

2020 DIETARY GUIDELINES ADVISORY COMMITTEE

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PUBLIC MEETING

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FRIDAY
OCTOBER 25, 2019

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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, SW, 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, RD, Member
 DR. TERESA DAVIS, PhD, Member
 DR. KATHRYN DEWEY, PhD, Member
 DR. SHARON DONOVAN, PhD, RD, Member
 DR. STEVEN HEYMSFIELD, MD, Member
 DR. HEATHER LEIDY, PhD, Member
 DR. RICHARD MATTES, PhD, MPH, RD, Member
 DR. ELIZABETH MAYER-DAVIS, PhD, 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. JAMIE STANG, PhD, MPH, RD, Member

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

2 9:02 a.m.

3 MEMBER de JESUS: Good morning. I'm
4 pleased to welcome everyone to the third meeting
5 of the Dietary Guidelines Advisory Committee on
6 day two.

7 I'm Janet de Jesus, from the Office of
8 Disease Prevention and Health Promotion at the
9 Department of Health and Human Services.

10 It is my pleasure to welcome our
11 morning speaker, Admiral Brett Giroir. He is the
12 16th Assistant Secretary for Health at the U.S.
13 Department of Health and Human Services. He
14 serves as the Secretary's principal public health
15 and science advisor, senior advisor for HRSA,
16 CDC, SAMHSA and chief opioid policy advisor.

17 He also oversees the Office of the
18 Surgeon General and the U.S. Public Health
19 Service Commissioned Corps.

20 His office leads many critical
21 national initiatives, including a historic new
22 plan to end the HIV epidemic in America, the

1 Physical Activity Guidelines, the Revised Common
2 Rule, and a cross-agency effort to improve the
3 outcome of patients with sickle cell disease.

4 Previously, Dr. Giroir served in
5 numerous leadership positions in the federal
6 government and in academic institutions. Most
7 notably, he was the first physician to be
8 appointed as an office director at the Defense
9 Advanced Research Project Agency.

10 As a pediatric critical care
11 physician, Dr. Giroir cared for critically ill
12 children for 14 years. He continues to bring
13 that hands-on patient-centered perspective to his
14 work as Assistant Secretary for Health, where his
15 primary goal is leading America to healthier
16 lives.

17 Please join me in welcoming Admiral
18 Giroir.

19 (Applause.)

20 DR. GIROIR: Well, good morning
21 everyone, and good morning to everyone who's
22 watching us in the virtual space.

1 I love introductions like that because
2 the introductions are longer than my remarks are
3 supposed to be.

4 (Laughter.)

5 DR. GIROIR: So, and I'm always very
6 jealous about the Department of Agriculture
7 because they really have wonderful architecture
8 and historic buildings, so it's really great to
9 be here.

10 I am really here because primarily, I
11 want to thank the members of the Committee. I
12 really do. We had such a long period of time
13 going through the process to understand how this
14 Committee would work to receive nominations.

15 And, I can tell you that when I met
16 with Secretary Azar and Secretary Perdue in his
17 office talking about the Committee, we were
18 floored by the credentials, and the passion, and
19 the commitment that all of you have.

20 So, I think this is, you know, this is
21 the rock star committee, Advisory Committee, and
22 we really appreciate your work.

1 I know how much time you have to put
2 into this. I think a lot of people understand
3 the time commitment that's involved, but I don't
4 think people understand the physical stresses of
5 all the travel and work that you need to be
6 through.

7 But, I think also people don't realize
8 it's a little bit emotionally stressful. And, I
9 felt that when I was on advisory committees.
10 Because, what you do really affects millions of
11 lives over the next few years. And the issues
12 are not easy. They're really rough science
13 engagement, but they're so very important. So,
14 the main reason I am here is to really thank you.
15 So, I do appreciate that.

16 I also want to thank all the staff who
17 put this together. This is not an easy lift by
18 any chance. So, if you're a staff member either
19 at USDA or at HHS who's worked on putting this
20 together, stand up, please.

21 (Applause.)

22 DR. GIROIR: So, my office is

1 primarily responsible for leading America to
2 healthier lives. We try to provide the road map
3 for being healthy where -- whether that's vaccine
4 policy, whether that's the elimination of viral
5 hepatitis, very recently the Physical Activity
6 Guidelines for Americans. So, we are all about
7 prevention and keeping people healthy.

8 And, every single time I talk, I talk
9 about the dynamic duo of nutrition and exercise.
10 And, that really is the foundation of all health
11 in my mind.

12 You look at our expenditures now, \$3.6
13 trillion dollars in the United States. \$6
14 trillion dollars by 2027, almost 19 percent of
15 the GNP, 90 percent of our expenditures on
16 chronic conditions.

17 I'm a pediatrician as you heard, and
18 of course, I'm extraordinarily thrilled that
19 we're able to move into the newborn to 24-month
20 age group, and also pregnancy and lactation.

21 But, if you look at some of the
22 estimates, today's two year olds, it is estimated

1 by the time they're 35, 60 percent of them will
2 be clinically obese.

3 Our country cannot survive 60 percent
4 of our 35 year olds being clinically obese with
5 the long tail not only of obesity, cardiovascular
6 disease, hypertension and diabetes, but we now
7 know that so many forms of cancer are linked to
8 improper nutrition and obesity. So, our country
9 cannot survive this.

10 If you look today, three-quarters of
11 our 17 to 24 year olds could not, could not meet
12 the standards for the military if they applied to
13 it. Three-quarters. About a third of that is
14 obesity and physical fitness. About a third of
15 that is education. About a third of that is
16 substance use disorder.

17 So, again, there is no way our country
18 is going to survive unless we get to some of the
19 root causes.

20 The promising news though, the
21 promising news is I know that with the
22 appropriate guidelines, it can serve as a basis

1 for all of us to move forward.

2 I know that by good nutrition, even
3 the estimates right now, that about half of all
4 cardiovascular mortality can be averted.

5 We also know that between easy things
6 like vaccination, elimination of smoking and
7 appropriate nutrition, we could prevent 42
8 percent of all cancers right now. That's what we
9 know about and I bet as things move forward,
10 we'll learn more and more about the prevention
11 that we can get.

12 I'm very excited about new cell
13 therapies for cancer, but I really want to put
14 the National Cancer Institute out of business.
15 And, I think we can go a long way with that by
16 just doing the kinds of things that, that you
17 recognize.

18 So, again, I, I do want to thank you
19 for all your work. I want everyone to know that
20 even though the schedule hasn't been right that
21 I've been able to be here on the previous
22 meetings, that we spent a lot of time, a whole

1 lot of time at the level, at my level and at the
2 level of the secretaries, trying to understand
3 what you're doing, caring about what you're
4 doing, trying to facilitate your work. And, I
5 just want everyone to understand that, you know,
6 as we say, we got your six, right?

7 We really got your back, we want you
8 to do the best job possible because so many
9 important things depend on the outcome of this
10 Committee.

11 Nutrition really is the foundation.
12 I'll say the dynamic duo of nutrition and
13 exercise together really has such profound
14 effects.

15 Oh, I forgot the one I really wanted
16 to talk about, which is my, my, my new latest
17 kick is we're learning more and more as you know,
18 and about every month there's a new great article
19 -- this is not my field -- but the impact of
20 nutrition and exercise on neurodegeneration.

21 This, perhaps to me, is one of the
22 most exciting areas because I turn 59 next week,

1 so I'm getting up to the age group where you
2 start worrying about these things. But, if you
3 look at the epidemiology of the aging population
4 and the fact that we don't have, we really don't
5 have a paradigm for neurodegeneration.

6 But, what we do know is if you don't
7 smoke, if you don't drink excessively, if you
8 have exercise and you have a good, healthy
9 nutritional program with high quality diet, you
10 can reduce your risk by about 60 percent.

11 If there was a pill that reduced your
12 risk of Alzheimer's by 60 percent, it would sell
13 \$10 trillion tomorrow.

14 So, I look forward as we open the
15 aperture on what nutrition can do for us. Food
16 is medicine, both preventative medicine as well
17 as healing medicine if you're sick.

18 And, again, I want to thank you so
19 much for your time, your commitment, your
20 passion. And, anything you need, we're there for
21 you.

22 So, thank you very much. Appreciate

1 it.

2 (Applause.)

3 CHAIR SCHNEEMAN: Thank you very much
4 for those comments. I know the Committee
5 appreciates having the support of both USDA and
6 the HHS as it moves forward with the work, and
7 the importance of the, the work.

8 So, I'm pleased to welcome you to day
9 two of our, our meeting -- oh great. And, I'm
10 welcoming both the people online as well as those
11 of you in, the, the room. And, loyal Nats fans,
12 who I'm sure would rather be watching the Dietary
13 Guidelines Advisory Committee than the --

14 (Laughter.)

15 CHAIR SCHNEEMAN: -- than the World
16 Series.

17 But, so, just to remind you of the
18 purpose of our public meeting. This meeting
19 three for the Dietary Guidelines Advisory
20 Committee. We are describing the status and
21 providing updates on the work of subcommittees
22 for the full committee discussion and decisions.

1 The subcommittees have been reviewing
2 evidence and providing advice to this parent
3 committee, and each subcommittee conducts its
4 work together between meetings, but all of the
5 decisions going forward are made by the full
6 committee in its public meetings.

7 So, the updates to be -- that will be
8 discussed and the presentations that we discussed
9 yesterday will continue today, are any of the
10 substantial updates to the 40 protocols that were
11 discussed at meeting two. So, any of those
12 revisions.

13 We are doing discussion and
14 deliberation on 19 new protocols that have been
15 developed by the subcommittees and we're able to
16 then review evidence that is available that some
17 of the subcommittees are bringing forward for
18 the, the committee, although most findings are
19 still to come. But we are starting that process
20 of looking at the evidence and developing
21 conclusion statements.

22 So, again, just to remind you that all

1 of the information is available on
2 DietaryGuidelines.gov. So, all of the protocols
3 that we will be talking about are being posted on
4 DietaryGuidelines.gov.

5 So, by going to the website,
6 identifying the questions and, then from those
7 questions that are of interest to you, you can
8 find the, the protocols. And also on that
9 website, you can track the progress of the, the
10 Committee as it, it moves forward with the, the
11 work.

12 So, in yesterday's discussion, we had
13 a presentation to look at the NESR approach to
14 the synthesis of evidence since that is the phase
15 that the committee is, is moving into as it
16 implements its protocols.

