions, iron being one of the main ones, where the pattern typically would have less than 90 percent of the RDA for females and women who are pregnant, females in those age categories.

Vitamin D and vitamin E are typically not met, as well as choline.

And vitamin D, there was an exercise from the 2015 DGAC that showed how vitamin D from dietary sources could be met, but in the general sort of current USDA food pattern, it's not consistently met.

[0:28:06] So, there will be a draft conclusion, or a conclusion statement I should say, provided in the May report, that summarizes all those data for nutrients across the board, and as I said, this step in

particular, or this question in particular will be informed based on the work being done in the other subcommittees.

So, as dietary patterns of interest that are identified in the Dietary Patterns group or other groups identify foods and food groups of interest that would want to be—that they want to be included in unique patterns, then those are things that I think could be discussed for modeling to then provide this type of exercise to understand how well those types of other patterns meet nutrient needs, and then if there are shortfalls, where those shortfalls can be made up.

[0:29:13] Alright, so, let's see. We're at question 2. So, we'll move forward with that question. So, question 2 is basically for those who are under 2 years, so these are birth to 24, same type of question. Can the USDA food pattern be established based on relationships identified in systematic reviews?

And then similarly, do those patterns meet nutrient recommendations for infants and toddlers? And if not, what can you do to make up for that?

And so, the process is going to be food pattern modeling. This is the same framework that you saw before.

[0:29:58] Only difference here is that the energy levels are now going from 600 calories to about 1,000 calories, but all the other steps are the same in terms of identifying the nutrient goals for each level, and then the food groupings associated with that, nutrients obtained, and then comparing the nutrient levels versus the goal.

So, this is the easy part of the presentation, just reminding you again of the population and data sources, which are the same.

And then, the same type of framework, where again, establishing those energy levels, and as I mentioned before, there are five energy levels, from 600 to 1,000, but instead of 200-calorie intervals, this time, we're looking at 100-calorie intervals.

And again, that covers the majority of the population, from ages 6 months to 24 months.

Now, for nutrient goals, as we heard yesterday, there are not a number of recommended daily allowances.

[0:31:07] There are only 3, and that includes protein, iron, and zinc. All other nutrients have an adequate intake. So, those are the established targets,

Now, the other big difference here is that, for this age group, we are considering the contribution from human milk in relation to complementary foods and beverages. And the way this will be approached is basically modeling what we would expect to be sort of average ratio between complementary foods and beverages and human milk consumption.

And that's what you have in the middle column there. And if you start at 6 months, and then on either side, you bracket 15 percent below in terms of the contribution from complementary foods and beverages, and then 15 percent above.

[0:32:08] Or, I should say that's actually human milk. So, 15 percent below the mean for human milk consumption, and then 15 percent above.

And so, in this particular example, at 6 months, if the mean is 20 percent from CFB and 80 percent from human milk, then 15 percent less would be 65 percent from human milk and shift those 15 percent of calories into the CFB. On the upside of that, basically it's just so it's rounded to 100 percent. This 95 percent would be from human milk if you add 15 percent to 80.

And so, that's the way you would basically then create sort of three scenarios for each age grouping.

[0:33:04] And that would give you a way to sort of understand where the variation might be.

There can also be a sensitivity sort of analysis here, where we look at, instead of using human milk, actually look at formula-fed infants or follow-on formula to sort of look at what the range of intake might look like in the nutrient would be.

Alright, so once that's done, then you establish the food group amounts for the 1,000 calorie pattern, and then for the patterns that are less than 1,000 calories, you'd reduce the food group amounts in a similar proportion so that you can keep the same food group density of the 1,000 calorie pattern.

[0:34:15] And then, you would do the same thing we've talked about before, which is looking at the nutrient profile and using the same type of calculation in terms of percent of a contribution from a food in an item cluster and the nutrients in that representative food.

This would include baby food but excludes infant formula and follow-on formula.

And then, you would take a look at the nutrient level achieved for each of those energy levels and compare that against nutrient goals.

[0:35:02] And usually, you want to get to at least 90 percent of the RDA or Adequate Intake.

And then, step 6, which is basically iteration and reevaluation. So, adjusting, if there are shortfalls, there are areas where you feel—or you find that you’re not meeting nutrient goals, then what types of adjustments could be made in order to meet those nutrient goals?

Alright, and as noted before, there will be conclusion statements presented in the May report.

Alright, so let’s move to question 3, which is about added sugar, and focused on how much added sugar can be accommodated in a healthy diet while still meeting food group and nutrient needs?

[0:36:01] And again, we’re focused on food pattern modeling.

So, the way this question is going to be addressed is using an analytic framework that basically is divided into 3 separate exercises.

So, the first exercise is about estimating the number of calories in the USDA Food Pattern that could be used for added sugar or “other uses.”

The second exercise is about understanding how to redistribute calories from the top sources of added sugar to foods and beverages that actually help to meet food group and nutrient goals.

And then, the third exercise is around estimating excess calories from sugar when the USDA Food Patterns are used, comparing typical choice versus the nutrient-dense choices.

[0:37:02] So, I’ll explain each one of those exercises in some detail in the next several slides here.

So again, you’ve seen this before, population and data sources are the same.

For exercise 1, related to estimating the calories remaining in a pattern, the way I think about this is this would potentially tell you, at the end of the day, how many of those calories can be used for a splurge, so to speak? Of the calories that are allocated, say in a 2,000 calorie level, if I meet my nutrient goals, what might I have left over for the occasional splurge?

[0:37:57] And we're focused on added sugar, but I think we're sort of talking about, in most instances, kind of a combination of solid fats, added sugars, in this analysis.

So, the way this will work is the base pattern is developed the same way as we talked about in the previous protocol for looking at the nutrient adequacy and assessing the various USDA food patterns for ages 2+.

And so, calories from all food groups and oils, which are from the nutrient-dense forms, are considered our essential calories, and the remaining calories are for other uses that include additional nutrient-dense foods from some food groups, solid fats, added sugars, or alcohol.

[0:39:01] Those are calories that are assigned based on a proportional intakes of solid fats and added sugars in the population.

And then, the assigned calories for added sugars for each of the 12 patterns were reported using nutrient profiles for 2+, so the overall population, and then for each life stage.

So, that—get back to—that will give us a sense, again, of the number of calories that are available after nutrient needs are met for other uses and might be informative in the other parts of our discussion.

Alright, so exercise 2 is the redistribution of calories from the top reported sources of added sugars to other more nutrient-dense food groups, and with a goal of meeting nutrient goals.

[0:40:08] So, this takes a few steps to walk through. So the first step, what I'm going to do is basically use an example using 14-18-year-old females, so, one specific age/sex group, and we're going to look at dairy foods with the idea of, if we understand how many calories are coming from sources of added sugar, and if we say, "Let's redistribute that to help meet the dairy foods group goal for this age group, what would that look like?"

So, here's one example. So, if we were to estimate the number of calories coming from the top sources of added sugar in this age/sex subgroup, and it's pretty consistent across most age/sex

groups, it's 70 percent of added sugar comes from sugar-sweetened beverages, desserts, and sweet snacks, coffee, and tea, candy and sugars, and breakfast cereals and bars.

[0:41:23] So, those are the top five sources of added sugar, and that accounts for 70 percent of the calories from added sugars, so not even—so, you've still got 30 percent of those calories remaining, but 70 percent of those calories is about 267 calories.

And so—or I should say there's current mean intake of added sugar total is 267 calories, and if we took the top five sources, which is 70 percent of that, that'd be 197 calories.

[0:41:57] And so, we would redistribute that 197 calories from added sugars towards meeting the food group goal, and we know, for dairy, dairy's somewhat of a shortfall for females in this age range.

So, the current mean intake for the target for a female 14-18 years old assigned that 1,800 calorie pattern, the goal is 3 cup equivalents of dairy, but the current mean intake in the population is 1.6, so that's a shortfall of 1.4 cup equivalents for dairy.

And so, if one cup equivalent of dairy foods for this age/sex subgroup is 85 calories, that means, in order to get a 1.4 cup equivalent, we need about 119 calories, and additional—of additional dairy foods to meet the food group goal of 3.

[0:43:02] So, if you remember, we said we had 197 calories to work with. And so, we're going to spend 119 to basically get that additional dairy, 1.4 cups of dairy, and now, that means we've got about approximately 80 calories remaining, and that 80 calories could be used towards meeting different food group goals, such as fruits, vegetables, or protein foods.

So, we've been able to, with this exercise, shift calories from less nutrient-dense foods, i.e. added sugars, to more nutrient-dense foods like dairy to make up a particular shortfall in a food group, and we still have 80 calories remaining, so we've been able to do that in an isocaloric way.

[0:44:06] So, instead of saying to a 14-18-year-old, "You should just eat more dairy," it's actually "No, let's make this particular substitution to move it into the dairy food groups to give you more room to actually be able to accommodate that without exceeding the calorie target of 1,800 calories."

So, what you then do is estimate, okay, what type of nutrient—what type of impact does that have in terms of nutrition for females 18-14 if you add that additional 1.4 cup equivalents of dairy foods?

And what you see here is an increase in protein, calcium, potassium, and vitamin D, which are meaningful increases here, especially for this age/sex subgroup, where I believe in the past we talked about protein being an issue that was—nutrient that was underconsumed, and calcium, potassium, vitamin D also being low in this particular group.

[0:45:15] Okay. So, the last exercise here is related to understanding, if we have excess calories from added sugar, what does that look like in terms of the number of calories when you're using typical choices versus more nutrient-dense choices?

And if you recall, when we talked about the analytic framework, or the process for developing the food patterns, the food patterns are developed using the nutrient-dense—the most nutrient-dense choices.

[0:46:00] And so, this says, “Okay, instead of using the nutrient-dense choice, let's actually use a typical choice, and TusaRebecca has used this example before, a nutrient-dense choice for, say a sweet would be animal crackers, because that has the least amount of sugar for something that's in the sweet dessert category, whereas the typical choice would be something like an oatmeal cookie.

So, there's clearly going to be a difference there in terms of the amount of added sugar. And so, what we want to do is be able to estimate what's the difference, and how much might that impact, especially with regard to energy balance?

