

2020 DIETARY GUIDELINES ADVISORY COMMITTEE

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PUBLIC MEETING

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WEDNESDAY

JULY 10, 2019

DAY 1 OF 2

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The Dietary Guidelines Advisory Committee met in the Jefferson Auditorium, at the headquarters of the U.S. Department of Agriculture, 1400 Independence Avenue, S.W., Washington, D.C., at 9:00 a.m., Barbara Schneeman, Chair, presiding. The meeting allowed for public viewing, both in-person and by Web.

MEMBERS PRESENT

DR. BARBARA SCHNEEMAN, PhD, Chair
 DR. RONALD KLEINMAN, MD, Vice Chair
 DR. JAMY ARD, MD, Member
 DR. REGAN BAILEY, PhD, MPH, RD, Member
 DR. LYDIA BAZZANO, MD, PhD, Member
 DR. CAROL BOUSHEY, PhD, MPH, RDN, Member
 DR. SHARON DONOVAN, PhD, RD, Member
 DR. HEATHER LEIDY, PhD, Member
 DR. RICHARD MATTES, PhD, MPH, RD, Member
 DR. TIMOTHY NAIMI, MD, MPH, Member
 DR. RACHEL NOVOTNY, PhD, RDN, LD, Member
 DR. JOAN SABATE, MD, DrPH, Member
 DR. LINDA SNETSELAAR, PhD, RD, Member
 DR. ELSIE TAVERAS, MD, MPH, Member
 DR. LINDA VAN HORN, PhD, RDN, LD, Member

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1 P-R-O-C-E-E-D-I-N-G-S

2 (9:01 a.m.)

3 DR. STOODY: Good morning. I'm Eve
4 Stody. I'm lead nutritionist of Nutrition
5 Guidance at USDA Center for Nutrition Policy and
6 Promotion and Designated Federal Officer to the
7 2020 Dietary Guidelines Advisory Committee.

8 I want to welcome everyone to the
9 second meeting of the Advisory Committee. We
10 have over 1,000 people who have registered for
11 this meeting with around 300 registered to attend
12 in-person and over 700 online. Thank you for
13 your interest in the dietary guidelines.

14 The meeting will be today from 9:00 to
15 4:30 and tomorrow from 8:30 to 12:30 and Dr.
16 Schneeman will do an overview of the agenda in
17 just a moment.

18 Now a few housekeeping items. For
19 those of you here in-person, you will notice that
20 each of us has a badge and you will need this
21 badge or a USDA badge in order to access the
22 halls of the building. So please keep your badge

1 visible at all times, and it designates to
2 Security that you are part of this group.
3 You'll also notice that some of the badges say
4 staff. And if you have any questions, please see
5 a member of the staff. If you'd like any
6 refreshments or lunch, the USDA cafeteria is --
7 We're in Wing 5, take a right and it's at Wing 3.

8 This is a meeting of the committee and
9 all meetings of the full committee are open to
10 the public. Fifteen of our 20 members are here
11 with us today. I do want to welcome in-person,
12 Drs. Donovan and Naimi who were not able to join
13 us for the first public meeting. Drs. Davis,
14 Dewey, Heymsfield, Mayer-Davis, and Stang were
15 not able to join us today, but we do have a
16 quorum of members for today's deliberations.
17 Throughout your deliberations, we ask the members
18 to state your name prior to speaking so that
19 everyone can follow the conversation.

20 As a quick reminder, the 2020 Dietary
21 Guidelines Advisory Committee has been
22 established to conduct an independent review of

1 current research on nutrition and health to be
2 considered by the Departments of Agriculture and
3 Health and Human Services in the development of
4 the next addition of the Dietary Guidelines.
5 Specifically, the charge of the committee as
6 outlined in its charter is to examine the
7 evidence on specific topics and questions
8 identified by the Departments. And these topics
9 and questions will be discussed throughout
10 today's presentations.

11 The topics and questions were
12 identified by USDA and HHS following a process of
13 federal and public input and prioritized based on
14 four criteria; relevance and importance to
15 developing public health guidance, potential
16 federal impact and avoiding duplication.
17 Following its review, the Committee will develop
18 a report that outlines its science-based review
19 and recommendations to the Departments. And then
20 they will submit its report to the Secretaries of
21 Agriculture and Health and Human Services for
22 consideration as the Departments develop the next

1 addition of the Dietary Guidelines.

2 The Committee has the very important
3 role of describing the state of current nutrition
4 science. Each addition of the Dietary Guidelines
5 that USDA and HHS develop, in our partnership,
6 builds upon the previous addition with scientific
7 justification for changes informed by the
8 Committee's scientific report, along with input
9 from the public and federal agencies.

10 To give you a sense for where we are
11 in the process, this is the second of five
12 meetings of the Advisory Committee. The last
13 Committee meeting will be in March of next year.
14 And the Departments request the Committee's
15 report by May of 2020. And this is so that USDA
16 and HHS can meet our mandate to release the next
17 addition of the Dietary Guidelines within five
18 years, which means we need to release it by
19 December of 2020.

20 As you can see on this slide, there
21 are multiple opportunities for public input in
22 this process, including comments on the topics

1 and questions the committee is addressing. A
2 public call for nominations for committee
3 membership, public comments throughout the
4 committee's deliberations, which is ongoing now.
5 And in spring of 2020, a call for comments on the
6 Committee's final scientific report once they
7 submit it to the Secretaries of USDA and HHS.

8 If you haven't done so already, please
9 save the dates for the remaining public meetings.
10 During this meeting -- actually tomorrow and
11 during Meeting 4, there will be opportunity for
12 oral comments to the Committee from the public.
13 Meeting 4 will be held outside of Washington D.C.
14 in Houston, Texas. And registration for each
15 meeting will be announced about one month prior
16 to the meeting date at DietaryGuidelines.gov and
17 through our Listserv. So please do sign up for
18 our Listserv updates at DietaryGuidelines.gov if
19 you haven't already done so.

20 More information on the Committee,
21 including the protocols they will be discussing
22 today can be found at DietaryGuidelines.gov under

1 Work Under Way. And we encourage you to follow
2 along.

3 So with that, I'm now going to turn
4 the meeting over to the Committee, which is
5 chaired by Dr. Barbara Schneeman. Dr. Schneeman.

6 CHAIR SCHNEEMAN: Great. Thank you,
7 Eve. So my understanding is they will adjust the
8 microphones to make sure it's heard. So let me
9 know if there's a problem.

10 So first of all, let me add my welcome
11 to that from USDA and HHS to the committee
12 members. It's great to see you all in-person
13 again. And also to the public who are either
14 here at USDA in the auditorium or watching
15 online.

16 My remarks -- this brief opening is
17 intended to review the agenda for today and
18 tomorrow so that we can focus -- I can focus then
19 on what we hope to achieve in this second public
20 meeting. And part of our goal then is to share
21 within the Committee, the tremendous amount of
22 work that has been done by the subcommittee since

1 our first meeting. Most of today's meeting will
2 be reports of the work done by the subcommittees
3 and then discussion by the full Committee.

4 So in the next several slides, I'll
5 provide you an orientation to the subcommittee
6 presentations, defining key terms and elements of
7 the protocols, and describing the standard NESR
8 criteria that apply across the various protocols.

9 So since Meeting 1, the subcommittees
10 have met by teleconference frequently. I think
11 you were all promised a significant amount of
12 work at the first meeting and I think we've
13 followed through on that and it won't change.

14 And so each Committee then has
15 discussed the specific questions that it will
16 address. They've received some additional
17 training on the approaches to examine the
18 evidence. And they've identified the order in
19 which they will develop their protocols for the
20 specific topics. And then they've actually
21 drafted protocols for some or all of its
22 questions. And those are the ones that will be

1 brought to the full committee for discussion
2 today.

3 So these are the subcommittee topic
4 areas. And I realize you probably can't read
5 that very well. But just to remind you, the
6 topic areas for the subcommittees are: dietary
7 patterns, pregnancy and lactation, birth to 24
8 months, beverages and added sugars, dietary fats
9 and seafood, and frequency of eating. And then
10 there's one cross-cutting working group on the
11 data analysis and food pattern modeling. And
12 that cuts across all of them.

13 So this gives you the subcommittee
14 members, but you'll get more details on that with
15 each subcommittee presentation. And also there
16 will be information on the USDA and HHS staff
17 that has supported the work of the Committee and
18 really helped the subcommittees make a tremendous
19 amount of progress since our first meeting.

20 So just as another reminder of the way
21 that the committee -- the Advisory Committee is
22 structuring its work. It's using one of three

1 approaches to examine the evidence; data
2 analysis, food pattern modeling, and the NESR
3 systematic reviews. And those reviews are either
4 original reviews conducted by the Committee or
5 using and/or updating existing NESR systematic
6 reviews. And again, for everything, there's
7 always additional information at
8 DietaryGuidelines.gov.

9 So for each approach that's used,
10 there's a protocol that details how the
11 methodology is being applied to a specific
12 question. So the protocols then are a plan for
13 how one of the scientific approaches will be used
14 and there's a protocol for each question. And
15 those protocols are created before the Committee
16 looks at the evidence. Again, to be objective in
17 how we approach each of the scientific questions.
18 Those protocols are posted online for the public
19 to view and better understand the approach that
20 the Committee is using. At this point, for this
21 meeting, we have 40 protocols that have been
22 drafted by the subcommittees for discussion

1 across the full committee today.

2 So to look at the components then of
3 the protocols, this just reminds you of the
4 various pieces of the protocol. There's an
5 analytic framework, inclusion/exclusion criteria,
6 the search strategy, and then the flow chart for
7 the literature search and screening. The
8 included articles/excluded articles with their
9 rationale.

10 So in our discussion of the
11 subcommittees today, we're really going to be
12 looking at the analytical framework and the
13 inclusion and exclusion criteria. With the goal
14 that we're trying to finalize these protocols so
15 that they can be implemented. And as they are
16 implemented, the protocols on-line will be
17 updated with the additional information.

18 So just then to look at those
19 components, the analytical framework defines the
20 core elements of the diet and health relationship
21 that's being examined. And it then serves as the
22 foundation for the rest of the systematic review

1 process. It informs the inclusion/exclusion
2 criteria and the literature search. It directs
3 the data extraction and risk of bias assessment.
4 And guides the strategy for synthesizing the
5 evidence that the Committee will do in grading
6 the conclusion.

7 So this next slide gives a template
8 that the committee members should be quite
9 familiar with by now. And you will see many more
10 of them today. And just you'll see this template
11 over and over again. And it gives the key
12 components of the analytical framework. The
13 intervention or exposure and the comparator
14 that's being used. And the population of
15 interest for the specific question that's being
16 examined. And it then has either and/or
17 intermediate outcomes or health outcomes,
18 depending on the nature of the question. And it
19 also then includes key factors that could impact
20 the relationship; co-founders and other
21 covariates or other moderators.

22 These analytical frameworks will also

1 include any key terms that need to be defined for
2 the specific question. And the subcommittees
3 have really worked to try to make sure we have
4 some consistent terminology where appropriate.
5 But then of course each analytical framework has
6 been tailored. And so I'm trying to cover the
7 general pieces so that the subcommittees can then
8 focus on how they've tailored the analytical
9 framework for their work.

10 So looking then at the inclusion and
11 exclusion criteria, these again are established
12 up-front so that they can be objective,
13 consistent, and transparent in identifying the
14 articles that will be included in each review.
15 They're also looked at to make sure that they're
16 relevant for U.S. Federal policy, and standard
17 criteria for the inclusion and exclusion criteria
18 are applied wherever possible.

19 However, some criteria do need to be
20 tailored to the specific review. And this just
21 gives some examples. Diet-related intervention,
22 exposures of interest, health outcome, endpoints

1 and/or intermediate outcomes, the dates of
2 publication, size of the study groups, study
3 duration, age of the study participants. Those
4 are examples of things that might need to be
5 tailored to a specific protocol.

6 So then this slide is a reminder that
7 these are generally items that can be
8 standardized across the protocol. So in terms of
9 the study design, the kinds of studies that have
10 been included in the -- will be included in the
11 systematic reviews and the types of studies that
12 will be excluded from the systematic reviews.

13 The focus is on peer-reviewed
14 publications, publications that are published in
15 English. And in terms of countries, we're
16 looking at very high or high human development.
17 So it's comparable to the U.S. population. And
18 obviously we're focused on studies that have been
19 conducted in humans. So the types of things that
20 dictate what studies get included.

21 Now where there might be more
22 tailoring within a particular protocol, looks at

1 the health status of study participants. And
2 part of this is guided by the overall purpose of
3 the Dietary Guidelines, which is to provide
4 recommendations about reducing risk for chronic
5 disease and promoting health in the general
6 population. And we recognize that sometimes that
7 means including individuals who are at risk, but
8 these are not about management of disease or
9 treatment of disease.

10 So included are participants who are
11 healthy, but it may include some subjects who are
12 at risk or might have been diagnosed with a
13 particular outcome. But it would exclude any
14 studies where the exclusive focus of the study
15 was treatment or management of individuals who've
16 already been diagnosed or who have already been
17 designated as having the outcome of interest.
18 And we'll see that applied as appropriate across
19 the various protocols.

20 Likewise with infants, the focus is on
21 full-term. But it can include some infants who
22 are low birth weight, small for gestational age.

1 But it would exclude studies where that was the
2 exclusive focus of the particular study. And
3 again, we'll hear more detail on that as we go
4 into individual protocols.

5 So of the protocols that we're going
6 to talk about today, 35 out of the 40 will be
7 focused on the systematic review protocols. So
8 that's the bulk of what we'll be hearing. But we
9 have five questions that will use the data
10 analysis framework. And again, just like with
11 the systematic reviews, the data analysis also
12 develops a protocol for each of its questions.

13 And so the framework describes the
14 overall scope of the question, the plan details
15 the data, and the subsequent analyses that are
16 included, and the analytical results. And so
17 today, our focus will be on the framework and on
18 the plan for those five questions. And again, as
19 the protocols are implemented, they will be
20 updated on the website.

21 So in today's agenda then, we'll be
22 going through the subcommittee presentations.

1 And we've allocated 45 minutes for each of the
2 subcommittees with the idea that we'll have a
3 presentation from the subcommittee chair. But
4 then also have time for discussion amongst the
5 Committee to raise comments and ask questions.
6 And the order of the presentations will be the
7 Data Analysis and Food Pattern Modeling, the
8 Dietary Patterns Subcommittee, the Frequency of
9 Eating, Pregnancy and Lactation, Birth to 24
10 Months, Beverages and Added Sugars, Dietary Fats
11 and Seafood. And this is the order that we've
12 projected. We've given you a tentative agenda.
13 However, the specific times may vary and be
14 subject to change based on the nature of the work
15 and the discussion that we need to go through.

16 Oh and I should comment as well that
17 the Committee has the protocols in their
18 notebook, so you have the reference material in
19 front of you. But all of the protocols are
20 available online. So if anyone needs further
21 information, you can get that online.

22 So each subcommittee will review its

1 work. It's going to describe the order its
2 developing its protocols. Which questions it's
3 dealing with now. Which questions it's left for
4 future. It will review the protocols themselves
5 and how they've been tailored to address the
6 question and address the topic that's been given
7 to it. And outline its next steps. And we're
8 asking that you keep the remarks at a high level,
9 so that there is time for discussion within the
10 committee for the protocols. And again, you all
11 have them in your binders.

12 So just to remind you then for
13 tomorrow's agenda, the focus will be on comments
14 from the public to the Advisory Committee. At
15 this point, since March, we've received 7,000
16 comments. And the public may have comments
17 specific to the 40 protocols that we are
18 discussing today. And we would encourage you to
19 submit those comments by Wednesday, July 24th.
20 Because part of the goal is to be able to start
21 implementing these protocols, so that the
22 committee can complete its work in the time frame

1 allocated.

2 But as a general observation, the
3 public comment period is open throughout the
4 Committee's work. So specific to the protocols,
5 it's helpful to get them sooner, rather than
6 later. But it's always open for comment.

7 So with that, let me just ask the
8 Committee, does anyone have a question or you
9 want to make another observation? Anything I
10 missed about where we need to go? Okay, they're
11 ready. Yes, so our first report then will be Dr.
12 Regan Bailey who is reporting for the cross-
13 cutting working group, the Data Analysis and Food
14 Pattern Modeling.

15 MEMBER BAILEY: Good morning,
16 everyone. So I'm here representing Working Group
17 7, which is comprised of the Jamie's; Dr. Jamy
18 Ard and Jamie Stang, Dr. Teresa Davis, Dr. Tim
19 Naimi, Dr. Schneeman, and supported by Dr.
20 Pannucci at the USDA.

21 Today we'll be describing the first
22 five questions that we will be tackling in order

1 of protocol development. And I'm not going to
2 read them here at this point because we'll have a
3 slide devoted to each question. The remaining
4 questions that we have to address include
5 beverages, added sugars, frequency of eating, and
6 how those relate to achieving nutrient and food
7 group intake recommendations.

8 We also have questions to answer
9 regarding food pattern modeling. So are changes
10 to the food patterns needed based on the
11 relationships identified in your committee work
12 and the systematic reviews? Can food patterns
13 for those under two years of age be established?
14 And finally, food pattern modeling questions
15 related to nutrient adequacy, the use of dietary
16 supplements and fortified foods, as well as added
17 sugars.

18 Before we begin, just a few key
19 definitions. We'll be using the phrase, stage of
20 life. And for data analysis and food pattern
21 modeling, this can mean different things. The
22 age groups for the definition of a stage of life

1 can differ based on the NHANES sampling weights
2 or by the dietary reference intakes. So the age
3 groups are not perfectly aligned in all cases.

4 The term, socioeconomic status is a
5 broad term that we use to include income in
6 dollars, poverty to income ratio, food security,
7 federal food assistance programs, and level of
8 education.

9 And finally, a RACC. This is the
10 reference amount customarily consumed in one
11 occasion as determined by the FDA. And this is
12 represented on the nutrition facts label.

13 So our analytic framework, our
14 population is the U.S. population. So we'll be
15 working with nationally representative survey
16 data. You'll see here in the blue boxes what
17 we'll be talking about today as the B24 protocols
18 and analytic frameworks are still under
19 discussion. Broadly, children and adolescents
20 are defined 2 to 19. Adults 20 to 64. Older
21 adults 65 and older. And pregnant and lactating
22 women.

1 I'll use the term demographic
2 subgroups quite a bit to represent that we will
3 have the data stratified by sex, by race,
4 ethnicity, socioeconomic status, and food
5 security status.

6 The data sources that we have
7 available are What We Eat in America survey
8 component of the NHANES. This data can be
9 analyzed to get nutrient data on foods and
10 beverages with the FNDDS. As Dr. Pannucci
11 described at our first meeting, we also have
12 what's called the FPED. This gives us data on
13 food groups and subgroups. As well as we have
14 the What We Eat in America food categories. So
15 these are foods as they are consumed, as well as
16 information on nutrient intakes from dietary
17 supplements, inclusive of antacids containing
18 calcium or magnesium.

19 So the first question is to describe
20 and evaluate current intakes of food groups and
21 nutrients. We'll be doing this looking at the
22 mean intakes of foods and subgroups, the usual

1 intake distributions, food category sources, food
2 group intakes compared to existing
3 recommendations and changes over time. And I'll
4 be a little bit more granular on the upcoming
5 slides.

6 In terms of looking at nutrient
7 intakes, we are first looking at nutrients from
8 foods and beverages alone. The most recent
9 iteration of the NHANES data, right now the
10 dietary supplement data is not available. And so
11 we're starting with foods and beverages alone to
12 assess mean and usual intake distributions. We
13 will compare those usual intake distributions to
14 the dietary reference intakes. And we'll talk
15 about that a little bit more in detail in
16 Question 3. Food category sources of these
17 nutrients. And then changes that occur over
18 time.

19 Very similar for food groups. We're
20 looking at population averages. This is from
21 NHANES 2015/16. And in general, when we look at
22 the average or the mean intakes, we'll be looking

1 at 2015/'16. When we're looking at the
2 population distribution, we have four years of
3 data from 2013 to 2016. So again, as I
4 mentioned, the percent meeting food group
5 recommendations and changes over time. And so
6 for food group intakes, you'll see that here with
7 the What We Eat in America food group categories.

8 Similarly for nutrient intakes, we'll
9 have the population average. We'll have the
10 usual intake distributions inclusive of foods and
11 beverages and total with dietary supplements.
12 Changes in intake of nutrients over time
13 comparing 2009/'10 to '15/'16. And then food
14 category sources of those nutrients.

15 The second question is to describe and
16 evaluate the prevalence of nutrition-related
17 chronic health conditions. Right now, these are
18 the nutrition-related chronic health conditions
19 under consideration. And I will not read these
20 as I again, will go through each of these in a
21 little bit more detail in upcoming slides.

22 The data sources that we have

1 available. Again, we have the NHANES data that
2 includes the dietary data, laboratory, physical
3 exam data. We also have the National Health
4 Interview Survey or NHIS. This is from 2017. We
5 have data from the National Vital Statistics
6 System in 2017. We have the PRAMS data, the
7 Pregnancy Risk Assessment Monitoring System. As
8 well as the SEER data, which is a wonderful
9 repository of information on cancer registry
10 statistics in the U.S. And this is from 2016.

11 In terms of the B to 24 group, we'll
12 be looking at the prevalence of low and high
13 weight for length, length for age, and weight for
14 age. This will come from the NHANES data. We'll
15 also be characterizing the prevalence of low
16 birth weight among U.S. infants by race,
17 ethnicity, and the age of the mothers using the
18 National Vital Statistics. We have data
19 available from NHIS on children birth to four
20 years of age on the prevalence of food allergy.

21 Looking at children 2 to 19, we're
22 interested in characterizing the prevalence of

1 underweight, overweight, obesity, and severe
2 obesity using the most recent NHANES data. As
3 well as differences in the obesity prevalence by
4 those demographic characteristics that I
5 mentioned earlier; those four components. And
6 the degree of urbanization. We'll also be
7 looking at changes in obesity and severe obesity
8 between 2007/'08 and 2015/'16.

9 For cardiovascular intermediate
10 outcomes among children, we have the prevalence
11 of hypertension, high LDL, and low HDL by the
12 demographic subgroups, as well as by BMI status
13 from 2013 to 2016. For children, we have data on
14 leukemia from SEER. And from NHANES, we have
15 data on pre-diabetes and type 2 diabetes from the
16 most recent survey cycles of NHANES.

17 For adults similar to children, we're
18 interested in characterizing the prevalence of
19 underweight, overweight, obesity, and severe
20 obesity from NHANES. As well as waist
21 circumference and waist circumference risk. And
22 then examining obesity by the demographic

1 characteristics and level of urbanization.

2 In adults, we have data from NHANES on
3 high triglycerides, high total cholesterol, low
4 LDL, high LDL, and the prevalence of
5 hypertension. So all of that data comes from the
6 physical exam in NHANES. From the National
7 Health Interview Survey, we also have the age-
8 adjusted prevalence of hypertension, coronary
9 heart disease, and prevalence of stroke.

10 For the Type 2 diabetes and pre-
11 diabetes, we will be able to have this
12 information from 2013 through 2016 for adults.
13 We'll also have the prevalence of metabolic
14 syndrome. So we have the prevalence of each of
15 the five individual risk factors for metabolic
16 syndrome. But we will also have the
17 characteristic of metabolic syndrome based on
18 those five risk factors.

19 We have data on chronic liver disease
20 outcomes from NHIS 2017. We have age-adjusted
21 chronic liver disease and cirrhosis from the
22 National Vital Statistics System. As well as

1 high ALT and AST from NHANES 2013 to 2016.

2 We've talked as a committee about how
3 to use the ALT and AST with regards to data on
4 alcohol consumption. So we're exploring options
5 about characterizing high liver enzymes relative
6 to alcohol intake. So that's a little bit more
7 that we'll have to discuss with what data are
8 available and sample sizes.

9 These ten cancers are available to the
10 committee through the SEER 2016 data. And we'll
11 have information that is age-adjusted and sex
12 specific, both incidence and mortality.

13 For pregnant women, we'll have the
14 prevalence of gestational diabetes from the Vital
15 Statistics System, as well as the PRAMS data. We
16 will have information on pregnancy-induced
17 hypertension.

18 For older adults, we have information
19 on low bone mass and osteoporosis. This is at
20 the femoral neck and lumbar spine. As well as
21 the prevalence of reduced muscle strength. And
22 you'll see that all of these years don't

1 perfectly overlap. That's because NHANES doesn't
2 collect the same information every year on every
3 topic. So there's exceptions noted in the years
4 throughout.

5 The third question is to describe and
6 evaluate the nutrients of public health concern.
7 There are no set definitions of what a nutrient
8 of public health concern is. In the National
9 Academy of Science's report and this working
10 group members agree that we should take what is
11 being called a three pronged approach.

12 So we'll look at the prevalence of
13 inadequate and excessive nutrient intakes
14 comparing current distributions to the dietary
15 reference intakes. When available, we'll
16 consider biological endpoints or validated
17 surrogate endpoints such as biochemical indices
18 of a nutrient status with validated cut-points,
19 in addition to the dietary intake of nutrients.
20 And finally, we would consider the scientific
21 evidence on the relationship between nutrient
22 inadequacy and excess on clinical health

1 consequences.

2 A few more definitions. The dietary
3 reference intakes as I'm sure you all know,
4 represent a set of reference values that are
5 established by the National Academies. We have
6 an acceptable -- I am so used to using the
7 acronym, so it's hard for me to actually say
8 these words. So it will be a little bit of an
9 alphabet soup. The AMDR, this is a recommended
10 percent energy intake for macronutrients. And so
11 we'll look below that and above that recommended
12 range, so AMDR.

13 The estimated average requirement or
14 EAR is what we use to estimate at the population
15 level, the risk of dietary inadequacy. When we
16 don't have scientific data that is compelling
17 enough to establish an EAR, we have what is
18 called an adequate intake or an AI. And this is
19 the level that is assumed to ensure nutritional
20 adequacy. So in the absence of nutrients with an
21 EAR, we have only an adequate intake. And then
22 we have the other end of the spectrum or the UL.

1 So this is the maximum daily amount that is
2 unlikely to cause adverse health consequences.

3 With the release of the new report on
4 sodium and potassium, we have another term to
5 include in the DRIs. This is called the Chronic
6 Disease Risk Reduction. This is the lowest level
7 of intake for which sufficient strength of
8 evidence exists to characterize a chronic disease
9 risk reduction. So right now, the CDRR is only
10 available for sodium. That's just the most
11 recently updated sodium and potassium nutrients.

12 And then finally the term, nutrients
13 of public health concern. As I mentioned, this
14 has been a phrase that is used throughout the
15 guidelines to represent a nutrient that is either
16 under-consumed or over-consumed relative to the
17 DRI and linked in the literature with adverse
18 health outcomes in a general population or in a
19 population subgroup.

20 Here is the framework. Very similar
21 to some of the previous questions. We'll have
22 nutrient intakes from total and from foods and

1 beverages alone. For nutrients with an EAR,
2 we'll use the cut-point method. There are some
3 assumptions to the cut-point method that the
4 distributions of requirements are symmetrical.
5 That assumption is violated for menstruating
6 women for the nutrient of iron. So the full
7 probability approach will be used for iron.

8 Again, comparing nutrients without an
9 EAR, we will look at those relative to the
10 adequate intake. We will examine prevalence of
11 the population that exceeds the UL or the CDRR,
12 as well as people who are the prevalence inside
13 or outside the AMDR. For added sugars and
14 saturated fat, we will use the 2015/2020
15 guidelines recommendations for less than 10
16 percent of total energy intake.

17 In terms of the data sources for the
18 other parameters, we have -- and I'll explain in
19 the next couple of slides -- laboratory data and
20 exam data from NHANES, the nutrient intakes as I
21 described from What We Eat in America, and
22 clinical health consequences that will be either

1 evidence from the systematic reviews that you are
2 all working on, as well as results from
3 nutrition-related chronic health conditions.

4 So the analytic plan for ages 1 and
5 older, again looking at the usual intake
6 distribution from foods and beverages and from
7 total inclusive of dietary supplements. In terms
8 of the biomarkers of nutrient status in children,
9 we would prefer to use the most recent survey
10 years. But you'll see here there are exceptions
11 noted, both in what years that the samples are
12 collected and in what survey waves.

13 So we have ferritin and transferrin.
14 We have low red blood cell folate, low serum
15 folate, low serum copper, low serum zinc, and low
16 25 hydroxy Vitamin D. You'll see the survey
17 years associated unless otherwise noted. For
18 children 6 to 19 years from 2003 through 2006, we
19 have Vitamin A and carotenoids, Vitamin C,
20 Vitamin E, B12, and B6.

21 Very similar in adults, we have data
22 on transferrin and ferritin. This is in women

1 who are to 20 to 49. We have low folate, both in
2 terms of serum and red blood cell. We have data
3 on unmetabolized folic acid in adults, copper,
4 zinc, Vitamin D. In addition to serum, B12, we
5 have elevated methylmalonic acid in 2013/'14.
6 And among pregnant women, we have the medium
7 urinary iodine concentration. Again, at the
8 bottom of this slide are the data on Vitamin A,
9 carotenoid CE, and B6.