17 And, we heard the subcommittee updates
18 for the Dietary Patterns Subcommittee, the
19 Dietary Fats and Seafood Subcommittee, Beverages
20 and Added Sugars, and we also moved from today's
21 agenda, the Frequency of Eating Subcommittee
22 report. So, we had that report yesterday.

1 And, then we had the opportunity for
2 committee discussion and it was a good
3 opportunity for the Committee to start thinking
4 about and discussing the overall format of the,
5 the report as we move forward. And, the notion
6 that we're using a life stages approach as we
7 report our findings to the Departments.

8 So, for today's agenda, we're almost
9 finished with the opening remarks, and we will
10 continue our subcommittee updates starting with
11 the Birth to 24 Months Subcommittee. And, Birth
12 to 24 has been working with Dietary Patterns.
13 So, we're going to have a bit of a, a joint
14 report.

15 And, then the Pregnancy and Lactation
16 Subcommittee, and then the Data Analysis and Food
17 Pattern Modeling working committee, followed by
18 committee discussion, closing remarks.

19 And, just to remind folks, we
20 announced yesterday and I'll note it again now,
21 that we're expecting to do all of the
22 subcommittee reports before having to take the

1 lunch break. So, we will probably be ending at
2 the, the lunch time today. That's what we are
3 anticipating for, for today's agenda.

4 And, the agenda doesn't show a break,
5 but we will try to work in a break since it, it
6 can be a long morning.

7 And, finally, let me remind you that
8 if the public listening to the presentations, if
9 you have comments that are specific to the new
10 protocols that are being presented and discussed
11 today, it's most helpful for our work if they can
12 be submitted by November 7th, so that they can be
13 considered before we start implementing the, the
14 protocols.

15 However, the comment period remains
16 open throughout the Committee's work ending in
17 2020. But, for those protocols, November 7 is
18 the important time.

19 So, those are my remarks for opening.
20 I'll just ask the Committee if you have any
21 questions or comments you want to raise at this
22 point, or, ready to go? Okay, so Dr. Dewey, do

1 you want to -- oh, okay.

2 MEMBER DEWEY: Thank you very much,
3 Barbara.

4 I first want to thank the members of
5 this subcommittee that are very dedicated and
6 hardworking. It's been a real pleasure to have
7 our weekly conference calls, and the staff that
8 has supported us, which are also amazing.

9 And, in particular, I'd like to thank
10 Elsie Taveras, because I was not able to be here
11 for the July meeting, and she was very good at
12 presenting our protocols at that time.

13 I'll tell you the punch line here, we
14 don't have any conclusion statements yet, but we
15 have made a lot of progress, and we have been
16 working very hard on both developing and
17 implementing all the protocols.

18 There are, you know, many protocols
19 available on the web, but I wanted -- I went
20 through and, and looked at well, how many
21 questions or relationships are we actually trying
22 to look at in terms of conclusion statements, and

1 I think it's at least 50.

2 So, you can imagine how confusing it
3 can get. And that's just the ones that our
4 subcommittee is looking at this age group as
5 you'll see in a moment. The other subcommittees
6 are also working on issues related to this age
7 group.

8 And the other aspect even though it is
9 many, many relationships we're looking at, we are
10 really only scratching the surface of the issues
11 around feeding infants and toddlers.

12 And, for the most part, the questions
13 we're looking at relate to what to feed, and we
14 aren't going to be able to really address the
15 issues of how to feed. For example, issues like
16 responsive feeding. But, that's work for the
17 future.

18 So, I'd like to start by explaining
19 that the Birth to 24 Months topics are, are being
20 addressed actually by four different
21 subcommittees as shown here.

22 And, on the next slides I will

1 describe the B24 topics that are addressed by
2 these different subcommittees. And I'd also like
3 to point out that all this information is
4 available on DietaryGuidelines.gov.

5 So, in our subcommittee, this is one
6 of the slides that shows the ones that we are
7 working on directly. That includes the
8 recommended duration of exclusive human milk
9 and/or infant formula feeding as it relates to
10 five different categories of outcomes.

11 And, I won't read through all of them,
12 but just to point out that one of those is
13 micronutrient status, and that actually
14 encompasses six different nutrients. So, there
15 are many questions embedded within that
16 particular topic.

17 And, then for the frequency and volume
18 of human milk or infant formula feeding, we're
19 looking at how that relates to two of those five
20 outcome areas, micronutrient status and growth
21 size and body composition.

22 And, then for the third topic shown

1 here, the overall question is how do dietary
2 supplements from either supplements or fortified
3 foods relate to three different outcome domains:
4 nutrient status, growth size and body
5 composition, and bone health.

6 And, there are four nutrients as shown
7 here, that we're focused on in terms of
8 supplements or fortified foods.

9 Now, in terms of complementary
10 feeding, we also have quite a suite a questions
11 we're examining that look at how both the timing
12 of introduction of complementary foods, and the
13 types of complementary foods are related to
14 outcomes in five domains shown here.

15 And, again for the micronutrient
16 status domain, we actually are, are focused on
17 six different nutrients, so there are multiple
18 questions embedded in that.

19 Now, in addition to the work that our
20 subcommittee is doing on complementary feeding,
21 the Data Analysis and Food Pattern Modeling
22 Subcommittee is going to be directly tackling

1 these questions of whether USDA food patterns
2 could be established based on relationships
3 identified, will they meet nutrient
4 recommendations, and is there evidence to support
5 supplementation or fortified foods to meet those
6 nutrient needs?

7 We haven't really started tackling
8 that yet, I think Regan will mention that a
9 little later.

10 Then, in terms of beverages, our
11 subcommittee is looking directly at how beverage
12 consumption relates to growth, size and body
13 composition. And, actually, the previous
14 pregnancy and birth to 24 months' work
15 encompassed some of, of this systematic review
16 process because they're included, beverages were
17 included, within the complementary food feeding
18 exposures.

19 And, again, the Data Analysis and Food
20 Pattern Modeling Subcommittee will be examining
21 other questions related to this. How does
22 beverage consumption by infants and toddlers

1 relate to achieving nutrient and potential food
2 group recommendations?

3 Then, in terms of added sugars, the
4 Data Analysis and -- sorry, it says B24 and/or
5 Beverages and Added Sugars Committees at the top
6 there -- will be looking at how added sugars
7 relate to three different types of outcomes.

8 And the Data Analysis and Food Pattern
9 Modeling Subcommittee is looking at how added
10 sugars may relate to achieving nutrient and food
11 group recommendations, and whether certain
12 amounts of added sugars can be accommodated in
13 the healthy diet while still meeting food group
14 and nutrient needs.

15 Now the, the top question there,
16 again, is related to the previous work that was
17 done because sugar sweetened beverages were part
18 of the beverages that were looked at. So, that
19 is a, a significant proportion of the added
20 sugars that children in this age group are
21 exposed to.

22 Then, in terms of types of dietary

1 fats, the Dietary Fats and Seafood Subcommittee
2 is looking at how dietary fats relate to four
3 different types of outcomes. And, in this age
4 group, the literature on some of those longer
5 term outcomes is probably very scant.

6 But, in terms of neurocognitive
7 development, that's an area where there's
8 probably a lot more to work with.

9 Then, in terms of seafood, the lead
10 subcommittee is -- we're still kind of working
11 out who's doing what, but the Dietary Fats and
12 Seafood will probably be taking the lead on how
13 seafood consumption in this age range relates to
14 neurocognitive development and risk of
15 cardiovascular disease. And I think we'll be
16 working closely with that subcommittee on those
17 questions.

18 Now, what I'd like to do at this point
19 is tell you where we are with the human milk and
20 infant formula protocols, which were presented in
21 July. And those are being implemented.

22 And these protocols either had no

1 revisions or very minor revisions that won't
2 result in substantive changes to the reviews. So
3 we won't spend committee time going over those
4 minor changes, but please note that all the
5 protocols are available at DietaryGuidelines.gov.

6 But one item that we do want to report
7 to the Committee is that we discussed the
8 parameters around how the studies define food
9 allergy.

10 We decided that it was best to review
11 studies in which food allergies were diagnosed
12 based on fairly rigorous criteria, gold standard
13 being food challenge, but also making room for
14 studies that included both food sensitization, as
15 well as some other evidence such as a history of
16 clinical reaction.

17 The Pregnancy and Lactation

18 Subcommittee is also discussing the exact wording
19 of that second criterion and so, we're -- we
20 still may have a few wording changes to, to put
21 here, but that's the, the basic principle. And
22 that aligns with the methods that we used in the

1 existing review from the previous project that we
2 are updating.

3 So, we would now like to update the
4 committee in our progress in implementing the
5 protocols presented in July. And, the first good
6 news is that the literature search is complete.

7 We actually used two different
8 literature searches for the human milk and infant
9 formula reviews. And, one was from the Pregnancy
10 and Birth to 24 Months Project, and the other was
11 new for the current 2020 Dietary Guidelines
12 Advisory Committee.

13 So, you may recall that across the
14 committee, some of the work we will do will
15 involve updating the existing NESR systematic
16 reviews.

17 And, in our subcommittee, those
18 existing reviews are from the Pregnancy and Birth
19 to 24 Months Project, which was completed just
20 prior to the work of this committee.

21 So, during that prior project, the
22 search for human milk and infant formula

1 literature captured over 35 years of research,
2 from January 1980 to March of 2016. And it
3 included human milk and infant formula literature
4 relevant to our current work.

5 Systematic reviews were completed for
6 food allergies and atopic allergic diseases,
7 cardiovascular disease outcomes, and diabetes
8 outcomes. And, systematic reviews were planned
9 but not completed for growth, size and body
10 composition, micronutrient status and
11 developmental milestones.

12 And the second literature search which
13 was recently conducted captures literature from
14 January 2016 through last month. And this search
15 allows us to update the existing reviews with
16 evidence from the last three years, as well as
17 examine nearly 40 years of evidence for our new
18 reviews.

19 Now, two NESR analysts independently
20 screened the literature search results using the
21 inclusion and exclusion criteria that we
22 presented in July, and data are being extracted

1 from the studies that met our inclusion criteria.

2 We decided to start with the
3 systematic review examining the relationship
4 between the duration, frequency and volume of
5 human milk and/or infant formula consumption, and
6 micronutrient status. And we think that this
7 will be one of the smaller bodies of evidence.

8 So, as you can see here, there are
9 currently between zero and ten articles included
10 for the various nutrients of interest, which
11 include iron, zinc, iodine, vitamin D, vitamin
12 B12, and fatty acids.