Because the concern is you might be meeting nutrient goals with typical choices, which is definitely possible, because it's not that they don't have nutrients, they're just not in the most nutrient-dense form.

[0:47:03] The problem is, is that you may be exceeding the calorie target in order to meet the nutrient goals.

So, this exercise has been done in a previous cycle in the 2010 DGAC, and this example just illustrates what this might look like and what we might be able to learn from this type of exercise.

So, basically, what you see here at the top of this graphic is the calories from solid fats and added sugars are in the lighter colors for each of the food groups, and ultimately, this contributes about 20 percent more calories when people are consuming foods in the typical food choice group versus the most nutrient-dense form consistently across these food groups.

[0:48:12] And so, what it means is the calories for other uses are already used up. That's number one. And number two is, if you are meeting nutrient goals using typical food choices, you are getting 20 percent more calories than you need on a daily basis.

So, this exercise, I think, illustrates what may be reflected in some of the comments we heard in public comment periods, where people talked about "Well, I followed the *Dietary Guidelines*, and I gained weight and developed chronic disease," and I think this is a data-driven way of showing, "Well, that's likely possible if you are making choices that are not the most nutrient-dense versions of the foods that you—that we're talking about."

[0:49:14] Because if you choose less nutrient-dense or higher energy-dense forms of these foods, then you are likely to exceed your calorie intake, even though you may be meeting nutrient goals.

So, I think this is really important to clearly articulate the results and the implications of this type of exercise.

I think there's another point to be made from this type of exercise, which is there are clearly differences in the amounts of solid fats and added sugars that are being added to or part of typical choices for various food groups.

[0:50:04] And you can see the proportion of those calories that are being added to, say fruits and vegetables is relatively low compared to grains, protein foods, or dairy. And as several others, including Rick Mattes have made the point before, palatability may be an important consideration in terms of increasing intake of food groups that we know that are underconsumed.

So, we may consider or think about the implications of saying the calories for other uses may be used to increase palatability with the goal of increasing foods that are underconsumed and decreasing their use for foods that are already overconsumed, such as grains and protein foods.

[0:50:59] And then, using lower energy-dense versions of foods that may not change the palatability as much, especially for things like dairy foods.

So, I think this is a really interesting potential example of how we might be able to bring together the issues around energy balance and nutrient density with the idea of helping people meet their nutrient needs but not exceed their calorie target.

So, that exercise will be presented in full in the May report as well, and I believe that is the last slide.

Dr. Regan Bailey: Thanks, Jamy. That was a really nice talk. This is Regan. I think these food patterns are the foundation of the HEI, and the HEI and similar patterns have been consistently shown to be related to reduced risk of chronic disease in systematic reviews by the Dietary Patterns subcommittee.

[0:52:11] And I think you did a really great job highlighting how nutrient-dense choices and typical choices will really vary in how total energy is consumed.

And I just wanted to say thanks for pointing that out. You did a really good job explaining all that.

Dr. Jamy Ard: Great. Yeah, I think this is really important, and is—I'm hoping that we can take some additional steps beyond where previous committees sort of left off with regard to advice to shift calories from higher energy-dense foods to lower energy-dense foods, but I really want us to try to get closer to what those shifts need to look like and where we think people might get the most bang for their buck.

[0:53:08] Because the general—the general information, I think we now have more data, and I think we have the ability to refine some of the recommendations to be even more specific with the goal of doing exactly what you said, meeting those nutrient needs and getting people closer to what we know, in terms of dietary patterns that are associated with disease risk reduction.

Dr. Regan Bailey: Yeah, I agree. Thanks.

Dr. Richard Mattes: This is Rick Mattes. Jamy, can you help me understand, if I recall, part of the definition of nutrient density involved a sodium contribution, and given that much of what you talked about here was density relative to meeting—staying within energy bounds, to what extent does sodium factor into this?

[0:54:13] And, I have a second question, too. If adjustments are made that impact beverage consumption, is there a consideration for meeting hydration needs in the modeling?

Dr. Jamy Ard: Okay, soon the sodium factor, for the purposes of modeling, the lowest-sodium option is generally chosen, but it's really, I think an important question around how does it impact energy intake?

[0:55:02] Because I think there are some data that suggest higher sodium intakes are associated with higher energy intake, but I think that's something that we need to talk clearly about, because I think it's just built into the definition of the most nutrient-dense form is also the form that is associated with the lowest sodium intake.

On the hydration status, I'm being told that we don't really address hydration needs, but we can assess water estimates in the foods. So, the moisture content of the foods can be assessed.

One of the other, I think challenges, is that beverages are not necessarily included. So, beverages that are not part of a food group are not included.

[0:55:58] So, that's things like sodas and so forth, are not part of the dietary patterns here.

And so, that may be an area for future research, I imagine, is to start to think about consumption of beverages in the sort of food pattern plans.

Dr. Ronald Kleinman: Jamy, I, just to drill down, I was a little surprised to see that milk intake, in the 70-year-old+ group, rises, and it looks like it rises to a level that you see in adolescence. I may be remembering that wrong. And I realize that there are no volume measures in this, it's just consumption, right?

Yeah.

[0:56:59] Dr. Jamy Ard: Yeah, so this is just percent of the—or proportion of the calories that are coming from milk in that particular item cluster. So, it could be—

Dr. Ronald Kleinman: Oh, yeah. Go ahead.

Dr. Jamy Ard: So, it could be that, if I understand this correctly, it could be that what may be happening is there may be, say more cream being used in coffee in the 71+. They may not be drinking a lot of skim milk, per se, if I understand that correctly.

Dr. Ronald Kleinman: Okay. And then, a second question was speaking about infant formula.

[0:57:59] I think you said that that's not included in the 6-12-month-old group?

Dr. Jamy Ard: Yeah. So, in that particular—let me get to that slide.

So, this pattern is based on the complementary foods and beverages relative to—excuse me—human milk, and when you—when we do the nutrient profile for the various foods, it includes baby foods but not human—not infant formula and follow-on formula.

But, as I think I said, in a sort of sensitivity analysis, it could be that what we do is use complementary foods and beverages and do a comparison between if we use human milk versus infant formula.

[0:59:09] Because I think one of the concerns, we've talked about is overconsumption of some nutrients because infant formula is fortified. And so, we would want to make sure that we're not exceeding the upper limit on some nutrients, and that would be more sort of a test case to understand in that particular scenario, when people are using infant formula plus complementary foods and beverages, what the nutrient profile looks like.

Dr. Ronald Kleinman: yeah, that's great, as long as you're doing that extra sort of validation or test that. Yeah. Thank you.

Dr. Jamy Ard: Okay.

Dr. Kathryn Dewey: This is Kay Dewey. I wanted to add to that. It was something that we discussed in a subgroup.

[0:59:59] The first step was to look at the human milk-fed infants, knowing that we had the most challenges in terms of nutrient gaps there, and then, as Jamy mentioned, depending on time and all that, go on to looking at mixed-fed, and then formula-fed.

At the 12-18-month ages, formula isn't recommended after 12 months, so that wouldn't really be a scenario, so it really only applies to 6 and 9 months.

But I realize, when looking at this slide, that we actually have a mixture of things going on in that table below that's not quite right. And so, we may need to have another call to straighten that out, and I apologize if I didn't catch this earlier, but the middle column, it's the percent of energy from human milk.

[1:00:56] It is the mean, as shown there, for 6 and 9 months, but the mean percent at 12 and 18 months is actually 35 percent, not 20. And so, I think what—for 12 and 18 months, what’s shown there is a zero human milk low estimate and high estimate, whereas the estimates shown there for 6-9 months are a low, a mean, and a high estimate.

So, it’s kind of two different ways of looking at it, and we’ll probably need to discuss that again to straighten that out.

Dr. Rachel Novotny: This is Rachel Novotny. I really—this is a great way for us to pull things together. I really like the direction.

I am a little confused, kind of following up on Rick’s question, I guess, and I guess another area for clarity about the beverages, because clearly, we’ve got milk and we’ve got coffee and tea.

[1:02:07] So, we do have some beverages in there, and so, I think just in terms of talking about this and next steps, if need be, to identify clearly what are beverages that are included, and which are not.

Dr. Jamy Ard: Yeah, I agree. It’s feeling like we need kind of a beverage food pattern, so to speak, something that really sort of models out when people are consuming a certain proportion of their calories as beverages from the top sources – coffee, tea. That includes added sugars plus sugar-sweetened beverages and fruits and juices—fruit juices, energy drinks, those types of things.

[1:02:59] What does—what does that start to look like, especially with displacement of other nutrients and those types of things?

Yeah, so is TusaRebecca able to comment?

Dr. Barbara Schneeman: Yeah, I think this is a great discussion, because it’s identifying some needs that we have, but certainly, needs for the future. But I think TusaRebecca, do you—can you add?

Dr. TusaRebecca Panucci: Sure. No, this is TusaRebecca Panucci. Jamy, you did a nice job describing that. I think one thing to clarify, just for simplicity for now, is that not all beverages contribute to food group amounts. Those beverages that do, like dairy or 100 percent fruit juice

or 100 percent vegetable juice, their contributions are accounted for in the patterns, because they contribute to a food group.

[1:03:56] But other beverages that don't contribute to a food group, like some sugar-sweetened beverages, or some—even coffee or tea, that are consumed and may provide some nutrients but don't contribute to a food group, any energy contribution from those would be accounted for in those remaining calories.

So, we can talk more and clarify in the protocol how those are handled.

Dr. Kathryn Dewey: This is Kay Dewey again. I have a question about slide 18, in terms of the calories coming from the different food groups. I saw, for legumes, 240 or so calories, and I'm just not sure I understand why that's so high compared to all the other ones.

[1:05:06] Could you discuss that?

Dr. Jamy Ard: Yeah. So, I think, again, my understanding would be that what you're looking at is, with—and I'm not—I admit I don't know the number of—I guess this is one cup equivalent, right, TusaRebecca?

Dr. TusaRebecca Panucci: Yes.

Dr. Jamy Ard: So, that's a cup equivalent of legumes, and they're just energy-dense in terms of the sort of calories. Because you can see, starchy vegetables are similar in terms of their contribution of calories, just because of the amount of starch within a legume, complex sugars, complex carbs.