10 So in terms of the next question which
11 is to describe and evaluate the current dietary
12 patterns on beverage consumption, this is really
13 going to be limited to data on the Healthy Eating
14 Index, both means and the component scores, as
15 well as food category contributions to total
16 intake. And this is a noted limitation. So we
17 don't have data on self-selected dietary
18 patterns. For example, are you a vegetarian? Do
19 you follow a specific dietary pattern? We really
20 have the Healthy Eating Index 2015 as how we will
21 evaluate dietary patterns based on the
22 availability of data.

1 In terms of beverage consumption,
2 we'll look at the types of beverages being
3 consumed, the percent consuming on a given day,
4 the volume variations in beverage consumption.
5 And then how those beverage types contribute to
6 energy, macronutrients, micronutrients, as well
7 as added sugar.

8 So a beverage pattern here can be
9 defined as the quantities, proportions,
10 varieties, and combinations of different
11 beverages in the diet. The definitions that are
12 being used are discrete beverage categories. So
13 that has been described to us as doing something
14 on purpose. Right? So these definitions are in
15 your binder. They're on the website. So I'm not
16 going to read those. But they include milk, 100
17 percent fruit juice, coffee, tea, diet beverages.

18 So diet beverages, this is where that
19 RACC definition comes into play. So a diet
20 beverages contains 40 calories or less per RACC.
21 So sweetened beverages on the other hand contain
22 more than 40 calories per RACC. And include

1 things like soft drinks, fruit drinks, and sports
2 and energy drinks. Water in any type; tap,
3 bottled, carbonated, enhanced, as long as it has
4 less than 5 kcal per RACC, it is considered by
5 definition to be water. And then alcoholic
6 beverages inclusive of beer, wine, liquor, et
7 cetera.

8 In terms of dietary patterns, as I
9 mentioned, we'll have the average HEI scores.
10 We'll have the distribution of HEI scores. We'll
11 be able to look at the population average change
12 in scores between 2003 and '04 and 2015/'16 and
13 the food category sources that contribute to
14 total energy intakes.

15 For beverages for two and older, we
16 have the percent who consumed. We have data on
17 sweetened beverage consumption, mean daily
18 beverage intake, and the percent mean energy of
19 selected nutrients. So the Federal Data Analysis
20 team has prepared data already, specifically on
21 carbohydrates, added sugars, protein, Vitamin C
22 and D, calcium, potassium, magnesium, phosphorus,

1 and caffeine. And once we identify the nutrients
2 of public health concern, we will also add those
3 to this list.

4 And then finally, the percent of daily beverage
5 calories consumed by those discrete types.

6 And I think this is our last question.
7 The question is how does dietary intake,
8 particularly dietary patterns track across life
9 changes from the introduction of foods, into
10 childhood through older adulthood. And it should
11 be noted that because we have the NHANES data to
12 address this question, it's not longitudinal. So
13 we don't have information on the same people and
14 how they're individual patterns change over time.
15 We can just look at life stages in certain years.
16 So that's a little bit of a limitation to
17 specifically address this question. The
18 introduction of foods is defined here. Any foods
19 that are complementary foods and beverages other
20 than human milk or infant formula.

21 On this slide, we have the analytical
22 framework. So we'll look at differences in food

1 category sources of nutrients across the
2 different life stages. Differences in mean food
3 group intake. So for two and older, the percent
4 of each age group who meets the existing food
5 recommendations. And then differences in
6 beverage categories and how they contribute to
7 energy and nutrient intakes across different life
8 stages.

9 Differences in food category
10 contributions to energy intake across different
11 life stages. So for infants and toddlers
12 receiving human milk, energy intake will be
13 limited to those complementary foods, not
14 inclusive of human milk or infant formula. And
15 for two and older, food category contributions to
16 energy intake will also be assessed. We'll also
17 be able to compare differences in HEI 2015 for
18 those two and older. So you'll recall that
19 before this committee's work, there were no
20 dietary guidelines for B to 24. So we don't have
21 a Healthy Eating Index to compare them to at
22 present.

1 Here's the analytic plan. Very
2 similar to the things that I mentioned before.
3 We have the food category sources. We have
4 population average intakes of food groups and
5 food subgroups. The percent of the population
6 that are meeting these recommendations, as well
7 as daily energy and nutrient intakes from
8 beverages across different life stages with the
9 same nutrients listed here as on the previous
10 slide. We also have the food category sources to
11 energy across different life stages. As well as
12 population average and component scores across
13 life stages.

14 So our next steps after we discuss
15 these five protocols will be to really have some
16 cross-cutting discussion with the B24 subgroup so
17 that we are all aligned on how the data and food
18 pattern modeling can best support the work of
19 your committee. We'll have cross-cutting
20 discussions with Beverages and Added Sugars on
21 the protocols specifically related to those
22 topics. We'll draft protocols for the frequency

1 of eating of course in conjunction with that
2 subgroup. And the plan is to have the
3 information on nutrient intakes from dietary
4 supplements this fall so that we can compare how
5 foods and beverages relate to total intakes. And
6 so how much is being contributed by dietary
7 supplements to answer some of those questions.
8 So our plan right now is to review the data
9 analysis results and then draft conclusion
10 statements.

11 So here are the members again of the
12 committee, as well as the support staff. And a
13 special thanks to the federal family that are the
14 Data Analysis Team who has already prepared a lot
15 of data for us. And will continue to develop the
16 data as we are requesting them. So thank you
17 very much.

18 Questions? I know that was a lot.
19 That was a lot for me and I'm a talker.

20 VICE CHAIR KLEINMAN: So Regan, one of
21 the questions that you brought up are the age
22 groupings because those are certainly going to

1 affect a lot of what the other committees are
2 talking about on many of the outcomes very, very,
3 very dramatically between different age
4 categories. And some of them require a much
5 finer categorization of age then let's say
6 NHANES. DRI is much more specific than NHANES.
7 So can you just elaborate a little bit more for
8 other members of the committee on how you're
9 thinking about that?

10 MEMBER BAILEY: So some of the
11 analysis has already been conducted. So we have
12 some that does have larger age groups; sometimes
13 two to 18 for example. We have the ability to
14 request data on smaller subgroups. And there are
15 a lot of federal reports that already exist with
16 smaller subgroups. So I think we'll try to
17 cobble together some of what we have and what we
18 need, to get at what you're talking about. But I
19 think especially in terms of a B to 24 subgroup,
20 the changes that occur in eating are so dynamic
21 at that time that we'll have to probably have
22 smaller age groupings than maybe even the DRI.

1 VICE CHAIR KLEINMAN: But even
2 thinking about age 20 to age 60 -- so 65 and
3 older, okay?

4 MEMBER BAILEY: Yes.

5 VICE CHAIR KLEINMAN: But there's a
6 lot of difference there too.

7 MEMBER BAILEY: Yes.

8 VICE CHAIR KLEINMAN: I mean I think
9 we're just going to end up with a hell of a lot
10 of data and a lot of analyses -- specific
11 analyses. But I guess there's no other way to
12 think about it.

13 MEMBER BAILEY: Yes, I think so. And
14 I think that's something that we can put in our
15 recommendations that the federal government try
16 to align in terms of life stages. But in terms
17 of the work of the committee, I think we kind of
18 have our hands tied as to what's available and
19 what we can request. Even the term older adult,
20 is it 60? Is it 65? Is it 71+? A very hard
21 question to grapple with.

22 We won't comment on our specific ages,

1 but yes I --

2 VICE CHAIR KLEINMAN: It's like my
3 definition of a -- I'm a pediatrician. My
4 definition of a pediatric patient is anybody
5 who's younger or shorter than I am.

6 MEMBER BAILEY: Yes. Well even
7 including 18 year olds and 19 year olds and using
8 the term children is something that I think we
9 all agree, a 2-year-old is very different than a
10 19-year-old. Although they both have a lot of
11 emotional needs and issues. In terms of their
12 nutrition, yes, very different.

13 CHAIR SCHNEEMAN: And just be sure and
14 say your name for the transcript.

15 MEMBER TAVERAS: Elsie Taveras. I have
16 two questions. One, in the analytic plan for
17 adults 20 years and older, there's an examination
18 of chronic liver disease outcomes. Particularly
19 I was thinking of prevalence of high ALT and AST.
20 So is that not available for populations under
21 20? I'm wondering why that's not an outcome in
22 the pediatric --

1 MEMBER BAILEY: Yes, I don't think we
2 considered it. It's certainly something that we
3 can look into. And that's why we have these
4 discussions. Because we were thinking about
5 fatty liver in terms of adults. But I think
6 that's a very salient point that if the data are
7 available in children, we should examine those as
8 well.

9 MEMBER TAVERAS: Yes. No, having seen
10 even 8 year olds with very high ALT and AST, I
11 would recommend that we try if the data's
12 available --

13 (Simultaneous speaking.)

14 MEMBER BAILEY: Yes, if it's
15 available, we'll certainly add that.

16 MEMBER TAVERAS: -- to populations
17 under 20. And then the other question I had was
18 about the data sources. So do we not have any
19 data available from PedNSS or WIC, the
20 supplemental nutrition program for Women,
21 Infants, and Children? Because there's
22 surveillance data that they have on prevalence of

1 overweight and obesity among women -- among
2 pregnant lactating women and infants under five,
3 I think.

4 MEMBER BAILEY: Okay, we can look into
5 that for sure. We've kind of thought mainly
6 right now about the data that we've described to
7 you. But there are other federal resources that
8 can be utilized.

9 MEMBER TAVERAS: And my last question,
10 sweetened beverages, are we including flavored
11 milk in that definition? I see soft drinks,
12 fruit drinks and sport drinks. But I just want
13 to make sure that --

14 MEMBER BAILEY: I'm going to punt that
15 one to Dr. Pannucci. But I think that the way
16 that the discrete beverage categories are
17 currently consumed is that it's milk as the base.
18 And that is not part of the sweetened beverage
19 category. But I would --

20 CHAIR SCHNEEMAN: I'm just looking at
21 the slide on Page 19.

22 MEMBER BAILEY: Yes, I don't have the

1 slide in front of me.

2 CHAIR SCHNEEMAN: And milk says plain
3 and flavored milk, other milk dairy drinks, and
4 milk substitutes.

5 Yes please, Rachel.

6 MEMBER NOVOTNY: Rachel Novotny. I am
7 interested -- and this is perhaps a B24 question.
8 I know you said you're going to work with them.
9 But on the analytic plan for one and above, the
10 usual intake distributions that exclude infants
11 receiving human milk -- I guess I'm --

12 MEMBER BAILEY: It's not excluding the
13 infants. It's excluding the data -- the
14 contributions from the infant formula or from
15 human milk. So it's not excluding the children.
16 It's just excluding those as a source of
17 nutrients.

18 MEMBER NOVOTNY: Yes, I guess -- but
19 that effectively excludes them. Correct? But
20 infants who would be receiving human milk-- I
21 guess what I'm getting at is I realize it's
22 difficult to estimate the volume in the milk.

1 You'd have to make an estimate. But I think the
2 converse is that we end up with an assumption
3 that the diet pattern of one and above excludes
4 human milk.

5 MEMBER BAILEY: Yes and I think that's
6 something that we'll have to discuss as we
7 develop the B24 protocol. This is just kind of a
8 first pass at what we're thinking. I know that
9 the databases that are available to analyze human
10 breast milk is an active area of investigation.
11 And you know, that the nutrient composition in
12 terms of fat and nutrients changes quite
13 dramatically. And so I think it's hard to
14 capture that with real accuracy. But I think
15 that's something that the B24 group -- that we'll
16 need to come together with the Data Analysis
17 working group to decide how to handle that
18 specifically.

19 MEMBER NOVOTNY: I would hope maybe we
20 could find a -- I think an estimate would be
21 better than assuming that.

22 MALE PARTICIPANT: You'll have to talk

1 up.

2 MEMBER NOVOTNY: Sorry, I'm thinking
3 that an estimate might be a better norm to set.

4 AUDIENCE MEMBER 1: Louder! We can't
5 hear in the back at all.

6 AUDIENCE MEMBER 2: We can't hear in
7 the middle either.

8 MEMBER NOVOTNY: Okay.

9 AUDIENCE MEMBER 3: You guys are
10 whispering to yourselves. This is supposed to be
11 a public meeting.

12 MEMBER NOVOTNY: Okay, sorry. Okay.
13 So my suggestion is that we see if we can find an
14 estimate so that we can include a pattern of
15 infants who are breast fed in 1+ age group. And
16 it not reflect only those who are not breast-fed.

17 MEMBER BAILEY: And I just said that
18 is an active discussion that the working group on
19 Data Analysis and Food Pattern Modeling would
20 have with the B24 Committee to figure out how we
21 can best estimate nutrient intakes in this
22 rapidly growing population changing, not growing.

1 Well they are growing too.

2 We apologize for the microphones. We
3 can hear each other up here, but we didn't
4 realize that we couldn't hear you. So it wasn't
5 intentional by any means.

6 CHAIR SCHNEEMAN: Okay, so we have
7 Rick Mattes and Sharon. Were you going to say
8 something also? Rick and then Sharon.

9 MEMBER MATTES: I'm Rick Mattes. So
10 I'm struck by the overlap or common goals for
11 what you're describing in both the Frequency of
12 Eating and the Beverages and Added Sugars
13 committees. And please take this -- it's
14 intended to be very constructive, rather than --

15 So if we in the end -- your modeling
16 is going to be based on the large surveys, the
17 epidemiology and so on. The subcommittees -- the
18 other two subcommittees will be looking at
19 randomized control trials and so on. It won't
20 surprise me that in the end there is some
21 disparity between those -- the outcomes from the
22 two sources of data. How are we going to deal

1 with that? Are we going to say -- we came up
2 with different answers based on the data set? Or
3 do we say there is a hierarchy of science here
4 and the stronger science -- this is what we're
5 going to base our recommendations on? If the
6 latter, maybe there's so much redundancy here, we
7 should be thinking about do we really need to do
8 the bazillion analyses you've got proposed there.

9 MEMBER BAILEY: I think what you will
10 identify in your systematic reviews will be
11 complementary to what we're doing. We will
12 identify for example added sugars. You might
13 come to a consensus statement on a recommendation
14 on added sugars. And then we would provide data
15 on the prevalence of intake of sugar-sweetened
16 beverages for example. We wouldn't say that,
17 that necessarily is -- you know, trumps what you
18 found. The data are what the data are. And
19 that's this working group kind of just telling
20 you, these are the facts. Not ma'am, but mister.

21 And so I don't think that it's a lot
22 of overlap. You're identifying relationships

1 with health outcomes. And we are providing
2 information on where Americans are at relative to
3 those recommendations. So I think it's kind of
4 more of a dovetail than overlap. But I'd love to
5 hear other people's opinions.

6 MEMBER BOUSHEY: This is Carol
7 Boushey. It's real short. I wanted to reinforce
8 that. Because this really does help inform or
9 find out what might work well when we're looking
10 at these randomized trials. But you'll give us
11 the gauge as to where we can start from; either
12 up or down.

13 MEMBER DONOVAN: Sharon Donovan. So
14 I guess I just want to reiterate what Rachel and
15 Elsie have said in terms of the B24 being a new
16 charter. That if we don't consider, you know,
17 human milk and infant formula and also the B24
18 Committee is talking about some of these follow-
19 on formulas that are actually fed to toddlers.
20 And we anticipate, particularly like iron and
21 other nutrient intakes will be quite different
22 compared to one year olds who move to cow's milk.

1 So you know, whether it's trying to
2 get access to other data sets -- Because
3 otherwise, we're not going to be able to make any
4 sort of recommendations if we're just considering
5 non --. And you know, not many women -- not a
6 high percentage of women breast feed for longer
7 than a year, but it is recommended. So our
8 committees can work on that. But I think that we
9 really need to do the due diligence about
10 collecting that data and discussing -- because
11 with DRIs, we use average intakes and average
12 consumption to at least extrapolate requirements.

13 CHAIR SCHNEEMAN: One thing that I
14 would like to hear some discussion from the
15 committee members, you've presented a way of
16 looking at the nutrients of public health
17 concern. You had a diagram for that looking at
18 three components of nutrients of public health
19 concern. And I'm interested in whether other
20 committee members find that a useful approach for
21 going forward or had some questions or comments
22 about how we might define nutrients of public

1 health concern. It's on Page 13, if you're
2 looking at the slides.

3 MEMBER BAILEY: So just a reminder,
4 it's looking at those three prongs. One being
5 dietary intakes. Two being biochemical. And
6 three being clinical health consequences. Are
7 there any other ways that we can think about
8 collectively to identify what are nutrients of
9 public health concern?

10 CHAIR SCHNEEMAN: Dr. Ard, you look
11 like you were posed to say something.

12 MEMBER ARD: (No audible comment.)

13 CHAIR SCHNEEMAN: Well I take that to
14 indicate support for the approach that you've
15 proposed. So let me turn the question around.
16 Does anyone see a problem with taking that
17 approach?

18 MEMBER VAN HORN: Linda Van Horn. The
19 only thing I think, hearkening back to the
20 discussion of the last round of the guidelines
21 related to dietary cholesterol. There was a
22 statement related to dietary cholesterol and that

1 no longer being a nutrient of concern. And there
2 was a tremendous amount of confusion in the
3 public as to what that meant. Everything from
4 woohoo, let's eat eggs to maybe we should, you
5 know, re-think what the role of dietary
6 cholesterol is.

7 So my only point is that while I think
8 the definition and the criteria are good, if for
9 whatever reason this group should come up with
10 another decision of that sort, I think we have to
11 be very explicit as to what that means and why
12 that was decided upon. So that we can establish,
13 you know, quite universally what is meant by that
14 decision.

15 CHAIR SCHNEEMAN: It sounds like
16 you're making sure we recognize all three
17 components. That it's not just one or the other,
18 but all three components. Great, thank you.
19 That's helpful.

20 MEMBER BOUSHEY: Linda, your comment
21 made me realize, the reality is every nutrient is
22 a public health concern. So we really need to be

1 careful when we actually label them that way and
2 how we write this up. Because we don't want
3 anyone to think that there isn't any nutrient
4 that isn't important.

5 MEMBER MATTES: Rick Mattes. So it
6 specifically says nutrients of concern, but there
7 are food constituents that are commonly consumed
8 with health implications. Do we want to talk
9 about phytochemicals and so on?

10 MEMBER BAILEY: I think the reason
11 that it is labeled a nutrient is because one of
12 the -- we need to have a DRI for it in order to
13 compare it to a reference standard. And we need
14 to have a validated biomarker. And so for a lot
15 of the phytonutrients and things like that, while
16 we recognize they exhibit a health effect. We
17 don't necessarily have that type of data that are
18 available to make the statement is my thinking
19 there.

20 CHAIR SCHNEEMAN: Yes, please.

21 MEMBER BAZZANO: Lydia Bazzano. I
22 just wanted to point out that the clinical health

1 consequences there are really the most -- I would
2 say, you know, those are the things that we have
3 to weigh most heavily. Because where we may not
4 have data -- where we do have data, that's what
5 needs to weigh the most heavily. And I
6 understand that there may not be data for
7 everything.

8 CHAIR SCHNEEMAN: I'm being reminded
9 to encourage everyone to be sure you speak up so
10 it's amplified well. Other questions or comments
11 about the presentation on the data analysis?

12 MEMBER NOVOTNY: Rachel Novotny. I
13 will speak as loudly as I can. Just raising the
14 question about the nutrients of public health
15 concern makes me wonder whether as we go forward
16 or not for now because I think we have our
17 agenda, but whether we actually do want to think
18 about foods or food groups or food patterning of
19 public health concern in the future.

20 MEMBER SABATE: Joan Sabate. That's
21 also my concern. I think going back to these
22 nutrients of intake, biological endpoints, or

1 clinical health outcomes, if we do not have
2 guidelines as far as some of the food
3 constituencies, such as phytochemicals and so on
4 and so forth, that means that what you're giving
5 priority to some food constituencies called
6 nutrients versus others that are not. Because
7 ultimately all of them come from foods.

8 So when we make in the hierarchy of
9 making decisions, are we going to just based on
10 the nutrients for which we have guidelines and
11 not for the ones that we don't even though they
12 have influence on health?

13 And finally, I mean this committee is
14 trying to define nutrients of intake or is trying
15 to guide the general public as far as what foods
16 to consume -- I mean what different proportions.

17 MEMBER NOVOTNY: Rachel Novotny. Just
18 to elaborate that again, I think also as we
19 communicate with the public about these things,
20 my feeling is that talking in nutrients has
21 contributed to turning to supplements rather than
22 foods. So again, just to reiterate, I think as

1 we look for language for these things, I think as
2 a food-based group, the more we can talk in
3 foods, the better.

4 CHAIR SCHNEEMAN: So Regan, I know you
5 pointed to the fact that when it comes to looking
6 at data for dietary patterns, knowing what kind
7 of pattern are you following, we're limited in
8 terms of the type of data there. And it might
9 help to amplify how this relates to the
10 discussion that we're currently having.

11 MEMBER BAILEY: Yes, so right now what
12 we're limited to is the healthy -- Sorry, Regan
13 Bailey. So to address that, we have data on the
14 Healthy Eating Index only. And the data that Dr.
15 Pannucci presented at the first meeting indicates
16 that most Americans or a high proportion of
17 Americans aren't doing that. We don't have data
18 on what they are doing. And that is something
19 that I think really needs to be addressed for --
20 I don't think can be addressed for this
21 committee, but certainly for future committees.
22 We have to know the current dietary patterns that

1 are being consumed, in addition to how they
2 relate to the Healthy Eating Index.

3 So I think -- I really hear what
4 you're saying and I appreciate it. But at this
5 current point, we're a little bit limited with
6 the data that we do have available to us
7 unfortunately. Don't shoot the messenger.

8 VICE CHAIR KLEINMAN: The messenger is
9 doing great.

10 CHAIR SCHNEEMAN: That may be the
11 perfect introduction to our next subcommittee
12 report. So thank you very much, Regan. I think
13 that was very helpful. And I appreciate the
14 comments from the committee. It's been a
15 tremendous amount of work.

16 So our next subcommittee is to focus
17 on dietary patterns. And Carol Boushey, the
18 chair of that subcommittee will give the report.
19 Carol?

20 MEMBER BOUSHEY: Thank you. So I was
21 introduced as Carol Boushey. I can confirm that
22 I am. And I represent the Dietary Patterns

1 Subcommittee. And good, there are the slides.
2 And you can see the other members of the
3 subcommittee up on the slides also. Okay, am I
4 hitting the wrong button? I was holding it
5 upside down. It does not work that way. So for
6 the next people, remember that.

7 The topic areas that the subcommittee
8 was tasked with are listed on this slide. The
9 first six have asterisks indicating that those
10 will be presented today.

11 As noted, we're the Dietary Patterns
12 Subcommittee. So the key definition that we are
13 using for dietary patterns in all the 2020
14 Advisory Committee reviews are the quantities,
15 proportions, variety, or combination of different
16 foods, drinks, and nutrients where available and
17 diets and the frequency with which they are
18 habitually consumed.

19 This definition was applied to all
20 analytical frameworks for the subcommittee, which
21 will be presented shortly and for the ones that
22 are not yet done. And this is an aspirational

1 definition that was developed by a panel of
2 international experts for the existing NESR
3 systematic reviews. And all information provided
4 by studies about the dietary patterns tested or
5 examined, including both foods and beverages,
6 macro and micro-nutrients will be extracted from
7 included articles.

8 So the two questions listed on this
9 slide, what is the relationship between dietary
10 patterns consumed in all-cause mortality? And
11 what is the relationship between dietary patterns
12 consumed and sarcopenia will be answered by
13 conducting original NESR systematic reviews. So
14 these have never been done before.

15 The four questions listed on this
16 slide with outcomes of neurocognitive health;
17 growth size, body composition, and risk of
18 overweight and obesity; cardiovascular disease;
19 and Type 2 diabetes will be answered by updating
20 existing NESR systematic reviews.

21 The analytical framework that was
22 brought up earlier is shown on this slide. And

1 illustrates the systematic review question
2 examining the relationship between dietary
3 patterns and all-cause mortality. Do you think
4 we ran out of batteries already?

5 DR. STOODY: So it looks like the
6 computer is shutting down, which is nice. So
7 we'll just pause for one second and have IT come
8 set it back up. So if you'll just hold, so we
9 don't continue the discussion without the visual.
10 So one second.

11 (Long pause.)

12 MEMBER BOUSHEY: Thank you so much.
13 We'll get rocking and rolling here again.

14 So I'm going to start at the beginning
15 of this slide. So you'll have heard this
16 sentence before. But just to make sure that
17 we're on the same page.

18 This is the analytical framework shown
19 on this slide. It illustrates the systematic
20 review question examining the relationship
21 between dietary patterns consumed and all-cause
22 mortality. The analytical framework provides a

1 foundation for the systematic review and helps to
2 inform the development of the inclusion and the
3 exclusion criteria.

4 The subcommittee defines all-cause
5 mortality as the total number of deaths from all
6 causes during a specific time-period. This is
7 the first analytical framework presented. The
8 others that you've seen today have been purely
9 demonstration frameworks. So for this
10 presentation, we will add animation to point out
11 all the parts and pieces of the analytical
12 framework.

13 The intervention or exposure of
14 interest is consumption and/or adherence to a
15 dietary pattern. The comparators are consumption
16 of and/or adherence to a different dietary
17 pattern and different levels of consumption
18 and/or adherence to a dietary pattern. The
19 outcome of interest in this particular case is
20 all-cause, total mortality.

21 The population of interest for this
22 particular case; intervention, exposure and

1 outcomes is -- the population of interest for
2 interventions and outcomes are children through
3 older adults, who are healthy and/or at risk for
4 chronic disease. For the question, the
5 subcommittee decided that infants and toddlers
6 from birth to 24 months were out of the scope.

7 Key confounders, which are factors
8 that may impact the relationship of interest in
9 this systematic review are shown on this slide.
10 And include sex, age, race, ethnicity,
11 socioeconomic status, physical activity,
12 anthropometry, energy intake, and smoking. From
13 this point forward, the analytical frameworks
14 will look like this and not have animation. But
15 they liked it so much, they did it twice.

16 Okay, the next framework should be
17 sarcopenia. It's coming. Yes, okay. The next
18 topical area is sarcopenia. This is the
19 systematic review framework examining dietary
20 patterns consumed and sarcopenia. The
21 subcommittee discussed and applied a definition
22 of sarcopenia based on the review of the

1 foundation for the National Institutes of Health
2 Biomarkers, Consortium Sarcopenia project. As
3 well as the consensus of three European working
4 groups that converge to operationally define
5 sarcopenia.

6 The definitions those groups presented
7 generally aligned on parameters of low skeletal
8 muscle or lean mass, low strength or weakness
9 and/or low muscle performance. That is mobility
10 impairment, walking, speed, or function.

11 Therefore, the definition for sarcopenia applied
12 to this systematic review is progressive and
13 generalized loss of skeletal muscle mass alone or
14 in conjunction with either or both low muscle
15 strength and low muscle performance.

16 In this particular case, we have
17 intermediate outcomes, which include low muscle
18 mass, strength, and performance. And sarcopenia
19 or severe sarcopenia as endpoint outcomes. The
20 population of interest for the intervention
21 exposure of dietary patterns includes
22 adolescents, adults, and older adults who are

1 healthy and/or at risk for chronic disease. For
2 this question, the subcommittee decided that
3 infants and toddlers from birth to 24 months were
4 out of scope.

5 The population of interest for the
6 outcomes of sarcopenia includes adults and older
7 adults who are healthy and/or at risk of chronic
8 disease. The confounders are sex, age,
9 socioeconomic status, anthropometry, total energy
10 intake, dietary protein intake, physical
11 activity, and physical disability.

12 The next analytical framework is
13 dietary patterns and neurocognitive health. The
14 analytical framework here illustrates the
15 question examining the relationship between
16 dietary patterns consumed and neurocognitive
17 health. The outcomes include developmental
18 domains as specified on the right, academic
19 performance, attention deficit hyperactivity
20 disorder, autism spectrum disorder, cognitive
21 decline, and cognitive impairment and dementia,
22 Alzheimer's disease, anxiety, and depression.

1 The population of interest includes children
2 through older adults who are healthy and/or who
3 are at risk for chronic disease.

4 For this question, the subcommittee
5 excluded infants and toddlers because the Birth
6 to 24 Month Subcommittee will be completing this
7 review. The key confounders; sex, age, race,
8 ethnicity, socioeconomic status, anthropometry,
9 total energy intake, alcohol intake, smoking,
10 physical activity, and family history of
11 neurocognitive disorders.

12 The next analytical framework focuses
13 on dietary patterns consumed and growth, size,
14 body composition, and risk of overweight and
15 obesity. The outcomes include weight and various
16 forms of weight, BMI, body composition and
17 distribution, percent fat mass, fat-free mass,
18 and incidents and prevalence of underweight,
19 failure to thrive, stunting, wasting, healthy
20 weight, overweight, and obesity.

21 The population of interest for the
22 intervention exposure and outcomes include

1 children through older adults who are healthy
2 and/or are at risk for chronic disease. For this
3 question, again, the committee excludes infants
4 and toddlers and the Birth to 24 Months
5 Subcommittee will be handling this. Key
6 confounders are sex, age, total energy intake,
7 physical activity, anthropometry at baseline, and
8 smoking.