13 These numbers may change slightly
14 because the NESR analysts have not yet finished
15 their manual search, which involves using the
16 references of the included articles as an
17 additional source of articles to screen.

18 However, due to having no articles or
19 a very small number of articles for some of these
20 nutrients, we anticipate that we will probably
21 have insufficient evidence to determine the
22 relationship between duration, frequency and

1 volume of exclusive milk, human milk, and/or
2 infant formula consumption with some of them, but
3 not all of them.

4 Our other important set of questions
5 revolves around nutrients from supplements and
6 fortified foods. And again, those protocols were
7 presented in July and, they are in the process of
8 being implemented.

9 As with our human milk and infant
10 formula protocols, these protocols had either no
11 revisions or minor revisions that won't result in
12 substantive changes to the review, and they are
13 available at DietaryGuidelines.gov.

14 And just to remind you, the specific
15 nutrients that were focused on here are iron,
16 vitamin D, vitamin B12, and omega-3 fatty acids.

17 The literature search for the
18 systematic reviews is in the final stages of
19 development and will be run very shortly.

20 In addition, we have been meeting with
21 the other subcommittees to discuss cross-cutting
22 topics that are relevant to this age group. In

1 particular with the Data Analysis and Food
2 Pattern Modeling Subcommittee, we've discussed
3 the availability of data for this age group, and
4 actually looking at three sub-age groups: 0 to 6
5 months, 6 to 12 months, and 12 to 24 months
6 because of the differences in infant feeding
7 recommendations and dietary patterns during those
8 periods.

9 We've also discussed the minimum
10 sample size that we might need, and the
11 feasibility of stratifying by the main milk
12 source, human milk or infant formula, or both, to
13 examine food group and nutrient intake at 6 to 12
14 and 12 to 24 months.

15 We've also tried to grapple with the
16 issues around adequacy of information on human
17 milk nutrient content, as well as discussed the
18 identification of priority nutrients for this age
19 group. And, after I finish, Regan will be
20 presenting more about what that subcommittee has
21 been working on for this group.

22 With the Dietary Fats and Seafood

1 Subcommittee, we've discussed the developmental
2 outcomes in the age range of 0 to 2 years, and we
3 are currently working with them on developing the
4 protocols for Birth to 24 Months.

5 So, our next steps will include
6 continuing to implement the protocols we
7 developed, which are listed here once again, and
8 we will also continue working across the
9 subcommittees to have conversations about the
10 cross-cutting topics relevant to this age group.

11 Finally, we will develop the remaining
12 protocols which are updates to existing
13 systematic reviews about complementary feeding.
14 As you may remember, those were tackled in the
15 previous Pregnancy through Birth to 24 Months
16 Project.

17 So we've held off on finishing any
18 further work on those protocols in order to focus
19 on getting the first reviews completed that I've
20 already shown you.

21 So I'd like to again thank all the
22 members and the really terrific support staff.

1 There's no way we could have gotten to this point
2 without their very, very hard work.

3 So, thank you very much.

4 MEMBER BAILEY: So, I am representing
5 the Data Analysis and Food Pattern Modeling
6 Working Group.

7 And, we thought that it would be
8 salient to describe the work that we're doing
9 specific to B24 right after Dr. Dewey's
10 presentation so it's fresh in your mind. And,
11 then we'll talk about what we're doing in the
12 two-plus group after Sharon Donovan talks about
13 Pregnancy and Lactation.

14 So, again, this is the group that I'm
15 representing with the members listed here on this
16 slide. Oh, there we go. I was looking at my own
17 computer, which is confusing.

18 (Laughter.)

19 MEMBER BAILEY: As if I'm not
20 confusing enough, right?

21 So, when we were here in July, we
22 presented the first of five protocols, and we had

1 an asterisk around all of those protocols that we
2 had ongoing discussions with the B to 24
3 subgroup.

4 So, that's what we're going to be
5 talking about in the next couple of slides this
6 morning. So, how we've extended the work, or
7 we're proposing to extend the work, to that age
8 range.

9 And, so just to be quite clear, we
10 always say the term B24 but it's actually birth
11 to less than 24 months, so that's something that
12 has been changed in the protocols throughout.

13 We utilize nationally representative
14 data sources for the work that we're doing in
15 this group. The life stages that we're talking
16 about, infants and birth to less than 24 months,
17 with exceptions that are noted on certain slides.

18 We, as Dr. Dewey mentioned, are
19 interested in looking at infants together, and
20 then stratified by primary milk source. So, when
21 I use the word stratified, that is simply to
22 reflect that we're looking at these two groups.

1 We will look at them together, and
2 then as two separate groups by the primary source
3 of milk. And in ages groups listed here. In the
4 12 to 24 months we'll also look at those children
5 who are not receiving formula or human milk as a
6 separate group.

7 Again, we've discussed at length that
8 we will be utilizing the NHANES data for most of
9 the work we're doing. Given the small sample
10 sizes of birth to less than 24 months
11 historically collected in NHANES, we need to
12 combine five survey cycles.

13 So, we will be representing ten years
14 of data for this age group, and we have data
15 that's available through all of the databases
16 that are listed here.

17 So, we will have energy and nutrients,
18 we will have food groups, food subgroups and
19 foods as they are consumed by What We Eat in
20 America, food categories. And, dietary
21 supplements with the database that's available.

22 Breastfeeding initiation and duration

1 will be collected, or is collected, and will be
2 analyzed through the national immunization
3 survey, and that's representative of 2017 to
4 2018.

5 These are some of the key definitions
6 that we're working with and we have aligned with
7 the B24 group to make sure that we're working
8 with the same kind of definitions. So, you will
9 see throughout the next couple of slides CFB,
10 that is used to represent complementary foods and
11 beverages.

12 Our definitions of infant formula are
13 presented here, so meeting the FDA standards, as
14 well as Codex Alimentarius.

15 Mixed feeding is a term that is
16 defined as having both human milk and infant
17 formula, but not complementary foods and
18 beverages. And, then exclusive human milk
19 feeding, which Dr. Mayer-Davis described
20 yesterday. And, so our definition is inclusive
21 of the WHO definitions of exclusive, or
22 predominant.

1 So, let's jump right in and talk about
2 the food groups and nutrients.

3 First, we're going to look at the
4 prevalence of initiation and duration rates for
5 breastfeeding. We will look at the prevalence of
6 food group intake, mean intakes of food groups
7 and subgroups, as well as food category sources
8 of food group intakes, when that information is
9 available.

10 So, we thought that the clearest way
11 to explain what we're hoping to do is with this
12 table. And, you'll see that this -- that the
13 columns in this table represent ages and months.

14 So, for less than 4 months, we will be
15 looking at the prevalence of complementary foods
16 and beverages, as well as 4 to less than 6
17 months.

18 In those 6 to 12 months of age, again,
19 we're going to look at the whole group of
20 infants, as well as stratified by primary milk
21 source for prevalence of food groups, and mean
22 intakes of food groups. And, for food category

1 sources, we'll look at infants combined by
2 primary milk source.

3 And, then for those 12 months to less
4 than 24 months, we will look at that primarily as
5 one group.

6 In terms of our analytical framework,
7 will have the mean intakes of nutrients from
8 foods, beverages, and dietary supplements, usual
9 intake distributions adjusted for within person
10 variation from foods alone, and from foods
11 inclusive of dietary supplements.

12 And, the exceptions to the life -- the
13 age groupings are listed here because for the
14 dietary reference intakes, one year olds are in
15 the 1 to 3 group. So, when we're comparing it to
16 the dietary reference intakes, that will be the
17 framework which we are using as the benchmark.
18 And, then of course, food category sources of
19 nutrient intakes.

20 When we're trying to describe the
21 nutrients of public health concern, again we will
22 be looking at these usual intake distributions

1 inclusive and exclusive of dietary supplements
2 compared to the DRI, stratified by infant milk
3 source as previously mentioned.

4 When we are trying to evaluate the
5 current dietary patterns and beverage consumption
6 patterns, we will be looking at food group and
7 subgroup intake, and there's an asterisk there
8 because not all subgroups are consumed in
9 sufficient -- with sufficient sample size to make
10 stable estimates.

11 So, when available, we will have
12 subgroup data but if sample size does not permit,
13 we will have the very high level food group
14 intakes.

15 We are proposing at this point that we
16 will standardize that based on 100 calories. So,
17 with two years and older, we have the Healthy
18 Eating Index, which is expressed as per 1,000
19 calories. Given the much lower calorie intake of
20 this age range, we're at least initially talking
21 about standardizing that to 100 calories.

22 In terms of beverage consumption, the

1 percent of infants and young children consuming
2 given beverage type, the amount that is consumed
3 in ounces, as well as the nutrient and food
4 component contributions, from these beverages.

5 In terms of next steps, right now what
6 we have is information from foods and beverages.
7 We will move on to be inclusive of dietary
8 supplements as that data is available. We'll
9 summarize the findings after we finalize the
10 discussions around the table today, and hopefully
11 have some draft conclusions available for you
12 soon.

13 And then the final piece of all of
14 this is the Food Pattern Modeling.

15 So, I'd like to thank the support
16 staff, Dr. Pannucci, Casavale, Emily Callahan,
17 Cheyenne, and Eve Stody, as well as the federal
18 data analysis team who's been providing data to
19 us throughout this process.

20 So, I think both Kay and I are happy
21 to have questions about either of the
22 presentations here today.

1 MEMBER MATTES: So, I understand
2 you're, you're addressing the issue of food
3 allergies.

4 How are you going to interpret the
5 evolving literature on early exposure and risk
6 for allergy, and how are you going, how are you
7 going to evaluate the, the different levels of
8 intake relevant to that since it's kind of a new
9 science?

10 MEMBER DEWEY: Yes, so the previous
11 Pregnancy to Birth 24 Months Project tackled that
12 already, and the paper has been published that
13 looked at how complementary feeding relates to
14 those -- well, the human milk and formula as well
15 as complementary feeding, but the question that
16 you posed as more to do with the foods, the
17 complementary foods.

18 And, the, there were two experts on
19 that tech that had training and background in
20 that area and did a terrific job with the staff
21 of looking, you know, food by food. So, peanuts,
22 fish, milk, et cetera, were all looked at

1 separately.

2 And, at the time the paper was
3 written, there was enough evidence for peanut to
4 be quite definitive about that issue,
5 particularly the need to introduce that in the
6 first year of life.