[1:06:05] **Dr. Kathryn Dewey:** Okay. So, then, for the protein foods like nuts and seeds, I'm assuming that's not a cup equivalent, that's some other unit?

Dr. Barbara Schneeman: I think it's an ounce equivalent.

Dr. Jamy Ard: Yeah, nuts and seeds are ounces.

Dr. Kathryn Dewey: Okay. So, that would just be helpful, on this table, to show what those servings or estimates are based on, just for clarity.

Dr. Jamy Ard: Yeah.

Dr. Barbara Schneeman: Yeah, that would be helpful.

Dr. Kathryn Dewey: And then, I think you mentioned that one of the nutrients that wouldn't be met is choline. Is there going to be some sort of discussion about perhaps some other models where that's considered a little bit more?

I know for the Pregnancy and Lactation subgroup; we're pretty concerned about choline.

[1:06:59] Dr. Jamy Ard: Yeah. So, we can absolutely talk about that. I think the nutrients that are evaluated and identified either as nutrients of public health concern, or specifically, very important for certain age/sex subgroups, I think that would be where we would talk about what are the strategies or alternative food groupings or use of supplements in order to be able to meet those particular needs.

Dr. Kathryn Dewey: Okay, thanks.

Dr. Barbara Schneeman: Great. Again, this is a great presentation, and I think sets up a lot of other discussions with the various subgroup reports.

[1:08:01] I just want to see if there's any—are there any more comments or questions from the committee members?

Dr. Joan Sabate: Yeah, Joan Sabate. I have a question. I see you presented one or two slides showing the preliminary results of using the Healthy American pattern. And my question is, based on the previous *Dietary Guidelines*, and what we're working on the current one, I mean are we going to see the results of using different food patterns, such as the Mediterranean diet or the vegetarian diet, and to see how these changes, as far as the distribution of the nutrients and as well as far as the distribution of the foods within each food group that representative of these food patterns?

[1:09:10] Dr. Jamy Ard: Yes. So, I think that's the idea is that, as that work emerges from the Dietary Patterns subcommittee, which we're on, and other committees, is put forward ideas related to the systematic reviews, then we would run this type of exercise using those patterns to evaluate nutrient adequacy, and then make determinations about where those food groupings, in terms of the amounts and the various nutrient contributions from those different food groups and subgroups come from.

[1:09:59] But that's the idea, is, yeah, if we identify some novel dietary pattern within our systematic review that's associated with decreased all-cause mortality or lower risk of diabetes or weight gain, excess weight gain, then we would, I think, put that forward for consideration in terms of food pattern modeling, to look at how well it performs across all the age/sex subgroups.

Dr. Joan Sabate: Thank you. A subsequent question would be, if I understood well, the methods employed, I mean there was a food representative of a particular food group that was the most nutrient-dense and other was the most typical choice.

[1:10:54] These do vary according to different age groups, different ethnic groups in America, because there is a variety of cultural patterns. It would be very informative if this exercise is done within the different cultural patterns or ethnic groups here in the US.

Dr. Jamy Ard: I think that's—

Oh, someone else?

Dr. Carol Boushey: I think, just as a—Carol Boushey just came in. I heard some of this. I just got to the phone.

So, one of the—actually, the thing about the cultural groups and different ethnic groups, that actually is really important, and I just wanted to mention that a lot of the work that's been done in this space, at least with at the University of Hawaii Cancer Center, the work represents five ethnic groups, I think.

[1:12:00] But I do agree with you that more should be done, but the parity across the ethnic groups is fairly strong the way that these patterns work, just as an FYI. Not that it shouldn't be done more, but just to let you know that that has actually started, and people can use that as a model to continue forward also.

Dr. Jamy Ard: So, yes, I think that's definitely something that we can discuss, and it may be, given our time frame, difficult to do within the current context. But certainly, an area for future research, and we'd have to think about how to sort of look at that sort of cultural interaction across either the entire 2+ population, or is that within certain sex and age subgroups, that gets to sort of smaller kind of representative estimates for typical choices.

[1:13:26] But I think it's important to look at the variation in intake patterns based on other important demographic and cultural factors.

Dr. Barbara Schneeman: I think another consideration along these lines is that, particularly as we've identified things that are useful in terms of how to use food pattern modeling, we can also, as part of our advice to the Secretaries, talk about how this kind of thinking can be used in the implementation of the *Dietary Guidelines*, particularly as that flexibility is needed for different age groups, different ethnic groups, and the choices people make.

[1:14:17] Okay, so any more questions or comments? Carol, we're excited you're with us now. Good morning.

Dr. Carol Boushey: Thank you. Good morning.

Dr. Barbara Schneeman: I think it might make most sense though, to go ahead and take our break now, because the next report will be the Dietary Fats and Seafood subcommittee, and once we start with that, we'd like to be able to finish that whole report.

[1:15:02] So, why don't we plan to be back at 10:30? We'll plan for a 15-minute break. And 10:30 Eastern time. Sorry. It's a half-hour of whatever time zone you're in.

And I, again, remind folks, please mute your phone. Do not close out. Because once you close out, you're closed out. So please, just put things kind of on mute or whatever you need to do, and then we'll be back in about 15 minutes. Okay?

[break 1:15:43-1:23:41]

Dr. Eve Stody: Just a note that we're on break for another 5 minutes, but we can hear a little background noise. So, for members who are on the line, make sure that your phone is muted. Thank you.

Dr. Linda Snetselaar: This is Linda Snetselaar, and I just unmuted my phone, just because I know I'll be next to speak. And I'm probably the reason for that.

Dr. Eve Stody: That's okay.

Dr. Linda Snetselaar: The noise.

Dr. Eve Stody: No, that's perfect. Just didn't want somebody to be off mute that didn't know it. But you know it, so you're good. Thanks. We'll get started in just 5 minutes.

[break 1:24:18-1:29:17]

Dr. Barbara Schneeman: Okay. Welcome back. We're ready to start the next part of our morning session. So, our next presentation will be from the Dietary Fats and Seafood subcommittee, and Dr. Snetselaar, I'll turn it over to you.

Dr. Linda Snetselaar: Thank you, Barbara. I want to begin by recognizing my subcommittee members – Drs. Regan Bailey, Joan Sabate, and Linda Van Horn, and additionally, Dr. Barbara Schneeman, who is our advisory chair rep.

[1:29:55] Our subcommittee presented three seafood systematic reviews at previous Advisory Committee meetings, and today, we will be presenting the revised conclusion statements related to seafood and neurocognitive development in health, and new evidence and conclusion statements related to dietary fat and cardiovascular disease systematic review.

At the January public meeting, this subcommittee presented the evidence and draft conclusion statements from the three seafood reviews. Based off of feedback from other committee members during the discussion at the meeting, we have decided to revise some of the conclusion statements after reconvening as a subcommittee.

The feedback included the evidence base being solely from prospective cohort studies and modifying the language so as not to imply a treatment effect.

[1:31:05] Additionally, this subcommittee decided to indicate that the associations are with measures of each domain's development as neurocognitive development is still a difficult outcome to capture definitively.

The first of the four revised conclusion statements shown here on this slide. So, from the question "What is the relationship between seafood consumption during pregnancy and/or lactation and neurocognitive development of the infant?"

The conclusion statement, as it was presented in January, is shown above, and the revised conclusion statement with red text indicating changes is below.

[1:31:58] The revised conclusion statement for the cognitive development domain is limited evidence suggests that seafood intake during pregnancy may be associated favorably with measures of cognitive development in the child, and we graded this as limited.

From the same question, dealing with seafood consumption during pregnancy, a conclusion statement as it was presented in January is shown above, and the revised conclusion statement with red text indicating the changes is below.

The revised conclusion statement for the language and communication development domain is limited evidence suggests that seafood intake during pregnancy may be associated favorably with measures of language and communication development in the child, and we graded this as limited.

[1:33:04] This is the third of four revised statements, and it is from the second seafood question, “What is the relationship between seafood consumption during childhood and neurocognitive development and health?”

A conclusion statement as it was presented in January is shown above, and the revised conclusion with red text indicating the changes is below. This is for the cognitive development domain.

Insufficient evidence is available to determine whether seafood intake during childhood and adolescence is favorably associated with measures of cognitive development in children and adolescence. The grade here is not assignable relative to favorable association.

[1:34:06] Moderate evidence suggests that seafood intake during childhood and adolescence has no unfavorable association with measures of cognitive development in children and adolescence, and the grade here is moderate in regard to no unfavorable association.

This is the third of four revised statements, and it is from the second seafood question. “What is the relationship between seafood consumption during childhood and neurocognitive development and health of the infant?”

A conclusion statement as it was presented in January is shown above, and the revised conclusion statement with red text indicating the changes is below. This is for the cognitive development domain.

[1:35:01] The revised conclusion statement for favorable association is insufficient evidence is available to determine whether seafood intake during childhood and adolescence is favorably associated with measures of cognitive development in children and adolescence. The grade here is grade not assignable for favorable association.

The revised conclusion for no favorable association is moderate evidence suggests that seafood intake during childhood and adolescence has no unfavorable association with measures of cognitive development in children and adolescence. And so, the grade here is moderate for no unfavorable association.

[1:35:56] Now, I will present the evidence and conclusions from the subcommittee's review of the question, "What is the relationship between types of dietary fat consumed and risk of cardiovascular disease?"

This is the analytic framework for the systematic review on dietary fats and CVD. We presented this at a previous Advisory Committee meeting, so I will not review this in detail. However, I will highlight the types of fat included saturated fats, polyunsaturated fats, PUFAs, monounsaturated fats, MUFAs, and dietary cholesterol.

We included studies that compared types of fat with different sources, amounts, and proportions of fat, and replacement with other types of fat or other macronutrients.

[1:36:59] Due to the short timeframe relative to the workload volume, the subcommittee updated the following exclusion criteria to narrow and strengthen the review. These additional exclusion criteria were applied prior to the completion of screening.

We excluded studies that assessed serum/lipid ratios solely as outcomes. We also excluded studies that only assessed blood pressure as an intermediate outcome in adults. We excluded observational studies that only examined intermediate outcomes. For these types of studies, we only included those that evaluated endpoint outcomes.