9 Cardiovascular disease is shown on
10 this slide. The analytical framework here
11 illustrates the review of dietary patterns
12 consumed and cardiovascular disease. The
13 intermediate outcomes include total cholesterol,
14 low density lipoprotein, high density
15 lipoprotein, triglycerides, and blood pressure.
16 The endpoint outcomes include cardiovascular
17 disease and specifications listed, stroke, venous
18 thrombosis, cardiovascular disease-related
19 mortality. The population of interest here
20 includes children through older adults who are
21 healthy and/or are at risk for chronic disease.
22 The key confounders are sex, age, energy intake,

1 physical activity, anthropometry, and smoking.

2 The Type 2 diabetes, that's the last
3 analytical framework that we finished before this
4 meeting. And this illustrates the systematic
5 review for Type 2 diabetes and dietary patterns
6 consumed. The intermediate outcomes include
7 hemoglobin A1c, glucose, insulin, and pre-
8 diabetes. The endpoint outcome is Type 2
9 diabetes. The population of interest for the
10 intervention exposure and outcomes includes
11 children through older adults who are healthy
12 and/or are at risk for chronic disease.

13 Key confounders as shown is sex, age,
14 total energy intake, physical activity,
15 anthropometry, and smoking. The inclusion and
16 exclusion here, these criteria were outlined in
17 Dr. Schneeman's presentation. And so we will
18 apply all of the ones that she outlined clearly
19 in her presentation. And then inclusion and
20 exclusion criteria unique to the various analyses
21 that we are doing -- are starting here.

22 And so for the 2020 Advisory Committee

1 systematic reviews, examining dietary patterns
2 consumed, we'll apply all of the inclusion,
3 exclusion criteria here for the intervention
4 exposure to operationalize the definition of
5 dietary patterns presented in this presentation.
6 And studies that examine -- So these will be
7 studies that examine consumption and/or adherence
8 to dietary patterns such as, as an example, the
9 dietary approaches to stop hypertension, DASH. A
10 vegetarian or a vegan dietary pattern, a low
11 carbohydrate dietary pattern and high fat dietary
12 pattern will be considered. They'll be measured
13 or derived using a variety of approaches as
14 specified in this inclusion criteria.

15 Studies must describe the dietary
16 pattern being tested or examined at a minimum
17 providing the foods and beverages consumed in the
18 pattern for inclusion. Studies that examine low
19 carbohydrate or high fat diets will be included
20 as long as they meet the percent specified as --
21 and this is in the second row, as being the
22 criteria which is less than 45 percent of energy

1 from carbohydrate, for low carb, and are greater
2 than 35 percent energy from fat, which is high
3 fat. And these are based on the AMDR.

4 And the exclusion criteria are studies
5 that do not provide a description of the dietary
6 pattern or that they label the dietary pattern,
7 but they do not describe the foods and beverages
8 or the base pattern is solely on nutrients. So
9 this is a very food-oriented group. And studies
10 that do not provide a description of the
11 macronutrient proportion examined or do not
12 examine the percentages specified for low
13 carbohydrate or high fat, if that is the pattern
14 that's being suggested. And then there are
15 corresponding inclusions for the active
16 comparators.

17 So for some specifics for each of the
18 outcomes that we're going to be looking at, for
19 all cause mortality, it's studies that are
20 reporting all-cause mortality. And then we'll
21 exclude studies that report only one mortality or
22 two because we're looking at mortality from all

1 causes. And then the inclusions for sarcopenia
2 were covered on the sarcopenia slide. We don't
3 have any exclusion criteria for the
4 neurocognitive health or for the growth size or
5 body composition, overweight and obesity. And
6 these inclusions were shown in the analytical
7 framework slides.

8 There are exclusions for CVD. And
9 that will exclude hypertensive disorders during
10 pregnancy and/or lactation. And for Type 2
11 diabetes, we'll exclude gestational diabetes
12 during pregnancy and/or lactation and Type 1
13 diabetes.

14 The dates of publications that we'll
15 be using are -- the reason they vary so much --
16 so we have actually three different date ranges
17 has to do if it's a new -- you know, if it's a
18 brand new systematic review or an update of NESR.
19 So the date range of the publication for the new
20 systematic reviews will be January 2000 to May
21 2019.

22 The date range of publications to

1 update existing systematic reviews for the
2 neurocognitive health outcomes will be August
3 2014 to July 2019. And this is in addition to
4 the included articles published from 1980 to
5 2014. And an additional search will be done to
6 capture outcomes that were not considered in the
7 existing review. The neurological health
8 outcomes have had many changes in the labels.
9 And we want to catch all those changes in the
10 labels that have occurred in current times.

11 The date range of the publication to
12 update the systematic reviews for growth and size
13 and body composition in CVD and Type 2 diabetes
14 will be August 2013 to July 2019. And this is in
15 addition to the included articles from the
16 previous systematic review of 1980 to 2014.

17 So our next steps as we move forward,
18 we will develop next the protocols for the
19 questions of what is the relationship between
20 dietary patterns consumed and certain types of
21 cancer? And then, the next question will be what
22 is the relationship between dietary patterns

1 consumed and bone health? Then in addition, what
2 we'll be doing as our next steps is implementing
3 the protocols for all of the questions that were
4 just presented. One, two, three, four, five, six
5 of them.

6 So many thanks to the DGAC
7 subcommittee members for enthusiastically
8 participating in weekly meetings. And
9 appropriately the support people are displayed in
10 the bottom box. And the reason I say that's
11 appropriate is because they represent the
12 foundation of this enterprise. They're tireless
13 in supporting all the activities or putting
14 together these efforts and really are
15 contributing to the success of the process.

16 So this slide represents the end and
17 being open for questions.

18 CHAIR SCHNEEMAN: Please.

19 MEMBER MATTES: Rick Mattes, one quick
20 question. For the key confounders for the
21 cardiovascular outcomes, did the committee
22 consider sodium in there as something to

1 contemplate? I know it's a can of worms.

2 MEMBER BOUSHEY: We did. We did talk
3 about it. It's just it's so poorly measured.
4 What are your thoughts? Do you think we should
5 put it in?

6 MEMBER MATTES: I agree rarely is
7 there an adequate measurement of it. But it does
8 seem to be an issue that's very much on a lot of
9 the populations mind. And we have an opportunity
10 to evaluate the science and make a statement
11 here. I don't know.

12 MEMBER BOUSHEY: Yes, so we have
13 different -- and the other thing, because of
14 being hard to assess, it may not be present in
15 the paper. So we could put it in the confounders
16 that won't kill the paper.

17 MEMBER MATTES: Yes.

18 MEMBER BOUSHEY: Yes, okay. I'll make
19 a note of that.

20 CHAIR SCHNEEMAN: Yes, so that becomes
21 a good measure and something where you want the
22 data -- you want to know if sodium has been a

1 part of the study and reporting.

2 MEMBER NAIMI: Tim Naimi. Thanks for
3 that nice presentation. So you listed in terms
4 of the patterns, that we'd be considering the
5 DASH and vegetarian, vegan, low carb, high fat.
6 Are there other patterns that are going to be
7 included or is that the list or is that still up
8 for debate?

9 MEMBER BOUSHEY: Those are e.g's. It
10 shouldn't be i.e. They're e.g's, they're
11 examples. So really the number of patterns
12 available are very wide. And the most important
13 conditions is that we can identify what the foods
14 that comprise the pattern. But it doesn't even
15 have to have a name to make it in as a pattern.
16 And we will take both theoretically derived
17 patterns, as well as hypothetically derived
18 patterns. And I realize that was on this slide,
19 but I didn't say it out loud.

20 MEMBER LEIDY: Heather Leidy. Two
21 quick questions. One is a follow up to that.
22 And I know these are now examples. But I thought

1 I'd just bring it back up. In terms of a low
2 carbohydrate diet, will there be ability to
3 separate those out in terms of the other macro-
4 nutrients? So there can be low carb high fat or
5 low carb high protein? It sounds like all
6 patterns are fair game.

7 But I guess my point is at the end of
8 the day, will they be grouped according to
9 certain dietary patterns that are listed like low
10 carbohydrate diets? And that might actually be
11 very different, depending on the macro-nutrient
12 content.

13 Do you understand what I'm saying? So
14 there's a pattern that's low carbohydrate, but
15 they're very different. There can be studies
16 that define that. But then within that, they can
17 have very different macro-nutrient compositions.
18 And just maybe a point to consider that some
19 things maybe shouldn't be grouped in terms of a
20 generalized pattern.

21 MEMBER BOUSHEY: You know, that's an
22 interesting point because we really are looking

1 at dietary patterns and they would all be
2 together. But that doesn't rule out that we
3 might not look at them, you know, by different
4 types. And I haven't -- others here have been
5 involved in this process before. And so I don't
6 know when we start doing the analysis -- Linda,
7 Linda -- I've been waiting for an opportunity to
8 say that, you know this. So is that something
9 that once we get to the analytical part, that we
10 can pull in parts and pieces and say what happens
11 if we take this one out?

12 MEMBER VAN HORN: Linda Van Horn.
13 I'll let the other Linda speak for herself. But
14 yes, I think this is definitely a topic that was
15 discussed in some of our calls, including the
16 sodium question, which of course is very much on
17 the hot button list at the moment. But I think
18 in some ways, this is reminiscent of the
19 discussion we just had earlier about nutrients of
20 concern.

21 MEMBER BOUSHEY: Yes.

22 MEMBER VAN HORN: I think we're in an

1 interesting point now in the fact that everyone
2 recognizes that eating patterns are more
3 descriptive of someone's totality of intake. But
4 I don't think there's any way you can separate an
5 eating pattern discussion from nutrients of
6 concern. And I think what we're experiencing
7 even as we're speaking is the fact that in many
8 ways, the discussion about eating patterns really
9 has to incorporate, the concept at least of
10 nutrients, especially macro-nutrients, but even
11 micro-nutrients.

12 I was thinking as you were speaking
13 about carbohydrates, one of the nutrients of
14 concern in this country is low fiber intake. You
15 know, the U.S. public eats less than half of the
16 recommended amount of dietary fiber, which we all
17 know is derived in complex carbohydrates.

18 So my only point is here, I don't
19 think we can eliminate from our consideration as
20 we think about dietary patterns, the macro-
21 nutrient or other distinguishing characteristics
22 that really differentiates across these different

1 eating patterns.

2 MEMBER BOUSHEY: And I appreciate that
3 completely. Where I'm coming from actually is
4 we're creating now -- we're putting together the
5 structure for these reviews, right, these
6 systematic reviews. And in order to not be
7 biased then, we really would have to make these
8 decisions a priori. That's why I'm asking the
9 question. Is that you know, right now we're
10 lumping these all together. But what you're
11 saying and I am really open to it, is then we --
12 a priori would need to somehow desegregate some
13 of these to capture what you were talking about
14 because that may be of importance. Because if we
15 put them all in and do it afterwards, that's not
16 following the rules. So that's why I was asking,
17 in the past, has this been done of desegregating
18 these exposures that you -- these studies that
19 you have found. That they met your criteria, but
20 now you're going to split them again.

21 MEMBER LEIDY: This is Heather again.
22 This is a follow up. I'm just thinking in terms

1 of the NESR search terms. It's hard to keep it
2 broad because if you're not having -- you know,
3 for example in this case, our discussion has been
4 about everything but protein. So as an example,
5 if you don't search by high protein diets and you
6 just go low carbohydrate diet, there's an
7 opportunity to actually miss some of those within
8 the NESR search criteria, which is something I
9 didn't think about. I guess maybe the search
10 terms will come later on down the road. I mean
11 we're already really establishing that. So
12 there's examples that are listed, but I'm just
13 not sure if that actually translates into all
14 encompassing search terms that will be able to
15 pick up all these different dietary patterns.

16 MEMBER BOUSHEY: And that's actually
17 an interesting one to check on.

18 CHAIR SCHNEEMAN: I think it might be
19 worthwhile if the staff could perhaps -- I know
20 you're sitting over there, but I can't see you.
21 Particularly this question on the search terms, I
22 think it would be helpful.

1 DR. ENGLISH: Yes, this is Laural
2 English. So to the first point earlier, I did
3 just want to touch on the fact that we will
4 extract all data that are reported to speak to
5 your concern about the other nutrients. So if
6 it's a low carbohydrate diet and they report the
7 nutrients -- the other macros, micros, we will
8 extract all information that is reported by the
9 article. And then we can group accordingly to
10 your earlier point in the evidence synthesis with
11 Mediterranean diets, low carbohydrate diet, et
12 cetera. So we can do that and plan to do that.

13 For the next question on the search
14 terms, we do develop a comprehensive search
15 strategy and there are MeSH terms in the PubMed
16 database. For example, ketogenic diet, low
17 carbohydrate diet, we also add in key words. So
18 we have developed a comprehensive search and it
19 is peer reviewed by a second librarian. And then
20 we also have test papers that confirm that our
21 search is appropriate. So we believe it is
22 comprehensive to that.

1 MEMBER LEIDY: Another real quick
2 question. This is on -- I don't think you need
3 to go there, but on Slide 15, it's the Type 2
4 diabetes. And for me, just more of a
5 clarification. The endpoint outcome is Type 2
6 diabetes. And I wrestled with this in the
7 frequency of eating and so I thought I'd bring it
8 up.

9 I'm wondering what the outcome is. So
10 when you look at the cardiovascular disease,
11 there's parentheses with qualifiers in terms of
12 what that endpoint is. With Type 2 diabetes, I
13 understand what Type 2 diabetes is, but it's
14 generally identified as a certain HbA1c. And
15 HbA1c is actually an intermediate outcome. So
16 I'm just wondering what the Type 2 diabetes
17 endpoint outcome will be. Except that if
18 somebody has Type 2 diabetes, but is that the
19 only criteria? Or is it really based on
20 somebody's HbA1c and the changes of that?

21 It's a moot point, but it's an
22 intermediate right now. And it seems odd why it

1 isn't in the endpoint outcome. And I'm not a
2 medical doctor, but generally people are
3 diagnosed with their HbA1c levels. And so that's
4 what I'm just trying to figure out why that's not
5 an endpoint instead of an intermediate.

6 MEMBER BOUSHEY: Well that's a good
7 question. Yeah, that's a good question. Jamy?

8 VICE CHAIR KLEINMAN: I mean I would
9 think it's both actually. And I think when
10 they're searching, they're searching for the
11 health outcome Type 2 diabetes. But when looking
12 at studies, they'll include studies that have
13 HbA1c's that are below the threshold for Type 2
14 diabetes. So one can follow that over time to a
15 diagnosis of Type 2 diabetes. I mean I'd ask the
16 staff, is that a correct interpretation? Yes, I
17 see head's bobbing yes.

18 DR. ENGLISH: Yes, this is Laural
19 English again. And yes, so to that point, it
20 would be diagnosed Type 2 diabetes. So if they
21 were looking at dietary patterns consumed in
22 those who were diagnosed with diabetes versus

1 those who did not, that's really to get at that.

2 But to your point, hemoglobin Alc, the
3 other intermediate outcomes, we would be
4 extracting the data that are reported for those
5 continuous measures or the particular levels. So
6 it would be included pretty much as Dr. Kleinman
7 mentioned.

8 CHAIR SCHNEEMAN: So Dr. Ard? I think
9 we had Dr. Ard and then Dr. Donovan.

10 MEMBER ARD: So I was just going to --
11 Jamy Ard, I was going to follow up on Heather's
12 question and point. And the answer that Laurel
13 gave around the macro-nutrient distributions and
14 the dietary patterns associated with that.

15 I think it will be important for us to
16 think about the categorization of those specific
17 types of dietary patterns. Because as we've
18 said, there's a wide range of what people define
19 as lower carbohydrate or lower fats. And
20 sometimes, I think it's probably just as
21 important to understand what was reduced in the
22 dietary intake, as well as what replaced it.

1 So in thinking about a lower
2 carbohydrate intake, I want to also know what
3 replaced the carbohydrate. Was that replaced by
4 fat intake or was that replaced by protein intake
5 and maybe even further. You could, you know, see
6 a branching of you know, well was that protein
7 mostly -- vegetable protein or animal protein?
8 Was that fat mostly saturated fat or unsaturated
9 fat?

10 So I think it will be important for us
11 in describing the results to, as best we can,
12 clarify what we mean when we say this is the
13 particular macro-nutrient dietary pattern. So
14 that we do avoid this sort of general lumping of,
15 well, it's just this. As we wouldn't necessarily
16 say, well, all vegetarian patterns are the same,
17 because there are different forms of vegetarian
18 patterns. And we would be specific to describe
19 well this is vegan or this is lacto-ovo, et
20 cetera.

21 So I think that will be important for
22 us to at least have a general working framework

1 of how we might want to categorize that. And
2 then put the studies in those relevant boxes, to
3 some extent. And it may not be at the level of,
4 well, this has to be less than 20 percent
5 carbohydrate or this has to be less than 100
6 grams per day of carbohydrate or to that extent.
7 But at least some general framework of
8 understanding not just what the reduced macro-
9 nutrient was, but what replaced it.

10 MEMBER BOUSHEY: Yeah.

11 MEMBER SNETSELAAR: I just wanted to
12 piggyback on that just a bit. I think too and
13 we've discussed in our committee, the idea that
14 the Mediterranean diet has many different
15 variations. And so this probably will be true of
16 all of the types of dietary patterns that we're
17 looking at. I just wanted to add that.

18 MEMBER BOUSHEY: Yes, that's
19 absolutely right. But Jamy, we've got -- I
20 really appreciate what you said. Because we've
21 been really sensitive to the complexity of this.
22 And I'm glad that this came up so that really

1 gives us additional guidance in moving forward.
2 I think we'll be able to find all the papers, but
3 it will be really somehow harmonizing them across
4 the spectrum in some way that makes sense with
5 regard to -- I mean really, what's available now
6 is far more than what we had previously, I do
7 believe.

8 MEMBER DONOVAN: So Sharon Donovan,
9 this is more just a general comment. Because I
10 noticed that your publication dates; one is May,
11 one is June, one is July. And it seems to me as
12 a committee we should decide what is the latest
13 date that we want all the systematic reviews to
14 go to. We've talked about this because there's a
15 bunch of new -- from the pregnancy B 24 that were
16 just published, but they only went to January of
17 2017. So while I understand we'll be ruling
18 these, it seems like we should be consistent --
19 or unless we can really justify why one should be
20 May, one should be June, and one should be July.

21 CHAIR SCHNEEMAN: Right. And actually
22 I have a feeling that when you're looking at the

1 date, that's the furthest out date, the closest
2 to now, the intent is to gather whatever is
3 currently available. And perhaps the staff could
4 comment on that. So May or June, I don't think
5 there was an intent to make a difference there.
6 It was probably when the protocol went into the
7 box.

8 DR. ENGLISH: Yes. This is Laural
9 again. Yes, that's correct. And we wanted to
10 get started as soon as possible after those two
11 first new -- the new questions were approved and
12 those protocols were approved. We did also
13 develop the search strategy and shared the search
14 strategy. And then conducted the search so that
15 the staff could get going on literature search
16 and screening.

17 CHAIR SCHNEEMAN: But we will be
18 consistent in terms of we're trying to gather the
19 most current data.

20 DR. ENGLISH: Yes, and if there was
21 anything published after May, between May and
22 July for instance, we could do a secondary search

1 to make sure that there were no additional
2 publications that were missed between that time
3 period.

4 MEMBER BOUSHEY: So is that something
5 we should adopt across the board then? Because
6 I'm sure that's happening in every subcommittee.

7 CHAIR SCHNEEMAN: Oh absolutely. Yes,
8 absolutely.

9 MEMBER BOUSHEY: Right, right.

10 VICE CHAIR KLEINMAN: Okay, we have
11 one more report before we take a break at 11:45
12 for lunch. And -- Oh, I'm sorry.

13 MEMBER MATTES: Rick Mattes, and I'm
14 thinking about this issue of the patterning and
15 macronutrients and so on a little further just in
16 case it helps your thinking as you go forward.
17 You could couch it in different ways. You could
18 talk about absolute level of each of those
19 nutrients. You could talk about proportion of
20 energy contributed by each of those nutrients.
21 You could talk about the amount relative to
22 recommendations of each of those nutrients. And

1 I don't know the right answer to that, but they
2 could well give you different answers. And so
3 you may want to think that through to make your
4 decision.

5 CHAIR SCHNEEMAN: Thank you. So Dr.
6 Sabate had a comment as well.

7 MEMBER SABATE: Joan Sabate. I have
8 two comments to make. One is in line of what was
9 discussed before as far as what replaces
10 carbohydrates, so foods coming from mainly
11 carbohydrates. And again since this is mainly a
12 committee that has to deal with foods. I think
13 besides whether it is protein or fat that is
14 replacing, I mean I think we at least have to
15 capture -- I mean if the foods that are high in
16 protein and fats are coming from vegetables or
17 from animal intake. Because I mean there are --
18 from the viewpoint, there are two ways, I mean to
19 accomplish a low carbohydrate diet.

20 The second point relates to a slide
21 that is Number 13 that we discussed because I am
22 a member of this committee in which we relate the

1 dietary patterns with anthropometrics, particular
2 overweight and obesity. And total energy intake
3 is listed as a key confounder. I think listing
4 as a key confounder may decrease the ability to
5 connect, I mean dietary patterns and overweight
6 and obesity.

7 I think before trying to use as a key
8 confounder, we have to analyze as a mediator
9 because some of the dietary patterns may relate
10 to the overweight and obesity mediating through
11 the total energy intake. Especially when we look
12 in descriptive epidemiology and how people, I
13 mean, consume these dietary patterns. So I think
14 that besides using as a key confounder, it has to
15 be studied as a mediator between dietary patterns
16 and anthropometrics. Because it could be that
17 the connection is mainly through total dietary
18 intake.

19 MEMBER NAIMI: Tim Naimi. Just I
20 wanted to, in terms of consistency, you were
21 controlled for smoking as a confounder for all
22 these. And you controlled for alcohol

1 consumption for the neurocognitive health, but
2 not for overweight and obesity and cardiovascular
3 disease and diabetes. And so I thought you
4 should probably be consistent one way or the
5 other. But I think it's an important potential
6 source of calories and other possible effects.

7 MEMBER BOUSHEY: That's a good
8 suggestion.

9 VICE CHAIR KLEINMAN: All right. I'm
10 so eager for lunch, I jumped to this last one.
11 So we are now at the third presentation. And we
12 will take a break for lunch at 11:45, so we have
13 plenty of time. And Dr. Heather Leidy's going to
14 present for the Frequency of Eating Subcommittee.

15 MEMBER LEIDY: I'm okay. I'm going to
16 try to use my slides.

17 CHAIR SCHNEEMAN: So Heather, you have
18 to really work at making sure you're heard.
19 Okay?

20 MEMBER LEIDY: Okay, sorry about that.
21 We have really short mics. And so I'm short, but
22 not that short. So I'll just -- I'm sorry if you

1 couldn't hear my comments earlier. I usually
2 have a big mouth.

3 So I will be presenting on behalf of
4 Steve Heymsfield who isn't able to be here today.
5 He is the chair of this committee. And then also
6 wanted to acknowledge Carol Boushey and then Rick
7 Mattes, as well as Ron Kleinman who were a part
8 of this committee as well.

9 And so it was pretty exciting to be a
10 part of this subcommittee. These are new areas
11 of questioning that we were able to tackle. And
12 you'll quickly find we spent a substantial amount
13 of time in the earlier weeks defining the topic
14 and working out the framework on the front end.
15 And so as we go through the slides, if you have
16 clarifying questions, feel free to ask. And the
17 rest of the committee, happy to chime in with you
18 all too. I'm going to try to add some rationale
19 behind some of the things that we've selected
20 because they may seem a little -- not off, but
21 just different. And so I'll try to add some
22 context to that.

1 And so our topics areas that we had
2 were the frequency of eating. And as you can see
3 the remainder, and Carol had already addressed
4 these with the previous topic. But just so
5 everybody's on the same page. You're really
6 looking at eating frequency and all-cause
7 mortality, growth, size, body composition,
8 overweight, and obesity, gestational weight gain,
9 postpartum weight loss, cardiovascular disease,
10 and Type 2 diabetes. And we are covering all of
11 the protocols today. And that's why they're in
12 an asterisk.

13 And so we really wanted to start with
14 identifying the key definitions. And so if you
15 have questions, feel free to raise them now
16 because it will help drive some of the rest of
17 the conversation.

18 And so eating frequency, we defined in
19 two manners. One is the number of daily eating
20 occasions. And then the second one is the timing
21 of daily eating occasions. And underneath that
22 then we have the timing of weekly eating

1 occasions, really identifying week day versus
2 weekend. Meal skipping and then also fasting
3 from a time restricted eating paradigm.

4 And so obviously now we have other
5 things to define. And so an eating occasion is
6 any ingestive event. And thinking in terms of,
7 you know, what we know from the lay audience and
8 the U.S. American diet, as well as how studies
9 are designed. That includes preload, so that is
10 really anything before another eating occasion.
11 So preloads, meals, and snacks. Within this
12 eating occasion, that includes all foods and/or
13 beverages. And then also whether they're caloric
14 or non-caloric.

15 Fasting was defined as an absence of
16 an eating event greater than eight hours during a
17 waking period in a 24-hour period. Again, we're
18 really trying to be sensitive to some of the more
19 recent research with time-restricted eating or
20 intermittent fasting, those types of concepts.
21 And so time-restricted eating, were really set
22 patterns of eating occasions throughout the day.

1 And so that's how that was defined.

2 And then lastly, meals were dependent
3 on timing throughout the day. So we're really
4 trying to get at, you know, what you typically
5 see as you know breakfast, lunch, dinner/supper.
6 And that's really around the morning, midday, and
7 evening eating occasions. Not that it's an
8 elephant in the room, but you know, obviously
9 snacking is another component. Due to the fact
10 that there really is no standard definition for
11 snacks, we felt the need not to include that as a
12 definition because it's just very variable. I
13 mean some base it on timing or energy or caloric
14 intake. And so we felt that because there's just
15 no standardization, those eating occasions will
16 be included as eating occasions. But we just
17 felt that we shouldn't really define snacks.

18 The next piece then is well what
19 frequency of eating is not? Because that really
20 came in the discussion. And so two points here.
21 The first is that we are not addressing the
22 frequency of intake of single foods, beverages,

1 or categories of foods or beverages. This is
2 really about when to eat, not what to eat.

3 But even in a call yesterday or the
4 day before, it came up that, you know, there will
5 be times that we can address other components --
6 nutrients, micronutrient content, whatever. But
7 the primary question within a study has to be the
8 frequency of eating. And then within that, we
9 can then look at different types of the foods
10 that were included within that. But this is not
11 really specifically looking at single foods, like
12 the frequency of milk consumption or frequency of
13 seafood consumption, something like that.

14 And then the second point are studies
15 that do not have eating occasions across the day.
16 And this really came about from this idea of meal
17 skipping and breakfast skipping or dinner or
18 whatever is in the research right now. But
19 you'll find that a lot of studies don't address
20 subsequent eating throughout the day. That it is
21 generally maybe if it's breakfast skipping, it's
22 they assess lunch and that's it. And we really

1 wanted to encompass with these outcomes, that
2 I'll share here in a minute, that these studies
3 really need to have eating occasions across the
4 entire day to increase the quality of the study
5 or to really adequately answer the question. And
6 so those are the two points to keep in mind.

7 Yes, for sure.

8 MEMBER ARD: So this is Jamy. So can
9 you help me sort of figure -- or talk through how
10 -- what's the difference between meal skipping
11 and time-restricted eating as you're
12 conceptualizing it? So if you're saying time-
13 restricted eating is a set pattern of eating
14 occasions, and I skip breakfast every day, which
15 one is that? Is that meal skipping or is that
16 just I don't start eating until noon?

17 MEMBER LEIDY: Sure. And feel free
18 for the rest of the committee to chime in. But
19 that really is encompassing both of those
20 aspects. Because there are studies that just
21 focus on breakfast skipping, which isn't really
22 time-restricted eating. But some time-restricted

1 eating components have a breakfast skipping
2 component. Or they just -- maybe they also have
3 breakfast and lunch skipping. So I think what
4 we're trying to do is really include that all
5 together. So you know, it depends on how the
6 NESR folks or how we compile the findings at the
7 end. But they can be separate, but they can also
8 be combined, depending on the study design.

9 MEMBER MATTES: Yes, I think the goal
10 here was to come up with terms that would be
11 captured in a literature search. And it may
12 actually be very similar, but to make sure we
13 captured all the papers, we used both terms.

14 MEMBER LEIDY: Anybody else?

15 VICE CHAIR KLEINMAN: I think also we
16 talked on the last call about intermittent
17 fasting for let's say religious reason or some
18 other purpose. And as long as that's not the
19 sole purpose of that study, then we would capture
20 those. So if for example, someone has a usual
21 consistent eating pattern, but fasts periodically
22 throughout the year, those will be captured. But

1 if they're fasting for four days, that's not the
2 kind of the study that we'll capture.