7 And, there's emerging evidence for all
8 of those categories and Ron may want to speak to
9 that. So, I think what we'll be looking at when
10 we get to updating the complementary feeding
11 protocols and doing the searches, is what has
12 emerged since the end date for the searches that
13 went into that previous publication.

14 And, there might be quite a few for
15 some of those food categories, so we'll have to
16 work at looking at whether there's more evidence
17 and the grade might change. But, we have been
18 looking carefully both at the, the timing and the
19 type of food.

20 Quantity, I, I think is probably less
21 of an issue in terms of the data that are
22 available for the relationship. But, just having

1 it in the diet is, is part of that issue.

2 You want to add anything?

3 VICE CHAIR KLEINMAN: No, I think
4 you've described it really well from the fish
5 and, and nuts and the others that are probably
6 furthest along at this point. But I don't think
7 there's really any definitive evidence that
8 anyone is willing to put into a guideline at this
9 point.

10 So, I think it's, you know, we'll have
11 to see how that evolves over the next six months.
12 I think the further question is about feeding
13 during -- mothers' intake of these food during
14 pregnancy. And, so, I guess we'll get to that
15 during that discussion.

16 But, that, that is something that has
17 changed dramatically since the previous
18 guidelines.

19 Are there other questions?

20 MEMBER MATTES: Ask one more for
21 Regan.

22 So, you'll be looking at, at other

1 beverages. Have you defined which ones -- so we,
2 the beverage gang, we have this table and I think
3 there's 28 possible beverages. If you did all
4 pair-wise comparisons, there would be 378 to look
5 at, which is clearly not manageable.

6 MEMBER BAILEY: Yes, I --

7 MEMBER MATTES: So, we're going to
8 have to prioritize some of these. Have you
9 thought about that?

10 MEMBER BAILEY: And, in the next
11 presentation I think we have the discrete
12 categories of beverages.

13 But you're right, we're not going,
14 especially in these young age groups, we'll focus
15 a lot on milk and milk substitutes, 100 percent
16 fruit juices, what are the sources of added
17 sugars?

18 But it will be a limited number. We
19 won't have sample size sufficient to look through
20 all of the different categories.

21 Interesting to know you guys are a
22 gang.

1 (Laughter.)

2 MEMBER BAILEY: We'll talk about that
3 offline.

4 (Laughter.)

5 VICE CHAIR KLEINMAN: Are there other
6 comments? Yes.

7 MEMBER SNETSELAAR: Just one more
8 quick question, this is Linda Snetselaar.

9 I was wondering, and, and I think you
10 alluded to this at the beginning of your
11 comments, but I was wondering what you might be
12 doing in terms of looking at food allergies and
13 the ways in which foods are introduced to
14 children eating fresh foods. Will you be looking
15 at that at all?

16 For example, how to identify an
17 allergy in a child? I think that's changed over
18 time. And, just wondered if you might be looking
19 at that concept.

20 MEMBER DEWEY: I'm not sure I
21 completely understand the question. We have been
22 trying to define the criteria for the search by

1 means of either a food challenge for defining
2 food allergy, or a combination of both food
3 sensitization and some sort of clinical reaction.

4 Is that what you mean?

5 MEMBER SNETSELAAR: Yes, exactly.

6 Thank you.

7 MEMBER DEWEY: Okay. And while I have
8 the microphone, I wanted to add one more comment
9 about the, the types of data that we're going to
10 try to be compiling for this age group. And it
11 had to do with the prevalence of introduction of
12 complementary food and beverages at 4 months, or
13 before 4 months, or at 4 to 6 months.

14 We met just the other day so some of
15 the things that we discussed didn't make it into
16 the slides, but I think it is probably worthwhile
17 to stratify by human milk or formula as
18 predominant milk even for that outcome, because
19 there's some evidence that the age of
20 introduction of other foods and beverages is
21 probably a bit earlier in formula fed infants.

22 MEMBER BAILEY: That's a good point.

1 We saw that in the FITS 2016 data so I think we
2 could also examine that similarly with the NHANES
3 data.

4 VICE CHAIR KLEINMAN: Any other
5 comments or questions? You've got a lot to
6 analyze.

7 All right, is -- Regan, are you going
8 to continue, or we're going to go to Pregnancy
9 and Lactation?

10 (Off-microphone comments.)

11 VICE CHAIR KLEINMAN: Great. Sharon?

12 MEMBER DONOVAN: Okay, so good
13 morning. My name is Sharon Donovan, and I'm
14 presenting on behalf of the Pregnancy and
15 Lactation Subcommittee shown on this slide.

16 And, like everyone else, I'd like to
17 thank this committee for their hard work, as well
18 as the support staff. And I think we've made
19 quite a bit of progress since the meeting in
20 July.

21 So, today I'll be presenting new
22 protocols, as well as the implementation of some,

1 some of the protocols that we presented in July.
2 And, we actually have some draft evidence
3 synthesis, grading, conclusion statements for two
4 outcomes related to folic acid.

5 So, as a reminder, the, the committee
6 is addressing three broad topics: dietary
7 patterns, dietary supplements and fortified
8 foods, and maternal diet.

9 And, these are the new protocols to be
10 discussed today, so the effect of dietary
11 patterns on human milk, micronutrient status of
12 the mother, and infant developmental milestones.

13 In terms of dietary supplements, we
14 have new protocols for B12, omega-3 fatty acids,
15 and vitamin D, and as was just discussed, new
16 protocols on the impact of maternal diet on food
17 allergies.

18 So, these are the protocols that were
19 presented in July that we're currently
20 implementing.

21 So, in addition to the three on the
22 previous slide for dietary patterns, we're

1 investigating gestational weight gain and
2 postpartum weight loss.

3 And, as Kay alluded to, this gets very
4 complicated because we have a number of nutrients
5 of which have multiple outcomes. So, I think
6 counted we're doing 40 systematic reviews in, in
7 Pregnancy and Lactation alone.

8 Okay. So, these, these are still to
9 come. These are protocols and development that
10 won't be presented today. So, hopefully at our
11 next meeting.

12 So, these are updates to the protocols
13 that were presented in July. So, in terms of
14 dietary patterns and gestational weight gain and
15 postpartum weight loss, we modified the inclusion
16 and exclusion criteria for the intervention and
17 exposure to clarify that basically what was
18 discussed yesterday in terms of the, the dietary
19 patterns, that specific macronutrient proportion
20 diets will be included when they fall outside of
21 the acceptable AMDR, and only studies that
22 describe all macronutrients.

1 Then, in terms of dietary supplements
2 and fortified foods, we had proposed in July to
3 only cover the supplements. And, based on
4 feedback from the public, we have amended that
5 protocol for iron to include both supplements and
6 fortified foods.

7 So, now I'll move on to the developing
8 the plan, so the new protocols. And, I have a
9 lot of analytical frameworks to present so you'll
10 see that in terms of like, exposures and
11 comparators, there's a lot of repetition. So,
12 I'm going to primarily point out the uniqueness
13 of, of each one so we can get through this a
14 little bit more quickly.

15 So, these are protocols related to
16 dietary patterns. So, just to remind you of the,
17 the definition of the dietary patterns that were
18 -- was discussed yesterday.

19 So, first, what is the relationship
20 between dietary patterns consumed during
21 lactation and human milk composition and
22 quantity?

1 So, I'll walk through this one in a
2 little bit more detail, but the analytical -- so,
3 the intervention exposure is consumption of
4 and/or dietary adherence to a dietary pattern
5 compared to consumption of a different dietary
6 pattern, or different levels of consumption.

7 So, the population in this case is
8 human milk composition and human milk quantity.

9 So, basically for composition we're including
10 women during lactation, healthy and/or at risk
11 for chronic disease. But for quantity, we're
12 focusing only on those mothers that are
13 exclusively or predominantly breastfeeding, so
14 that we can get more accurate assessments of
15 intake. And, they will be healthy or at risk for
16 chronic disease.

17 So, we have a, a number of outcomes in
18 this. So this, and we, and this was mentioned
19 yesterday, but we will be looking at milk
20 collected after 14 days postpartum.

21 So, this is more representative of
22 mature milk as opposed to colostrum. So, some of

1 the standard macronutrients: water soluble
2 vitamins, fat soluble vitamins, minerals.

3 One of the aspects of human milk
4 minerals is that they, they're quite invariable.
5 They're tightly regulated at the mammary gland
6 with the exception of iodine and selenium. So,
7 we're focusing on those two.

8 We're also including some bioactive
9 proteins where there's, where there's data. And
10 again, this was mentioned before.

11 So, in terms of -- these are -- as you
12 will see as we go through, these are a lot of our
13 standard key confounders that we are carrying
14 through so I'll predominantly mention when we
15 have additions to that.

16 So, again, there's -- we're using the
17 standard NESR criteria that was described by Dr.
18 Schneeman, and we also are using the criteria for
19 these sets of questions related to dietary
20 patterns that are consistent with the Dietary
21 Patterns Subcommittee.

22 You'll see that for a lot of our

1 searches we are going back to 1980 because this
2 has not been previously included in the Dietary
3 Guidelines so we're trying to capture a broader
4 database. But again, for this, we're only going
5 to 2000 because as was mentioned yesterday, this,
6 this is more of a relatively new type of
7 analysis.

8 So, these are the, the types of
9 studies. Again, kind of following the standard
10 NESR inclusion and exclusion criteria with the
11 exception that for studies related to human milk
12 composition and quantity, we are -- decided to
13 include some cross-sectional studies because we
14 felt there might be insufficient longitudinal
15 studies to address these questions.

16 Okay, so the next analytical framework
17 is dietary patterns on infant developmental
18 milestones, including neurocognitive development.

19 So again, same intervention and
20 exposure. You can see the developmental
21 milestones. And, we're looking at this related
22 to a couple different outcomes, and they're

1 consistent with what Linda Snetselaar reported
2 yesterday in terms of looking at cognitive,
3 language, communication, movement, motor and
4 motor development, social, emotional, academic
5 performance, ADD, ADHD, anxiety, depression and
6 ASD.

7 And, we're looking at infants and
8 toddlers, birth -- B24, but also in this case,
9 looking at longer terms outcomes because a lot of
10 these, particularly language development and
11 academic performance, we'll need to look at, at
12 later ages.

13 So, a lot of the, the same key
14 confounders, we're also including aspects that
15 have been known to impact infant cognitive
16 outcomes, which include where they -- so, family
17 history and diagnosis of neurocognitive
18 disorders, maternal substance abuse. We also
19 have in here things related to parity, child sex,
20 breastfeeding practices, so duration and
21 exclusivity. Again, standard NESR criteria and
22 2000 to to be determined.