We also excluded RCTs with interventions that lasted less than 4 weeks, and we excluded studies that only examined human milk or infant formula as the only source of dietary fat.

[1:38:03] This flowchart illustrates the literature search and screening results for this review. After screening, there were 238 articles which met the criteria. As a reminder, the review built upon the 2015 committee's review on saturated fat and cardiovascular disease outcomes in adults. Therefore, there were different data ranges used in this search.

For children, the literature search included articles published in January 1990 or later. This resulted in 37 included articles focusing on children and CVD outcomes. For adults, the current literature search included articles published in January 2010 or later, and this resulted in 201

included articles to add to the evidence reviewed by the 2015 committee, with 94 included articles focusing on endpoint outcomes.

[1:39:15] Our review of the evidence of studies in children included 37 articles with 22 of these articles from 7 RCTs, 16 articles from 14 prospective cohort studies, and it should be noted here that 1 RCT was also analyzed as a prospective cohort study.

For population characteristics, the studies predominantly were conducted in the US and Northern Europe, and that included Finland, the Netherlands, and the UK.

The majority of RCTs and prospective cohort studies were conducted during childhood and early adolescence, ranging in age from 4-13 years and had 1-5 years of follow-up.

[1:40:08] One RCT, the STRIP study, was initiated at a very early age, 7 months, and it continued for about 19 years. Some prospective cohort studies had longer-term follow-ups, and those follow-ups ranged from 15 to 20 years.

Then, focusing on intervention and exposures, most articles from RCTs came from 2 trials, the STRIP cohort in Finland and the DISK cohort in the United States. These trials provided dietary counseling to reduce or limit saturated fat and dietary cholesterol intake. They included increased PUFA intake and that was encouraged but was often not the central focus on these interventions.

[1:41:02] The remaining RCTs modulated dietary fat intake by providing different food products. Among the prospective cohort studies, most of the studies focused on saturated fat and PUFA, with fewer studies focusing on MUFA or dietary cholesterol.

Only a few studies directly addressed replacement of the fat or dietary source of fat, and there were a variety of methods used to assess diet. That included food frequency questionnaires, diet records, and 24-hour recall, with about half of the methods being validated.

For outcomes, the majority of the studies assessed intermediate outcomes, predominantly blood lipids. Few studies assessed blood pressure. And for CVD endpoint outcomes, there was only 1 study, which was limited by use of indirect measure of exposure.

[1:42:05] For saturated fat and blood lipid outcomes, the evidence from RCTs showed that consuming less saturated fat and less dietary cholesterol resulted in lower blood total cholesterol and LDL

cholesterol throughout childhood, particularly in boys. The evidence from prospective cohort studies was consistent with RCTs.

For PUFA, the evidence showed that higher PUFA intake resulted in lower total blood cholesterol, and this again, was particularly in boys. There is less evidence that prospective cohort studies on this topic were important in terms of this particular outcome, but this was broadly consistent with RCTs.

[1:43:03] For MUFA, there were few studies, either RCTs or prospective cohort studies, which focused on MUFA intake, and for those, the results were predominantly null.

The effects of types of fat on blood pressure were difficult to discern, and this was due to the advice given to reduce sodium consumption in one of the RCTs, the STRIP study, and additionally, there were fewer prospective cohort studies on this topic, and their results, again, were predominantly null.

We have six draft conclusion statements for dietary fats and risk of cardiovascular disease in children.

The first that was shown here focuses on CVD endpoint outcomes. Insufficient evidence is available to determine the relationship between intakes of types of dietary fat during childhood and CVD health outcomes during adulthood, and here, the grade was not assignable.

[1:44:10] The second draft conclusion statement pertains to blood pressure as an intermediate outcome. Insufficient evidence is available to determine the relationship between intake of types of dietary fat during childhood and blood pressure throughout childhood, and here, the grade was not assignable.

These three draft conclusion statements focus on the types of dietary fats.

So, there's strong evidence to demonstrate that diets lower in saturated fat and cholesterol during childhood result in lower levels of total blood cholesterol and LDL cholesterol throughout childhood, again, particularly in boys, and the evidence here is strong, and grade of strong.

[1:45:04] Moderate evidence suggests that diets higher in PUFA during childhood result in lower levels of total blood cholesterol throughout childhood, particularly, again, in boys, and the grade here is moderate.

Insufficient evidence is available to determine the relationship between MUFA intake during childhood and total blood and LDL cholesterol throughout childhood. The grade here is not assignable.

The last statement refers to replacing saturated fat with other types of fat or carbohydrates. Few articles examined replacement of types of fat in children, and therefore, our draft conclusion statement is: insufficient evidence is available to determine the relationship between replacement of saturated fat with PUFA, MUFA, or other macronutrients during childhood and total blood LDL/HDL cholesterol or triglycerides throughout childhood and adulthood, and here, the grade is not assignable.

[1:46:19] That wraps up the evidence for studies in children looking at dietary fats and risk of cardiovascular disease, and now, we will turn to studies in adults. As a reminder, this subcommittee's review of dietary fats and CVD in adults is building upon the 2015 Advisory Committee's review of saturated fats and CVD outcomes.

The 2015 review considered evidence prior to January 2010 and included studies dating all the way back to the 1960s.

[1:46:58] The 2015 conclusion statements are shown here on this slide, and these were our starting points as we reviewed and synthesized the evidence from the 201 articles in adults which were included in our own search, and that included 94 studies on CVD health outcomes.

I'm going to pause here so that you have a moment to review and read these conclusion statements.

[1:47:54] I will first review the evidence pertaining to adult studies with endpoint health outcomes. These outcomes include cardiovascular disease, CVD, myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease, stroke, and cardiovascular disease-related mortality.

94 articles met inclusion criteria for our current review. There were 90 articles from 48 prospective cohorts and 4 articles from nested case controls.

In terms of population characteristics, most studies were conducted in the US, Scandinavia, Southern Europe, and Japan.

The majority of participants were middle-aged or elderly adults with overweight.

[1:48:55] Focusing then on exposures, the studies predominantly measured dietary exposure with validated food frequency questionnaires.

The studies focused primarily on saturated fats, omega-3, polyunsaturated fats, total polyunsaturated fats, or monounsaturated fats. There were fewer studies that focused on N6, PUFA, or dietary cholesterol, and only a few studies directly addressed dietary source of types of fat.

In terms of outcomes, many studies examined incident CVD, inclusive of multiple fatal or non-fatal events, such as MI, CHD, and stroke, while other studies examined specific subsets of CVD outcomes.

And then finally, the common limitations.

[1:49:56] The majority of studies did not control for all key confounders, and many studies did not have CVD as a primary outcome, but rather, as a secondary outcome.

Our subcommittee decided to break up our review of dietary fats by types of fat, and I will start with summarizing the evidence pertaining to saturated fats.

There were 35 articles from prospective cohort studies that focused on saturated fats. Evidence since January 2010 showed that replacement of saturated fat with PUFA was primarily significantly associated with lower risk of CHD and CVD mortality.

These findings are consistent with conclusions made from the 2015 Dietary Guidelines committee report, which considered systematic reviews including RCTs, prospective cohort studies that dated back to the 1960s.

[1:51:01] There were fewer more current studies which examined other specific CVD health outcomes, such as heart failure and stroke alone.

Studies which looked at replacement of saturated fat with total carbohydrates tended to be inconsistent with mostly known associations with CVD outcomes. Among these studies, most studies did not specifically differentiate between the type of carbohydrate, such as complex or simple, and this was related to replacing saturated fat, and in this situation, that idea of looking at the complex and simple carbohydrates was very important.

Based on our review of the evidence, we have drafted the following conclusion statements.

[1:51:59] Strong evidence demonstrates that replacing saturated fat with PUFA in adults reduces the risk of CHD events and CVD mortality, and the grade here is strong.

Insufficient evidence is available to determine if replacing saturated fat with PUFA in adults affects the risk of stroke or heart failure due to inclusive results. The grade here is not assignable.

Insufficient evidence is available to determine if replacing saturated fat with different types of carbohydrates, complex and simple, in adults affects the risk of CVD, and the grade here is not assignable.

[1:52:55] Next, I will summarize the evidence pertaining to monounsaturated fats.

There were 26 articles from prospective cohort studies, and they focused on MUFA.

Evidence that we examined was broadly consistent with conclusions from the *2015 Dietary Guidelines* report.

In studies where total MUFA intake was examined, predominantly null associations between total MUFA intake and risk of cardiovascular disease were observed.

In studies that assessed replacement of saturated fat with total MUFA, predominantly null associations were also observed.

There were only a few studies which examined and reported the specific food source of MUFA. The source of fat is important because MUFA is found in both animal sources and plant sources, and often, the animal sources are also associated with saturated fats.

[1:53:56] Among the few studies that examined food sources, MUFAs from plant sources were generally associated with lower risk of CVD compared to MUFAs from animal sources.

Because our review of the evidence resulted in similar findings regarding replacement of saturated fats with MUFA, as in the 2015 guidelines conclusion statement, we decided to carry that conclusion statement forward, and it currently reads evidence is limited regarding whether replacing saturated fats with MUFA confers overall CVD or CVD endpoint benefits.

One reason is that the main source of MUFA in a typical American diet is from animal fat. And because of that cooccurrence of saturated and monounsaturated foods, it is difficult to tease out the independent association of MUFA with CVD.

[1:55:01] However, evidence from RCTs and prospective studies have demonstrated benefits of plant sources of monounsaturated fats, such as olive oil and nuts on CVD risk, and the grade here is limited.

Moving on to summarize evidence pertaining to omega-3, polyunsaturated fats, as a reminder, because this evidence is building upon the *2015 Dietary Guidelines* report, which focused on saturated fats but also provided evidence on other types of fat, this search went back to January 2010.

There were 47 articles from prospective cohort studies that focused on omega-2s, and these studies found predominantly beneficial or null associations between intake of N-3 PUFAs and CVD risk.

[1:55:59] In particular, the total EPA and DHA from food sources were mostly consistently associated with lower risk of CVD.

Based on our review of the evidence, we have drafted the following conclusion statement: moderate evidence suggests that total intake of N-3 PUFA, particularly EPA and DHA from food sources in adults, is associated with lower risk of CVD, and here, our grade is moderate.