3 MEMBER LEIDY: Yes. And again, we
4 really had the mindset on the front end is you
5 know, intermittent fasting has changed to the
6 definition of time-restricted eating. But there
7 are still a number of studies that have never
8 been examined looking at every other day. And so
9 you know, when we look at that, we'll be able to
10 capture that. But to your point, you know, it's
11 not a prolonged fasting period that we're trying
12 to capture.

13 MEMBER NOVOTNY: Rachel Novotny. I'm
14 wondering about water, especially with the
15 frequency of consuming water throughout the day.
16 We may not find a lot of studies on that, but
17 just, what are your thoughts for handling water?

18 MEMBER LEIDY: Yes, so we had that
19 included in our definition that it's any eating
20 occasion, caloric or non-caloric. So even those
21 that are water and non-caloric will be included
22 in the analyses. Although as we all know, it's

1 very difficult -- many studies don't actually
2 assess water intake unless that's the only thing
3 that they're changing. But that would be
4 included in our -- that would be captured in the
5 search terms in terms of -- because we're
6 searching for any eating or drinking occasion.
7 And that would be included.

8 MEMBER NOVOTNY: So fasting with water
9 is not fasting in your definition. It's drinking
10 water.

11 MEMBER LEIDY: In our definition, it
12 would not be considered fasting because that
13 would be an ingestive event. But we also have
14 the caloric and non-caloric component to that.
15 Is that in agreement? Okay.

16 In terms of the inclusion and
17 exclusion criteria, these were the standard NESR
18 criteria used. So I won't go over this slide.
19 And we'll get to some of the things that are a
20 little bit different with these research
21 questions. So I'll just go ahead and move on.

22 And so again, this is the analytical

1 framework. It's nice, we've only had one of
2 these so far. But in the afternoon, we're going
3 to see quite a few, I would imagine. The first
4 part is the intervention and exposure, which is
5 really the definitions that I just touched on.
6 So I'm going to kind of go past that because the
7 inclusion/exclusion criteria are there.

8 In terms of the age of the study
9 participants, you can see here that it's children
10 to older adults. And we are not focusing on
11 infants under the age of two. And that's in our
12 infants and toddlers. And so that's in the
13 excluded criteria. And then in terms of the date
14 of publication, the committee also felt that
15 going from January of 2000 to the present was
16 also appropriate. But we did this for two
17 specific reasons and we thought long and hard
18 about this.

19 The first one is the methodology using
20 that we have is quite different now than it was
21 50 years ago in terms of some of the outcomes and
22 the methods of capturing eating frequency. And

1 so we felt to be consistent, 2000 and beyond
2 would be the best consistent data with that.

3 And then the second piece too is --
4 you know, it's interesting much like probably
5 dietary patterns. But eating frequency has a
6 tendency to go through waves of research. And so
7 I remember, I went back and looked last night to
8 make sure, you know, some of the first big
9 studies that came out were like in the 1950s.
10 And there were a cohort that came out. And you
11 didn't see it again until the '70s and then the
12 '90s. And so the challenge that we found is, you
13 know, this is the first time we've asked these
14 research questions. And so it would be nice to
15 go back and look at the totality of the data.

16 The problem is as we know, eating
17 patterns and eating frequency has changed over
18 the past 50 years. Whereas, you know, 50 years
19 ago, three meals was the staple with very little
20 snacking. And so the control group there would
21 be far different than the control group from like
22 2000s on where there's -- you know, there's a lot

1 of meal skipping now and more eating occasions.
2 And so that's why we felt it best to go from 2000
3 to the present. Because that's the most
4 consistency that we have with dietary patterns
5 and our control comparators would be more
6 consistent with that. So that's why we chose to
7 go with 2000 and beyond.

8 In terms of the health status of the
9 study participants, again the NESR standard
10 criteria were included. Although, you know, this
11 is more of an interesting thing, you know. Based
12 on looking at the other presentations, I think
13 we're the only ones that included this. But we
14 actually excluded subjects who had post-bariatric
15 surgery. And our thinking on this was, you know,
16 when individuals go through post-bariatric
17 surgery, they would be healthy. Maybe overweight
18 or still obese, but you'd have a cohort of
19 healthy individuals so they should theoretically
20 be included.

21 But as you know with post-bariatric
22 surgery, they are recommended or prescribed

1 smaller meals with more increased eating
2 frequency. And we felt that wasn't generalizable
3 to the rest of the population. And so we chose
4 to include those in our exclusion criteria for
5 that reason. It seems a little weird that we
6 just added that on. But it really is because
7 they change their eating patterns.

8 In terms of dietary data collection,
9 this was also something I think that's unique to
10 our committee. We wanted to have the highest
11 quality data that we could capture given that
12 this is the first time this question has been
13 asked. And so we -- I feel like this is probably
14 a little bit stricter than what you would think.
15 But we chose a minimum of three days of dietary
16 data collection on at least two occasions. And
17 the intent of that was really to capture habitual
18 eating frequency or eating habits. That it
19 wasn't just a single day.

20 And the other thing too with eating
21 frequency, as an example with meal skipping, a
22 lot of times you'll see that there's one eating

1 occasion, and then the data in these studies are
2 only captured at that next eating occasion. And
3 so you don't get the rest of the entire day. And
4 it's really difficult to make recommendations
5 when you're not capturing, you know, over a 24-
6 hour period, as well as over the days to look at
7 habitual intake. And so that's why we chose the
8 three days of dietary data.

9 But as a note, because the question
10 that came up is the food frequency questionnaires
11 because they're done one time. But if you -- you
12 know, a lot of the ones that are validated are
13 over the last week or months or years. And so
14 the food frequency questionnaires would be
15 included within this data. This would be
16 acceptable because they are capturing over a
17 three day period. But we do want with the food
18 frequency questionnaires, there would be two
19 separate time points for those to be included.
20 Does that make sense so far?

21 And then in terms of the size of the
22 group, we chose 15 participants for studies using

1 a within subject analyses and then 30
2 participants for studies using between subject
3 analyses or at least including a power
4 calculation. It wasn't and, it's or. And so if
5 somebody -- if a group or research publication
6 has less than those, but have a power calculation
7 that adequately is powered based on a lower
8 sample size, we felt that was appropriate. Again,
9 our intent is really to increase the quality and
10 to have enough power within a study to detect the
11 differences in the outcomes that they are
12 proposing.

13 Okay, so now we can get into the
14 actual questions. And all of these questions,
15 we're using the NESR system review to answer
16 those questions.

17 So the first one is what is the
18 relationship between frequency of eating and all-
19 cause mortality? And what we've done here is
20 you'll see very similar framework. Some of the
21 ones that are in black in terms of the key
22 confounders, potential confounders, and potential

1 covariates are consistently used with other
2 subcommittees. And then some of the ones are
3 specifically for us. And then as we go along
4 with each of the research questions, if something
5 has changed, they're highlighted in red. So
6 we'll kind of just work through this now.

7 And so the top piece, we've already
8 covered; the intervention exposure versus the
9 comparator. And the population is included
10 there. In terms of the key confounders, again,
11 we have sex, age, race/ethnicity. Total energy
12 intake is in italics, which is really difficult
13 to see. So I'm going to address that now. And
14 so this was an interesting one that came up. And
15 it's also to your point, Dr. Sabate.

16 Total energy intake is actually -- if
17 you look at that, it's a key confounder, but it's
18 also a potential covariate. Because we're trying
19 to see whether it's a confounder or mediator.
20 And so we felt that it was appropriate for these
21 research questions with the frequency of eating
22 to include it both ways. And so the only way

1 that a study would be dinged is if they're not
2 using it in one or the other manner. So that's
3 why we went with it from that aspect.

4 We did include habitual eating
5 frequency, which I think is probably unique to
6 our research questions. And again, there's a lot
7 of studies out there that will do eating
8 frequency studies. But baseline assessments are
9 not included. And we felt that it was critical
10 to know when somebody's habitually fallen from an
11 eating pattern to know whether it's the change in
12 their habitual eating patterns versus just the
13 eating pattern itself. And so that's why we
14 wanted to include that as a key confounder.

15 And then we have smoking,
16 anthropometrics and menopausal status. In terms
17 of the potential confounders, we are I believe,
18 the only group that has socioeconomic status as a
19 potential confounder, not a key confounder. And
20 just given the research question, we felt that we
21 did not want that in the risk of bias as a key
22 confounder. So it is included, but it's included

1 as a potential confounder.

2 We also have physical activity,
3 cultural practices, eating environment. So in
4 essence, who you eat with, where it is, whether
5 it's work, school, or you know, around an
6 exercise schedule. Thinking in terms of holiday
7 eating or seasonal eating. Sleep schedules,
8 trying to get shift work, dentition, hydration
9 status, pregnancy status, and pubertal status.
10 And so all of these potential key confounders, we
11 felt were important for the frequency of eating,
12 but not served as a key confounder.

13 And then lastly, the potential
14 covariates would be related to different aspects
15 of energy. And so we have diet energy density,
16 as well as the energy state of the diet. In
17 terms of energy, we were trying to think of it
18 two ways -- one with the diet and one from a
19 physiological energy. And so the first part we
20 wanted to use as a covariate is as I said, the
21 energy balance of total energy intake --

22 I'm sorry, let me go back. Energy

1 state of the diet. So whether it's an energy
2 restriction diet or an energy surplus or an
3 overfeed study. But then as well as thinking in
4 terms of energy from an energy balance, whether
5 somebody's in an energy-restricted state or an
6 energy surplus state, thinking in energy intake
7 and energy expenditure. And then we also
8 included portion size macronutrient content,
9 location of eating occasion, habitual eating
10 frequency, and biochemical changes.

11 And again, you'll see again, some of
12 these are listed both ways. So as a key
13 confounder, as well as potential covariate to see
14 whether they are truly a confounder versus a
15 mediator. And so that's why we have it as such.
16 And I don't think we've actually defined all-
17 cause mortality, but that is the total number of
18 deaths from all causes during a specific time
19 period.

20 The next question that we had is what
21 is the relationship between the frequency of
22 eating and growth, size, body composition, and

1 risk of overweight and obesity? And I'll only
2 highlight the changes that we had within this
3 versus the others. And so if you look at
4 obviously the endpoint outcomes were very similar
5 to what Dr. Boushey had presented with the
6 dietary patterns. So I'm not going to go into
7 that because they are identical.

8 Our key confounders here, the only
9 thing that we added as a key confounder was
10 physical activity. And that's really driven by
11 when you're thinking in terms of some of these
12 outcomes related to obesity. A lot of these
13 studies that have eating frequency also have a
14 physical activity or exercise component. And so
15 we felt that even if they didn't have an exercise
16 component for these types of outcomes, it was
17 critical to have an assessment of their physical
18 activity or energy expenditure status. And so
19 that's why that is a key confounder.

20 Potential confounders, same as the
21 previous one. Although we did add medication and
22 substance use. And this is related to any types

1 of substances or medications that would affect
2 body composition or obesity status, those
3 aspects. So we felt it was important for this
4 question to include those.

5 And then the potential covariates, the
6 only thing that we added was a specialized diet
7 including all liquids diets. There are studies
8 that look at eating frequency and have diets that
9 are just all beverages. And so we felt that was
10 important because that's not very representative
11 of the population of who are consuming those.

12 Whoops. The next question that we had
13 is what is the relationship between frequency of
14 eating during pregnancy and gestational weight
15 gain. Whoops, sorry about that. There we go.
16 So it's pregnancy and gestational weight gain.

17 In terms of our intervention/exposure
18 versus comparator. The population was changed
19 obviously to women during pregnancy. Gestational
20 weight gain, I think this might be -- I don't
21 know if we've -- I guess we haven't heard it at
22 this point. So it's change in maternal body

1 weight from baseline before and during pregnancy
2 to a later time point during pregnancy and/or
3 right before delivery. As well as weight gain in
4 relationship to weight gain recommendations based
5 on pre-pregnancy BMI. And as I said, the
6 population is women during pregnancy.

7 The key confounders here, we did add
8 pre-pregnancy anthropometrics within that. The
9 potential confounders very similar to previous,
10 except we added the history of gestational
11 diabetes and history of gestational hypertension.
12 And just to make sure we're defining gestational
13 weight gain. That's a weight a woman gains
14 during pregnancy. And no changes to our
15 potential covariates within this model.

16 The next one is what is the
17 relationship between the frequency of eating
18 during lactation and postpartum weight loss?
19 Within this, this is women during lactation, is
20 the population. And just a side note is that
21 women who are not lactating would not be included
22 within this. We're really focusing on women

1 during lactation.

2 Postpartum, the endpoint is changes in
3 weight from baseline postpartum to a later time
4 point during the postpartum period. And
5 postpartum weight retention if gestational weight
6 gain is controlled for. We're defining
7 postpartum weight retention as the amount of
8 weight that remains during the postpartum period
9 minus the woman's pre-pregnancy weight.

10 And we've added some key confounders,
11 a little bit different than the previous ones.
12 And that being pre-pregnancy anthropometrics and
13 gestational weight gain. But no differences in
14 potential confounders. And given a potential
15 covariate, we included the lactation duration
16 thinking that is a critical point in terms of how
17 long an individual woman has been lactating.

18 The next question is what is the
19 relationship between the frequency of eating and
20 cardiovascular disease? And within this model,
21 we have same things on the intervention/exposure
22 versus the comparator. In terms of the endpoint

1 outcomes, we have cardiovascular disease. And
2 you can see those that are listed within that, as
3 well as stroke, venous thrombosis, cardiovascular
4 disease-related mortality. And then we also have
5 the intermediate outcomes listed here, which is
6 very similar to the other subcommittees that have
7 used that.

8 Key confounders and potential
9 confounders were similar to the previous ones.
10 In terms of potential covariates, those that are
11 highlighted in red were ones that we added for
12 this specific outcome of -- these outcomes of
13 interest. And that being dietary sodium and
14 potassium, as well as dietary fat composition.

15 And then the last research question is
16 what is the relationship between the frequency of
17 eating and the risk of Type 2 diabetes? Again,
18 very similar as what were previously discussed.
19 Endpoint is Type 2 diabetes. And we can see that
20 our intermediate outcomes here again are you
21 know, glucose, insulin, hemoglobin A1c, and pre-
22 diabetes. Our key confounders, potential

1 confounders, and potential covariates are the
2 same as the ones that are used previously. So
3 I'm not going to list all those.

4 I'm quickly realizing though with our
5 group, we have a lot more of these than the
6 dietary patterns. So I'm not sure if we're maybe
7 being more specific or all encompassing. I'm not
8 sure how that works. But we do have quite a bit
9 that we're targeting. The nice part is these
10 don't eliminate studies in terms of the potential
11 covariates or potential confounders. It's just
12 something that we're trying to keep an eye on as
13 we go forward. And I think this is probably
14 driven by the fact that this is the first time
15 these questions are being asked.

16 In terms of next steps, we will begin
17 screening search results, extract data, and
18 conduct risk of bias assessments, prepare the
19 evidence synthesis, develop graded conclusion
20 statements, and then document limitations and
21 research recommendations.

22 And so with that, I just wanted to

1 acknowledge the members and the support staff.
2 It's been a really great opportunity working
3 within this group, especially this support staff
4 have been overly helpful. When questions get
5 raised, it's great -- they come back with
6 examples and things for us to consider. And so
7 it's been a great opportunity. So with that,
8 I'll field any more questions if you all have
9 them.

10 MEMBER DONOVAN: Thanks, that was
11 great. The only thing I would add, on the
12 frequency of eating and postpartum weight loss,
13 you have lactation duration, but you might also
14 want to consider exclusivity. So if a women is
15 exclusively breast-feeding versus mixed feeding -
16 - so if that's reported.

17 MEMBER NOVOTNY: I actually got
18 thinking about --Rachel Novotny -- whether you
19 might want to include monthly in frequency of
20 eating. I mean it would need further
21 elaboration. What I'm thinking about is lower
22 income who change your eating patterns at the end

1 of the month. And eat less, start skipping
2 meals. I'm not quite sure how you get at that.
3 But it would be -- you would probably want
4 socioeconomic status or food security status with
5 that question.

6 MEMBER LEIDY: That's a really good
7 point. And you know, the same was true with some
8 of our terms that we were still -- as of
9 yesterday, still battling back and -- not
10 battling, discussing back and forth. You know,
11 we have it within a 24-hour period. But in
12 essence, if you're doing intermittent fasting and
13 it's every other day, it actually needs to be
14 extended to about 48 hours or if it's across the
15 week.

16 So we're not limiting studies based on
17 that. We're just trying to capture eating
18 patterns. And if it's longer than -- you know, I
19 think our minimum would be a 24-hour period. But
20 it would be great if we could extend that. And
21 you're exactly right. I mean eating patterns
22 across a month given SES status would be

1 critical, if those studies exist and if they
2 actually have that.

3 MEMBER TAVERAS: Elsie Taveras.
4 Heather, I wonder if -- I saw sleep schedule.
5 But I wonder if sleep duration should also be
6 included and frequency of eating and body
7 composition, gestational weight gain, and
8 postpartum weight loss. Duration as opposed to
9 just schedule. Right? Because you're thinking
10 of -- I'm thinking of duration separate from
11 maybe circadian misaligned eating. So that was
12 one suggestion.

13 And then I also wondered -- I didn't
14 see any mention as key confounders or potential
15 confounders of screen use. So frequency of
16 eating, especially if that eating is in front of
17 a screen and exposed to advertising. I just
18 wondered if the committee thought of how screens,
19 television viewing played into any of these
20 relationships.

21 MEMBER LEIDY: To answer your point
22 about the sleep, I think that's a critical

1 component. We put that in thinking of shift
2 workers. But then, you know, especially with
3 breakfast skipping, there is some correlational
4 data that suggested that's related to sleep or
5 the sleep duration or the quality of sleep is
6 potentially driving some of the meal responses.
7 And so something for us to think about to
8 include.

9 In terms of the screen use, to my
10 recollection, we didn't include that
11 specifically. But we did talk about where or
12 when or who the eating occasion is with. So if
13 it is at home versus out at a restaurant or
14 something like that, that's included. But just
15 because they're eating at home doesn't mean that
16 they're eating as a family unit. Or that they
17 don't have something else in terms of screen
18 time. So I think that's something that we should
19 probably think about capturing. We do have some
20 components of that, but not a specific statement
21 about screen time. That's a really good point.

22 MEMBER DONOVAN: Sharon Donovan. I

1 guess the comments about end of the month, it
2 also made me think that you have habitual eating
3 patterns for both pregnancy and lactation. And I
4 think that women change their eating behaviors
5 and frequency during these periods of time. So I
6 think it's okay to look within these time
7 periods, differences in eating frequency. But
8 I'm not sure you want habitual in as a key
9 confounder.

10 MEMBER LEIDY: I think our intent was
11 to capture -- Feel free to chime in. But it was
12 to capture what they were habitually consuming
13 before. So this would be pre-pregnancy. So it
14 depends on what we're qualifying as baseline.
15 But if they, you know, became pregnant, their
16 eating frequency may change. And then
17 postpartum, it may change as well.

18 And so we were trying to figure out
19 just to capture that habitual period of time.
20 Because if their eating patterns are most likely
21 changing, but nobody has really quantified how
22 they're changing. And so that's why we felt that

1 it was important. Again, not that it's going to
2 exclude a study. But that the quality of the
3 study will be evaluated a bit differently if
4 they've captured that versus if they haven't.

5 Rick, I don't know if you want to --

6 MEMBER BAILEY: This is Regan Bailey.
7 Short mic here too. My question was surrounding
8 the diet assessment. I'm not sure that most of
9 the food frequency questionnaires capture that
10 rich contextual detail of timing and screens and
11 with whom you're eating, the way that a 24-hour
12 recall can. So are there any validated
13 questionnaires that assess purposeful versus
14 nonpurposeful skipping of meals or time-
15 restricted feeding that could be considered?

16 MEMBER LEIDY: There are.

17 MEMBER BAILEY: Okay.

18 MEMBER LEIDY: But that's a good
19 point. Again, we're thinking in terms of -- I
20 think we went in thinking highest or best quality
21 of research or data. And so thinking, you know,
22 three dietary recalls would capture that more

1 effectively than food frequency questionnaires.
2 They're still included, but the rating may be a
3 little less. But there are questionnaires.
4 We've actually used them that look at screen time
5 and different components of that. So I think,
6 you know, food frequency questionnaires can also
7 capture time duration. They're just different
8 questions.

9 So maybe we just need to think about
10 whether -- you know, right now, we just have food
11 frequency questionnaires included. But you're
12 suggesting that we, you know, maybe call them
13 something a little bit different if it's an
14 eating occasion questionnaire or something like
15 that. I know breakfast skipping questionnaires -
16 - I guess we would need to define what a food
17 frequency questionnaire is. And so we have that
18 generally, but what we think, I think as
19 nutritionists or dietitians, a food frequency
20 questionnaire might be different than some of
21 these other ones and they're just eating
22 questionnaires. And so I think maybe we need to

1 include that as well.

2 MEMBER BAILEY: Okay, thanks for that
3 clarity. The way that I understood it originally
4 was that a food frequency questionnaire would be
5 better than the recalls at getting habitual
6 intakes. So that really is helpful in terms of -
7 -

8 MEMBER LEIDY: I'm sorry, yes. The
9 only reason I brought that up is because our
10 first thought is well they wouldn't be included
11 because it's not three days. And then it's well
12 no, food frequency questionnaires, the ones that
13 are generally validated are longer term. But you
14 know, I think if we're rating them, most of us --
15 the reason we included the three day minimum was
16 thinking of dietary recall assessments as the
17 first. But that we didn't want to exclude any
18 studies that have food frequency questionnaires
19 because some of them do get eating occasions.

20 MEMBER BAILEY: Okay.

21 MEMBER LEIDY: So yes, that's the tier
22 that we were thinking of.

1 MEMBER BAILEY: Great. And then just
2 a followup on that same slide. So a study that
3 has fewer than 15 people but a power calculation
4 that they are adequately powered would be
5 included.

6 MEMBER LEIDY: Correct.

7 MEMBER BAILEY: Okay, thank you.

8 MEMBER SABATE: Joan Sabate. I just
9 would like clarification on the number of daily
10 eating occasions. Because this is the exposure
11 for most of the outcomes that you are relating
12 to, and I put that as an example. Based on your
13 definitions, if somebody has a caloric intake of
14 1, 2, or 3 times a day, plus drinks water seven
15 times a day is the total number of eating
16 occasions of ten. Will this number of ten, will
17 be different than somebody that has just ten
18 small meals -- caloric meals a day? And will
19 both be the same number and will be related to
20 the outcomes by this numerical way?

21 MEMBER LEIDY: Go ahead.

22 MEMBER MATTES: Yes, we actually

1 thought about that some. So eating frequency can
2 affect total energy intake multiple ways. One is
3 energy actually contributed by the eating event.
4 The other is by just changing the physiology --
5 the behavior of the individual so that it alters
6 subsequent intake. And so frequent consumption
7 of water may actually have an impact on the
8 energy value in foods selected when there is an
9 energy yielding consumption pattern event. So I
10 think we want to count total in just the
11 frequencies to be able to capture both of those
12 ways frequency impacts intake.

13 MEMBER LEIDY: But I think, you know
14 -- so that's our search strategy. And then once
15 the findings come in, I think we would comment on
16 whether those eating occasions had calories or
17 didn't or even the food form or those aspects.
18 So I don't think -- much like the dietary
19 patterns, I don't think we're going to -- you
20 know, once we see the studies in their totality,
21 you know, we may be able to pair some together.
22 But if there are very specific differences like

1 caloric content, then I think they need to be
2 treated separately.

3 MEMBER SABATE: But I think this
4 should be stated from the beginning. Because one
5 thing is to have the number of frequent
6 occasions. And another one is to -- besides
7 having the number, I mean to compute which ones
8 contribute calories versus which ones do not
9 contribute with calories, which is mainly water.
10 Because it's a completely different approach,
11 especially in the context of intermittent fasting
12 and things of this sort. I'm not saying that
13 what you are saying isn't relevant, but it may
14 get the confusion between the two approaches that
15 I'm proposing.

16 MEMBER MATTES: So let me ask a
17 question. Would it change your interpretation if
18 multiple ingestive events were primarily water
19 versus a low calorie beverage?

20 MEMBER SABATE: I think so --
21 definitely so.

22 MEMBER MATTES: So you think water is

1 a unique source of input? I mean what we're
2 trying to capture is something about frequency,
3 not source of nutrients, energy, or whatever.
4 It's a behavior of how often something is
5 ingested.

6 MEMBER SABATE: I think this is an
7 important question. I'm not saying what you're
8 proposing is irrelevant. But I'm just saying
9 that there is a big definition between a dietary
10 pattern that includes two or three caloric eating
11 frequencies -- sorry, eating occasions versus
12 having ten occasions in which they are caloric
13 derived. I mean the one that is three plus
14 water, I mean many people -- I mean this is one
15 pattern versus -- I will say we have to separate
16 the specific number whether it brings calories
17 into the frequent occasion or not is very
18 relevant.

19 MEMBER LEIDY: Except that our
20 fundamental research -- the fundamental question
21 of interest is really -- and that's why I put it
22 back up -- it's the number of eating occasions

1 and the timing. The caloric content isn't --
2 it's not answering that question. We've gone
3 around about with that, it really is a separate
4 question because we're really just seeing about
5 timing, not so much the content within those. We
6 will have that and we'll be able to document that
7 and look at you know, macronutrient content or
8 energy within each of those occasions. But that
9 first global definition is really about when to
10 eat -- when or the number to eat versus the
11 caloric content within those.

12 It's a really good point and we've
13 talked about that. But I think we felt that,
14 that was the truest definition of eating
15 frequency was just based on number and timing.

16 MEMBER MATTES: Yes, and water, we
17 tend to think of it as essential but inert in
18 some ways. And it really isn't. I mean it
19 alters gastric emptying, GI transit time. It may
20 acutely influence appetitive sensations. It has
21 real physiological implications too. And so I
22 think it's artificial to draw a line with that

1 kind of an event.

2 MEMBER LEIDY: But that's a really
3 good point. And that's something that we didn't
4 use as a key confounder. In that, there's a lot
5 of studies that don't capture or quantify water.
6 And there are others that do. So we need to
7 probably go back and be sensitive of that because
8 there are a number of studies that will be ad
9 libitum water consumption throughout the day or
10 that's not even stated in their strategy. And I
11 don't think we actually have that as a key
12 Covariate. And we might want to think about
13 putting that in. Because those studies that
14 focus on water will have it documented. Those
15 that don't, don't. And we're not really -- we're
16 not listing that as something of a point of
17 concern.

18 MEMBER VAN HORN: Linda Van Horn.
19 Just an important point to this discussion
20 relates to children. And we're probably all
21 familiar with the fact that, you know, appetite
22 regulation in children is something that's a

1 great interest in prevention of obesity. And the
2 type, as well as the amount of calories is
3 important evidently. Especially for children
4 whose -- from the literature I've read and I'm
5 sure most of you have -- their ability when
6 they're drinking a sugary beverage, for example,
7 to regulate their caloric intake in subsequent
8 meals is not the same as when they're consuming
9 either water or some other type of food. But the
10 sugar, you know, liquid candy so to speak has a -
11 - doesn't seem to have the same impact in terms
12 of energy intake in subsequent meals, that it
13 does with other foods.

14 So my only point is to recognize that
15 children may have a different, you know, response
16 than adults. And it would be valuable to be able
17 to separate that, if the data exists.

18 MEMBER LEIDY: Well and that's an
19 interesting point too because Rick and I are both
20 also on the Beverage Subcommittee. And so I
21 think that question will also -- that will be
22 more specifically addressed there with beverages.

1 Just a point that there's a lot of cross-talk
2 with some of these. And I guess fortunately,
3 we're on both.

4 VICE CHAIR KLEINMAN: Yes, and I was
5 going to add that food patterns as well -- so
6 beverage food patterns and food frequency all
7 have to integrate the information that's being
8 analyzed. And so I think that gets to the points
9 that you're making, Linda, and others have made.
10 Lydia?

11 MEMBER BAZZANO: Hi, Lydia Bazzano.
12 I just wanted to ask about -- the difference
13 between fasting and meal skipping is really the
14 intentionality. So you're capturing that in the
15 confounding or covariates more.

16 MEMBER LEIDY: Yes. And again, that
17 point was really just looking at our search terms
18 and what you typically see fasting not --
19 overnight fasting. It's fasting across the day,
20 trying to target that intermittent fasting. And
21 then there's this other concept of meal skipping.
22 And I think Jamy brought that up. A lot of those

1 can be synonymous, but we want to just separate
2 them basically for the search strategy.

3 VICE CHAIR KLEINMAN: Well if there
4 are no other -- Oh Tim?

5 MEMBER MATTES: Can I just follow up
6 on Rachel's initial comment because I think it
7 was an interesting one about -- about the
8 possibility of a say a monthly cycle and eating
9 frequency. We talked about SES as a covariate.
10 What about something like food insecurity --
11 Would that be better?

12 VICE CHAIR KLEINMAN: We talked about
13 that.

14 MEMBER NOVOTNY: Yes, I know. I was
15 trying to think about how it would be modeled to
16 whether that would be -- you know, I think we're
17 talking about a population -- the population,
18 which I think it is most relevant probably is a
19 food insecure one. But whether we would want to
20 in some way stratify by socioeconomic status too.
21 So I guess to be -- I would be inclusive in the
22 pole. So maybe include as possible confounders,

1 but consider possibly using a covariate -- one of
2 them as a covariate -- probably the food security
3 one.