1 So, the next framework is again,
2 dietary patterns during pregnancy and maternal
3 micronutrient status. Same interventions and
4 comparators.

5 The micronutrient status that we're
6 looking at in the mothers is iron folate, B12,
7 vitamin D, iodine and omega-3 fatty acids. Our
8 population is women during pregnancy, healthy or
9 at risk for chronic disease.

10 In terms of key confounders, we are --
11 we've added as a factor to be considered not as a
12 key confounder, gestational diabetes because
13 there is some evidence that the metabolism of
14 some of these micronutrients can be different in
15 women with gestational diabetes. Again, standard
16 criteria here.

17 So, those were the, the dietary, the
18 new dietary patterns analytical frameworks. So,
19 now, moving on to the relationship between
20 nutrients from supplements and/or fortified foods
21 consumed before and during pregnancy, and
22 lactation.

1 So, we have five nutrients altogether.
2 I'll talk about iron and folate later. We
3 presented those in July and were now implementing
4 those.

5 But, these are the new frameworks:
6 B12, omega-3, and vitamin D. And, for each of
7 these nutrients, we're investigating all five of,
8 of these outcomes, so you can do the math.

9 Just a reminder of again, using
10 standard definitions of dietary supplements from
11 ODS and fortification from the FDA.

12 We also had to define some of the
13 criteria. So, because this is including before
14 pregnancy, we considered the time of up to six
15 months prior to pregnancy as being the before
16 pregnancy time frame.

17 Pre-pregnancy BMI is being defined
18 based on health records for up to one year before
19 to up to and including the first trimester,
20 because we oftentimes don't have those
21 measurements from -- in health records.

22 Gestational weight gain defined

1 according to the CDC. And, again, gestational
2 diabetes. Again, diabetes occurring during
3 pregnancy in women not previously diagnosed, and
4 this is consistent with what was used in the
5 pregnancy, or B24 Project.

6 Okay, so now we'll talk about B12
7 first. So again, we have five outcomes, so I
8 will explain the first one in a little bit more
9 detail, and then just highlight the differences.

10 So, this one is on B12 and from
11 supplements and/or fortified foods consumed
12 before and during pregnancy and lactation on
13 micronutrient status. So, we're looking at
14 exposure to B12 either from supplements,
15 fortified foods, or the combination, compared to
16 those who were not exposed, or exposed to a
17 different level of intake.

18 So, women before and during pregnancy
19 and/or lactation, healthy or at risk for chronic
20 disease.

21 For our B12 markers, we're considering
22 B12, methylmalonic acid, homocysteine, and

1 holotranscobalamin in, in the maternal
2 circulation. We're also looking at folate,
3 hemoglobin, mean corpuscular volume and red blood
4 cell distribution width. And, our population is
5 women during pregnancy and/or lactation.

6 So, the, the standard key confounders
7 for other factors to be considered, we're
8 including substance abuse, alcohol or drug
9 intake, and gestational age.

10 We also I can point out, we're as a
11 key confounder, we have vegan or vegetarian diets
12 in here as well for B12.

13 So, but this is the relationship
14 between B12 and risk of gestational diabetes.
15 So, these are the same. So, in this case we have
16 intermediate outcomes, which could be reported --
17 we're not using these as diagnostic. Basically,
18 the end point for diagnosis is gestational
19 diabetes.

20 We have added a couple additional
21 confounders in a family history of diabetes or
22 prediabetes, and under other factors to consider,

1 we have prior history of a large for gestational
2 age infant, or enrollment in an
3 intervention/prevention trial.

4 So, these data will be extracted.
5 They're not considered a key confounder, but we
6 are asking the staff to collect data on this.

7 This is the framework for B12 on the
8 risk of hypertensive disorders during pregnancy.
9 So, again, we have some intermediate outcomes.
10 Blood pressure and proteinuria. And, then the
11 health outcomes are eclampsia, preeclampsia, and
12 gestational hypertension.

13 In terms of the, the key confounders,
14 we added here diagnosis of gestational diabetes
15 because sometimes these co-occur quite commonly.
16 Smoking, history or diagnosis of hypertension or
17 cardiovascular disease. Under other factors
18 we've added also physical activity to be
19 extracted.

20 This is B12 and human milk
21 composition. It's a little bit more simple. The
22 only outcome here is B12 concentration in human

1 milk. And we didn't have any additional
2 confounders or other factors.

3 Okay, this is on, on B12 on infant
4 developmental milestones, including
5 neurocognitive development.

6 So, again, these are the same outcomes
7 that I reported previously for looking at the
8 developmental -- or I'm sorry, dietary patterns
9 and infant neurocognitive outcome. And again,
10 the, the outcomes and confounders are very
11 similar to the dietary patterns except now the
12 vegan and vegetarian diets.

13 So, we've, you know, done our best to
14 try to be as consistent not only internally, but
15 also as we work with other committees.

16 Okay, so for all of the B12 analytical
17 frameworks, again, the standard
18 inclusion/exclusion criteria.

19 So, again, the same types of studies
20 and continuing to include cross-sectional studies
21 only for human milk composition, and going back
22 to 1980 for these, these outcomes.

1 So, now we have the analytical
2 frameworks for omega-3 fatty acids. So, these
3 basically looking at relationship between the
4 intake and the same five outcomes that I just
5 described. So, I again, I'll try to go through
6 this pretty concisely.

7 So, we have exposure to omega-3 fatty
8 acids through supplements, fortified foods, or
9 the combination compared to a different level of
10 exposure. For our nutrient status we're looking
11 at fatty acid status in red blood cells and
12 plasma of the omega-3 fatty acids, and omega-6
13 fatty acids.

14 So, alpha linolenic acid,
15 docosahexaenoic acid, and EPA. And then linoleic
16 acid and arachidonic acid.

17 So, in terms of the key confounders,
18 we're including fish and other seafood
19 consumption, and obesity status. Again, there's
20 some, some indication of differences based on
21 maternal BMI and, and those were the additions
22 for the omega-3 fatty acids.

1 So, these again, omega-3 fatty acids
2 and risk of gestational diabetes very much the
3 same. Same intermediate outcomes for the, the
4 previous nutrients and the endpoint of
5 gestational diabetes. And again, including fish
6 and seafood.

7 Here, other factors could be included
8 in an intervention/prevention trial and the large
9 prior infant as well. And, family history of
10 diabetes/prediabetes. So, again, consistent with
11 the other nutrients looking at these outcomes.

12 Again, the same. The omega-3s and the
13 hypertensive disorders. And omega-3s and human
14 milk composition and we're going to basically
15 look at fatty acid composition. So, not only
16 obviously the omega-3s, but the, the whole fatty
17 acid composition in the milk where available.

18 And this is the infant -- so this is
19 relationship between again, maternal consumption
20 from supplements and fortified foods before and
21 during pregnancy, and infant developmental
22 milestones.

1 So, while the B24 is going to be
2 looking more directly at the intake of the
3 infant, this would be potentially effects
4 mediated for maternal diet through milk.

5 So, again, the same, same outcomes
6 including again, breastfeeding practices,
7 intensity and duration. So, hopefully, being
8 able to pull out exclusive from partial
9 breastfeeding. Again, same inclusion/exclusion.

10 So, now we're going to do vitamin D
11 again, with the five outcomes.

12 So, for vitamin D status, I just want
13 to point out that the way we're, we're looking at
14 vitamin D status is 25 hydroxy vitamin D. In
15 terms of for all of the vitamin D outcomes, we've
16 added basically as another factor to be
17 considered, is sunlight exposure and use of
18 sunscreen.

19 So, we know that not all papers will
20 provide that, so we didn't want to include it as
21 a key confounder, but we do want to collect that
22 data when, when possible.

1 So, again, very, very similar in terms
2 of now vitamin D and gestational diabetes,
3 vitamin D and risk of hypertensive disorders, and
4 vitamin D and human milk composition.

5 And in this case, we're trying to
6 capture all of -- any or all of the vitamin D
7 forms that could be reported in, in the human
8 milk. And, you know, lastly, the vitamin D and
9 neurocognitive development. So, same
10 inclusion/exclusion criteria.

11 Just again, these are as Kay had
12 mentioned, available on DietaryGuidelines.gov, so
13 if you want more detail you can certainly visit
14 those.

15 So, the last new protocol I wanted to
16 discuss is: What is the relationship maternal
17 diet during pregnancy and lactation, and risk of
18 infant and child food allergies and atopic
19 diseases?

20 So, this is just one outcome and we're
21 looking at again: What is the effect of maternal
22 diets on this?

1 So, this is very broad. Dietary intake
2 of foods and food groups, either not consuming
3 that food or a different amount of that food.

4 So, this is going to be a very broad search.

5 Our outcomes, we have food allergies,
6 allergic rhinitis and atopic dermatitis.

7 Dermatitis and rhinitis are often times on the
8 atopic march prior to diagnosis of food
9 allergies, but we, as Kay mentioned, had some
10 discussions about including food sensitization on
11 its own because sensitization alone does not
12 indicate that that child will actually manifest
13 an allergic reaction.

14 So, in terms of outcomes, we have
15 timing of introduction of our key confounders --
16 I'm sorry, timing of introduction of
17 complementary foods and beverages, types of
18 complementary foods and beverages, family history
19 of atopic disease and if reported, urban/rural
20 environment, exposure to animals, pets and farms,
21 because all of those have been implicated in
22 affecting allergy.

1 And again, other factors to be
2 considered could be indoor/outdoor environments
3 if that's reported.

4 But, we're trying to make this a very
5 broad search because as Rick mentioned, this is a
6 rapidly developing area and so we'd like to try
7 to determine the impact of maternal diet. Okay,
8 so again, the same types of criteria here.

9 So, that was the conclusion of all
10 the, the new protocols, and so now I'd like to
11 just talk about two where we've actually
12 implemented the plan.

13 So, even though in July we, we had
14 done the analytical framework for iron first, we
15 decided to actually start implementing the, the
16 plan for folic acid.

17 So, the questions that we've been
18 investigating is was the relationship between
19 folic acid supplements, from supplements and/or
20 fortified foods consumed before and during
21 pregnancy on human milk composition, and risk of
22 gestational diabetes. So, these are two of the

1 five outcomes that we're looking at related to
2 folic acid.

3 So, looking at the first question.
4 So, just a reminder of this analytical framework,
5 which was presented back in July looking at folic
6 acid from supplements, fortified foods, or a
7 combination on human milk folate composition.