Topics still under review by our subcommittee are N-6 PUFA and CVD health outcomes, dietary cholesterol and CVD health outcomes, dietary fat with a focus on food source and CVD intermediate outcomes.

[1:56:56] The next step for our subcommittee will be to complete the topics still under review, as outlined on the previous slide, submit the review of dietary fats and CVD for peer review, and complete our draft report.

And that concludes our presentation today. Thank you all of the subcommittee members and the support staff, who have made this work possible, and I do want to especially thank the NESR team, who have done a great deal of work in terms of providing us with data to allow us to make the conclusion statements and the grades. Thank you.

Dr. Barbara Schneeman: Great. Thank you, Linda. So, we'll open the discussion up from the committee members for comments, questions, even subcommittee members, if you want to amplify on any particular point?

[1:58:04] Dr. Elizabeth Mayer-Davis: So, this is Beth Mayer-Davis. I have a question, if I can do that.

Can you hear me?

Dr. Linda Snetselaar: Yes.

Dr. Barbara Schneeman: Yeah.

Dr. Elizabeth Mayer-Davis: Okay, thanks. So, I'm curious about the findings in kids regarding fat and cholesterol, where it was emphasized that the association seemed to be particularly true for boys. I'm wondering if that was driven by results from the STRIP study in particular. I'm wondering if those results really had to do with the situation pre-puberty, because I'm not thinking of a reason that there would be a sex differential, especially before puberty.

[1:59:02] And I didn't note any discussion or any comment about a sex differential for adults.

So, I'm wondering if that might be real or sort of artifact.

Dr. Linda Snetselaar: Yes, I think puberty, I think puberty makes—certainly plays into this, and we were certainly seeing that in the DISK study, too, which both Linda Van Horn and I were involved in, and I might ask Linda to comment on this as well, but I think that definitely was at play when we were looking at children.

Linda, would you comment also, please?

Dr. Linda Van Horn: Yeah, thank you. Hi. This is Linda Van Horn, and thanks, Beth. Good question, and we've spent a lot of time thinking about this.

[1:59:56] The STRIP study, you know, as everyone is probably aware, is truly phenomenal in the fact that they have followed their children from 7 months of age to, in fact, they still published papers this past year in this age group of now 20-year-olds.

And the point that you're making is one that also was of interest to us. Because of the duration of the time in life course events, including puberty, the STRIP data are particularly useful,

because of course, it helps to open some black boxes that have been in existence for quite a while in regard to the role of hormones in regard to influencing lipid levels and differences that we see in men and women as adults in the future.

[2:00:55] And so, what we really recognize, primarily, you're right. The majority of those data were derived from the STRIP study that illustrated this point. DISK, unfortunately, we did look at Tanner staging, but unfortunately, the study ended before Tanner 5, so we were not able to get a clear picture from beginning of puberty to the end of puberty to determine whether dietary intake during those pre-adolescent years ultimately resulted in a lower LDL cholesterol level in either boys or girls after they achieved puberty—completed puberty.

So, the STRIP data really are the best and the only data that we have to confirm those kinds of observations, and it's definitely derived primarily from their data, suggesting, again, that in boys, there seems to be a particular benefit.

[2:02:03] I think the other little interesting twist that I'll just throw in here, because we don't have sufficient data yet to really look at these questions, but I think as we go forward with additional research related to metabolomics and bio—microbiome issues, it's possible that we'll be able to further identify pathways or do additional deeper investigation related to some of the mechanisms that might potentially underly those associations.

But the idea that male/female differences can certainly exist is something that I think we, as a community, are very interested in and are only now beginning to truly focus on in a variety of different diet relationships.

[2:03:00] **Dr. Linda Snetselaar:** Thank you, Linda. And just to add one more comment. Beth, please know that we did try to continue to follow the DISK population, which would have provided, I think, some very interesting data, but those requests to NIH were not funded.

And I think it's just important to keep in mind that some of these longitudinal studies can be so incredibly important to our understanding of exactly what you were talking about.

Dr. Ronald Kleinman: So—

Dr. Elizabeth Mayer-Davis: Okay, thank you.

Dr. Elsie Taveras: Linda, this—oh, sorry.

Dr. Ronald Kleinman: I can wait.

Dr. Elsie Taveras: This is Elsie. I had a quick question, which I think you answered.

[2:03:55] Do you know when the—and how they assessed for puberty? How did STRIP measure pubertal development? Because I wonder if that began at—how early there was, because I'm just thinking of pubertal effects that could determine or could explain some of these sex differences that we've seen in some other studies.

But just what Beth was saying, we see that a little later. And so, I wondered if you saw in any of the studies how early they began assessing pubertal development and how they were—was it just Tanner staging, and was it self-reported Tanner staging?

Dr. Linda Van Horn: Linda, do you—Linda S., do you want me to address that one?

Dr. Linda Snetselaar: Yes.

[2:04:55] **Dr. Linda Van Horn:** Hi.

Dr. Linda Snetselaar: I certainly know what we did in DISK, but Linda, please respond to the STRIP study.

Dr. Linda Van Horn: Yeah. Well, again, STRIP started earlier than DISK did, and to my knowledge, they were not using Tanner staging, or at least not as reported. I believe there was a lot of self-report that was involved with that determination, but exactly what methods were used really were not addressed in the literature that we reviewed.

I'm sure we can go back and look at that but recognizing that the difficulty or the complexity of achieving that even in the DISK study, which came at a later time, took a bit to implement.

[2:05:55] So, whether that was something that was done at some later time during the STRIP study or not, I really don't know, but I believe self-report was definitely involved.

Be that as it may, though, sorry, just to finalize that, be that as it may, though, the differences were in regard to blood lipids, total cholesterol, LDL cholesterol, etcetera.

Dr. Elsie Taveras: Yes, good point.

Dr. Ronald Kleinman: So, this is Ron. I have followed this STRIP actually from the beginning, and I find it very convincing. And so, I appreciate what you're recommending here. Then, I just pulled up this letter that we saw the other day from the group from this expert workshop on saturated fats and health, the letter to the Secretaries.

[2:06:56] And they come really to just the opposite conclusion, that saturated fat in the diet doesn't impact heart disease or stroke. So, I was just wondering, how will we discuss that or reconcile these differences of opinion in the report?

Dr. Linda Snetselaar: Very good question. I think that what we are trying to do, at least in our subcommittee, is look very carefully at the studies that have been done. We're also looking very carefully at who may have funded studies in terms of some of the results that we're looking at, and just being very, very careful to try to base our thoughts and our ideas on what we see as the current evidence.

[2:08:07] We are going back to what was done in the past, because many of those studies were very expensive long-term clinical trials conducted at multiple sites, and that—those studies still hold and are incredibly important.

And I feel that we just have to be true to what we're seeing in terms of the data that are out there right now in terms of the studies that are being done.

I would love for my other committee members to respond to this as well.

Dr. Ronald Kleinman: I will add that it's unfortunate that they didn't provide any references in this letter, so the **[crosstalk 2:08:59]** studies and metanalysis, a little hard to—

[2:09:03] **Dr. Linda Snetselaar:** Exactly. Yeah, since it would be easier, it would be much easier to respond if they had done that, yes.

Dr. Ronald Kleinman: Yeah.

Dr. Linda Van Horn: Yeah. And this is Linda Van Horn. To add to that, and Ron, you know, you're raising, of course, very important points that I know are top of mind for a lot of individuals, but again, as Linda pointed out, we're really trying to be true to the evidence base on the systematic review that was done to derive the manuscripts that we're looking at. So, we're reporting on the basis of what we've reviewed.

And I think for myself, it was fascinating, with this vast number of papers, to look at that—the variability in terms of assessment methodologies, certainly diet assessment using a food frequency questionnaire, as we know, is not always as specific and detailed as other methods is one thing.

[2:10:06] The other thing that I think is something we are trying very hard to tease apart is that the term cardiovascular disease is intended to be sort of a multi-factored term that includes not only coronary heart disease, but also, heart failure, stroke, PAD, you know, a variety of different aspects of cardiovascular disease.

And what we're finding, at least on the basis of the studies that we're reviewing, is that one size doesn't necessarily fit all.

And just as we were talking about male/female differences, it's very likely that there are differences in terms of subgroups as well as realizing that one of the very important distinguishing features is BMI.

[2:11:01] And looking at a diet high in carbohydrate, for example, in BMI—in a population with a BMI in the 20s, BMI 20-25, is a very different story than looking at a population like ours, where the average BMI is well above that, 25, 26, etcetera.

And so, recognizing that, again, dietary approaches that are consistent with improvement and prevention of cardiovascular disease, especially looking at the intermediary endpoints – lipids, blood pressure, etcetera – really does factor into the ultimate evaluation of those studies and where and how diet is measured and the outcomes that were reviewed.

[2:12:04] So, I think, again, as Linda points out, we worked with the evidence. We worked with the papers as we read them, and those other statements related to inconsistencies, etcetera, in those data, really should be evaluated head-to-head before any further conclusions could be reached.

Dr. Ronald Kleinman: Mm-hmm. Well, I appreciate what you're saying, and also, I appreciate your review of this, because it's very informative. I guess, as you've just described it, Linda, in the discussion, it's going to need to go through some of these methodologic considerations, which may lead to different interpretations.

[2:12:59] It'll end up being pretty nuanced discussion, I imagine, given the complexity of this literature.

Dr. Linda Snetselaar: That's why we need a little more time to do that.

Dr. Barbara Schneeman: Yes, this is Barbara. So, I just wanted to add to the—okay, go ahead, Joan.

Dr. Joan Sabate: Okay. I just wanted to add to the discussion, that we have to recognize that, yes indeed, there are a few recent articles that seems to indicate that saturated fat may not have the effect that it was portrayed in the past.

However, I mean things—there are other reasons that may explain these results.

And I would say one is that the background diet, the context is different now than it was in the traditional, I would say randomized clinical trials done in the 60s.

[2:14:07] And another issue is that, in some of these papers, I mean what they are comparing is the replacement with simple carbohydrates. So, the saturated fat may not have an effect when it's compared with simple carbohydrates as far as cardiovascular disease. And this may mask, or this may complicate the interpretation of the results.