4 VICE CHAIR KLEINMAN: I think we think
5 of those as an effect modifier potentially and so
6 it would be a covariate. And I think it's a very
7 good idea to include it.

8 MEMBER LEIDY: Yes, it's a good thing
9 to add as well.

10 VICE CHAIR KLEINMAN: Tim?

11 MEMBER NAIMI: I just wanted to return
12 to this theme one more time -- this issue about
13 mediators versus confounders. And this very
14 important issue about whether we consider total
15 energy intake as a mediator or confounder or
16 both. And my hope is that you present both. So
17 you have for example, total energy intake and
18 anthropometry as mostly kind of pitched as
19 confounders. And I understand that if you want
20 to isolate out the effects of frequency, then
21 that's appropriate.

22 But I would say for the public -- and

1 I think this is where we should consider what the
2 public -- if God forbid I was interested in
3 losing weight, I would want to know does fasting
4 help me lose weight? And then to me, it would be
5 a secondary question as to whether it's because
6 of reduced overall caloric intake because you
7 have fewer eating occasions or because of its
8 impact on metabolism.

9 So I think it would be nice to report
10 both of those things. But to consider like what
11 would the public find potentially most
12 interesting?

13 And then my other quick question was
14 again, to come back to alcohol. Is it part of
15 total energy intake? And even if it is, you
16 might want to control for patterning, which has,
17 you know, bodily impacts on cardiovascular
18 disease or diabetes. So that's not listed as a
19 confounder or potential confounder anywhere. So
20 just something to consider.

21 VICE CHAIR KLEINMAN: All right, are
22 there other questions or comments? Then I think

1 it may be getting close to time for an ingestive
2 event. So we will adjourn until 1 o'clock. And
3 that's it. Thank you all. Wonderful
4 presentations.

5 (Whereupon, the above-entitled matter
6 went off the record at 11:40 a.m. and resumed at
7 1:02 p.m.)

8 CHAIR SCHNEEMAN: So, I think we'll
9 get started again. Hopefully, everyone had an
10 enjoyable lunch. And we're going to continue
11 with our subcommittee reports. I'm going to turn
12 it back over to Dr. Kleinman.

13 VICE CHAIR KLEINMAN: Terrific. So,
14 our next report comes from the Pregnancy and
15 Lactation -- wait? Oh, yeah.

16 CHAIR SCHNEEMAN: I forgot one public
17 service announcement. Please be sure you speak
18 into the microphone, speak loudly, and say your
19 name before you start your comments. So, just to
20 help to make sure that we keep everything open.
21 Great. Sorry.

22 VICE CHAIR KLEINMAN: So, Ron

1 Kleinman. And the next report is going to come
2 from the Pregnancy and Lactation Subcommittee.
3 And Dr. Sharon Donovan is going to give us that
4 report.

5 MEMBER DONOVAN: Thank you, and good
6 afternoon. And I'm Sharon Donovan and I'm
7 presenting on behalf of the committee members
8 that you can see on this slide. Oh, I need the
9 advancer.

10 Okay, so the Pregnancy and Lactation
11 Subcommittee has three main topic areas. And the
12 first we're going to discuss is dietary patterns
13 during pregnancy and lactation.

14 And within this topic area, we will be
15 conducting five new systematic reviews, which are
16 shown on the left side of the screen. And the
17 two that are in blue will be the ones that we're
18 going to be discussing today.

19 We also have four existing reviews
20 that were done as part of the Pregnancy and Birth
21 to 24 Months project that many of you may have
22 seen. They were just recently published in AJCN.

1 For those who will be updating them,
2 because the last date that they were searched was
3 January 2017, so we'll be updating those
4 searches.

5 So, we began by focusing on the new
6 reviews. And then, as I mentioned today, we'll
7 do gestational weight gain and postpartum weight
8 loss.

9 So, the second two areas, two
10 questions, are second dietary supplements and
11 fortified foods, which, you can see the
12 dietary -- the nutrients that we'll be focusing
13 on, are folic acid, iron, B12, omega-3 fatty
14 acids, Vitamin D, and iodine.

15 And the committee decided to start
16 with folic acid and iron. So, those are the ones
17 we'll be presenting today.

18 For each of these nutrients there are
19 five health outcomes, which you can see on the
20 right side.

21 So, basically, these are up to 30
22 systematic reviews that we'll look at the effects

1 of supplements and fortified foods.

2 The final question relates to maternal
3 diet and food allergies, and atopic, allergic
4 diseases. And we have not started on that one
5 yet.

6 So, jumping right into dietary
7 patterns, so the two questions that we have is,
8 What is the relationship between dietary patterns
9 consumed during pregnancy and gestational weight
10 gain, and dietary patterns during lactation and
11 postpartum weight loss? And so we'll be
12 conducting new systematic reviews.

13 So, just to remind you, we're using
14 the standard definition of dietary patterns that
15 was presented earlier.

16 So, this is our first analytical
17 framework. So, I'll set this up for you. So,
18 this is looking at dietary patterns during
19 pregnancy and gestational weight gain.

20 So, the intervention and exposures and
21 the comparators, again, are consistent with how
22 Dietary Patterns subcommittee defines dietary

1 patterns.

2 So, we're looking at -- the key
3 confounders are shown below. And for all of the
4 ones that are in black, these are going to be
5 consistent for all of the dietary pattern
6 questions. And the ones that we've shown in blue
7 are specific to the outcome that we're
8 investigating.

9 So, as you can see, for this one,
10 which was related to pregnancy and gestational
11 weight gain, we have age, race, ethnicity,
12 socioeconomic status, physical activities,
13 smoking, parity, and anthropometry, which, in
14 this case, is pre-pregnancy BMI.

15 So then, the one specific for this are
16 history and diagnosis of gestational diabetes,
17 and gestational hypertension. So, from now on
18 I'm not going to repeat the ones that are in
19 black.

20 So, I think it was mentioned earlier,
21 the main outcomes for gestational weight gain
22 will be that change in maternal body weight from

1 baseline, either pre-pregnancy or early in
2 gestation, we'll be keeping track of that, and
3 either right at delivery or near delivery.

4 And then we'll be comparing that
5 weight gain in relation to recommendations based
6 on pre-pregnancy BMI.

7 So, again, our population, as women
8 during pregnancy, they're healthy, or at risk for
9 chronic disease.

10 So, the second analytical framework,
11 looking at dietary patterns consumed during
12 lactation, and postpartum weight loss.

13 Again, what's different about this one
14 is we will be focusing in just on women during
15 lactation. So, if women aren't lactating, then
16 their dietary patterns will be evaluated by the
17 Dietary Patterns Subcommittee.

18 So, we're looking now at change in
19 weight from baseline postpartum, so close to
20 delivery, we'll be recording that, and then
21 whatever the later time point postpartum.

22 So, again, we understand the papers to

1 be quite variable, but we'll be keeping track of
2 that.

3 And then we'll look at postpartum
4 weight retention if gestational weight gain has
5 been accounted for.

6 So, again, the only new confounder for
7 this will be breastfeeding. And what we mean by
8 breastfeeding is not only whether or not -- well,
9 obviously, this is lactation, so they will be
10 breastfeeding.

11 But we'll be looking at are they
12 exclusively breastfeeding, or are they mixed
13 feeding. So, combining breast milk and infant
14 formula. Okay.

15 So, our standard inclusion and
16 exclusion criteria are, we're using the standard
17 NESR criteria. And then, in terms of dietary
18 patterns, we're using the ones that have been
19 established for dietary patterns.

20 So, inclusion and exclusion
21 criteria -- again, either women during pregnancy
22 or women during lactation, only human studies.

1 And for temporality, we're looking
2 studies that assess outcome -- exposure prior to
3 outcome, and excluding those that assess outcome
4 prior to exposure. So, that's to control for
5 reverse causality.

6 Also, I should point out -- and this
7 is something that we're doing in a number -- is
8 that we're excluding studies in the case of
9 pregnancy, where they might have singleton and
10 multiple births, but they've combined that data.

11 So, they can have singleton or
12 multiple, but they have to have presented that
13 separately.

14 The same thing for postpartum. If
15 they have combined data for lactating and non-
16 lactating women together, then we're going to be
17 excluding those.

18 If there's a paper that has both and
19 they're reported separately, we'll include it,
20 but it's only the pooled data that will be
21 excluded.

22 Okay, so this is exclusion for health

1 status. And again, we've talked quite a bit
2 about this, so we will include studies that
3 enroll some or all mothers classified as
4 underweight or obese during pregnancy. That's
5 the only thing that sort of different there. We
6 will enroll, again, studies for some mothers
7 maybe diagnosed with a disease which could
8 include obesity.

9 So, we will exclude studies that
10 exclusively enroll women who give birth pre-term,
11 or they exclusively enroll women diagnosed with
12 either severe undernutrition or hospitalized with
13 an illness or injury.

14 So, we're really looking at healthy
15 populations, or those at risk for chronic
16 disease.

17 Okay, so now, switching to the next
18 set of questions, which is the relationship
19 between nutrients from supplements and/or
20 fortified foods consumed before, during pregnancy
21 and lactation, and a specific health outcome.

22 So, we're really focusing again on

1 these nutrients, not necessarily in the foods,
2 but unless they're fortified foods or
3 supplements. And again, the first two nutrients
4 we chose to focus on were folic acid and iron.

5 So, in terms of key definitions, this
6 is the definition for dietary supplements. It is
7 basically the definition from the Office of
8 Dietary Supplements.

9 But you can see that this does include
10 not only nutrients, but potentially other dietary
11 ingredients. But again, we will be focusing on
12 the key nutrients, the six key nutrients that we
13 were assigned.

14 And then, in terms of fortification,
15 again, we're using the FDA definition of
16 fortification, which was also used in the 2015
17 Dietary Guidelines, so again, trying to use
18 standardized, accepted definitions for
19 supplementation and fortification.

20 So, starting with our first question,
21 so this is the relationship between folic acid
22 from supplements and fortified foods. And in

1 this case we're looking at before, during
2 pregnancy and lactation, and all five outcomes.

3 So, again, I'll just set up this
4 analytical framework. Again, we're looking at
5 exposure to folic acid from dietary supplements,
6 which can be a single supplement or multiple, and
7 fortified foods, or a combination of supplements
8 and fortified foods. And then we'll be -- we
9 have comparators basically focusing on different
10 levels of folate.

11 So, in this case, we're looking at --
12 we've just decided for the before-pregnancy
13 exposure. In all cases, we're looking at six
14 months pre-pregnancy. So, we've set that as our
15 time frame, and then during pregnancy and/or
16 lactation.

17 So, in terms of the markers of folate
18 status, we have folate, Vitamin B12, hemoglobin,
19 mean corpuscular volume, and red blood cell
20 distribution width.

21 We chose not to include homocysteine,
22 because it's not a specific bio-marker for folate

1 status.

2 So, the key confounders are shown at
3 the bottom, and these will be used for all the
4 folic acid questions, with the addition of some
5 additional ones for certain outcomes.

6 So, this is looking at folic acid
7 before and during pregnancy on gestational
8 diabetes. Again, the intervention and
9 comparators are the same.

10 For the key confounders, we have added
11 in blue family history of diabetes or pre-
12 diabetes.

13 We have the intermediate outcomes.
14 This was discussed previously, so I guess based
15 on what we're deciding with diabetes in terms of
16 hemoglobin, A1C, or whether that will be
17 considered an intermediate, as well as an
18 outcome. So, we need to be consistent there.

19 But really, what we've tried to do for
20 our specific pregnancy and lactation outcomes is
21 mirror the criteria that are being used in other
22 outcomes, so that we're trying to be as

1 consistent as possible.

2 So, the next is basically looking at
3 folic acid from supplements and fortified foods
4 on hypertensive disorders of pregnancy. So, same
5 intervention comparator.

6 Our intermediate outcomes are blood
7 pressure and proteinuria, and the health
8 outcomes, these hypertensive disorders of
9 pregnancy, were used in the criteria established
10 by the American College of Obstetrics and
11 Gynecology, which were recently updated in 2019.
12 So, we're looking at eclampsia, pre-eclampsia,
13 and gestational hypertension.

14 The key confounders. The only
15 addition here is diagnosis of gestational
16 diabetes, because there's some reports that --
17 between gestational diabetes and hypertensive
18 disorders during pregnancy.

19 The next is looking at human milk
20 composition. And the original question was human
21 milk composition and quantity.

22 And basically, the committee felt as

1 we discussed this, that there isn't really good
2 evidence for any of these micronutrients
3 impacting the quantity of human milk, so we're
4 basically focusing on human milk composition.

5 So, very simple outcome, we're
6 basically just looking at folate in human milk.
7 And basically the same intervention comparators,
8 and no new key confounders for this outcome.

9 And then our last outcome for folic
10 acid is basically looking at developmental
11 milestones, including neurocognitive development.
12 So, this is a little bit different because we're
13 actually not focusing as much on the mother.
14 We're focusing on the child.

15 And basically our -- I'm sorry. It
16 helps to advance the slide.

17 The developmental outcomes are similar
18 to what had been previously reported. We don't
19 have things like Alzheimer's, or some of the
20 longer-term outcomes. But we do include anxiety,
21 depression, autism, ADHD.

22 And because we know if we stayed

1 within the B-24, that there would be very few of
2 these measures that would be valid, other than
3 developmental milestones.

4 We've actually considered both infants
5 and toddlers, and even children and adolescents.
6 So, we will be trying to expand that to be able
7 to capture more of these neurocognitive,
8 neurodevelopmental outcomes.

9 So, in terms of key confounders, we
10 have added child sex, gestational age at
11 delivery, and breastfeeding.

12 So, in this case, whether or not the
13 child was breastfeeding, and also the duration
14 exclusivity. So really, we're kind of calling
15 this breastfeeding practices.

16 Okay, so overall, exclusion and
17 inclusion criteria, we're basically using the
18 standard criteria that Dr. Schneeman presented
19 this morning.

20 The types of studies. Again, we had
21 some discussion about this. Due in large part to
22 the fortification of the food supply with folate,

1 so we wanted to extend the searches back farther,
2 back to 1980, rather than 2000.

3 And we also decided to include some
4 cross-sectional studies, and then controlled
5 before and after, so these could be studies that
6 perhaps looked at human milk folate before the
7 fortification of the food supply and after, but
8 also, we felt in this case there would be very
9 few longitudinal studies on human milk
10 composition.

11 So, we feel that cross-sectional
12 studies in folate intake are appropriate. So,
13 those are the only two differences there.

14 So, again, inclusion criteria, human
15 participants only. There really isn't anything
16 that's that different in terms of the inclusion
17 criterial.

18 We will use studies, we will include
19 mothers with obesity, being at risk of chronic
20 disease, and we'll include studies where some of
21 the children or the mothers may have gestational
22 diabetes, hypertension, but exclude ones where

1 they're only diagnosed with those, and also
2 excluding pre-term infants.

3 Okay, so I feel like I'm moving
4 through this pretty quickly.

5 So, the next nutrient that we looked
6 at was iron. And so this, again, will be very
7 similar to folic acid, in terms of the
8 intervention and exposure.

9 And we had a long discussion about
10 this, but we actually decided to include only
11 iron from supplements, and not from fortified
12 foods.

13 And the thinking is that in high and
14 very high-income countries, iron is more likely
15 to come from supplements, rather than fortified
16 foods.

17 So, if you have comments, you can make
18 comments on that. But that was -- Kay Dewey was
19 one of the proponents of that.

20 Also, in terms of iron, we decided not
21 to look at human milk composition because all of
22 the minerals are tightly regulated at the level

1 of the mammary gland and there's a lot of
2 evidence that shows that iron supplementation has
3 no impact on human milk iron content.

4 So, for iron we only have four
5 outcomes and we're not including a systematic
6 review on iron from supplements and fortified
7 foods and milk iron.

8 So, again, these are going to be very
9 similar to the folate. This is looking at iron
10 consumed before and during pregnancy and
11 lactation, and micronutrient status.

12 So, basically, same intervention and
13 exposures. It's just in this case we're looking
14 at iron only from supplements.

15 The outcomes will be iron status,
16 which will basically encompass however that was
17 reported in the manuscripts, so we didn't want to
18 list all of the options. They had diagnoses of
19 iron deficiency, iron deficiency anemia, and
20 anemia.

21 The population -- again, women during
22 pregnancy and lactation -- and we will be looking

1 at iron supplementation up to six months prior to
2 conception.

3 So, for all of the iron outcomes, the
4 only new key confounder that's consistent for all
5 of them is now baseline hemoglobin.

6 So, we then -- the next analytical
7 framework is iron on gestational diabetes. So,
8 again, the intermediate outcomes and endpoint
9 outcomes will be the same as folic acid in
10 gestational diabetes. The only new key
11 confounders that we've added here is now family
12 history of diabetes and pre-diabetes, as well as
13 baseline hemoglobin.

14 So, the next is, again, iron and
15 hypertensive disorders during pregnancy. Again,
16 same intermediate outcomes and health outcomes.
17 And the new key confounder in this case is
18 diagnosis of gestational diabetes. And then the
19 last one for this is looking at neurocognitive
20 development and the outcome.

21 So, again, very similar to folate in
22 terms of the outcomes, expanding the population

1 up to 18 years of age in the offspring, and now,
2 in addition to hemoglobin, bringing in child sex,
3 gestational age of delivery, and breastfeeding.

4 So, for the iron and dietary
5 supplements, again, the standard criteria are
6 used for the overall NESR, as well as for folic
7 acid and health outcomes.

8 So, basically, the next steps, after
9 incorporating any additional comments we receive
10 at this meeting, is to go to our next set of
11 dietary patterns questions.

12 So, we've done the two on gestational
13 weight gain and postpartum weight retention. The
14 next are human milk composition and quantity,
15 developmental milestones, and micronutrient
16 status. And then we will start on the next set
17 of analytical frameworks for dietary supplements
18 and fortified foods.

19 So, we haven't necessarily decided yet
20 on the order, but the next are B12, omega-3 fatty
21 acids, Vitamin D, and iodine. And then, for
22 each of those four, we will likely be looking at

1 all five outcomes.

2 So, it's another 20 potential
3 systematic reviews. So, we have a lot of work
4 ahead of us.

5 So, I just would like to acknowledge
6 our committee members and our support staff, and
7 I would like everyone else to really say how
8 wonderful the support staff is and how hard
9 they're working.

10 And we have our weekly phone calls and
11 they're always prepared and very helpful when we
12 have questions. So, that's all we have.

13 VICE CHAIR KLEINMAN: Thank you very
14 much. We're open for questions or comments.
15 Linda?

16 MEMBER VAN HORN: Linda Van Horn.
17 First of all, I just want to congratulate your
18 group. That was a tremendous amount of work just
19 to get it organized. This is a topic area that
20 is so in need of this kind of scrutiny, and I
21 think you made a terrific start, as far as going
22 ahead with it.

1 Three things -- bear with me -- stuck
2 out to me as you were going through your list,
3 and I can see at the end you included one of
4 them, which was unsaturated fatty acids, and
5 three especially, related to neurocognitive
6 development, and possibly other aspects related
7 to even gestational diabetes, or things of that
8 sort.

9 CHAIR SCHNEEMAN: Linda?

10 MEMBER VAN HORN: Oh, sorry. Still
11 having trouble? Sorry. Okay.

12 And so, but two other things seem
13 important to me. One, the idea of only focusing
14 on supplemental iron to me, even in the developed
15 countries, seems potentially problematic.

16 Why? Because we have many women who
17 are attempting, at least, to become vegetarians
18 or semi-vegetarians, or what have you. And not
19 only that, we also have women who forego the
20 supplement, the dietary supplement, that's
21 recommended, because, frankly, they don't want to
22 be constipated.

1 And so, you know, at least in the work
2 that we've been doing over the last six years,
3 we've noticed that this is a trend, at least in
4 an industrialized country, with people who are
5 educated, but just basically don't take those
6 factors into consideration, in terms of a
7 recommended supplement.

8 So -- and especially since our food
9 supply now is so heavily fortified with iron in
10 various foods, it would just seem to me
11 unfortunate not to be able to really look at,
12 with or without supplemental iron, the impact on
13 your outcome.

14 So, I know that's a lot more work
15 maybe. But if it's possible, it would seem
16 relevant to be able to incorporate that if it is
17 possible.

18 And then the third thing -- sorry, one
19 more last thing, and that relates to gestational
20 hypertension and the concerns that, of course, we
21 have with preeclampsia and eclampsia, and
22 gestational diabetes, as well as hypertension,

1 the topic we raised earlier about sodium, and
2 also calcium.

3 If you think about it, the DASH
4 diet -- I mean, wouldn't we want all pregnant
5 women to follow something like a DASH diet to
6 reduce their risk for hypertension, as well as
7 obesity or excessive gestational weight gain.

8 So, as this set of guidelines will be
9 the launch for recommendations related to diet in
10 pregnancy, as well as those first two years, I
11 just think if it's possible to be able to look at
12 some of those factors that could in fact be
13 influencing the common problems with pregnancy
14 related to gestational hypertension and diabetes,
15 wouldn't we want to have a better sense of the
16 diet, the dietary pattern, that could help reduce
17 those risks. So -- sorry, that was my --

18 MEMBER DONOVAN: No. I mean, those
19 were all --

20 MEMBER VAN HORN: And others may
21 disagree.

22 MEMBER DONOVAN: No, they were good

1 points. And I think in terms of the supplemental
2 iron and fortified -- iron from fortified foods,
3 that was one of the original questions that we
4 got.

5 So, I think we could consider changing
6 the search terms so we could get both of those,
7 and then be able to compare that.

8 The omega-3s. Again, with the omega-
9 3s, we will be looking at all five outcomes with
10 that.

11 The last one I think is interesting,
12 because we don't have a question related to
13 dietary patterns in gestational -- well, but
14 actually, let me correct that.

15 So, that was one of the
16 previous -- let me see. Let me make sure I'm
17 right. Because there were some of those
18 systematic reviews that were done as part of the
19 pregnancy -- so yes, part of the pregnancy and
20 birth.

21 We have gestational diabetes,
22 hypertensive disorders during pregnancy, from

1 gestational age at birth and birth weight related
2 to dietary patterns. So, that's not one of our
3 new ones, but we will update that, so we will get
4 that.

5 VICE CHAIR KLEINMAN: Any other
6 comments or questions?

7 MEMBER BOUSHEY: Okay, I concur. I
8 just want to say, I concur --

9 VICE CHAIR KLEINMAN: Say your name.

10 MEMBER BOUSHEY: Carol Boushey --
11 concurs with Linda's comments -- thank you very
12 much -- so that -- because you said, I don't know
13 if others do. So, I'm letting you know, I do.

14 CHAIR SCHNEEMAN: I wanted to come
15 back on this point of iron and fortified foods.
16 And I'm not sure I fully understood the rationale
17 behind why you might do it, because I think iron
18 is part of the enrichment, so just like folic
19 acid is part of the enrichment. That's why it's
20 in fortified foods. It seems like the same logic
21 would hold for iron.

22 MEMBER DONOVAN: So, any other people

1 on the committee? Because I think I was not on
2 that call where this was discussed. And I
3 actually came back and asked. So, do you
4 remember some of the --

5 (Off-mic comment.)

6 MEMBER DONOVAN: I think it's also
7 perhaps just because during pregnancy in
8 particular, I mean, the iron supplement level is
9 so high.

10 But again, I don't think it's a big
11 deal to just include that in the search terms.
12 It's not a new question. Right?

13 It was part of the original question
14 that we decided as a committee. But I will bring
15 it back and make that decision with the staff.

16 VICE CHAIR KLEINMAN: All right.
17 Either the post-ingested event coma is settling
18 in, or the questions have been asked. Anyway,
19 thank you very much, Sharon. That was a great
20 presentation.

21 So, we'll move on now to birth to
22 24 months. And Dr. Elsie Taveras is going to

1 present that. And she needs the clicker.

2 MEMBER TAVERAS: It's going to do much
3 for the post-prandial. So, bear with me, please.

4 I'm Elsie Taveras. I am presenting
5 for the Birth to 24 Months Subcommittee. Our
6 Chair, Kay Dewey, was not able to be here today,
7 but we have a number of our subcommittee
8 participants, including Sharon and Ron and Lydia.

9 So, I'm going to get started by
10 telling you a little bit about the protocols that
11 we are going to discuss today.

12 We have eight protocols that we've
13 completed, and five additional protocols that are
14 yet to be completed.

15 This slide shows the five topic areas
16 that we're presenting today that relate to
17 feeding human milk and infant formula.

18 So, you'll see that we're looking at
19 duration, frequency and volume of human milk or
20 infant formula, with growth, size and body
21 composition, with micronutrient status, with
22 developmental milestones, with food allergy,

1 atopic allergic diseases, and with long-term
2 health outcomes.

3 And this slide shows the three topic
4 areas that relate to specific nutrients from
5 supplements and fortified foods. We'll be
6 covering four specific nutrients: iron,
7 Vitamin D, Vitamin B12 and omega-3 fatty acids,
8 with three separate outcomes: nutrient status,
9 growth, size and body composition, and bone
10 health.

11 And the five topic areas still to be
12 completed all relate to complementary feeding,
13 with micronutrient status, growth, size and body
14 composition, developmental milestones, food
15 allergy, and bone health.

16 So, let's begin by looking at the
17 protocols we've developed to examine human milk
18 and infant formula topics. And I'll warn you all
19 in advance that these are very complicated, with
20 a number of different comparators. So, bear with
21 me.

22 But also, I want to say ahead of time

1 that all of the protocols are available to the
2 committee, but also to the general audience and
3 on the Web.

4 So, our three human milk/infant
5 formula questions will be answered with new,
6 original, systematic reviews. And the three
7 questions that we will be asking are, what is the
8 relationship between the duration, frequency and
9 volume of exclusive human milk and/or infant
10 formula consumption, with growth, size and body
11 composition?

12 What is the relationship between
13 duration, frequency and volume of human milk
14 and/or infant formula consumption and
15 micronutrient status?

16 And what is the relationship between
17 the duration of exclusive human milk and/or
18 infant formula consumption and developmental
19 milestones, including neurocognitive development?

20 We have also two human milk/infant
21 formula questions that will be answered with
22 updates to existing systematic reviews similar to

1 the pregnancy and lactation reviews.

2 There are existing reviews on the
3 following two questions that we plan to update.
4 And the two questions that will be updated
5 through updating of existing systematic reviews
6 are the relationship between the duration of
7 exclusive human milk and/or infant formula
8 consumption, and food allergies and atopic
9 allergic diseases, and what is the relationship
10 between the duration of exclusive human milk or
11 infant formula consumption, and long-term health
12 outcomes?

13 We'll start, as we have with the other
14 frameworks, with some key definitions.

15 We defined human milk as mother's own
16 milk provided at the breast, or expressed and fed
17 fresh or after refrigeration or freezing, and we
18 will not be examining donor milk.

19 Infant formula is commercially-
20 prepared infant formula, meeting FDA or
21 international food standards.

22 And complementary foods and beverages

1 are foods and/or beverages other than human milk
2 or infant formula, provided to an infant or young
3 child, to provide nutrients and energy.

4 We also have definitions for feeding
5 methods, which you'll see throughout our analytic
6 frameworks.

7 The first is human milk feeding, which
8 is feeding human milk alone, or in combination
9 with infant formula and/or complementary foods or
10 beverages, such as cow's milk.

11 Exclusive human milk feeding, which is
12 feeding human milk alone, and not in combination
13 with infant formula and/or complementary foods or
14 beverages, such as cow's milk. This definition
15 is inclusive of the World Health Organization
16 definitions of exclusive and predominant
17 breastfeeding, which permit limited quantities of
18 drops or syrups containing vitamins, minerals, or
19 medicines, water and water-based drinks, such as
20 sweetened water and teas, fruit juice, oral
21 rehydration salt solutions, and ritual fluids.

22 Our definition for mixed feeding is

1 feeding human milk and infant formula, but not
2 complementary foods and beverages. And our
3 definition for topping up is feeding infant
4 formula after human milk during a single feeding
5 session.

6 So, I'm going to pause a bit. And
7 similar to Carol, I have some animation, because
8 of the complexity of this analytic framework.

9 So, this is our analytic framework for
10 a new systematic review on the relationship of
11 the duration, frequency and volume of human milk
12 and/or infant formula consumption, with growth,
13 size and body composition.

14 In the box on the left, you can see
15 our comparators of interest are divided into two
16 groups -- I think I have several clickers -- the
17 top group being which is in red here, shows three
18 specific comparisons we want to use to examine
19 duration of human milk and/or infant formula
20 consumption.

21 These comparisons align with the first
22 feeding decisions that caregivers have to make.

1 A caregiver's first decision is whether or not to
2 feed human milk, so we will examine comparisons
3 of infants who ever consume human milk -- that
4 is, any amount of human milk -- with infants who
5 never consume human milk -- that is, completely
6 or entirely formula-fed infants.

7 Among infants who are fed human milk,
8 subsequent decisions caregivers have to make are
9 how long to feed human milk at all, and how long
10 to feed it exclusively.