8 And in terms of we really didn't have
9 any different key confounders. These are kind of
10 our standard ones.

11 So, we from the search, there were
12 four databases that were searched resulting in
13 7,817, which was reduced to about 4,500 after
14 removal of duplicates. After initial screening,
15 we -- of titles, abstracts and full texts, we
16 ended up with 16. And there were no new articles
17 added.

18 So, the ones that were then included
19 after going through our inclusion and exclusion
20 criteria, we had four articles. And, of those
21 three were RCTs and one was an uncontrolled
22 before-and-after study.

1 All four address specifically the
2 question is: What is the relationship between
3 folic acid from supplements during lactation and
4 human milk folate? So, there -- there were none
5 that looked at fortified foods.

6 So, the sample characteristics of the
7 three randomized controlled trials. They had on
8 average, between 14 and 23 per group. They were
9 conducted in the U.S. and Canada. An average age
10 of 33 years, mostly white and high SES for two
11 studies. The other study was in adolescents,
12 mostly white and low SES.

13 The intervention doses were 300 mcg,
14 400 mcg and 1 mg, and also looked at the five
15 methyltetrahydrofolate form as well.

16 They were initiated within one week
17 postpartum, or three months postpartum, and they
18 lasted between 12 to 16 weeks. All reported
19 human milk folate concentrations. They also,
20 some reported on metabolized milk folate, soluble
21 folate binding milk, milk folate binding protein.

22 The uncontrolled before-and-after

1 study, this was conducted in Japan of 16 mothers.
2 There was very little evidence or data presented
3 on the participants. They basically just said
4 the women in the study were from the same SES
5 group. So, basically before and after they were
6 the same mothers. But, it was a weakness of the
7 study.

8 They gave 1 mg of folic acid,
9 initiated anywhere between three and 25 weeks
10 postpartum and the trial was for four weeks.

11 So, the studies use slightly different
12 methodological approaches to measure the folate,
13 but none of the studies found an association
14 between folic acid supplementation in lactating
15 women and human milk folate levels. And, the
16 actual levels reported were fairly consistent
17 among the studies.

18 When we began the assessment, the
19 studies were direct and precise. The results
20 were very consistent. We had some concerns
21 regarding risk of bias and generalization due in
22 large part to that the populations were quite

1 homogeneous.

2 So, our again, these are draft
3 preliminary conclusion statements that moderate
4 evidence suggests the consumption of folic acid
5 supplements during lactation, among women in high
6 or very high HDI, high development index
7 countries, does not influence folate levels in
8 human milk.

9 No evidence is available to draw a
10 conclusion about the relationship between folic
11 acid from supplements consumed before and/or
12 during pregnancy and human milk folate, and no
13 evidence is available to draw a conclusion about
14 the relationship between folic acid from
15 fortified foods before and/or during pregnancy
16 and lactation in human milk folate.

17 So, for these latter two, we had grade
18 not assignable.

19 So, the second question, the
20 relationship between folic acid and gestational
21 diabetes and the analytical framework consistent
22 with intermediate and point outcomes that we,

1 that I previously presented.

2 Again, searching four databases
3 resulted in 829 articles which we ended up with
4 eight that remained after screening, and only one
5 that was included in the final systematic review.

6 It was a non-randomized control trial
7 that addressed the question of what is the
8 relationship between folic acid from supplements
9 consumed during pregnancy, and risk of
10 gestational diabetes?

11 It was a large study of over 7,800
12 participants conducted in China. Mothers between
13 the ages of 20 and 40, nonsmokers and
14 nondrinkers. They gave doses of 0, 400 or 800
15 micrograms per day, and they based the dose based
16 on genetic polymorphisms in, of the mothers, and
17 also the stage of pregnancy.

18 The again, initiation was not clear
19 because they talked about pre-pregnancy, but then
20 they stated that they recruited the mothers
21 during the first trimester. So, as we started
22 looking at the paper it would have been a great

1 paper but it, you know, there was just some
2 concerns about the details.

3 So, among the women who consumed folic
4 acid supplementation based on genotype and stage
5 of pregnancy, there was a significantly lower
6 incidence of gestational diabetes compared to
7 women who did not consume folic acid supplements.
8 So, 3.2 in the control and .27 in the
9 intervention.

10 But when we assessed the evidence,
11 there were concerns regarding risk of bias and we
12 felt there was insufficient evidence to evaluate
13 the directness, precision, consistency or
14 generalizability of the results.

15 So, our draft conclusion is that
16 there's insufficient evidence is available to
17 draw a conclusion about the relationship between
18 folic acid from supplements and/or fortified
19 foods consumed before and/or during pregnancy,
20 and the risk of gestational diabetes. So, grade
21 not assignable.

22 So, just to conclude, we have as Kay

1 mentioned also with B24, we've been having a lot
2 of cross-cutting discussions with the other
3 subcommittees. So, we've had some joint meetings
4 again with Dietary Patterns, Fats and Seafoods,
5 Food Pattern Modeling.

6 And, we also provided evidence on the
7 analytical frameworks pertinent to pregnancy and
8 lactation to the Beverages and Added Sugars
9 committee.

10 So, again, I'd just like to thank our
11 committee. We've really, I think, made an
12 incredible amount of progress in the last few
13 months and again, none of this would be done
14 without the support staff and just really
15 appreciate everybody's hard work.

16 Thank you. You don't have to clap.

17 (Laughter.)

18 VICE CHAIR KLEINMAN: Does anybody
19 dare ask a question?

20 (Laughter.)

21 MEMBER DONOVAN: And, we're exhausted.

22 VICE CHAIR KLEINMAN: Rachel?

1 MEMBER NOVOTNY: I'm on this committee
2 but as I was thinking about it, I'm not clear if,
3 if there's a need to distinguish, or precisely
4 what the distinction is between before pregnancy
5 and pre-pregnancy.

6 It seems before pregnancy gives an
7 early start date, and then pre-pregnancy gives an
8 end window to the period, but I think they're the
9 same definition, but what do you think?

10 MEMBER DONOVAN: Well, we had said,
11 and so maybe this is we need to look at the
12 precision of how we're describing it, but we did
13 say that it was six months.

14 So, we're looking in terms of like,
15 the supplements and fortified foods. But, for in
16 terms of like, BMI outcomes, that, pre-pregnancy
17 weight could be up to a year prior to pregnancy.

18 MEMBER NOVOTNY: So, I think in our
19 definition we said before pregnancy was six
20 months prior, and pre-pregnancy was up till the
21 first trimester. But, in fact, aren't they both
22 the same window? Whether you're referring -- I

1 mean it's before pregnancy, what are we measuring
2 before pregnancy? It's also BMI.

3 So, before pregnancy BMI, the window
4 would be defined as six months prior to up to the
5 first trimester, up to and including. And, so
6 would pre-pregnancy BMI be six months prior and
7 up to and including?

8 MEMBER DONOVAN: Well, I think in the
9 framework we said that we would consider pre-
10 pregnancy BMI up to a year, and then up through
11 the first trimester.

12 And I think for the fortified foods
13 and supplements, that was six months. Because we
14 thought many women can be taking supplements who
15 are planning to get pregnant, or some nutrients
16 that could be stored in -- you know, like vitamin
17 D or iron could be influenced.

18 But there's, you know, there's so many
19 so I want to kind of make sure that we're clear
20 on that.

21 MEMBER NOVOTNY: I guess, what are we
22 measuring before pregnancy besides BMI I guess is

1 the other question?

2 MEMBER DONOVAN: Well, for the
3 supplements and fortified foods, if there was
4 evidence of use of those supplements prior to
5 conception.

6 MEMBER NOVOTNY: Oh, I see. Okay.

7 MEMBER DONOVAN: So, women who may be
8 prophylactically or planning to be, you know,
9 using advice that they should be starting to take
10 folate. Things like that.

11 MEMBER NOVOTNY: Okay. Because I
12 think in our key confounders, we have
13 anthropometry before pregnancy, too. And, so
14 that's where I was getting confused as to how
15 we're distinguishing --

16 MEMBER DONOVAN: I think that was --

17 MEMBER NOVOTNY: -- pre-pregnancy BMI
18 and before pregnancy BMI.

19 MEMBER DONOVAN: Okay. Yes, we can,
20 we can look at it.

21 MEMBER NOVOTNY: It's just a --

22 MEMBER DONOVAN: I think that was

1 primarily --

2 MEMBER NOVOTNY: -- it's a definition.

3 MEMBER DONOVAN: -- to capture pre-
4 pregnancy BMI and obesity.

5 But, yes, I mean if you're on the
6 committee and it's confusing, then we definitely
7 need to go back and make sure that --

8 (Laughter.)

9 MEMBER DONOVAN: -- we're precise in
10 that language. I'll make a note.

11 MEMBER ARD: I have a question.

12 VICE CHAIR KLEINMAN: Jamy?

13 MEMBER ARD: Jamy Ard. One quick
14 question.

15 On the key confounders in the analytic
16 framework related to hypertensive disorders, you
17 mentioned that there was the addition of
18 gestational diabetes because of an association
19 between the two.

20 But there was not, you don't have
21 hypertensive disorders in the gestational
22 diabetes analytic framework as a key confounder.

1 Would that -- because I'm not, I, I can't tell,
2 it's just not in my area of clinical expertise,
3 but I don't know if there's a, just a general
4 association or if it's you know, sort of
5 unidirectional, but just something to consider.

6 MEMBER DONOVAN: Yes, so for the
7 gestational diabetes, we do not have diagnosis of
8 hypertension. So, that's something we can go
9 back and look at. I don't think it's a
10 unidirectional. Oftentimes, they're just co-
11 occurring.

12 VICE CHAIR KLEINMAN: Steve?

13 MEMBER HEYMSFIELD: I have a very
14 minor semantic comment. The word -- statement
15 "dietary supplements."

16 In my world, the obesity world, has
17 very specific meaning in a regulatory framework,
18 which is Dietary Supplement Health and Education
19 Act, DSHEA.

20 And, so I don't think that's what's
21 meant by dietary supplements here, right? From
22 what I see, these are specific micronutrient

1 supplementation. It's not dietary supplements
2 like with various herbal constituents and so on,
3 right?

4 MEMBER DONOVAN: No, because we're
5 specifically looking at these five nutrients.
6 So, we're only looking at these five nutrients as
7 supplements or in fortified foods.

8 So, if they were using other, you
9 know, St. Johns Wart, or other things, then
10 that's not being captured in any of our searches.