And as Linda said, I mean it's true that there is a clear difference between CHD and CVD, and we have to be very careful to what of these two entities or group of disease we're referring to.

[2:14:53] So, the relationship between saturated fat and CHD, I think it has been clear for many decades, and probably still is the same. However, when we go into CVD, maybe not as clear.

And also, when we compare saturated fat with—decreasing of saturated fat but then increase in simple carbohydrates, maybe we then see get **[indiscernible 2:15:21]** it is evident when it's replaced with unsaturated fats, particularly PUFA.

So, I think this could be some of the situation that now makes things more complicated, and we have to be very clear as far as what we are particularly comparing to.

Dr. Ronald Kleinman: Thank you.

Dr. Barbara Schneeman: So, and indeed, Ron, I think you were referring to the public comment that was submitted.

Dr. Ronald Kleinman: Yeah.

Dr. Barbara Schneeman: And I just want to add to the discussion that part of the protocol and consideration in developing the protocol has been to look at intermediate outcomes that could be considered surrogate endpoints.

[2:16:11] And we've tried to work closely and interact well with NIH on some of their clinical guidelines to make sure that what we're identifying when we look for these intermediate outcomes are consistent with what NIH has used in their clinical guidelines as well.

And so, that's another consideration in terms of the protocol and how we've been looking at the evidence.

Dr. Ronald Kleinman: Mm-hmm. Good.

Dr. Barbara Schneeman: So, there's—go ahead.

Dr. Linda Van Horn: I was just going to add one more comment that Joan was relating as far as things have changed.

[2:17:00] And I think the other very interesting factor that we're facing at this point, and I'm sure everyone's aware of the literature showing that the overall population, LDL cholesterol has come down over the past decade or so but has also kind of leveled off.

And when we think about what kinds of changes have occurred in the US dietary intake, probably one of the most major changes has been of the identity of trans fats being equal if not worse to saturated fats as adversely affecting blood lipids.

And I believe, in many ways, we're seeing some benefits from the removal of trans fats from various products in the American food supply, and that has helped as far as that goes.

[2:17:59] But we're also, as I mentioned, recognizing that this has leveled off, and also appears to be almost increasing at this point.

And so, trying to work with the current dietary intake and looking at levels of various fatty acids becomes newly important.

And as we go forward in recognizing even within the current situation, what are those drivers that continue to increase blood lipids and affect risks for cardiovascular disease?

So, from the fatty acid perspective, as we've just reviewed, saturated fat replaced with polyunsaturated fat continues to be a major benefit when we look at the totality of the evidence.

[2:19:01] Dr. Barbara Schneeman: Great. This is very good information. Linda Snetselaar, I have a very minor thing. It's on slide—I believe it's slide 16.

Where we have the draft conclusion statement coming from our look at children. It says—the end phrase there says, “throughout childhood and adulthood.” And I think the reference was—I'm just worried about that phrase “throughout childhood and adulthood,” and I don't want to misinterpret it.

Do you understand my concern? It's—

[2:19:59] It's really the impact is the children move into adulthood, as we've discussed. I think it's just a wording thing, that to make sure it's clear, we could perhaps handle it in a discussion.

Dr. Linda Van Horn: Right. I think I see what you're saying, Barbara. And yes, the intent is—the question is, if diet that has been replaced with polyunsaturated or other fatty acids or macronutrients during childhood results in improved blood LDL or HDL cholesterol or triglycerides in adulthood. There really are insufficient data yet to be able to really draw a meaningful conclusion. Isn't that right, Linda Snetselaar?

[2:20:56] Dr. Linda Snetselaar: I'm sorry. I got cut off and I just got back on. What was the question again?

Dr. Barbara Schneeman: I think we've got it now then. I think—

Dr. Linda Snetselaar: Okay.

Dr. Barbara Schneeman: Great. Thanks, Linda. Thanks to both Lindas.

Dr. Ronald Kleinman: I think, just as a real quickie there, I think there's a typo on slide 6. It's cognitive outcomes of childhood, adolescence, and the last words says infant. Oh, wait a minute. I think that's slide 6. Yeah. Let me see. “During childhood and neurocognitive...” Yeah, so seafood consumption during childhood and neurocognitive development of the child and adolescent, right?

You're consuming the seafood during childhood, and you evaluated these outcomes in child—in children and adolescents?

[2:21:57] So, that last word, that word “infant” in the box there should be replaced by children and adolescents.

Dr. Barbara Schneeman: Yeah, and I think you're referring to the blue box right underneath the header?

Dr. Ronald Kleinman: Yeah, sorry.

Dr. Linda Snetselaar: Oh yes, I see now. Yes. Thank you. We'll change that.

Dr. Ronald Kleinman: Alright. Once copy editor, always a copy editor, right?

Dr. Linda Snetselaar: Yes. We will change that. Thank you.

Dr. Kathryn Dewey: And Barbara added—this is Kay Dewey. I think there were two slides that were the same, this one and the next one. And I think maybe one of them was supposed to be language and communication, but cognitive was shown in both.

[2:22:58] **Dr. Linda Snetselaar:** Kay, we will make that change, too. Thank you.

Dr. Kathryn Dewey: Great. Thanks.

Dr. Jamy Ard: This is Jamy.

Dr. Barbara Schneeman: We want to—

Dr. Jamy Ard: This is Jamy Ard. I had a question that is more about the question and the sort of conclusions relative to the questions.

So, the conclusions are focused on substitutions of one type of fatty acid for another, so replacing saturated fatty acid with PUFA, or in some cases, replacing it with carbohydrate.

Dr. Linda Snetselaar: Yes.

Dr. Jamy Ard: But it doesn't quite get at the question of, well, is there a certain amount of saturated fat intake that's reasonable?

[2:23:58] Because at one level, if we take the conclusions to their natural sort of extension, it would be, well, eat as little saturated fat as possible and replace it with these types of things. But it doesn't quite get at, well, how much is okay?

I mean because we know with trans fats, it's basically eat as—that's the case, right? There's no amount that we would say is acceptable. As little as possible.

Dr. Linda Snetselaar: Right.

Dr. Jamy Ard: But with—and I think, to me, that's what the letter from the—from that group was sort of getting at is, right, there's a target for saturated fat intake, but the way we've got the conclusions drafted, it doesn't quite get at that issue of, well, how much is reasonable in terms of still being associated with a lower risk of cardiovascular disease?

[2:25:03] Is that something that we could actually glean from the literature that you had to review, or is it all relative to changes in one fatty acid for another, or one type of food group for another?

Dr. Linda Snetselaar: So, are you sort of thinking about like dose effect, that—going in that direction? Because we certainly could go back to the research and look at that more closely.

Dr. Jamy Ard: Yeah, I guess it is sort of a dose relationship, sort of what's the upper—I guess if we were to use upper tolerable limit for saturated fatty acids, assuming background dietary pattern that is generally associated with a lower risk of cardiovascular disease.

[2:26:03] **Dr. Linda Van Horn:** Well, you know, broadly—

Dr. Linda Snetselaar: Linda, do you want to respond to this? Oh, go ahead.

Dr. Linda Van Horn: Oh, more broadly, the recommendation is under 10 percent of total fat intake is recommended, and in fact, American Heart Association recommends 7 percent or less. To our knowledge, there is no biologic requirement for saturated fatty acids, and because of the fact that this group is also reviewing eating patterns, what we recognize is that, in order to achieve all of the other nutrients, as Regan and Jamy and the group that just described all of that, is our concern, the fact of the matter is, that in order to achieve the levels of LDL cholesterol population-wise, dietary intake of saturated fat that is 7 percent or lower is

consistent with meeting all of the other nutrient density recommendations related to dietary fiber, and fruits and vegetable intake, and whole grains, etcetera, etcetera.

[2:27:25] So, I think, in fact, the DISK study was specifically designed to look at reductions in saturated fat intake in pre-adolescent children, specifically looking at growth and development over the course of puberty in order to conclude efficacy as well as safety in growing children.

And of course, you know, there was no concern whatsoever in regard to adherence to that level of intake.

[2:27:58] So, I think population-wide, in looking at the equations that still hold up, for every 1 percent reduction in saturated fat, there's a 2 percent improvement in overall risk. I think the benefits of keeping total saturated fat intake lower and achieving the replacement issues that we've been identifying, poly fat, mono fat, plant protein, etcetera, is consistent with the overall dietary pattern recommendations that we're also trying to make.

And again, we still have yet really to look at some of the specificity in regard to carbohydrates and protein. It just is that saturated fat and fatty acids have sort of been the focus for so long in terms of cardiovascular disease, and we're only now fine-tuning all of the macronutrients and their best combination in order to achieve the health and longevity we're looking for long-term.

[2:29:12] *Dr. Joan Sabate:* If I may add, I think Jamy, you asked a very interesting question and a very poignant one that I think deserves consideration.

My immediate reaction is to concur with what Linda just said, that to our knowledge, there is no biological need for saturated fat, since our bodies **[indiscernible 2:29:41]** we have.

So, it's not a necessary nutrient.

With respect to your question, if there is a safe intake, I think in most of the epidemiological studies kind of addresses this question in a monotonic linear relationship.

[2:30:00] And in the spectrum of the studies that I do remember, I mean there is not a threshold or a lower limit that you can go as far as saturated fat beyond which there is no greater effects as far as cardiovascular disease or technically, coronary heart disease.

So, my immediate answer is that, yes, indeed, I mean the lower the saturated fat, I mean the lower the risk of coronary heart disease, based on the literature that we have available.

Dr. Jamy Ard: So, should we—should we have a conclusion statement that says that, or is that necessary?

[2:30:56] Dr. Joan Sabate: As Linda said, I mean saturated fat is part of the foods that we typically consume, even plant sources of fat also contain some saturated fats. So, saturated fat is not only present in animal products, it's also present in many plant foods, and nuts, to some extent, has also a small percentage of saturated fat.

So, I think it's—I wouldn't say practically impossible, I mean to have a diet with zero saturated fat.

So, I would not go to the extreme, probably, to state a limit, but I mean that's my opinion. I mean I would like to see what others think about this issue.