11 And therefore, the second comparison
12 that we are going to make is the comparison of
13 different durations of any human milk consumption
14 among infants who are human milk-fed, and
15 consumption and comparison of different durations
16 of exclusive human milk consumption prior to the
17 introduction of infant formula. That's a
18 mouthful.

19 But essentially, our top group looks
20 at duration. And our bottom grouping then looks
21 at three specific exposures and comparators,
22 examining frequency and volume of human milk

1 and/or infant formula consumption.

2 So here, we want to examine
3 comparisons. First, comparisons of different
4 intensities or proportions or amounts of human
5 milk consumed by mixed-fed infants.

6 Next, we want to examine comparisons
7 of different intensities or proportions or
8 amounts of human milk consumed at the breast
9 versus by bottle in infants fed human milk as
10 their only source of milk.

11 And third, we want to examine
12 comparisons of consuming human milk or infant
13 formula, with consuming both human milk and
14 infant formula, during a single feeding session.
15 For example, topping up a human milk feeding with
16 infant formula.

17 We will examine all of these
18 comparisons in healthy infants and toddlers. Our
19 outcomes, as I mentioned earlier, is growth, size
20 and body composition outcomes that relate to
21 human milk and infant formula comparisons, and
22 they represent a range of outcomes that we will

1 look at and examine throughout the life span.

2 And finally, on this slide, very tiny
3 at the bottom there are key confounders that
4 we've identified, and some of these are similar
5 throughout all of our slides: race/ethnicity,
6 socioeconomic status, types and amounts of
7 complementary foods and beverages and infant
8 formula, childhood diet, birth weight, fetal
9 growth, smoking, mode of delivery, and maternal
10 body mass index.

11 Our next analytic framework is similar
12 in the examination of our interventions and
13 exposures, duration, frequency and volume, but
14 looks at outcomes of micronutrient status.

15 Here, you'll observe that our
16 comparisons of interest are divided into the same
17 two groups as I showed in the previous slide for
18 growth, size and body composition.

19 The bottom grouping is a little bit
20 smaller than it was on the previous slide. We
21 retained the comparison of different intensities
22 or proportions or amounts of human milk consumed

1 by mixed-fed infants.

2 However, we decided that the breast
3 versus bottle and the topping up comparisons, are
4 less relevant to examine in relation to the
5 micronutrient status outcomes you see on the
6 current slide.

7 In this case, our outcomes will
8 include micronutrient status in infants and
9 toddlers, specifically, iron, zinc, iodine,
10 Vitamins D and B12, and fatty acids.

11 This next analytic framework is for
12 the new systematic review on the relationship
13 between the duration of exclusive human milk or
14 infant formula consumption, and developmental
15 milestones, including neurocognitive development.

16 Here are comparators and -- sorry, our
17 intervention and exposures and comparators all
18 relate to duration of consumption.

19 Frequency and volume are not part of
20 this question. And therefore, the comparisons of
21 interest here include only the comparisons of
22 ever versus never consuming human milk and/or

1 different durations of any and exclusive human
2 milk feeding.

3 In this slide, you will also notice
4 our outcomes of interest are developmental
5 milestones, including cognitive,
6 language/communication, movement/physical and
7 social-emotional developmental outcomes, as well
8 as a range of other outcomes, including academic
9 performance, attention deficit disorder, anxiety,
10 depression, and autism spectrum disorder.

11 You'll notice also that these outcomes
12 will be examined in infants through adolescence.
13 That's our population for this analytic
14 framework.

15 The next framework examines human milk
16 or infant formula consumption with food allergies
17 and atopic allergic diseases.

18 Similar to the previous slide,
19 frequency and volume are not part of this
20 question, and therefore, the comparisons of
21 interest are identical to the previous slide.

22 The outcomes of interest here are food

1 allergies, allergic rhinitis, and atopic
2 dermatitis, throughout the life span, and asthma,
3 starting at two years of age.

4 And that was intentionally done so
5 that we are really capturing asthma, and not
6 transient, recurrent wheeze that happens prior to
7 the age of two.

8 Finally, this framework is to update
9 an existing systematic review on the relationship
10 between the duration of exclusive human milk
11 and/or infant formula consumption, and long-term
12 health outcomes.

13 Again, you'll observe that frequency
14 and volume are not part of this question. And
15 again, the comparisons of interest are identical
16 to the previous two slides.

17 The outcomes of interest here include
18 a number of intermediate outcomes, including
19 intermediate cardiovascular disease outcomes and
20 intermediate diabetes outcomes, and a number of
21 endpoint health outcomes in both of those
22 categories.

1 Both of these endpoint health outcomes
2 will be examined among children through older
3 adults.

4 For inclusion and exclusion criteria,
5 for of the questions related to human milk or
6 infant formula consumption, we propose using the
7 standard inclusion and exclusion criteria that
8 were described by our committee chair for
9 publication status, language of publication,
10 study participants, and health status of
11 participants.

12 But we have number of ways that we are
13 tailoring the inclusion and exclusion criteria
14 for a few of the categories.

15 First, we propose including literature
16 published from 1980 to the present. This will
17 align with the existing systematic reviews that
18 have already been conducted, with examined the
19 literature back to 1980.

20 Additionally, 1980 was the year that
21 the US Congress passed the Infant Formula Act,
22 which established nutrient requirements for

1 commercial infant formulas in the US, and thus,
2 health effects associated with formula
3 consumption before 1980 might be different.

4 So, that was the reason that we
5 tailored a bit the date of publication.

6 Second, we propose including studies
7 with at least 30 participants per group, or a
8 power analysis indicating that the study was
9 appropriately powered for the outcome of
10 interest, and excluding studies with fewer than
11 30 participants per group with no power analysis.

12 You may have noticed that our age of
13 study participants varies across our analytic
14 frameworks. And we wanted to acknowledge and
15 justify the variability in age and outcome across
16 the reviews.

17 We want to look at studies that
18 examine human milk or infant formula consumption
19 in relation to growth, size, body composition,
20 atopic diseases, and long-term health outcomes,
21 throughout the life span.

22 So, you'll see that for those outcomes

1 we are including -- the age of participants is
2 throughout the life course. However, for asthma,
3 for cardiovascular disease and diabetes outcomes,
4 the age of study participants begins at age two
5 years.

6 That's consistent with the existing
7 systematic reviews on human milk and infant
8 formula. These decisions were also made, as I
9 already mentioned, because an asthma diagnosis
10 under age two may actually represent transient,
11 recurrent wheeze, rather than asthma.

12 In addition, there is some uncertainty
13 regarding whether and how intermediate outcomes,
14 such as blood lipids in infants and toddlers, may
15 relate to subsequent cardio-metabolic risk.

16 We thought it was most important to
17 address whether and how human milk or infant
18 formula consumption may impact child development.
19 And thus, we did not go beyond adolescence.

20 And finally, we thought it was most
21 important to examine nutrient status during the
22 period of infancy and toddlerhood, when human

1 milk and infant formula are being consumed.

2 Finally, we proposed tailoring the
3 standard criterion for country. Our inclusion
4 criteria for our analytic frameworks on infant
5 formula or human milk consumption will include
6 studies conducted in countries ranked as high or
7 very high in human development, and we will
8 exclude studies conducted in countries ranked as
9 medium or lower human development.

10 So, with that I want to switch our
11 focus to look at the protocols we've developed to
12 examine topics related to specific nutrients from
13 supplements and fortified foods.

14 The approach to answer this next set
15 of questions that examines specific nutrients
16 from supplements or fortified foods consumed
17 during -- between birth to 24 months, and
18 multiple health outcomes, will be original,
19 systematic reviews.

20 As noted on this slide, there are four
21 public health nutrients of interest for these
22 questions, which are iron, Vitamin D, Vitamin B12

1 and omega-3 fatty acids.

2 So, four nutrients of interest, three
3 outcomes of interest, which are nutrient status,
4 growth, size and body composition, and bone
5 health, resulting in 12 analytic frameworks.

6 Again, some key definitions. And I
7 won't read these word-for-word. These -- I know,
8 sorry, Gene. I know you really wanted me to read
9 these.

10 These are the key definitions
11 discussed by our subcommittee, that are provided
12 on each analytic framework with this set of
13 questions.

14 The definition for dietary supplements
15 is from the 1994 Dietary Supplement Health and
16 Education Act, is provided here on the slide.
17 And the definition for fortification is as
18 defined by the US Food and Drug Administration,
19 and is also available online.

20 So, we'll start with our first
21 analytic framework examining nutrients, nutrient
22 status. This next set of systematic review

1 questions examine the relationship between a
2 specific nutrient -- in this case, iron -- from
3 supplements and/or fortified foods, again,
4 consumed during infancy and toddlerhood, birth
5 through 24 months, and the specific nutrient
6 status outcomes.

7 The intervention or exposure of
8 interest in this next set of slides that you will
9 see, is consumption of a specific nutrient --
10 again, here I'm showing iron -- from supplements
11 and/or fortified foods or beverages.

12 The comparators for consumption of the
13 nutrient from supplements are, consumption of the
14 specific nutrient at a different dosage or
15 frequency, from supplements, and/or consumption
16 of the nutrient from fortified foods.

17 The population of interest for the
18 intervention/exposure, comparator and outcomes
19 include infants and toddlers, birth to 24 months,
20 who are healthy and/or at risk for chronic
21 diseases.

22 The outcomes discussed by our

1 subcommittee as most relevant for iron
2 consumption include iron status, including iron
3 deficiency and anemia, zinc status and copper
4 status.

5 And here, the key confounders are
6 similar to ones I have shown before, but in this
7 case include feeding practices, anthropometry at
8 birth or baseline, gestational age, prenatal
9 vitamin supplement use, and baseline nutrient
10 status.

11 So, similar to the previous slide,
12 this analytic framework is also examining
13 supplements -- sorry, a nutrient -- in this case,
14 Vitamin D, from supplements and/or fortified
15 foods consumed from birth to 24 months, and in
16 this case, Vitamin D nutrient status as the
17 outcome.

18 Again, our intervention or exposure of
19 interest and comparator is the specific nutrient
20 of interest, which here is Vitamin D.

21 The outcome of interest for this
22 framework is Vitamin D status and anemia. And

1 the same key confounders as the previous slide
2 are shown here, with the exception of the
3 addition of sun exposure for Vitamin D.

4 Similar to the previous two slides of
5 iron and Vitamin D, this slide shows the analytic
6 framework for Vitamin B12 and nutrient status.

7 And again, similar to the previous two
8 slides, the intervention or exposure of interest
9 and comparator relates here to the nutrient of
10 Vitamin B12, the same population of interest as
11 presented on the previous slides.

12 The outcomes for nutrient status
13 include Vitamin B12 and folate status. And the
14 key confounders are all, similar to the previous
15 slides, with the addition here of -- as a key
16 confounder, of maternal vegan diet.

17 And finally, this question examines
18 omega-3 fatty acids from supplements and/or
19 fortified foods, from birth to 24 months, with
20 the exposure or intervention of interest and
21 comparator being omega-3 fatty acids.

22 We are examining the same population

1 of interest as the previous slides. And here,
2 the outcome of interest is fatty acid status.

3 So, next we are -- this is the
4 analytic framework. And this is good. The next
5 series of slides are going to look very similar
6 as the previous four, with the specific nutrient,
7 so iron, Vitamin D, Vitamin B12, and omega-3
8 fatty acids.

9 But the next series of slides look at
10 growth, size and body composition. Again, the
11 slide I'm showing here shows iron and intake of
12 iron from supplements and/or fortified foods.
13 That's the intervention or exposure and
14 comparator.

15 The outcomes here are growth, size and
16 body composition outcomes. And these will be the
17 same for the next series of slides looking at
18 growth, size and body composition as the
19 outcomes.

20 The same population of interest for
21 both intervention exposure and outcome in this
22 slide is similar for the previous sets of

1 questions.

2 And our key confounders here include
3 key confounders that are similar in the previous
4 slides: sex, race/ethnicity, socioeconomic
5 status, parental education, feeding practices,
6 anthropometry at birth or baseline, and
7 gestational age.

8 I'll go fairly quickly through these
9 next slides, because really the only difference
10 in the next three slides is the nutrient of
11 interest.

12 In this case, it's Vitamin D. In the
13 next analytic framework it's Vitamin B12, and in
14 the next framework it's omega-3 fatty acids. In
15 all of those slides, the outcome is the same --
16 growth, size and body composition.

17 And finally, the next four slides, all
18 similar to the previous eight, look at a specific
19 nutrient, but now shifting the outcome to bone
20 health.

21 And I'll pause for a minute to define
22 our outcomes -- our bone health outcomes. Here,

1 the outcomes include bone mass, bone mineral
2 density, bone mineral content, biomarkers of bone
3 metabolism, rickets and fractures.

4 And so, what you'll see in the next
5 series of slides, this one shows the specific
6 nutrient of interest is iron. And the next
7 series of slides will show the specific nutrient
8 with the same bone health outcomes and the same
9 key confounders.

10 So, for example, this next slide shows
11 Vitamin D as the specific nutrient of interest
12 from supplements and/or fortified foods, and the
13 outcome, again, in this slide, is bone health.

14 In this slide, the specific nutrient
15 of interest is Vitamin D, and the outcomes are
16 the same. Sorry, that was supposed to be
17 Vitamin B12. And the outcomes are the same, the
18 bone health outcomes.

19 And finally, the specific nutrient of
20 interest in this final slide is omega-3 fatty
21 acids, with the same bone health outcomes as the
22 previous slides.

1 Our inclusion and exclusion criteria
2 that we propose will be the standard criteria for
3 the criteria, or for the categories shown here on
4 this slide. But in the upcoming slides, I'll
5 illustrate, again, where we are tailoring the
6 inclusion and exclusion criteria for this set of
7 questions.

8 So, first, the criteria shown here for
9 the intervention/exposures correspond to what was
10 illustrated on all of the analytic frameworks.
11 Specifically, for inclusion criteria, we will
12 include studies that specify the dosage amount
13 and fortification level received of each of the
14 specific nutrients.

15 We'll also include studies that
16 examine animal products that contained added
17 nutrients as a result of feeding the animal a
18 specialized diet.

19 Follow-up formula will be considered
20 as a fortified food or beverage. The
21 subcommittee discussed the interest in examining
22 evidence of follow-up formula, but recognized the

1 lack of an accepted definition, and potential
2 overlap with infant formula.

3 There are no name or claim
4 requirements for toddler milks, and there's a
5 wide variation and statement of identity for what
6 a follow-on formula is.

7 For exclusion criteria, studies that
8 do not specify the dosage amount or fortification
9 level received or the specific nutrient, will be
10 excluded, as well as studies that vary nutrients
11 other than the nutrient of interest, without
12 controlling for that variation.

13 We also propose tailoring, similar to
14 the previous set of analytic frameworks, the age
15 of study participants, for bone health outcomes
16 the age will include only children and
17 adolescents ages two to 12 years.

18 We also are proposing to tailor the
19 sources of foods, beverages or nutrients. For
20 the sources of these we -- given the age of
21 intervention and exposure, and that it is birth
22 to 24 months, we will consider studies in which

1 infant formula is examined, as long as it meets
2 the FDA or international standards.

3 Our next steps are to implement the
4 protocols that we discussed today, eight in
5 total, followed by developing the remaining
6 protocols, which all relate to complementary
7 feeding.

8 We also plan to meet with the Data
9 Analysis and Food Pattern Modeling, Cross-cutting
10 Working Group, to discuss assessing food group
11 and nutrient intakes among children birth to
12 24 months.

13 I want to acknowledge our subcommittee
14 members and the overwhelming amount of work and
15 support that we get from the USDA staff. It's
16 been an incredible amount of work, as Sharon
17 mentioned, developing these protocols, and many
18 more to come.

19 And it wouldn't be possible without
20 all the help that we get from the staff, so thank
21 you.

22 VICE CHAIR KLEINMAN: Thank you very

1 much, Elsie. We're open for questions and
2 comments. This is a new topic and a lot of work
3 has been done by the Birth to 24 Committee
4 working on it before we got to it. But a lot of
5 work continues. Questions? Comments? Rachel?

6 MEMBER NOVOTNY: Thank you. That was
7 really great to see how much you've broken down
8 the human milk piece. I appreciate that.

9 I have a question and it's part
10 relating back to our earlier conversations. And
11 I think I understand at least somewhat your
12 rationale for the definitions of complementary
13 feeding and exclusive breastfeeding. But I'm
14 thinking specifically again about water.

15 And I know that typically we have
16 thought of complementary feeding as beginning to
17 add new foods and often around complexity of
18 nutrients. But also, different types of ways of
19 eating.

20 And so, I'm thinking again about the
21 definition of complementary foods is to provide
22 nutrients and energy. So, presumably, water is

1 not a complementary food. And then, the
2 predominant feeding would include water in your
3 definition of exclusive breastfeeding.

4 So, I guess I would like to be able to
5 pull away the predominant feeding from the
6 exclusive breastfeeding, not necessarily for all
7 analyses, but perhaps for some that have to do
8 with eating patterns around when things besides
9 the breast have been introduced, or the human
10 milk have been introduced.

11 And then, similarly on the
12 complementary foods, I wonder if we want water as
13 a pattern, or as a food, to be able to be
14 identified.

15 So, I'm not positive of the answer,
16 but I think it's an inconsistency that will
17 evolve with our other approaches. And I think
18 this first has to hang together as a B24
19 question.

20 But I think even as a B24 question,
21 there might be some reasons to be able to pull
22 those things out to keep it together or apart.

1 MEMBER TAVERAS: But you're right,
2 Rachel, that the definition of complementary
3 foods and beverages does not include water.

4 And that also is consistent with the
5 World Health Organization definition, that allows
6 water in the definition of predominant
7 breastfeeding and exclusive breast milk feeding.

8 But is your question about whether --
9 I don't think your question is whether water
10 should be. It's how water is --

11 MEMBER NOVOTNY: Whether it could be
12 identified --

13 MEMBER TAVERAS: It could be
14 identified.

15 MEMBER NOVOTNY: -- in that setting,
16 so that it could be pulled out. And I think
17 there was a time when we were more strict with
18 exclusive breastfeeding.

19 And for some of our questions about
20 habits around food and drink, it might be --
21 useful to be able to pull it apart and similarly
22 with the complementary.

1 MEMBER TAVERAS: It's a good point I
2 will - it will depend on how much it's being
3 reported. I think it was a good point even in
4 the adult studies, about the lack of studies
5 actually saying how much water is consumed.

6 And I suspect that we might run into
7 the same issue in the Birth to 24 Month group.

8 VICE CHAIR KLEINMAN: I mean, I think
9 until the WHO did come up with that broader
10 definition of exclusive breastfeeding, water was
11 not included, nor was anything else.

12 But then, along came a couple of
13 things. One, recommendations to supplement with
14 Vitamin D and iron in the exclusively breastfed
15 infant, and a struggle to help families
16 understand how you call something exclusive, but
17 yet you supplement.

18 And then, I think the other
19 consideration is hydration at that age and how
20 you ensure adequate hydration, which can, by and
21 large, be assured through exclusive
22 breastfeeding, but occasionally requires water,

1 particularly during the first few weeks
2 postpartum, when bilirubin metabolism is an
3 issue.

4 So, there's nothing very clean about
5 this, and it does pose some challenges to us.
6 And I suppose we -- I mean, we can ask the
7 question whether water intake can be identified.
8 But I don't think we're going to get a clean set
9 of outcomes based on information about water
10 intake.

11 Juice and other things, that -- and
12 teas, I think that's where you get into
13 predominant. And that makes it even more
14 challenging for us. And I suspect many of us
15 would just as soon consider that complementary
16 feeding.

17 But in an effort to be consistent with
18 worldwide recommendations and common practices,
19 that's why it's lumped together.

20 So, I don't think I'm shedding any
21 light on this, but I'm just trying to say why
22 it's more --

1 MEMBER NOVOTNY: But maybe we can just
2 code whether it's exclusive or predominant if
3 it's identified. And that would give the
4 potential to do an exclusive analysis.

5 VICE CHAIR KLEINMAN: Yeah. Thank
6 you.

7 CHAIR SCHNEEMAN: This is Barbara
8 Schneeman. I'm wondering if we also want to ask
9 the staff about pulling out that kind of
10 information.

11 It sounds like you're coming to the
12 fact that it needs to be data that's collected if
13 it's available --

14 MEMBER TAVERAS: If it's available.

15 CHAIR SCHNEEMAN: Yeah. And so, I
16 don't know if the staff wants to comment on that.

17 MS. GUNGOR: Sure. This is Darcy
18 Gungor. And this definition came about actually
19 during the Pregnancy and Birth to 24 Months
20 project and sort of has been carried over into
21 this one.

22 And I think there was just an

1 acknowledgment among experts of that team, and
2 now of this team, that there are sometimes not
3 great definitions and great parameters and
4 descriptions of what is fed to infants.

5 And so, I think the intention was to
6 sort of capture the spectrum of full
7 breastfeeding, both exclusive and predominant,
8 but we absolutely extract as much data and as
9 many definitions as are provided in every
10 research article, in terms of the feeding
11 exposures.

12 And so, if there are clear definitions
13 of predominant versus exclusivity in what's fed
14 and when, all of those data are pulled, and we
15 can certainly present it in that way.

16 CHAIR SCHNEEMAN: And, Darcy,
17 including water? Because I think that was the --

18 MS. GUNGOR: If it's presented, it
19 would be available for you to look at. Yeah.

20 (Off-mic comment.)

21 MEMBER BOUSHEY: Hi. This is Carol
22 Boushey, and that was really -- that was

1 fantastic. There was so much to go through.

2 Looking at weeds here, and it really
3 is, in that first grouping, I guess I had thought
4 that there would be something on parent
5 education.

6 In the second group, parent education
7 is listed in your key confounders, but it isn't
8 in the first group. And so I was curious as to
9 what made these two concepts so different that
10 parent education wouldn't be listed as a
11 confounder?

12 MEMBER TAVERAS: That's a very good
13 question. I don't --

14 MEMBER BOUSHEY: Oh, okay. Well good.
15 Take it back to the group.

16 MEMBER TAVERAS: I'll look to the
17 staff. Was that an omission, maybe?

18 MS. GUNGOR: Is the question whether
19 there is parent education on the framework for
20 growth, size and body composition?

21 MEMBER TAVERAS: As a key confounder.

22 MS. GUNGOR: Yeah, I think that would

1 be picked up as a part of socioeconomic status,
2 perhaps? I think we tended to --

3 MEMBER BOUSHEY: Socioeconomic status
4 is in the other group also. That's why it kind
5 of jumped out at me.

6 MS. GUNGOR: Yeah, that's a great
7 point.

8 MEMBER BOUSHEY: So --

9 MS. GUNGOR: I think that the --

10 MEMBER TAVERAS: Yeah. No, that's a
11 good point.

12 MS. GUNGOR: -- the distinction, when
13 it was put on sort of down the road for the
14 developmental milestones, I think was to make
15 sure that that specific indicator was there as
16 well. But we can certainly bring that back to
17 the team.

18 MEMBER BOUSHEY: And then, this is
19 also minor. The race/ethnicity, when that's
20 listed, is that for the parent, or is that for
21 the child?

22 MEMBER TAVERAS: That's a good

1 question.

2 MEMBER BOUSHEY: Because we do --
3 these are mixed. You know, they're mixed parent
4 and they're mixed child. So, I just wasn't
5 clear.

6 MS. GUNGOR: It's a good question. I
7 think the intention is to extract it for the
8 infant. But I think if it's presented for the
9 level of the parent, I think we would extract
10 that as well.

11 MEMBER BOUSHEY: So, I mean, I just --
12 I mean you can pick what you want. I just want
13 to be clear on that.

14 MEMBER BAILEY: Elsie, again, great
15 job. Lots of information.

16 CHAIR SCHNEEMAN: This is Regan
17 Bailey.

18 MEMBER BAILEY: Sorry, Regan Bailey.
19 Short microphone, tall person. When you have the
20 nutrient status, does that need to be more clear
21 in terms of biomarkers? Are you -- what is
22 status?

1 MEMBER TAVERAS: So, where we expect
2 to have actual biomarkers, we made note of it.
3 So, I can pull them up, but in several of them,
4 particularly for the bone health outcomes, we
5 included biomarkers.

6 But I don't think we -- if there were
7 biomarkers for every single outcome. Is that
8 what you're asking, Regan?

9 MEMBER BAILEY: Yeah, I was just
10 asking for like Vitamin D status. Is that
11 serum 25 hydroxy D? Is that dietary intakes?

12 MEMBER TAVERAS: Yeah. So here we
13 didn't include the exact biomarker. But yes,
14 where available, we plan to include biomarker
15 status as well, as our for-short status,
16 essentially.

17 CHAIR SCHNEEMAN: I guess just to
18 follow up on that question, because I was curious
19 about the same thing, because there's a
20 difference in looking at intake versus looking at
21 status from a clinical biomarker.

22 So, is the aim to look at a

1 biochemical or clinical status marker?

2 MEMBER TAVERAS: Yes, if it's
3 available.

4 CHAIR SCHNEEMAN: Oh, okay. And then,
5 I know you also had fatty acid status. And so, I
6 was interested in knowing what do you think would
7 be included in that?

8 MEMBER TAVERAS: So, that's a good
9 question, because we didn't have a list for the
10 fatty acid outcomes there.

11 MS. ENGLISH: Yeah. This is --

12 MEMBER TAVERAS: And biomarkers.

13 MS. ENGLISH: Yeah. This is Laurel
14 English. I just wanted to add on there that we
15 do have some more specific examples included in
16 the inclusion/exclusion criteria that's posted
17 online in the protocols.

18 But as a typical standard approach, we
19 extract anything that is reported. So, for the
20 example of fatty acid status, we would certainly
21 extract omega-3s, omega-6, omega-9. I think the
22 subcommittee discussed red blood cell membrane.

1 So, if it's reported, we will
2 certainly extract it and it would be available
3 for the evidence that this is.

4 MEMBER DONOVAN: Yeah, this is Sharon
5 Donovan. I recall the same conversation, because
6 these are all so zero to two years of age. So, a
7 lot of the standard markers that we might expect
8 in adults may not be available.

9 So, I think the idea was whatever in
10 the paper that they're reporting as their iron
11 status marker, and then we'll basically pull it
12 all. And then, in the analysis phase we'll need
13 to go through that.

14 But it also talks about like some of
15 the bone markers may not necessarily be validated
16 in this age. So, you know, we -- the issue with
17 this whole area is that the amount of evidence
18 may not be very deep.

19 So, we're trying to cast the net
20 widely, at least at this point, in terms of --
21 but this is really -- status, we were thinking
22 primarily biomarkers, because we're going to be

1 collecting the intake, and then we're looking at
2 the effect on whatever the health outcome is.

3 MEMBER NOVOTNY: Can I just ask a
4 question. And I feel kind of stupid because I'm
5 on the committee, but I can't remember the
6 conversation around when we looked at specific,
7 like omega-3 fatty acids in growth, size and body
8 composition, when we looked at human milk
9 feeding, we looked longer than just B24.

10 But for all of the specific nutrients
11 on growth, size and body composition, we were
12 only talking about birth to 24 months. For bone,
13 we're going farther.

14 But I'm just thinking that some of the
15 aspects on growth may not play out yet in the
16 first two years. So, I think the committee
17 should maybe reconsider for just mainly for
18 those -- the bone and the growth for growing
19 longer.

20 MEMBER TAVERAS: No, I agree. For
21 bone and growth for sure.

22 MEMBER DONOVAN: For bone it's already

1 through 18. But for some reason, for the -- it's
2 there for the human milk but not for the specific
3 nutrients on growth and size and body
4 composition.

5 VICE CHAIR KLEINMAN: Linda.

6 MEMBER VAN HORN: Just quickly. First
7 of all, adding my compliments and accolades to
8 the work that's been done, two quick things. One
9 relates to, I'm so happy to see inclusion of mode
10 of delivery.

11 I think as we're looking at a rapidly
12 escalating interest in the microbiome and
13 understanding the differences, in terms of
14 C-section versus vaginal delivery as it affects
15 the microbiome, it's of interest to consider that
16 aspect, not only -- I think I saw it in one
17 slide, but I didn't see it in the others.

18 And of course, only if it's available.
19 And it may be or may not. So, that was one
20 comment. The other, in the interest of both
21 Vitamin D and also bone health, I was surprised
22 that there was no mention of dietary calcium or

1 sources of calcium.

2 And my concern is related to the large
3 number of moms who really don't understand the
4 difference between dairy milk and plant-based
5 milks, and how different those can be in terms of
6 source and bioavailability of dietary calcium.

7 So, I just, again, it may not be
8 available. But again, with the end in mind, it
9 would be --

10 MEMBER TAVERAS: Right, good to
11 include it.

12 MEMBER VAN HORN: -- good to consider
13 it. Yeah.

14 MEMBER TAVERAS: No, that's a good
15 point.

16 VICE CHAIR KLEINMAN: Rachel?

17 MEMBER NOVOTNY: Rachel Novotny. Just
18 wondered about the rationale for the very high
19 development countries. I assume it's more and
20 longer human milk feeding. But wonder if you had
21 anything more to say?