11 MEMBER HEYMSFIELD: Okay.

12 MEMBER BAILEY: I think the frameworks
13 have a definition somewhere --

14 MEMBER DONOVAN: Yes.

15 MEMBER BAILEY: -- don't they?

16 MEMBER DONOVAN: Yes. We're actually
17 using the ODS and --

18 MEMBER BAILEY: Well, it's the --

19 MEMBER DONOVAN: -- you're using the
20 DSHEA definition.

21 MEMBER BAILEY: Yes, you're the DSHEA
22 definition.

1 MEMBER HEYMSFIELD: Oh, it is. Okay.

2 MEMBER BAILEY: Yes.

3 MEMBER DONOVAN: Yes, I have that on
4 our --

5 CHAIR SCHNEEMAN: Actually though,
6 that reminds me of a question of -- so, with the
7 supplementation, are you looking at it if it
8 might come in with a multi-vitamin supplement?
9 It's not just, or is it only that they have to
10 supplement with one specific nutrient?

11 MEMBER DONOVAN: Yes, because many of
12 the prenatal supplements are combined.

13 MEMBER DEWEY: Can I add that --

14 MEMBER DONOVAN: Yes.

15 MEMBER DEWEY: -- but that when we
16 look at the evidence and the results have to be a
17 contrast, where the only difference is folic
18 acid.

19 So, if they're getting multivitis, it
20 could be multivitis without and multivitis with.

21 CHAIR SCHNEEMAN: I see.

22 MEMBER DEWEY: That kind of thing.

1 VICE CHAIR KLEINMAN: Tim?

2 MEMBER NAIMI: It was very
3 interesting.

4 When you talk about there are so many
5 possible comparisons between all these
6 micronutrients and different outcomes, and some
7 of them may not have a biologically plausible
8 explanation.

9 So, are these, and I know we don't get
10 to ask the questions in terms of what's assessed,
11 but is there in terms of summarizing the
12 evidence, how do you, how do you address that?

13 MEMBER DONOVAN: Great question.

14 (Laughter.)

15 MEMBER DONOVAN: I mean many of them
16 are, you know, we can certainly provide the
17 evidence between sort of the omega-3s and
18 neurocognitive outcomes and others.

19 But again, some of them we'll just
20 have to see how we're able to, to discuss that.
21 Because I would agree that there is, it's not
22 necessarily clear that some of the nutrients and

1 some of these outcomes have, you know, have clear
2 mechanistically.

3 MEMBER NAIMI: B12 and diabetes.

4 MEMBER DONOVAN: Yes.

5 MEMBER NAIMI: And, there are many
6 examples that have no basis.

7 VICE CHAIR KLEINMAN: I think the
8 sentence will start although there is no evidence
9 of biological plausibility as to. We're still
10 working on it.

11 MEMBER DONOVAN: The idea was looking
12 at sort of key nutrients and key important
13 outcomes.

14 VICE CHAIR KLEINMAN: Yes.

15 MEMBER DEWEY: Do you want us to speak
16 and talk about folic acid and human milk and why
17 we're not surprised by the results? Oh, you want
18 me to?

19 (Laughter.)

20 MEMBER DEWEY: So, with the one
21 conclusion statement, we can really stand behind
22 today is the one that the folic acid supplements

1 during lactation and in these populations,
2 doesn't affect folate levels in milk.

3 And honestly, we knew that already
4 from decades of work and the biology of how folic
5 acid is taken in and then what happens in terms
6 of memory gland biology. So, that was not a big
7 surprise.

8 But I totally agree with the idea that
9 the discussions of our sections of the report
10 need to address biological mechanisms. Not in
11 great depth, but at least allude to what we
12 understand.

13 VICE CHAIR KLEINMAN: And, there are,
14 you know, potential research questions that will
15 come out of some of these where there isn't an
16 obvious link but potentially, there is some
17 metabolic pathway that could impact it.

18 And, around folate, I think what we
19 talked about is the absence of studies in folate
20 insufficient mothers and whether there was --

21 MEMBER DEWEY: Exactly.

22 VICE CHAIR KLEINMAN: Yes, so, there

1 is more to learn about this although we addressed
2 this question I think quite correctly.

3 MEMBER DONOVAN: Yes, so our
4 conclusion statement very specifically says in
5 high HDI countries.

6 So, we can't conclude whether it would
7 be beneficial in women who are folate deficient.
8 And, also the addition of folate to the food
9 supply through flour has kind of raised
10 everybody's --- but nobody's really specifically
11 looking at that anymore because it's there.

12 So, you know, that's why we try to
13 think maybe there were some older studies prior
14 to the fortification.

15 MEMBER BAILEY: So, maybe it would be
16 helpful to just clarify that in your language.
17 Because there are high development index
18 countries that don't have fortification. So,
19 maybe just in highly or in countries with
20 fortification, or in folate replete populations
21 or something like that, it might just be adding a
22 little clarity.

1 VICE CHAIR KLEINMAN: Yes, that's a
2 good point.

3 MEMBER DONOVAN: Yes, I think in terms
4 of our statements, you know, we're trying to work
5 with a common language but, you know, in our
6 discussion, we can provide more evidence and
7 flesh things out a bit.

8 VICE CHAIR KLEINMAN: Yes. Any other
9 comments or questions?

10 Oh, Regan?

11 MEMBER BAILEY: So, I'm really
12 interested in the research on the quantity of
13 human milk. What does that literature look like?
14 Isn't there tremendous diurnal variation and how
15 are you guys addressing that?

16 In addition to all the amazing work
17 you're doing, you have a lot of challenges
18 inherent within each of your questions, so.

19 MEMBER DONOVAN: Yes, right. Well, we
20 haven't gotten to any of those searches yet. I
21 mean there's several ways to measure milk
22 quantity through 24 hour weighing or stabile

1 isotopes. But, so we would try to look at the
2 methods that are being used and then, you know,
3 when we're grading the evidence.

4 But yes, I don't think that a lot of
5 these micronutrients will have much of an effect.
6 But, it actually might be interesting when we get
7 to the beverages. Potentially. The fluid
8 intake.

9 CHAIR SCHNEEMAN: So, speak up.

10 MEMBER DEWEY: I would be happy to.

11 So, we've understood for a while that
12 the regulation of milk production is governed by
13 endocrinological factors and physiological
14 factors, but mostly driven by infant demand.

15 So, maternal nutrition is a very minor
16 player and particularly in well-nourished
17 populations. And if it is a player, it's more on
18 the level of energy balance and those sort of
19 really macro and micronutrients we don't know of.

20 I don't know of any mechanisms by
21 which their intake would affect those mechanisms
22 that determine milk production.

1 Again, the biology here is what we
2 really need to look at. And it's interesting
3 because in, in dairy cows it's different, and
4 maternal nutrition of the cow can make a
5 difference. But they've been bred for very high
6 levels of production, way beyond what human women
7 do.

8 (Laughter.)

9 MEMBER DEWEY: So, it's a very
10 different situation. We don't really a great
11 model from the animal literature.

12 VICE CHAIR KLEINMAN: I thought where
13 you were perhaps going with that also is the,
14 there are differences in concentrations in human
15 milk depending upon when the milk is sampled. Is
16 that what you were -- yes, and so one further
17 need for our group is to be sure that the
18 methodologies for collection are similar between
19 studies, right?

20 Because if you're collecting early in
21 the lactation or at the end of it, or it happens
22 to be at night vs. the morning, or let's say

1 early in the lactation cycle versus very late,
2 and, you know, we could go on and on.

3 So, and sometimes the studies don't
4 actually talk about that at all. And, so that
5 makes comparisons even more challenging.

6 MEMBER DONOVAN: Yes, so one of the
7 decisions we made was milk after two weeks. So,
8 to try to get some of the colostrum.

9 But you're 100% correct that if it's
10 foremilk vs. hindmilk, or different times of the
11 day. So, that would be considered as the
12 evidence is being abstracted and we can, we can
13 look at that.

14 If it's a single sample, you know, and
15 they don't define when it was taken, particularly
16 as we start looking at some of the omega-3 fatty
17 acids and fatty acids, since those tend to be
18 higher in the hindmilk.

19 So, very good point, Ron.

20 VICE CHAIR KLEINMAN: Oh, further
21 question.

22 MEMBER NAIMI: One more question.

1 You guys are trying to distill out the
2 effect of supplements and, so I was just
3 wondering in the protocols I might have missed
4 it, but how do you try to account for, you know,
5 baseline consumption of a particular thing such
6 as folate, apart from the supplements?

7 Is it possible to do that and should
8 that be kind of a key confounder for all of those
9 -- for each of the micronutrients?

10 MEMBER DONOVAN: Well, I mean I think
11 from the dietary from Regan's committee will be
12 getting levels of intake, so we can speak to that
13 more generally.

14 But unless in those specific papers
15 they did any sort of a diet record, I think it
16 would be very difficult for us to determine, you
17 know, the intake within a specific study.

18 But we will have intakes of those
19 nutrients, you know, from the NHANES and other,
20 other data sets.

21 CHAIR SCHNEEMAN: And it also comes
22 back, it also comes back to this point that in a

1 country that fortifies, chances are you have a
2 pretty high level of intake.

3 MEMBER DONOVAN: And then one of the
4 things we thought about is, you know, almost gets
5 back to dietary patterns is people are, you know,
6 consuming less carbohydrate, that is a large
7 contributor to folate intake.

8 So, you know, if we look at dietary
9 patterns, we might actually see differences in
10 folate consumption which, you know, could be
11 problematic.

12 VICE CHAIR KLEINMAN: Linda?

13 MEMBER SNETSELAAR: I just wondered,
14 and I don't know how this plays into the
15 equation, but many moms today will pump and you
16 had mentioned the idea of demand and how
17 important that is. Are there any studies that
18 have been done looking at that concept?

19 MEMBER DEWEY: Yes, you can actually
20 increase the stimulus for milk production by
21 pumping, in addition to nursing directly at the
22 breast. The body interprets that as increased

1 demand and will respond to that.

2 So, yes, it gets more and more
3 complicated these days because so many women are
4 pumping.

5 MEMBER DONOVAN: And then we'll also
6 take into account if it was pumped milk, if it's
7 been frozen and in terms of nutrient composition.

8 VICE CHAIR KLEINMAN: Joan?

9 MEMBER SABATE: In the analytical
10 framework for vitamin B12 and I think for other
11 key nutrients, supplements, you put into the key
12 confounders vegan/vegetarian diets. I mean I
13 wonder as far as using these as a confounder.