Dr. Linda Van Horn: The other thing, Jamy, is that we, as Linda pointed out, we have yet to really finish the evaluation, given the magnitude of papers that we're still looking at.

[2:32:03] I think the point you raised is a good one. I don't believe that, on any of the given papers that we're reading, that very answer is likely to come forward. We really do have to rely on the totality of the evidence that continues to point to the area, the percent of saturated fat associated with improved population-wide lipid levels is less than 7 percent of saturated fat intake with intake of the unsaturated fatty acids included to derive the eating pattern that we're trying to recommend.

So, because, again, this is our Advisory Committee report, and the *Dietary Guidelines* themselves, will be made as a result of this report, I think we, certainly in our discussion, can raise that very important issue.

[2:33:05] And perhaps reiterate the value of having a saturated fat intake that is no more than 7 percent, and there's no limit on how low the saturated fat intake could be.

But in order to, again, meet all the other nutrient needs required across the life course, the eating pattern that will ultimately be—that will ultimately result as the *US Dietary Guidelines* for 2020, will take all of those factors into consideration.

Dr. Barbara Schneeman: So, this is Barbara. I'm also reflecting back on how this very type of issue was handled in the 2015 report, and we can certainly look back and see what they did,

because I think that committee was also probably looking very closely at the DRI report, the macronutrient report, which dealt with the different types of fatty acids.

[2:34:14] But then, also, had to factor their recommendations in to the kind of dietary patterns that were being encouraged and recommended, of which some saturated fat is going to be a part of those dietary patterns.

So, I think there are—and Linda, I appreciate your comment, of these are the kind of things that we're probably going to have to address in our discussion.

So, additional comments or questions?

[2:35:00] So, maybe we're ready for another non-controversial topic? Let's go over to Beverages and Added Sugars, and Beth Mayer-Davis, the chair for that subcommittee. So, Beth, are you ready?

Dr. Elizabeth Mayer-Davis: Sure. After that introduction to this non-controversial topic?

Dr. Barbara Schneeman: So, let me just observe that—I just want to note that I think we should go ahead and get started with the presentation. We can go a little bit after noon to finish up the presentation, and we can always have more discussion after lunch. Our hard time is that we have to reengage at 1:00 for the webinar.

[2:35:59] Okay?

Dr. Elizabeth Mayer-Davis: Okay, perfect. Yes. Alright, so I'll try to do this efficiently, but clearly.

So first, here's the subcommittee, and I have—it's been wonderful to work with this group of people.

So, at the previous meeting, we talked about beverages during pregnancy and birth weight. And so, today, we have quite a bit to cover on beverages and growth, size, and body comp, plus added sugars and cardiovascular disease, and then we'll turn our attention to alcohol and all-cause mortality, as well as an update as to our plans between now and when the report is finished.

So, I just want to remind everyone that, at the end of the day, we will be bringing together information from the data analysis approach, the food pattern modeling, as well as work done by the 2015 committee, and the systematic reviews.

[2:36:58] And it's really the systematic review piece of this that I'm going to be talking about today, but that's not the only piece that we'll be considering ultimately.

So, first, "What is the relationship between beverage consumption and growth, size, body comp, and risk of overweight and obesity?"

So, this is a reminder of our analytic framework, and since we last spoke about this, we did further refine our comparators so that we'll be looking at different amounts of a given beverage of interest, or looking at a particular beverage versus a solid form of that item, or looking at beverage versus water.

We also will be doing a comparison of sugar-sweetened beverage versus a low- or no-calorie-sweetened beverages as a specific and only example of comparing two different beverages head-to-head.

[2:37:55] And then, for dairy milk, we also did have interest in different amounts of fat, because that's obviously of considerable importance, just from a public health perspective.

Also, starting out with sugar-sweetened beverages, because the *2015 Dietary Guidelines* included articles up to December of 2011, we focused on the literature published since January 2012 rather than going all the way back to January 2000, and again, that was partly because of where the *Dietary Guidelines* from 2015 left off, and partly just as a matter of reasonable workload and trying to focus our attention in the best way possible in the time that we had.

So, with that, so all beverages, with a start of some 17,000 after removing duplicates, going through the screening process for titles and abstracts and full text, we ended up with a total of 214 articles, 61 for milk, 41 for juice, 72 for sugar-sweetened beverages, 37 for low- and no-calorie-sweetened beverages, and then 8 for the comparison between those 2.

[2:39:15] So, looking now towards the summary of evidence, a couple of notes first.

When we were looking at children, we did want to be careful between healthy growth versus excessive growth that would be unhealthy or considered to be unhealthy. So, for healthy growth, we focused on height and lean mass, whereas otherwise, we focused on adiposity, and

across studies, there were lots of different ways to measure what it would be considered as a component or a marker of adiposity, and you see some of those measures there.

But we did need to be careful to discern between those two, healthy growth versus adiposity.

[2:39:58] And then, for adults, our focus really was completely on adiposity, and again, a variety of ways in which different studies measured adiposity in some way or another.

So, let's start with milk. There were 61 articles related to milk and growth, size, and body composition.

In total, 29 for children, and these were—included studies covering ages 2 to 14. That wasn't our exclusion criteria, that was just what was in the literature. So, there were 25 prospective cohort studies and 4 RCTs with analytic samples ranging from 49 to over 13,000.

And then, for adults, there were 32 articles, including 24 prospective cohort studies, 7 RCTs, 1 medallion randomization study, and analytic sample sizes ranging between 31 and almost 53,000.

[2:41:01] So, for children, most of the studies looking at various markers of adiposity did not find any statistically significant results, and the few that did were not consistent as to the direction of the associations.

There were 4 studies that focused on height as a marker of healthy growth, 1 RCT finding no effect of milk on height compared to water, but that study was only 12 weeks, which, when you're looking at height, was not obviously particularly long, and there were 3 cohort studies that did show a significant positive association between milk intake and height in children that had a much longer duration of follow-up.

There were 7 cohort studies looking specifically at different types of milk with regard to fat level, and also, flavored milk in relation to adiposity outcomes in children, but those results were not consistent.

[2:42:00] For adults, the studies of milk found no significant associations between milk intake and adiposity for most of them, and the few that did find a significant association were inconsistent in their direction of effect.

So, the body of evidence for both children and adults had quite a few limitations related to consistency and definition of the exposure. Many of the studies had approaches to assessing intakes that were not validated. There were certainly a lot of studies that did not well control for potential confounding. And again, there were inconsistencies in findings.

So, the conclusion statements then for children: limited evidence suggests that milk intake is not associated with adiposity in children.

[2:42:57] Limited evidence suggests that higher milk intake is associated with greater increase in height compared to lower intake in children.

And there's insufficient evidence to draw a conclusion about the relationship between the type of milk, either milk fat content or flavoring, and adiposity in children.

For adults, limited evidence suggesting that milk intake is not associated with adiposity in adults.

So, moving to juice, the body of evidence included 41 articles, 22 articles for kids. 21 of those were prospective cohort studies, and 1 was an RCT, with analytic sample sizes from 21 to over 15,000.

And for adults, there were 19 articles with 14 prospective cohort studies and 4 RCTs, along with 1 non-randomized control trial, and again, sample sizes ranging from about 26 to a little over 50,000.

[2:44:03] For children, the studies that were of higher quality found little or no effect in the relationship between juice and growth, size, or body comp, and inconsistent findings otherwise. And you see here a list of—a pretty substantial list of limitations in that particular body of evidence.

For adults, the RCTs that were available were rather short duration, with modest sample sizes, and the cohort studies, although there were large sample sizes, there were some consistent findings there, but quite a few limitations in terms of adjustment for confounding in particular, and also, some problems with definition of the exposure.

And so, for conclusion statements for children, we have that limited evidence suggests that 100 percent juice intake in children is not associated with growth, size, body composition, or risk of overweight or obesity in children.

[2:45:09] For adults, we have as a draft statement, limited evidence suggesting 100 percent juice intake is not associated with measures of adiposity in adults.

Alright, for sugar-sweetened beverages, and here, I will just remind everyone that this, again, is just part of the evidence that, in total, we'll be looking at. We are also considering the data analysis, the food patterning, and the work of the 2015 Guidelines. And so, here, what I'll present is the evidence review that we did according to our inclusion/exclusion analytic framework.

So, for sugar-sweetened beverages, there were a total of 79 articles.

[2:45:58] 46 in children, including ages 2 to 15, with 43 prospective cohort studies, just 2 randomized control trials, and 1 non-randomized control trial. The sample sizes ranging from 40 to over 15,000.

For adults, there were 26 articles, 23 prospective cohort studies, 3 RCTs, and again, 1 non-randomized control trial, with analytic samples from 47 to 49,000.

And these studies looked at different amounts of sugar-sweetened beverage or sugar-sweetened beverage intake compared to water.

So, for children, the RCTs showed a relationship between a decrease in sugar-sweetened beverage and a decrease in BMI or other similar measurements, BMIz for example. The prospective cohort studies showed a positive relationship between sugar-sweetened beverage intake and measures of adiposity.

[2:47:04] There were quite a few limitations with this literature. We should note there were some inconsistencies across subgroups, inconsistency in methods, particularly regarding definitions of exposure, age of the kids, duration of follow-up, and quite a number of the studies had very high attrition.

For adults, the experimental studies had inconsistent results and various limitations related to definition of exposure and generalizability in particular, and some small sample sizes.

The prospective studies showed a positive relationship between sugar-sweetened beverage and at least one measure of adiposity, and this relationship though, was not consistent **[no audio 2:47:52]** different markers of adiposity.

[2:47:57] And so, our conclusion, first for children, moderate evidence suggests that high sugar-sweetened beverage intake is associated with greater adiposity in children.

And for adults, limited evidence suggests that higher sugar-sweetened beverage intake is associated with greater adiposity in adults.

So, turning now to low- and no-calorie-sweetened beverages, there were 37 articles, 17 for children age 2 to 16 years, and these were all prospective cohort studies with durations ranging from 6 months out to 12 years, and analytic sample sizes from 49 to 11,654.

Now, let me stop here for just a minute, because we have one of our committee members saying that they can't hear anything, and can others hear me? Or am I talking to the air?