22 MEMBER TAVERAS: The very high what?

1 Sorry?

2 MEMBER NOVOTNY: Human development
3 level of inclusion criteria of your population.

4 MEMBER TAVERAS: So, it's partly to be
5 consistent with the existing reviews. Is that
6 right?

7 VICE CHAIR KLEINMAN: Yeah, it was
8 meant to be representative of the US population,
9 rather than globally.

10 MEMBER NOVOTNY: Okay. I thought it
11 went one level down.

12 VICE CHAIR KLEINMAN: It's very high
13 and high.

14 MEMBER NOVOTNY: And most of the rest
15 are just high, are they not?

16 VICE CHAIR KLEINMAN: No, they're
17 both.

18 MEMBER NOVOTNY: Oh, they're both.
19 Okay.

20 MEMBER TAVERAS: The very high and
21 high is one of the general standard criteria, and
22 was what was used for the existing reviews.

1 MEMBER BOUSHEY: I have just one other
2 little small thing. Carol Boushey. And thanks
3 for bringing up calcium. That's where I was
4 going next, but I won't say that now. But what I
5 will share is that having the older ages for the
6 bone is a great idea.

7 But in the analytical framework, those
8 higher ages aren't included. So, you want to
9 make sure those get in there.

10 MEMBER TAVERAS: Thank you for
11 pointing that out.

12 VICE CHAIR KLEINMAN: All right, I
13 think that we've exhausted that topic, for the
14 moment anyway. So, turn it over to you, Barbara.

15 CHAIR SCHNEEMAN: Right. So, we're
16 actually -- if you advance the slides, we're
17 scheduled to have a break at 2:30 that hopefully
18 no one will object if we give you all ten extra
19 minutes.

20 We do try to hold to the time schedule
21 as much as possible because we know that people
22 are watching online and various other ways. So,

1 why don't we break now. And then we'll expect
2 you back at 2:45.

3 (Whereupon, the above-entitled matter
4 went off the record at 2:21 p.m. and resumed at
5 2:47 p.m.)

6 CHAIR SCHNEEMAN: I will, once again,
7 remind the Committee members, please make every
8 effort to say your name and speak as directly
9 into the microphone as you possibly can. So, it
10 helps both with the transcription as well as
11 people hearing who are participating either
12 online or in the room. So, that would be great.

13 So, we are ready for our next two
14 subcommittee presentations. And so our next one
15 is the beverage -- beverages and added sugars
16 subcommittee and Rick, I believe you are going to
17 do the presentation for that.

18 MEMBER MATTES: Right. Thank you.

19 CHAIR SCHNEEMAN: Microphone.

20 MEMBER MATTES: Okay. Yep, got the
21 mic on. Okay, so here's the list of Committee
22 members and, as you can see, that Beth is

1 actually the subcommittee chair, but since she is
2 not here I'm sitting in for her.

3 I think if we were to run this
4 presentation through iThenticate, relative to
5 what's already been done, we would be expelled
6 for plagiarism.

7 (Laughter.)

8 MEMBER MATTES: We've already covered
9 much of this, but we will go through it, just so
10 it is on record and clear.

11 CHAIR SCHNEEMAN: But this is
12 government, so ---

13 MEMBER MATTES: Right. Right, right.
14 Okay, so, our questions fall into three primary
15 topic areas. And the first is the role of non-
16 alcoholic beverages and consumption on a number
17 of different outcomes, including, anthropometric
18 measures and each of those is assessed across the
19 life span, but also, the role of non-alcoholic
20 beverages during pregnancy and effects on birth
21 weight, standardized for gestational age and sex,
22 as well as gestational weight gain. And then,

1 the third question under this topic area concerns
2 non-alcoholic beverage consumption during
3 lactation and its effects on postpartum weight
4 loss and still --- still, oh, there we go, sorry
5 about that. And human milk composition and
6 quantity.

7 So the subcommittee has worked through
8 the first four of these -- they are the ones
9 highlighted with the asterisk. The one that we
10 haven't gotten to yet is human milk composition
11 and quantity.

12 The second topic area is added sugars
13 and is largely parallel to the way we have
14 handled the beverages question -- some small
15 differences in terms of the general population.
16 We've added questions related to risk for
17 cardiovascular disease and type 2 diabetes and
18 for the analysis concerning pregnancy. We have
19 taken out birth weight but retained gestational
20 weight gain. And then for lactation, the impact
21 on milk composition and quantity is removed, but
22 postpartum weight loss is retained.

1 Alcohol will be the third main area
2 and again, we haven't gotten there yet and the
3 questions there are defined here, but since we
4 haven't gotten to them, I won't belabor those.

5 Whoops, sorry about that.

6 So, the four questions that we will
7 present in a little bit more detail are listed
8 here. The way we will be approaching them is
9 through the NESR systematic reviews.

10 We do have a couple of definitions
11 that are probably worth specifying. We are using
12 the same definition of beverage pattern, but I do
13 want to, kind of, emphasize the orientation here,
14 because pattern can evoke many different
15 concepts, it can be circadian, infradian,
16 seasonal, cultural, nutrient and so on. And
17 different subcommittees are indeed, picking up on
18 them in different facets, so the frequency of
19 eating group will be looking more at temporal
20 patterns, the dietary pattern group will be
21 looking more at sources.

22 So our focus here really is primarily

1 on quantity, on portion size, and as Regan
2 pointed out first thing this morning, we will
3 definitely have to work across subcommittees to
4 integrate all of this as we go forward.

5 Our definition of gestational weight
6 gain is drawn from the CDC and is pretty
7 straightforward -- women -- the weight women gain
8 during pregnancy and the IOM 2009 definition is
9 used for post-partum weight retention. It is the
10 amount of weight that remains -- interesting
11 choice of words -- during the post-partum period,
12 minus the woman's pre-pregnancy weight.

13 Okay. We are the beverage group, so
14 it's incumbent on us to define beverages in a bit
15 more detail than some of the other groups have
16 ventured into. And we have defined ten discrete
17 -- no, I shouldn't say that -- we have defined
18 ten categories. They are not as discrete as one
19 might hope, but, so one large cluster is milk or
20 dairy products, and as you can see on the slide,
21 so under milk there are gradations based on fat
22 content, under flavored milks there is flavor

1 added, but it is also still gradations of fat
2 content. And then there is dairy drinks and
3 substitutes. A lot of these plant-based milk-
4 like beverages, milk shakes and that sort of
5 thing.

6 And then we get to the non-alcoholic
7 beverage sources and one category there are
8 hundred percent juices and they can either be
9 fruit or vegetable.

10 For diet beverages, I want to take a
11 little bit of an opportunity -- or a side track
12 here -- it includes low calorie, sweetened. Now
13 it says here, high intensity sweetened. We've
14 talked about thinking of our questions in the
15 context of the population and communicating
16 messages and so on. I would like to put in a
17 statement that we consider -- rather than calling
18 them high intensity sweeteners, we have an
19 opportunity here to try to standardize language
20 in this field. High intensity, I would argue, is
21 really not the right word because nothing is
22 sweeter than nine percent sucrose. These things

1 aren't sweeter than plain old sugar. It is just
2 you can get to that level of sweetness at a much
3 lower concentration. So it really isn't an
4 appropriate term. They aren't artificial because
5 stevia is not artificial. We could call them
6 high potency but that sort of medical-izes it and
7 I don't think that's desirable. They are not
8 non-caloric because aspartame is caloric.

9 So, I would argue that we adopt the
10 terminology of low calorie sweetener. It
11 probably conveys most clearly to consumers what
12 the primary goal of their use may be and it's as
13 fitting a description as I think we are going to
14 come up.

15 So, we do include beverages with low
16 calorie sweeteners in them, but also in that
17 category are beverages that have just been
18 diluted with water.

19 And then, obviously a very big issue
20 amongst consumers is sweetened beverages. And
21 there we have soft drinks, fruit drinks, sports
22 beverages and then other items that -- specialty

1 teas and coffees, smoothies and so on.

2 Nutritional beverages would include
3 meal replacement products, smoothies that have a
4 specific, intentional nutrient content, protein
5 shakes, and then other -- what we are calling
6 functional drinks -- beverages that somebody
7 believes contains something that has some special
8 physiological impact. Right?

9 And then we have, clearly, coffee and
10 tea that can be either sweetened or unsweetened.

11 Plain water, which could be subdivided
12 by tap or bottle and then flavor, or enhanced
13 water, so, with gas in it or some flavoring.

14 Relevant to the discussion we've been
15 having about water -- do we include it, do we not
16 include it -- let me, also, just take this
17 opportunity to just point out that any beverage
18 is almost entirely water. All right. On a
19 weight basis there is no beverage that isn't
20 mostly water. And it is really just a gradation.
21 So if we consider water sort of the vehicle or
22 the most elemental of things that we drink, we

1 can add a little odor to it, or we can add a
2 little gas to it and I don't know to what degree
3 you think that fundamentally changes it. We can
4 add a low calorie sweetener to it -- to what
5 degree does that change it? We can add an actual
6 sweetener to it, or some fat to it, or some
7 protein to it. We can make it more or less
8 viscous as we go on. It is just a continuum --
9 and we have to decide where we want to draw the
10 line in that continuum, and it may be this is one
11 of those issues we identify and say, next,
12 dietary guidelines committee -- think about it.

13 (Laughter.)

14 MEMBER MATTES: Okay. Then -- so this
15 is our first analytical framework and it has to
16 do with growth, size, body composition, risk of
17 overweight and obesity. And we have taken those
18 ten beverage categories and put them in the first
19 box as our intervention exposure and the
20 comparator will be the consumption of any one of
21 those relative to a different type of beverage, a
22 different amount of that same beverage, compared

1 to a beverage with different nutrient content, a
2 different sensory property or a different
3 physical form -- so gradation in viscosity, for
4 example. There are quite a few studies out there
5 comparing beverages to a solid food even within
6 the same -- so a juice compared to a whole fruit,
7 or a vegetable compared to a blended vegetable --
8 and so on.

9 And I think it is important to have
10 these distinctions because it does, in fact,
11 allow us to compare across categories to see to
12 what degree is it -- is whatever health outcome
13 we are measuring, really due to the fact of
14 delivery system -- it's a beverage -- relative to
15 what property it also conveys. Is it just a
16 delivery system for nutrients -- and is the
17 nutrients, is it the sensory thing -- is it
18 really something special about sweetened
19 beverages that has a health impact, or is it just
20 something about the vehicle that changes how we
21 react to sweetness?

22 So by having broken this down as

1 discretely as we have, we can, I think, get much
2 deeper into the question of where the actual
3 impact lies -- where the mechanism lies.

4 So our outcomes on this one are the
5 same as a number of other groups have identified
6 the anthropometric sorts of indices, which
7 primarily fall into various measures of
8 adiposity. Our key confounders are sex, age,
9 race, ethnicity, sociodemographic status, total
10 energy intake and anthropometric measurements
11 pre-period of time that we are studying so that
12 we can see what effect of a change of beverage
13 consumption may have had.

14 One thing we don't have in here, and
15 I noticed nobody else, sort of, raised questions
16 about what their subcommittee included or didn't
17 include, but I want to throw it out so that ---
18 it sort of dawned on me that we didn't include
19 customary beverage intake on this one. We do on
20 some others, and again, if we want to look at
21 what effect a change in beverage intake has had
22 we may want to include that so we -- as we talk

1 about it -- I think we ought to consider that.

2 The second analytical framework
3 focuses on birth weight. We have the same
4 exposures and comparators. The difference here
5 is in the outcome. So obviously we are looking
6 at birth weight and relative to age, length,
7 gestational age and sex. And in this framework
8 the intervention is on the woman -- on the mother
9 --- and the outcome is on the infant. So it is a
10 distinction here that is different from the other
11 analyses that we have undertaken.

12 The third analytical framework is
13 gestational weight gain. Again, the same
14 intervention, same comparator, the outcomes,
15 though are gestational weight gain and weight
16 gain in relation to recommendations based on pre-
17 pregnancy and BMI.

18 The primary population here is the
19 woman -- the pregnant woman -- and the key
20 confounders are maternal age, race, ethnicity,
21 socioeconomic status, pre-pregnancy beverage
22 intake, pre-pregnancy BMI, smoking. And once

1 again, we have gestational diabetes in several of
2 the other analytical frameworks, but we didn't
3 include it in this one. It seems to me relevant
4 if we are looking at gestational weight gain. So
5 we may want to consider that during the
6 discussion period, as well.

7 Our final analytical framework is on
8 postpartum weight loss -- same intervention,
9 same comparator. The outcomes here though are
10 change in weight from baseline to some later time
11 point during the postpartum period and post-
12 partum weight retention if gestational weight
13 gain is controlled.

14 The key confounders are maternal age,
15 race, ethnicity, socioeconomic status, pre-
16 pregnancy beverage intake, pre-pregnancy BMI,
17 gestational weight gain is used here, smoking,
18 and breast feeding status. And the one that we
19 don't have here, again, is gestational diabetes
20 that may be relevant that we can discuss
21 momentarily.

22 In terms of inclusion and exclusion

1 criteria, we are using the same standard criteria
2 that have been described multiple times before.
3 For the upper part we have tailored a few of
4 them. We are setting a date going forward for
5 which papers to include of January 2000 and it
6 will go through the end of June 2019.

7 In terms of study duration, we decided
8 that we should set a minimum of eight weeks. The
9 rationale being that a lot of our outcomes are
10 weight-related and it just takes time to measure
11 a change in body weight that is something other
12 than a transient shift in fluid balance. And
13 even eight weeks is probably truly a minimum, but
14 we were afraid of losing too many papers if we
15 went too much further than that.

16 In terms of inclusion and exclusion,
17 in terms of study participants, the inclusion
18 criteria, as I mentioned, we will be looking over
19 the lifespan so those categories are defined on
20 this slide. And I think are consistent with some
21 of the other groups, though, I guess not all.

22 And, by definition the complement is

1 we will not be looking at beverage consumption in
2 infants and toddlers.

3 In terms of birth weight we will only
4 be looking at humans, excluding animal trials.

5 And gestational weight gain we will be
6 looking at females who are pregnant, capable of
7 becoming pregnant, and then their offspring.

8 And consistent, I think with the
9 exclusion criteria that Sharon outlined for their
10 subcommittee, we will be excluding protocols that
11 don't uniquely identify outcomes for single
12 versus multiple pregnancies. And for women who
13 are in hospitals for reasons other than their
14 pregnancy.

15 And then for postpartum weight loss we
16 have added postpartum women who are lactating as
17 inclusion criteria and obviously, those that
18 aren't will be excluded.

19 And finally for inclusion and
20 exclusion, with regard to health status, we will
21 be including studies that enrolled participants
22 who are healthy in the general population, and

1 people who may have a health condition but aren't
2 targeted because of their health condition, to be
3 included in the trial. We will be excluding
4 studies that exclusively enroll participants who
5 are -- including individuals with obesity as the
6 target group.

7 In terms of postpartum weight loss,
8 what we are including that is a variation on the
9 theme, are studies that enroll mothers with
10 infants born full term and studies that enroll
11 some mothers with infants who are born full term,
12 but may also have low birth weight, or low --
13 small for gestational age -- offspring. And for
14 this one we actually will exclude studies that
15 exclusively enroll pre-term infants, but also
16 studies that exclusively enroll mothers with
17 obesity, which is a difference from the other
18 analytical models.

19 Next steps will be to finish our
20 analysis in the general population focusing on
21 human milk composition and quantity -- whoops,
22 sorry --- so the last question in that category.

1 Then we will move on to the added sugars category
2 and you can see listed there the different
3 outcomes we'll be focusing on and then finally
4 alcohol.

5 And we do want to thank the staff's
6 outstanding job in keeping us on track and
7 providing us with the information we needed to
8 give our advice. So, I will stop there.

9 CHAIR SCHNEEMAN: So, we can --this is
10 Barbara -- we can take some questions or comments
11 or I think you threw out a few things that sounds
12 like you would like input on. And particularly
13 from, I think the B through 24 and the pregnancy
14 and lactation groups.

15 MEMBER DONOVAN: For the questions
16 that you had about -- this is Sharon Donovan --
17 the gestational diabetes. I think it might make
18 sense to add that to your confounders. And I
19 understand the question with postpartum weight
20 retention is, you know, what is the impact of
21 beverage intake during lactation and postpartum
22 weight loss? But to me, it would be

1 interesting, just beverage intake postpartum and
2 I understand it is a different question, but I
3 think that women who aren't breast feeding might
4 choose to start to drink more alcohol, for
5 example, or make different dietary choices.

6 So, but I understand we were given the
7 questions to address, but you will have studies,
8 I think, that have non-lactating women in them.

9 MEMBER MATTES: Yes, that is a good
10 point. I wouldn't be surprised if, in some of
11 those papers they are the comparison group. So,
12 we might be able to pick up some of that
13 information.

14 MEMBER NOVOTNY: Rachel Novotny. Yes,
15 on the gestational diabetes. I think, though,
16 the question may be a bit of harmonization
17 amongst our groups. I think we were taking this
18 -- correct me if I'm wrong -- approach, a very
19 minimalist approach, of things that would exclude
20 studies from, you know, from their ranking. So
21 maybe we need another box for some things that we
22 want to consider in analysis, but that maybe

1 wouldn't necessarily ding the study. And I am
2 not sure where that is a must-include.

3 MEMBER MATTES: Actually, could I ask
4 the staff -- because when we were working on
5 these models, there was a third box, for a while
6 and it kind of disappeared. Can you comment on
7 that?

8 DR. KINGSHIPP: Sure. This is
9 Brittany Kingshipp. So we do have a supplemental
10 document -- it is not part of the formal analytic
11 frameworks that you have shown -- that we have a
12 list of additional Covariates that will be
13 considered. So for instance if a study presents
14 information on -- for instance, gestational
15 diabetes, like you all were talking about --- we
16 would pull that information and present it to
17 you, but it wouldn't be considered in the list of
18 key confounders -- the confounders that actually
19 are considered in the risk of bias when we are
20 assessing these studies. And so, it is just a,
21 just kind of a tier down from those lists that
22 are on the analytic framework, but something that

1 we would still be considering.

2 MEMBER ARD: Jamy Ard. So, to
3 continue on that point, I think it might be
4 useful to --when there are similar outcomes or
5 populations, we might want to really sort of
6 compare -- which confounders do we really believe
7 are key? So, for example, like I've looked at
8 parity. Parity is included for pregnancy- and
9 lactation-related outcomes, but not frequency of
10 eating in sugar sweetened beverage when it comes
11 to gestational weight gain. And so, I would want
12 to say, okay, if we are going to say it is key
13 for gestational weight gain in this one
14 particular question, do we have a rationale for
15 not including it in others, or should it be, when
16 it comes to gestational weight gain, parity is
17 something that we are going to consider across
18 all of the particular questions?

19 So it might be good for us to just
20 have a grid or something that we can share across
21 committees to make sure that we are at least
22 consistent in our rationale. And it's, right

1 now, it feels sort of haphazard, like, oh yes, I
2 thought about this one. What about it? But we
3 could probably harmonize that a little bit.

4 CHAIR SCHNEEMAN: Yes, this is Barbara
5 Schneeman. And Jamy, I think that is a good
6 point. Certainly one of the points here is
7 making sure we all know what is going on with
8 each of the subcommittees and looking for exactly
9 those kind of items. So, it is probably a bit of
10 homework to make sure if something is relevant in
11 one area, we're consistent across. It's a very
12 good point. Tim?

13 MEMBER NAIMI: Tim Naimi. I don't
14 know if it was in our other box, but physical
15 activity is another key covariant in most ---
16 physical activity is a key covariant, key
17 confounder, for a lot of the other groups and I'm
18 not sure if it was in our other box that
19 disappeared or whether it is just an omission. I
20 don't know if anyone remembers.

21 MEMBER MATTES: I will let Brittany
22 give the real answer, but I'm pretty sure it is

1 in the other box.

2 DR. KINGSHIPP: Yes, you are correct.

3 MEMBER MATTES: We decided that it
4 wouldn't be in a lot of the papers, and so if we
5 put it as a key confounder we would be
6 downgrading a lot of relevant papers. But I
7 think it is ---

8 DR. KINGSHIPP: That is correct, yes.

9 MEMBER MATTES: -- yep.

10 CHAIR SCHNEEMAN: And going forward
11 it's probably important to make sure we have
12 those other boxes visible as part of the
13 protocols, as well. So, Heidi?

14 MEMBER LEIDY: Same type of thing, but
15 I think the grid will really help. But I was
16 thinking that, you know, with our sugar sweetened
17 -- or the beverages one, we also have the
18 criteria for the eight weeks, for when looking at
19 changes in obesity-related outcomes. But I don't
20 think that we have it in the eating frequency --
21 and there may not be in the other ones. So I
22 think having a grid like that and then having a

1 discussions in terms of what we should
2 standardize I think would be great. And that is
3 just another one that came to mind.

4 CHAIR SCHNEEMAN: So, Eve, I'm going
5 to -- hopefully that is something that we can
6 work with staff to put together going forward.
7 Great. Eve is nodding her head yes, for the
8 record.

9 MEMBER SABATE: Joan Sabate. As far as
10 the analytical frame -- as far as the analytical
11 framework between the beverages and the growth
12 size, body composition and risk of overweight and
13 obesity, one of the key confounders is total
14 energy intake. This is, I assume, total energy
15 intake for the whole diet. And then, if that is
16 the case, I mean, how are we going to distinguish
17 between the beverages that carry energy versus
18 the ones that they do not? And how are we going
19 to, you know, do this, as far as you want to
20 answer the question, if carrying energy into the
21 beverages versus not, has an impact on the
22 outcomes of interest regardless of the other

1 components of the diet?

2 MEMBER MATTES: Yeah, we definitely
3 spent some time talking about this. The issue is
4 I don't think there are a lot of papers that will
5 differentiate the beverage contribution to total
6 daily energy intake. But we're looking at
7 primarily intervention kinds of studies. What we
8 will see is: to what degree did the addition or
9 subtraction of a particular beverage have an
10 impact on the health outcome?

11 So we want to know what the energy
12 intake was prior to the intervention to be able
13 to determine what impact the change in beverage
14 consumption had. That was the rationale for
15 putting it in there.

16 If we had data on beverage energy
17 intake prior to the intervention, that would be
18 wonderful. But I don't think it's reported very
19 often.

20 MEMBER SABATE: Would you be able to
21 answer the question if energy beverages versus
22 beverages that has no calories, I mean, has an

1 impact on the outcomes of interest?

2 MEMBER MATTES: If what happens -- if
3 the mechanism of, say, weight gain with beverage
4 consumption is due to lack of compensation for
5 that energy, then it would be essential to know
6 the pre-energy intake to be able to assess that.

7 MEMBER SABATE: Yes. But what about
8 during the intervention? That's one thing.

9 And the second thing is: are you going
10 also to consider study designs other than
11 intervention studies?

12 MEMBER NAIMI: I think they're
13 primarily intervention studies in our bailiwick.

14 They're actually in your slides, the
15 kinds of studies we're going to.

16 CHAIR SCHNEEMAN: Right. So yes, the
17 inclusion criteria for the studies is the same as
18 for all of the -- that's the standard protocol.
19 So if you just go back to --

20 MEMBER SABATE: So once you took the
21 studies, particular studies, how are you going to
22 --

1 CHAIR SCHNEEMAN: Right, it's just the
2 quality of the evidence varies by the type of --

3 MEMBER SABATE: Correct.

4 CHAIR SCHNEEMAN: -- study. So we're
5 not pulling out something as only looking at one
6 type of study here. It's the same inclusion
7 criteria.

8 MEMBER SABATE: But if the adjustment
9 is just for the total energy intake, then you
10 will not be able to see the difference between
11 one versus the other. Because, I mean, you don't
12 take into consideration the energy that is
13 carried on the beverage.

14 MEMBER MATTES: If it's an
15 intervention study where the intervention is a
16 manipulation of the beverage, then we need a
17 baseline to be able to determine what that change
18 in beverage -- what impact that change in
19 beverage intake had.

20 So that -- maybe I'm missing your
21 point, but it seems to me we need that
22 information in order to draw a conclusion about

1 the role of the beverage.

2 MEMBER SABATE: Yes. But on an
3 epidemiological study, for instance, I mean if
4 you adjust for the total energy intake, the
5 energy of the beverage is included in the
6 adjustment.

7 MEMBER NAIMI: Well, I think you're --
8 are you alluding to the fact that I think you're
9 thinking primarily of intervention studies --

10 MEMBER SABATE: That's correct.

11 MEMBER NAIMI: -- in which case you'd
12 like to know the baseline.

13 But I think you're thinking of
14 something which I was concerned about, which is
15 if you're looking at an epidemiological study,
16 you would actually like to be able to control for
17 the non-beverage calorie intake of the person,
18 you know, over the study period to isolate out
19 the effect of the beverage as opposed to all of
20 the -- so I think it depends on the study design.

21 MEMBER SABATE: Correct. Yes.

22 MEMBER MATTES: I think for this

1 committee, it's drawing primarily from clinical
2 intervention. So I think the point I've been
3 making is relevant, but to the point of
4 epidemiological trials, I actually think that
5 your group is more likely to answer that
6 question.

7 (Laughter.)

8 MEMBER BAILEY: Can't put this one on
9 me, Mattes.

10 So we'll have the nationally
11 representative survey data that we can look at
12 the contribution that beverages make towards
13 total energy intake. But we don't have beverage
14 intake in some sort of exposure controlling for
15 energy intake.

16 So, we will have prevalence estimates,
17 and means, and distributions, and contributions,
18 but not necessarily controlling for it, the words
19 you're saying, yeah.

20 MEMBER MATTES: So it's the complement
21 of studies that will give us the answer I think.
22 Yeah.

1 MEMBER SABATE: No, but one thing is
2 a descriptive of what the American population is
3 doing. Another thing is in a longitudinal study,
4 not an intervention, a short intervention. And
5 to answer the question, the consumption of a non-
6 calorie beverage versus one calorie beverage has
7 an effect on obesity, I mean this is a very valid
8 question that is within I think the scope of this
9 committee.

10 CHAIR SCHNEEMAN: So Carol, did you
11 want to say something?

12 So I -- yeah, okay.

13 MEMBER BAZZANO: This is Lydia
14 Bazzano. I was just going to point out that, you
15 know, in most nutritional epidemiology and with
16 the longitudinal designs, we take into account
17 total energy intake. And it's just that if there
18 is measurement error around that, I don't
19 necessarily know if you could pluck out the part
20 of the beverage specifically in order to get that
21 information.

22 But you can look at whether the

1 beverage as a whole seems to contribute to the
2 outcome.

3 CHAIR SCHNEEMAN: So Dr. Sabate, my
4 understanding is you're -- are you trying to make
5 sure that we account for beverages that have
6 calories and beverages that don't have calories?
7 Is that part of what you want to make sure we
8 want to account for?

9 MEMBER SABATE: I wasn't aware that
10 the subcommittee was only looking or majorly
11 looking at the interventional studies. I think
12 there is some part of the literature that is
13 trying to also look at these from a longitudinal
14 perspective.

15 So put in simple terms, if somebody
16 has zero energy coming from the beverages that
17 this person consumed versus another individual
18 has 50 percent of their daily calories coming
19 from beverages, if we adjust for total energy
20 intake while making the two beverages equal,
21 therefore is not going to be any effect, just by
22 mathematical definition.

1 So what I'm saying is one thing is to
2 adjust for the diet other than beverage, and
3 another thing is to take away the effect of the
4 energy in the beverage that may have on the
5 outcome. I don't know. Probably Timothy can
6 explain it better.

7 MEMBER MATTES: Well, if you take the
8 example of somebody who took 100 percent of their
9 calories from sugared soda, let's say, and then
10 you control for their total energy intake, you
11 will over-control. You will basically -- so the
12 more that, the more that somebody's total
13 calories come from beverages, and then you
14 control for total energy, or over-controlling and
15 you're basically controlling away the -- you're
16 trying to isolate the effect of a beverage, so
17 you would like to control for energy intake from
18 things other than that beverage, or at least
19 other than beverages to distill out that in a
20 longitudinal or epidemiological study as opposed
21 to a intervention study.

22 CHAIR SCHNEEMAN: So it sounds like

1 this is a factor that will come into play when
2 we're looking at the observational data.

3 MEMBER BOUSHEY: So if you do find
4 some longitudinal studies that address this, then
5 you can or you will only limit it to
6 interventions.

7 MEMBER MATTES: I understand your
8 point. It's well taken. I'm not sure that we
9 have included longitudinal studies in the array
10 of terms that we are going to be looking at.

11 So if that's something we should
12 change, that's something we should change.

13 DR. KINGSHIPP: Rick, can I clarify?

14 MEMBER MATTES: Yeah, please.

15 DR. KINGSHIPP: Just from the staff
16 perspective. And so it is correct that the
17 slides that Dr. Schneeman presented earlier, the
18 standard criteria, are being used for these
19 beverage consumption questions. So we will be
20 including any prospective/retrospective cohort
21 trials. So in that case we might have
22 observational longitudinal data.

1 It is true that we are also including
2 experimental studies, RCTs, that sort of thing.
3 So I mean we haven't got into them yet, so we
4 don't yet know what the proportions and breakdown
5 will be, but both types of study designs will be
6 included.