[2:48:58] *Dr. Richard Mattes:* I can hear you.

Dr. Elizabeth Mayer-Davis: Okay, thank you. Alright. Okay, great. I'm sorry for—everyone, sorry for that interruption. So, okay.

Dr. Regan Bailey: But Heather and Jamie Stang, Heather Leidy and Jamie Stang both—sure.

Dr. Carol Boushey: Right.

Dr. Elizabeth Mayer-Davis: It sounds like there are just two committee members who are not able to hear right now. Okay, that looks like maybe the two of those are linked. So, I'm going to let the technical folks take care of that, and I will carry on, unless Barbara, you tell me to do otherwise. Okay, I will carry on. Alright.

So, for adults, we had 20 articles with 14 from prospective cohort studies and 6 from RCTs, with analytic samples ranging from 50 to over 51,000.

For children, the majority of these studies showed no association for the main outcome measures in the study populations with similar limitations that we've seen in some of the other bodies of literature, particularly inadequate adjustment for potential confounders, and in some cases, short study duration, and again, a number of studies with quite high attrition.

[2:50:19] For adults, a well-designed RCT and a large prospective cohort found associations between low- and no-calorie-sweetened beverages and reduced adiposity.

There were limitations in experimental studies though, with regard to study duration, and some gaps in terms of any assessment of compliance with the intervention, as well as differences in the comparators.

There were also limitations in the cohort studies, including, again, high attrition, as well as differences in assessment methods and difficulties relative to insufficient adjustment for potential confounders.

[2:51:03] And so, our conclusion statements for children: limited evidence suggests no association between low- and no-calorie-sweetened beverage consumption and adiposity in children.

For adults, limited evidence suggests that low- and no-calorie-sweetened beverage consumption is associated with reduced adiposity in adults.

Okay, then there was a rather small body of evidence that compared directly low- and no-calorie-sweetened beverages versus sugar-sweetened beverages.

So, for children, these were 2 articles. They actually were both from the same RCT.

And for adults, there were 6 articles, 5 from RCTs and 1 prospective cohort study.

[2:51:55] For children, the evidence was too limited to draw a conclusion about the relationship between, or the comparison between the low- and no-calorie-sweetened beverages versus the sugar-sweetened beverages in regard to adiposity.

And for adults, the evidence—excuse me—the evidence was relatively consistent suggesting no association between—for sugar-sweetened beverages compared with low- and no-calorie-sweetened beverages with regard to adiposity, but the studies had quite small sample sizes and a variety of problems that you can see here on this slide.

So, for conclusions for children: insufficient evidence is available to determine the relationship between sugar-sweetened beverage consumption compared to low- and no-calorie-sweetened beverages on adiposity in children, so grade is not assignable there.

[2:53:00] For adults, limited evidence suggests no association between sugar-sweetened beverage compared to low- and no-calorie-sweetened beverages on adiposity in adults.

Okay, so now, we're going to move to the next topic, which is "What is the relationship between added sugar consumption and risk of cardiovascular disease?"

And this is our analytic framework, and there's just a couple things I want to point out here, which is that, with regard to the intermediate outcomes, we looked at intermediate outcomes across the age range 2+ through adulthood for experimental studies, but with regard to observational studies, we only looked at intermediate outcomes for the kids.

[2:54:00] And the reason for that is obviously the RCT's a strong design no matter what, and it's just in the adults where we would—where we had more data to work with, where we had outcomes that are listed over here in terms of the actual clinical events for—related to cardiovascular disease, stroke, etcetera. So, that's how we dealt with that. And that's really the main thing I need to point out here, I would say. So...

Alright, so for inclusion and exclusion, we also added some criteria since the last time that we met regarding study duration and sample size criteria, and we also focused the intervention or exposure criteria, just covering a majority of total sugars intake.

So, for duration, for inclusion, we stuck to a minimum of 4 weeks for experimental studies, although we didn't impose a duration for the observational studies that we used for intermediate outcomes for kids.

[2:55:11] But we did restrict to observational studies that enrolled at least 1,000 participants.

For intervention/exposure, we looked at consumption of added sugars, particularly sugars from the overall diet or from a food or beverage that represented a large portion of overall added sugar intake, particularly sugar-sweetened beverage.

We did not, for this question of added sugars and CVD, we did not look at the issue of low- or no-calorie sweeteners or sugar alcohols.

Okay, so with that, the literature search started with over 5,000 papers, and then through the screening process, we ended up with 26 papers, and again, the publication range here was September of '14 to September of 2019, and that was picking up from the previous *Dietary Guidelines* work.

[2:56:18] So, that's important to note, too, this publication date range limited to September of '14 to September of '19.

Okay, so with that, we had 26 articles, including 3 in kids, 1 RCT, 2 prospective cohort studies, and analytic sample from 478 to 2,000+, and then 23 papers for adults, 6 RCTs, including 2 that were crossovers, plus 17 prospective cohort studies, with sample sizes ranging across those designs from 47 to almost 354,000.

[2:57:01] So, in terms of exposure, something that turned out to be important in this literature, several of the stronger studies, the higher-quality studies, measured exposure at multiple time points and incorporated that information appropriately in their statistical analysis, but many studies only assessed added sugars once, and some of the studies with particularly long follow-up times, you can imagine, this creates a weakness in the design, so that was something that we all paid attention to.

For outcomes, again, children, we just have intermediate outcomes. For adults, CVD/CHD mortality was the most commonly-assessed outcomes in the body of literature.

For children, there was 1 RCT and 1 high-quality prospective study that documented detrimental effects of added sugars on total and HDL cholesterol, which by the way, those 2 were the only 2 measured in the respective studies as 2 markers, whereas there was 1 weaker prospective study that found no effect of added sugars on blood lipids, but that particular study had significant study design limitations.

[2:58:15] In adults, for RCTs, there were mixed results, but there were multiple limitations, including some very small sample sizes, and also, 1 study with a behavioral intervention in which there turned out to be no difference in sugar-sweetened beverage intake between the intervention and control, as well as some inadequate adjustment for confounders.

For prospective cohort studies, there were mixed results, but studies with multiple measures of added sugar over time did show an association with CVD mortality.

[2:58:56] And so, for concluding statements here, and again, these are draft, like everything today, limited evidence suggests that higher intake of added sugars is associated with worse lipid profile in children, and again, this is limited for the grade.

And for adults, limited evidence suggests that higher intake of added sugars in adulthood is associated with increased risk for CVD mortality.

Continuing now, there was insufficient evidence available to determine association between added sugars in adulthood in terms of cardiovascular disease risk profile, intermediate outcomes, that is, risk of stroke, risk of incident ischemic CVD events, risk of PAD, and risk of heart failure.

[2:59:54] And across all of these, you can see that we had either 1 or 2 studies available, hence, insufficient evidence. Grade not assignable for those.

Now, for added sugars and growth, size, body comp, and risk of overweight and obesity, this is a body of evidence that we're actually not reviewing, partly—and it was partly addressed in the last by review of sugar-sweetened beverages and this outcome, so we've not gone further with that.

And we've also not addressed added sugar consumption and risk of type 2 diabetes.

For added sugars and growth, size, and body composition, I want to draw your attention for a moment to the 2015 DGAC, in which it was found that there was strong and consistent evidence to show that intake of added sugars from food and/or sugar-sweetened beverages were associated with excess body weight in children and adults, and that reduction of added sugars and sugar-sweetened beverages in the diet reduces BMI in both children and adults.

[3:01:16] And so, for the 2020, this literature that we're addressing includes literature from 2012 to 2019 and focused on sugar-sweetened beverages as the key source of added sugars.

And so, thus far, our evidence review for sugar-sweetened beverages and growth, size, and body composition does align in part with the 2015 conclusion and our committee's also looking forward to more information that we'll have regarding dietary analysis and the food patterning work.

[3:02:00] Alright, now turning to a different topic—

Dr. Barbara Schneeman: Beth? Beth?

Dr. Elizabeth Mayer-Davis: Yes?

Dr. Barbara Schneeman: Can I interrupt? I'm wondering, given the time, if we should basically start this discussion after the lunch break? Would that—

Dr. Elizabeth Mayer-Davis: Sure, yeah.

Dr. Barbara Schneeman: Would that work? And maybe, why don't we just check in with the—

Dr. Elizabeth Mayer-Davis: No, that's perfectly fine.

Dr. Barbara Schneeman: —and see if there are any questions or comments right now with respect to what you have covered. Because it's kind of shifting to a different topic.

Dr. Elizabeth Mayer-Davis: It is. That's perfectly fine. Sure.

Dr. Barbara Schneeman: So, yeah. Okay. So, why don't—are there any comments or questions at this point from the committee members?

I'm hearing none for right now.

Dr. Elizabeth Mayer-Davis: I think everyone's hungry.

[3:02:56] Dr. Barbara Schneeman: Well, at least the East Coast people are probably hungry.

Dr. Elizabeth Mayer-Davis: Why don't—after we do—oh, go ahead, Barbara.

Dr. Barbara Schneeman: Well, I was going to say, if we go ahead and break, then we can start again at 1:00 pm Eastern time, and whatever time that is in the different time zones, and then, we can start here, but also have a broader discussion of the whole presentation.

Dr. Elizabeth Mayer-Davis: Sounds good.

Dr. Carol Boushey: I think that's just fine, Barbara, and we can do the time calculations.

Dr. Barbara Schneeman: Thank you, thank you.

Dr. Carol Boushey: Just to confirm, we have to log off now, correct? And start over in the afternoon?

Dr. Barbara Schneeman: Yes. I'll let Eve explain it.

Dr. Eve Stoody: Yeah, so for both the public as well as the committee members, the committee members, you'll log in with the information for the Friday pm session, similar instructions, just different link in **[indiscernible 3:04:01]**.

[3:04:02] And then, the public, you'll have a separate link as well, and that was emailed through our Gov delivery, and is also available at DietaryGuidelines.gov.

So yes, everybody will log off for now, and then sign in using the Friday pm information. So, thank you.

Dr. Barbara Schneeman: Okay. We'll be **[indiscernible 3:04:22]**

Great. And thanks, Beth. I appreciate your comments, Beth.

Okay? Talk to you all later.