7 MEMBER NAIMI: Okay. Good. Thank you.

8 And just to make a general point, I
9 mean of course intervention studies are good
10 because they can be well, carefully controlled.
11 But they're good for determining short-term
12 effects.

13 And as you mentioned, Rick, the
14 ability to look at an impact on something like
15 weight, you know, oftentimes a longitudinal study
16 which can go over years or even decades may be
17 more relevant.

18 So I expect we'll have both kinds of
19 studies to look at, but I don't know. We'll see.

20 CHAIR SCHNEEMAN: So, I think we have
21 Dr. Sabate's comments about what's needed in
22 terms of the observational data. Okay? Great.

1 Thank you.

2 So we have one more subcommittee to go
3 through. So I want to be sure we have time to do
4 that. So that is the Dietary Fats and Seafood,
5 and Dr. Snetselaar.

6 MEMBER SNETSELAAR: Thank you.

7 My subcommittee on Dietary Fats and
8 Seafood, I have Regan Bailey, Joan Sabate, and
9 Linda Van Horn. So thank you so much for being a
10 part of the committee. Also Barbara Schneeman
11 was the Advisory Committee chair rep.

12 So for our particular subcommittee, we
13 have two topics areas: dietary fats, and seafood.
14 And there were three seafood questions,
15 specifically on seafood intake during pregnancy
16 and lactation, and childhood and neurocognitive
17 and cardiovascular outcomes.

18 And then our second topic on dietary
19 fats included all-cause mortality, cancer,
20 cardiovascular disease, and neurocognitive
21 development and health.

22 And I am including here some key

1 acronyms so that just as I'm going through the
2 slides these will be familiar.

3 You've heard them probably already
4 today: N-3, N-6, PUFAs, MUFAs, EPA, DHA, CVD,
5 and methylmercury.

6 And these are our seafood questions.
7 I'm not going to read through them in detail
8 because I will be showing you the analytic
9 framework for each one. The systematic review
10 protocols that our subcommittee will develop will
11 answer these three questions on seafood
12 consumption and health.

13 We began with a definition of seafood
14 that was taken from the 2015-2020 Dietary
15 Guidelines for Americans, definitions for
16 seafood. And that definition includes marine
17 animals and -- okay, one more. There we go.

18 So seafood is defined as marine
19 animals that live in the sea and in freshwater
20 lakes and rivers. And it includes, for example,
21 salmon, tuna, trout and tilapia. And the
22 shellfish examples would be shrimp, crab, and

1 oysters.

2 And then we are also going to be
3 looking at seafood in terms of the
4 characteristics. And as you see here, type,
5 source is very important; the amount and
6 frequency of intake; and then the timing of
7 exposure.

8 And this is our first analytic
9 framework, our first question. And that is: what
10 is the relationship between seafood consumption
11 during pregnancy and lactation and neurocognitive
12 development of the infant?

13 And I'm going to be going through
14 separate elements within this analytic framework
15 in the next few minutes.

16 So this first slide is focusing on the
17 box that includes intervention and exposure
18 versus comparators. And we will be looking at
19 seafood consumption as it was defined earlier.
20 And the seafood consumption will examine studies
21 that look at types, sources, amounts of seafood
22 consumed, or different frequency and timing of

1 seafood consumption.

2 And then here highlighted are
3 populations that we are considering. They
4 include looking at infants, toddlers, children,
5 and adolescents, birth to 18 years.

6 And the measures of neurocognitive
7 development will be very consistent with those
8 addressed by other subcommittees. So, once again
9 we're trying to be very consistent in the work
10 that we're doing with this particular
11 subcommittee so that across the board our
12 subcommittees are focusing on those same
13 characteristics for neurocognitive development.

14 Okay, moving on to key confounders.
15 We are paying particularly close attention to
16 sources of confounding that will include child
17 age, sex, birth weight, gestational age, maternal
18 age, race, ethnicity, SES, anthropometrics,
19 parity, smoking, dietary patterns.

20 And components of the maternal diet
21 will include alcohol intake, dietary supplements,
22 particularly n-3 polyunsaturated fatty acids and

1 iron. And then we'll also be looking at non-fish
2 dietary exposure to n-3 polyunsaturated fat.

3 We're looking at parental education,
4 family history of neurocognitive disorders. And
5 we will be looking at key confounders that
6 include ADD, ADHD, anxiety, ASD and depression.

7 And then additionally we will be
8 looking at key covariates. And these are likely
9 to impact the relationship between seafood
10 consumption and health. And they include key
11 nutrients. For example, n-3 PUFAs, selenium,
12 environmental chemicals, mercury, PCBs for
13 example, and then blood or human milk biomarkers
14 of seafood intake, and infant feeding mode.

15 And then our second question will
16 focus on seafood consumption during childhood and
17 neurocognitive development. And the
18 intervention, exposure, and comparator here is
19 similar to the previous question.

20 And once again the boxes in red
21 include our population. We are going to be
22 focusing on seafood consumption from birth to 18

1 years of age, with neurocognitive endpoint
2 outcomes assessed from age 2 years and older
3 throughout adulthood.

4 And outcomes which reflect both
5 neurocognitive development and neurocognitive
6 health will also be considered, as you see here
7 on this particular slide.

8 And then, again, key confounders and
9 key covariates are similar to our previous
10 question. However, infant feeding mode will be
11 considered as a potential source of confounding
12 rather than a key covariate.

13 And then our final seafood question
14 focuses on seafood consumption during childhood
15 and risk of cardiovascular disease. And
16 intervention, exposure, and comparators are the
17 same as in our previous analytic framework.
18 Cardiovascular disease outcomes to be examined
19 near those across the rest of the project.

20 And once again we have here
21 population. Our focus here will be on seafood
22 consumption during childhood. We'll be assessing

1 intermediate outcomes in children, adolescents,
2 adults, and older adults, and then endpoint
3 outcomes in adults and older adults as well.

4 And then key confounders and
5 covariates, we'll consider the relationship
6 between seafood intake during childhood and
7 cardiovascular disease. This is going to be
8 similar to those I identified earlier, but it
9 will include family history of cardiovascular
10 disease.

11 And then very importantly, we will be
12 looking at inclusion/exclusion criteria. And the
13 inclusion/exclusion criteria for seafood
14 questions are consistent with the standard
15 criteria as you've already seen in terms of the
16 committees' systematic reviews. As you can see,
17 we are including study design, publication
18 status, date of publication, language of
19 publication, country, and health status of
20 participants.

21 And more specifically here in terms of
22 our subcommittee's role, there will be studies

1 that measure seafood consumption. Again, it is
2 important to keep in mind that there will be some
3 exclusions. So fish oil or n-3 PUFA, supplement
4 studies, and studies that only examine biomarkers
5 of seafood intake will not be included. And this
6 would include studies that evaluate infant
7 formulas with added DHA and EPA.

8 And now moving on to our dietary fats
9 questions, this is our second topic. The focus
10 on dietary fat consumption will be at each stage
11 of life. We'll be looking at neurocognitive
12 development and health, and risk of
13 cardiovascular disease, cancer, and all-cause
14 mortality.

15 Some key definitions. Saturated,
16 monounsaturated, polyunsaturated fat types will
17 be looked at. We'll be looking at omega-3
18 polyunsaturated fatty acids, EPA and DHA, and
19 then omega-6 polyunsaturated fatty acids and
20 cholesterol.

21 You might note here that we have not
22 included trans fats. And one of the reasons for

1 that is that some work was done to look at intake
2 since 2012. And intake was at about 1.5 grams
3 per day. And trans fats are also not included in
4 federal food and nutrient databases, and they've
5 been not used in a lot of studies. So that's one
6 of the reasons you do not see trans fats in that
7 list.

8 In key definitions, we feel -- and
9 certainly this is borne out in the literature --
10 that sources of fat are very important as we talk
11 about dietary fats. So dairy, eggs, meat, and
12 plant sources will be important.

13 We'll be looking at amounts of
14 specific types of fat and proportions where we're
15 looking at ratios. And then replacement, where
16 saturated fat may indeed be replaced with
17 polyunsaturated fat, and then also carbohydrate
18 and protein replacement in terms of saturated
19 fat.

20 It's important I think here to note
21 that our committee was not tasked with looking at
22 overall amounts of dietary fat. And so we will

1 rather be focusing specifically on types of fat
2 and certainly amounts of types of fat.

3 And so the first question that we are
4 looking at is the relationship between types of
5 dietary fat and neurocognitive development and
6 neurocognitive health. And this analytic
7 framework reflects our definition of types of fat
8 that will be used across the dietary fat
9 questions. The neurocognitive endpoint outcomes
10 are consistent with previously presented analytic
11 frameworks on this particular outcome.

12 And then again, looking at those red
13 squares where we're identifying our population.
14 We will be evaluating studies conducted in
15 infants, toddlers, children, adolescents, adults,
16 and older adults.

17 Key confounders will include sex, age,
18 race, ethnicity, socioeconomic status, BMI,
19 smoking, outcome. And age-specific key
20 confounders will include neurocognitive
21 development, birth to 18 years, parental
22 education, neurocognitive health, 19-plus years,

1 education, ADD, ADHD, anxiety, ASD, depression,
2 Alzheimer's, a family history of neurocognitive
3 disorders. And we'll also be looking at mercury
4 in fat that originates from seafoods. And that
5 will be considered as a key covariate for this
6 particular question.

7 And then all-cause mortality, the
8 relationship of dietary fat to all-cause
9 mortality at each stage of life. The
10 intervention, exposure and comparators are the
11 same as previously described for dietary fat
12 analytic frameworks. And all-cause mortality
13 outcome has already been described with several
14 of the other presentations. And we will be
15 examining studies conducted in subjects 2 years
16 and older.

17 And then key confounders are similar
18 to those considered previously: total energy and
19 alcohol intake, physical activity and
20 anthropometry, a family history of CVD, cancer,
21 and diabetes.

22 Covariates will be considered also to

1 include carbohydrate and protein intake, and
2 other types of dietary fats and BMI.

3 And then the next question involves
4 cancer. And here, in terms of the analytic
5 framework, we're describing examining the
6 consumption of dietary fats and risk of certain
7 types of cancer. And so you see the different
8 types of cancer on this particular slide.
9 Intervention, exposure, and comparators are
10 basically what we've previously described.

11 And just important to keep in mind
12 that we did add liver to our list of types of
13 dietary cancer since we have been seeing that in
14 the literature recently.

15 And then our population. We will be
16 evaluating studies that assess dietary fat in
17 subjects at each stage of life. And outcomes
18 will be assessed in subjects 2 years and older.

19 And then looking at types of cancer,
20 again one of the things to keep in mind is that
21 we will consider menopausal status as a
22 moderator. And key confounders listed on this

1 slide are similar to previous analytic
2 frameworks, except that there's the inclusion of
3 family history of cancer outcome, a variety of
4 cancer-specific confounders that include hormonal
5 contraceptive use, the age of menopause for
6 breast and endometrial cancer, IBD for colon and
7 rectal cancer, lung disease and exposure to lung
8 carcinogens for lung cancer, and then viral liver
9 infection for liver cancer.

10 And then our final analytic framework
11 addresses the relationship between types of
12 dietary fat consumption and risk of
13 cardiovascular disease. The intervention
14 exposure comparators, the target populations and
15 the outcomes are consistent with what I've
16 described previously in terms of our analytic
17 framework.

18 And then key covariates. They are
19 similar to previous analytic frameworks
20 presented, except for the inclusion of family
21 history of CVD or diabetes, and the exclusion of
22 anthropometry which was considered to be a key

1 covariate.

2 And then additional key covariates
3 include carbohydrate and protein intake, other
4 types of dietary fats, baseline CVD risk category
5 which might be high, moderate, and low, and
6 duration of intensity of the intervention, and n-
7 3 polyunsaturated fat supplement use.

8 And then as you see here, our
9 inclusion/exclusion criteria is consistent with
10 standard criteria across the subcommittees. I
11 think it's important to note here for our
12 specific subcommittee that studies that do not
13 assess the consumption of types of dietary fat,
14 so that might be studies that only include
15 biomarkers or that only assess total fat intake,
16 our overall macronutrient consumption will be
17 excluded.

18 And then next steps. The literature
19 database searches and screening for seafood and
20 neurocognitive outcome questions are complete,
21 and hand searches and data extraction will begin
22 shortly.

1 The literature search for seafood and
2 CVD will be conducted this summer. And the
3 subcommittee plans to begin work on the dietary
4 fats questions, starting with all-cause mortality
5 reviews.

6 And I want to again thank my
7 subcommittee and, also, in particular thank our
8 support staff who have done an incredible job in
9 terms of working with us on every single call.
10 The calls happen once a week and certainly have
11 been an incredible help to all of the work for
12 this particular subcommittee. And are one of the
13 reasons that we have gotten quite far along in
14 terms of the work that we have done so far. Many
15 thanks.

16 CHAIR SCHNEEMAN: So, I think we can
17 take some questions or discussion on the
18 protocol. Protocols. Yes?

19 MEMBER MATTES: Sorry if I missed it;
20 can you clarify what is outcome-specific key
21 confounders? Are they for a given outcome you'll
22 pick from that list which you use?

1 MEMBER SNETSELAAR: Say that again?

2 MEMBER MATTES: What is the definition
3 of outcome-specific key confounders?

4 MEMBER SNETSELAAR: They are just
5 specifically related to the work that we are
6 doing for the specific question we're asking.

7 MEMBER MATTES: So, for example, you
8 might pick ADD for one paper and ADHD for another
9 paper, or you would expect all of these in any
10 paper that you selected?

11 MEMBER SNETSELAAR: No. I think we
12 would certainly be looking at one at a time.

13 MEMBER MATTES: Okay. Otherwise, I
14 was going to say, you'd probably ding a lot of
15 papers if you had all of those in at once.

16 MEMBER SNETSELAAR: Yeah. And it's
17 important to keep in mind that confounders and
18 covariates aren't eliminating papers. So,
19 certainly, our exclusion criteria will do that.
20 But that's something to keep in mind.

21 MEMBER NOVOTNY: I don't know if you
22 know -- I wasn't aware of -- oh, this is Rachel

1 Novotny -- of freshwater fish being in the
2 seafood group. Do we know that the freshwater
3 fish have similar levels of mercury and other --
4 or what is the rationale for including freshwater
5 fish with seafood?

6 MEMBER SNETSELAAR: I think the idea
7 is that we want to be sure that we are
8 generalizing to other populations. And, in the
9 Midwest, for example, that type of fish are
10 probably the kind of fish that would be consumed.
11 So, that's the reason.

12 I'm happy to have one of my
13 subcommittee members also maybe talk about that.
14 But we thought that there definitely was a reason
15 for including freshwater fish.

16 Linda, would you like to respond?

17 MEMBER VAN HORN: Linda Van Horn.
18 And, yes, as the person who probably glows in the
19 dark from all the Coho salmon we eat out of Lake
20 Michigan, you know, I think there are many
21 sources of freshwater fish across the country
22 that are consumed all the time. Freshwater fish

1 are potentially contaminated and, therefore,
2 definitely should be included, we think, in the
3 fish and seafood category.

4 MEMBER SNETSELAAR: I guess the name,
5 I would prefer to call it fish and -- fish and
6 seafood or something, or seafood and fish.

7 MEMBER BOUSHEY: And to add to that --
8 this is Carol Boushey -- to add to that, of
9 course, we have fish that live in both, you know,
10 that Coho salmon that you eat.

11 CHAIR SCHNEEMAN: I think the
12 important point is that it's captured and it's
13 also identified as to whether it's fresh or
14 seafood.

15 Other questions or comments? Oh,
16 please.

17 MEMBER VAN HORN: Sorry. This is
18 Linda Van Horn again. And I'm on this
19 subcommittee, but when we were going through our
20 slides and you don't have any chance to put it
21 all in perspective, this is probably a parking
22 lot issue. But it occurred to me, especially

1 after all of what we've heard today, that, you
2 know, adverse pregnancy outcomes are a risk
3 factor for cardiovascular disease.

4 And what's of interest as I was
5 looking at all of this, realizing we're talking
6 about the entire population now, if there are
7 dietary factors associated with adverse pregnancy
8 outcomes -- as we were thinking earlier about
9 gestational diabetes, gestational hypertension,
10 et cetera -- and maternal intake of these types
11 of foods, any of them -- I'm thinking fatty acids
12 but it could be any of them -- that relate to the
13 maternal risks, I also wonder if, because of the
14 adverse pregnancy outcomes, the child, the
15 offspring, is at greater risk for depression,
16 anxiety, you know, any other developmental
17 problems that still could stem from initial diet-
18 related relationships maternally. I don't think
19 there's a whole lot of data that anybody's really
20 looked at those connections across the lifespan.

21 So, again, as I say, I think this is
22 way too much, you know, to try to expect us to do

1 within this particular environment and all these
2 questions that we're already trying to address.
3 But I think, if it's possible on the basis of any
4 data that do exist that relate these connections,
5 we should recognize those as being potentially
6 important as we go forward. Because if it all
7 starts with maternal nutrition, there's reason to
8 think, you know, we should be more mindful of
9 those relationships.

10 CHAIR SCHNEEMAN: Yeah, go ahead.

11 MEMBER ARD: Jamy Ard. So, one
12 question comes to mind related to fish and
13 seafood consumption. In thinking about the
14 definitions and the things that are considered in
15 analysis of type, source, amount, and frequency,
16 timing, one of the other things that comes to
17 mind from some data I can recall is the
18 preparation. So, a high proportion of seafood
19 consumption, especially fresh water fish and
20 seafood, is fried, right?

21 And so there are data that suggest
22 that there's a different impact of seafood, or

1 maybe the beneficial impacts are not there when
2 the preparation is taken into consideration.

3 MEMBER SNETSELAAR: And our committee
4 did definitely talk about that. And I was
5 thinking that it was still listed somewhere. But
6 I will need to look at that again.

7 I don't know, Joanne, you may remember
8 more about that than I. But we have talked about
9 that, definitely. That's a good point.

10 MS. SPAHN: The subcommittee did
11 identify preparation. And we had said that that
12 would be an element of seafood we would extract
13 and would present in evidence tables for the
14 committee's evaluation during synthesis.

15 CHAIR SCHNEEMAN: So it's part of the
16 data extracted.

17 MEMBER SNETSELAAR: I remember that
18 specifically because it was something that I felt
19 strongly about.

20 CHAIR SCHNEEMAN: Other questions or
21 comments about getting the analytical framework
22 down?

1 We do have -- we can move to the
2 committee discussion, just a general discussion.
3 And I think what we did the last time was just go
4 around and allow each of the committee members,
5 if you have comments at this point reflecting on
6 any one particular protocol, or just thinking
7 about the way forward from here, it would be
8 great to have as part of our closing comments
9 from today.

10 So I'm going to start with you, Elsie,
11 because I know you're going to pop out soon.

12 MEMBER TAVERAS: None that come to
13 mind at the moment.

14 MEMBER ARD: So, I'll steal Rick's
15 comment from earlier about sodium. And I wonder
16 if there might be some unifying concepts or ideas
17 or themes that go across the age span and
18 different questions that we might -- may not, you
19 know, sort of have all the data to, or specific
20 questions to address per se, but we might take
21 the opportunity to pose either areas for
22 additional work or at least speak to the idea

1 that, you know, A, this is what we were tasked to
2 look at, but, B, these are some other things that
3 we might need to consider that would modify the
4 effects that we're reporting out on. And sodium
5 would obviously be one of those that's measured.

6 CHAIR SCHNEEMAN: Heather?

7 MEMBER LEIDY: This is Heather Leidy.
8 Just a small comment. I really like the grid
9 idea. So, I think just that will help clear up
10 some of the inconsistencies I think that we have.
11 But something else that I had talked with a few
12 folks about, and that being it seems we're at the
13 stage now where, you know, as we start getting
14 the data, or summaries, there's going to need to
15 be, I think, a lot of crosstalk between a lot of
16 the different committees. And we haven't really
17 done that so much in our subcommittee calls.

18 And so I think I would just like to
19 see more where some of the chairs are sitting on
20 -- are able to call in on some of our
21 subcommittees, because I think the crosstalk
22 would be really helpful moving forward. So

1 that's something that came to mind today, that
2 there's a lot of things that I think now we can
3 start being a little bit more integrative.

4 MEMBER NAIMI: Tim Naimi. Nothing to
5 add at this time.

6 MEMBER MATTES: Rick Mattes. I was
7 going to make that same point. I think that we
8 have to integrate more to avoid redundancies and
9 to make sure we capture everything, because a
10 couple of new ideas came out.

11 MEMBER BOUSHEY: This is Carol
12 Boushey. And I have a similar comment to what
13 Jamy said, and Rick and everyone.

14 I think we sometimes some of the
15 language needs to be harmonized a bit. We're
16 talking about the same thing but we use different
17 words, and I think -- which is fine because those
18 words are there, otherwise we wouldn't have
19 picked them out to use them, but it might be
20 easier for us to actually do comparisons if we're
21 using the same terms.

22 CHAIR SCHNEEMAN: Sharon.

1 MEMBER DONOVAN: Pretty much the same.
2 I was surprised, for example, like with the
3 beverages, that there's quite a bit related to
4 pregnancy and lactation. And so, in addition to
5 make sure the covariates are consistent, but also
6 how we're defining gestational weight gain,
7 postpartum weight retention. So I think we need
8 to kind of clean those up before we actually
9 start the systematic reviews.

10 MEMBER SNETSELAAR: I don't really
11 have a lot to add. I think that being consistent
12 across the subcommittees, which has already been
13 indicated. But one thing, for example, parity
14 was brought up as something that might certainly
15 be a part of many of the different subcommittee
16 questions. So, I could just see that there are a
17 variety of things that we might want to look at,
18 which I'm sure has probably been primed already
19 anyway.

20 MEMBER SABATE: Okay. Joan Sabate.
21 On the presentations before the break,
22 particularly the one on birth to 24 months, there

1 was quite a lot of discussion and presentations
2 on the specific nutrients and nutritional status.
3 I think this is quite interesting and very
4 important from the nutritional viewpoint.

5 But I'm a little bit surprised by this
6 emphasis, and particularly in the context of, if
7 this is the task of this committee, or is the
8 task of the Institute of Medicine, the one that
9 issues the dietary DRIs, you know our outcomes in
10 general is health, not nutritional studies. And
11 going into specific nutrients when they come from
12 different sources, that could be the nutrients in
13 foods, the foods that have been supplemented or
14 also taking independent supplements. See,
15 basically we are just focusing on nutrients
16 independent of the source.

17 And I don't know to what extent we are
18 going to -- once we get the nutritional status, I
19 mean, if we are going to make food
20 recommendations based on nutritional status or
21 based on health outcomes.

22 MEMBER NOVOTNY: Rachel Novotny.

1 Yeah, echoing most of what I heard. In addition,
2 thinking about the analytic frameworks and
3 harmonization in presentation that I think will
4 help our conversations to be more to the points
5 we are trying to make. I think, even
6 analytically, I think there may be some
7 commonalities on, of course, the classic "what to
8 do with energy" that is always going to be there,
9 particularly for some of our overweight outcomes.
10 I think it could be useful to have some analytic
11 crosstalk as well.

12 MEMBER BAILEY: Regan Bailey. Just
13 echoing the -- and will be of no surprise to the
14 federal staff, who I keep talking about this with
15 -- but harmonization and standardization of the
16 terms that we are using, things like, what is a
17 life stage? And that we're all on the same page
18 about the terms that we're using. What is a
19 covariate versus what is a confounder? How we
20 define nutrients of public health concern versus
21 shortfall nutrients. So, really having some
22 clarify around those terms I think would be

1 helpful.

2 I really like, Jamy, your idea of the
3 grid for having consistent confounders and
4 covariates for each outcome. And, Heather, you
5 had some good ideas on that as well. And I think
6 that is mainly what I wanted to say. Thank you.

7 MEMBER VAN HORN: And, Linda Van Horn.
8 I've been pretty vocal, so I'll try to keep it
9 short. But I, likewise, agree with Jamy on the
10 sodium question for sure. That's got to be
11 something that we address because it's so
12 relevant to everything we're doing.

13 And also what Regan was just referring
14 to as far as nutrients of concern. In teaching,
15 one of the things that I use continually is the
16 wonderful slide that shows what are the
17 recommendations and what are the current American
18 eating behaviors. And I think that just sends
19 such an important message.

20 And one thing that was brought up
21 about beverages, I think it was Joan who said,
22 you know, is there a percentage of energy intake

1 from beverages that should be recognized as being
2 excessive in relation to obesity, weight control,
3 things like that? I don't think we know the
4 answer to that. But I think, you know, I
5 remember an AJCN paper that once demonstrated
6 that those who had higher intake of caloric
7 intake from beverages were more often overweight
8 or obese.

9 And so, you know, practical questions
10 like that that are relevant to public health, you
11 know, I think beginning with the end in mind, you
12 know, it would be helpful if we could provide
13 some guidance and direction on that as well.

14 MEMBER BAZZANO: This is Lydia
15 Bazzano. I don't have any additional comments at
16 this time.

17 CHAIR SCHNEEMAN: Ron, come back to
18 you.

19 VICE CHAIR KLEINMAN: Yeah, I mean, I
20 think everyone's summarized my thoughts pretty
21 well. I do think that our focus should be on
22 health outcomes, just as Joan said.

1 And I think, in fact, it is. Where we
2 have focused on specific micronutrients, it's in
3 the context of ultimately understanding the
4 impact of that micronutrient status on health
5 outcome. So I think, in a way, that's an
6 intermediate step to health outcomes where that
7 comes up. But I totally agree that this has to
8 inform the public about how to improve their
9 health through what they eat. And I think that's
10 the goal.

11 I've been incredibly impressed with
12 the amount of information that is going to be
13 generated from this process. What Carol was
14 saying before, as we were chatting, when I
15 started this I couldn't have imagined the number
16 of questions that each of these topics would
17 generate. I thought they were fairly
18 straightforward. And, you know, 10 minutes, 15
19 minutes, we could go through at least a couple of
20 these topics. And they continue to expand.

21 So I would say that we have to keep in
22 mind that it's important to cover what's

1 important, but to keep in mind that expanding
2 this analytic framework means that we get an
3 extraordinarily expansive evidence base that
4 we'll then have to deal with.

5 And so, to some degree, I'm quite
6 comfortable with where we are now. I do think
7 sodium is an important consideration and we
8 should bring that in. And I particularly
9 appreciate that comment about a need for
10 longitudinal observations so that we can put diet
11 in context with these isolated aspects of diet.

12 So, those are two of the more
13 important things, I think, for us. And then we
14 have talked about creating a grid for some time
15 now. And I think that's a must. And that's
16 something that we can talk through as well with
17 the subcommittee chairs on one of those -- on our
18 regular calls. And I know that the staff, I
19 think, is currently working on that. So I think
20 we're on our way towards the next stage of this
21 process. Thank you.

22 CHAIR SCHNEEMAN: Great.

1 VICE CHAIR KLEINMAN: And I did want
2 to -- sorry, I did want to say that I really
3 appreciate all the work that those who presented
4 today put into the presentations. I thought they
5 were terrific. I've been sitting in on three
6 subcommittees now, and Barbara's been sitting in
7 on four. And I thought the summaries were
8 outstanding.

9 And I had some insight into the work
10 that went into putting those together, both by
11 the staff, as well as the members of the
12 committee and those who presented. And it's very
13 impressive, and it made a great difference today.
14 So, thank you all for that.

15 CHAIR SCHNEEMAN: Great. Thank you
16 for those comments. I think, Ron, you've
17 captured a lot of what has been going through my
18 mind. First of all, just to thank everyone for
19 the work that they've done on the subcommittees
20 and then in the presentations today.

21 And I hear what you're saying. I
22 think we've made some progress toward harmonizing

1 terminology, but I agree with everyone, that the
2 discussion today shows that there's more we need
3 to do. And also the more we need to do to
4 facilitate the crosstalk among the subcommittees,
5 because I think that's going to be critical for
6 the work going forward.

7 I'm going to just do some practical
8 things. I'll remind folks who are interested in
9 making comments, if the public is interested in
10 making comments on the protocol, they will be
11 most useful to the committee if they could be
12 submitted by July 24th. You're welcome to submit
13 them any time, but to be most impactful, July
14 24th would be great.

15 And as the committee continues to move
16 forward with its work and it starts to implement
17 these protocols, there will be updates to the
18 web. So we want to be sure and encourage people
19 to stay on the listserv that USDA and HHS have,
20 to visit the website, because that will be an
21 ongoing source of information. I think both
22 departments have really committed themselves to

1 try and be as transparent as possible. And so
2 getting information out there is a key part of
3 that.

4 We are prepared to adjourn at this
5 point. I would remind folks that we will
6 reconvene tomorrow morning. And tomorrow morning
7 we start at 8:30. This morning we started at
8 9:00. So, we'll start a little bit early. And
9 we're looking forward to hearing the public
10 comments for the committee tomorrow.

11 And we, yes, we'll come right back
12 here. So, again, thank you. Thank you all for
13 attending and being here. And thank you to the
14 committee for all your hard work.

15 (Whereupon, the above-entitled matter
16 went off the record at 4:13 p.m.)

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In the matter of: 2020 Dietary Guidelines
Advisory Committee Meeting

Before: USDA

Date: 07-10-19

Place: Washington, DC

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