14 And the other thing in case, I mean
15 that is the one to proceed. I think it will be
16 wise to separate --

17 MEMBER DONOVAN: Yes.

18 MEMBER SABATE: -- I mean vegan versus
19 vegetarian diet, if by vegetarian we interpret
20 lacto-ovo vegetarian.

21 MEMBER DONOVAN: Certainly that's a
22 good point. So, right now they're combined but

1 they, that data would be extracted separately so
2 we'll be able to look at those separately.

3 MEMBER DEWEY: If I could just add, I
4 think one of the important considerations as it
5 being a potential confounder is that many
6 pregnant and lactating women who are at least
7 vegan and maybe even vegetarian, are advised to
8 take vitamin B12. And so the consumption of
9 supplements and the dietary pattern are linked
10 quite strongly.

11 So, that's why it's an important
12 confounder in my view, because we don't -- when
13 we're looking at the outcomes, we have to figure
14 out what they're related to.

15 MEMBER SABATE: But beyond being a
16 confounder, I mean it could be also an effect
17 modifier.

18 MEMBER DONOVAN: It could be.

19 MEMBER SABATE: So, I mean stratifying
20 by this parameter will give very useful
21 information.

22 MEMBER DONOVAN: Absolutely, you know,

1 but we're dependent on the studies to have done
2 that. And, we think it's a logical thing to do
3 but it isn't always in their papers.

4 VICE CHAIR KLEINMAN: All right, well
5 --

6 MEMBER DEWEY: I have a question for
7 Linda. Can I ask that?

8 So, I have a question for the Dietary
9 Fat and Seafood Subcommittee, because I was
10 looking back over all of the protocols we just
11 presented this morning and, in terms of the
12 omega-3 fats in the B24 protocol.

13 So, we're looking at intake of that
14 from supplements or fortified foods, and but the
15 outcome domains do not include neurological or
16 cognitive development. That's what we were
17 given.

18 So, my question is I don't remember
19 what is the definition of the types of dietary
20 fat exposures that you're subcommittee is looking
21 at. Does it include supplements or exclude
22 supplements?

1 MEMBER SNETSELAAR: What I presented
2 the other day excluded supplements. That doesn't
3 mean that some of our eventual questions might
4 not get into that area when we look at total fat,
5 for example. But what I presented with ADD,
6 ADHD, and ASD excluded supplements.

7 CHAIR SCHNEEMAN: Because they were
8 seafood questions, right?

9 MEMBER DEWEY: So, perhaps we can
10 discuss this when we have some cross-talk on the
11 --

12 MEMBER SNETSELAAR: Yes, most
13 definitely.

14 MEMBER DEWEY: -- upcoming protocols?
15 Thanks.

16 MEMBER SNETSELAAR: Most definitely.

17 VICE CHAIR KLEINMAN: All right, well
18 I think we've earned a little break. So, 15
19 minutes, is that --

20 CHAIRMAN SCHNEEMAN: Yes, I think 15
21 minutes.

22 VICE CHAIR KLEINMAN: Okay.

1 CHAIR SCHNEEMAN: And, just before we
2 go on break, I do want to once again remind
3 everyone who's listening, that what we're hearing
4 from the committee reflects their findings and
5 their conclusions. We haven't formulated any
6 recommendations yet.

7 So it's -- these are sort of our
8 initial findings and conclusions that we're
9 presenting for discussion.

10 VICE CHAIR KLEINMAN: Work in
11 progress.

12 CHAIR SCHNEEMAN: Yes. So, what about
13 --

14 VICE CHAIR KLEINMAN: All right, so
15 10:55?

16 CHAIR SCHNEEMAN: Yes, sounds good.

17 VICE CHAIR KLEINMAN: Great.

18 (Whereupon, the above-entitled matter
19 went off the record at 10:40 a.m. and resumed at
20 10:58 a.m.)

21 CHAIR SCHNEEMAN: Okay, so, Dr. Regan
22 Bailey will be giving the subcommittee report, so

1 I think we're ready.

2 MEMBER BAILEY: Okay, last and
3 certainly not least, Data Modeling -- Data
4 Analysis and Food Pattern Modeling.

5 Again, so I spoke a little bit earlier
6 specific to the B24 group. Now we're going to be
7 looking at the other set of questions that we are
8 addressing, and those are listed here, and we'll
9 go through each one of those so I won't read
10 those to you now.

11 So, we're implementing the plan for
12 two years and older for all of the protocols that
13 we discussed at the July meeting. And, the final
14 piece as I mentioned previously, is the Food
15 Pattern Modeling and, what changes need to be
16 based on the work that you all are doing in your
17 systematic reviews, and are those food patterns
18 possible for two years and younger?

19 So, just some general updates to those
20 protocols that we presented in July. So, infants
21 and toddlers again specified as birth to less
22 than 24 months, we added specificity to age

1 groupings and population subgroups in our
2 analytical plans.

3 Added sugars and caffeine are being
4 referred to as food components, rather than
5 nutrients, as they are not nutrients. And I'm on
6 this bandwagon to get the word dietary component
7 so that it's representative of foods, beverages
8 and supplements. But right now, it's a food
9 component. And then individual nutrients
10 contributed by beverages that were not specified.

11 Until we determine what those
12 nutrients of public health concern are, and then
13 we're going to have that discussion towards the
14 end of the talk. But, all of our protocols are
15 aligned with those particular nutrients.

16 So, some protocol-specific updates.
17 Dietary patterns and beverage consumption, we're
18 looking at changes over time.

19 So, our comparator group will be
20 NHANES 2005-2006. Current intakes of food groups
21 and nutrients, and changes in average nutrient
22 intakes from food and beverages was added to the

1 analytical plan for adults and older adults, to
2 be consistent with life stage.

3 And the prevalence of nutrition
4 related chronic health disease. So, dentition
5 was added to the analytical framework and the
6 analytical plan.

7 So, for all of the questions that we
8 will be addressing, our, our sample is the United
9 States.

10 So, we, I mean really all of the data
11 sets that we're looking at are nationally
12 representative, so that these can inform the
13 Dietary Guidelines. And that's the reason why we
14 rely so heavily on these sources.

15 And we discussed a little bit about
16 this yesterday, but here's the specific slide
17 that I alluded to with the exact life stage
18 groupings, and of course these are not perfect.
19 They aren't set in stone.

20 Some of the publications that we have
21 have different age groupings. But this is just
22 kind of an overarching framework.

1 And, then we will have data available
2 to us by sex, race, ethnicity, socio-economic
3 status, and inclusive of food security status.

4 Again, we will be utilizing the NHANES
5 data What We Eat in America survey components,
6 with the requisite databases that are listed here
7 to get nutrient content, food groups, and foods
8 as they are consumed from foods, beverages, and
9 dietary supplements. So, just as a refresher.

10 Again, and we've presented these
11 before, but this stage of life is often variable.
12 It can depend on whether it's available in the
13 NHANES the way that the reports are written,
14 and/or by the dietary reference intake groupings.

15 Socio-economic status is the broad
16 term that can reflect any of the indicators that
17 are listed on this slide.

18 So, we will be discussing some of the
19 newer protocols and how the relationship to
20 achieving food and nutrient recommendations vary
21 by the frequency of eating, by beverage
22 consumption, and there's a separate protocol for

1 alcohol from the other beverages, as well as
2 consumption of added sugars.

3 So, the first question is what is the
4 relationship between the frequency of eating and
5 achieving food group and nutrient intake
6 recommendations?

7 We will look at the total number of
8 eating events, as well as person described. I
9 didn't want to say subject. Participant
10 described eating occasions such as breakfast,
11 lunch, dinner and snacks. And, their Spanish
12 equivalents.

13 So, snacks just a note here, that
14 those are inclusive of drinks or extended
15 consumption.

16 So, there's interest in when people
17 are eating, time of day. Does time of day have
18 an impact on meeting food and nutrient
19 recommendations? But this is something that we
20 are discussing with the frequency of eating. How
21 do we operationalize those times of the day? And
22 that's part of ongoing work and discussions that

1 we're having.

2 So, as I mentioned, we'll look at
3 frequency of eating with and without those naming
4 conventions. So, the number of eating events in
5 a 24 hour time period. So, the way that the 24
6 hour recall is collected is midnight to midnight.

7 So, we have information available on
8 the hourly consumption of eating events, the
9 number of snacks, which can include beverages,
10 and we've been looking at that inclusive and
11 exclusive of water. Because a water only event
12 really increases the total number of ingestive
13 events in a 24 hour period, as well as time of
14 day.

15 And then we have the hour time stamps
16 for some of the, for the reports in NHANES.

17 We're also looking at the proportion
18 of food group and subgroup intakes and dietary
19 components by eating event type, with and without
20 naming conventions. And the naming conventions
21 are what I described earlier.

22 So, our next question that we'll be

1 presenting to you is what is the relationship
2 between beverage intakes and achieving food group
3 and nutrient recommendations?

4 These are the beverage categories that
5 we are looking at, and this is part one of two.
6 So, there are two slides that give you the
7 discrete beverage categories. And, just a
8 reminder that beverage pattern refers to the
9 quantities, proportions, varieties or combination
10 of different beverages within the diet.

11 So, we'll have these discrete beverage
12 categories as well as those listed on this slide.

13 So, specific between a diet beverage
14 and a sweetened beverage is the 40 calories per
15 reference amount customarily consumed.

16 Water from all sources, whether it's
17 carbonated, flavored, if the definition is less
18 than five calories, and then alcoholic beverages.
19 And we'll have a whole discussion on that
20 category coming up in a few slides.

21 So, for the non-alcoholic beverage
22 questions, we will be looking at the food and

1 dietary components per eight ounce of discrete
2 beverage consumption, okay?

3 And so we'll also be providing data on
4 what beverages contribute. So, as the percent of
5 total daily energy, how they contribute to
6 selected nutrients and dietary components, how
7 they contribute to food groups, and how daily
8 beverage cat -- calories, excuse me, vary by
9 discrete beverage type.

10 Specific questions have been an area
11 of interest is the prevalence of intake of
12 nutritionally fortified beverages, as well as
13 cow's milk and milk substitute beverages.

14 So, this is the alcohol specific
15 question. So, it would be inappropriate to use
16 the eight ounces there because eight ounces is a
17 very different animal, if you will.

18 So, we're using the alcoholic drink
19 equivalent here. So, understanding that wine,
20 beer and spirits, differential amounts all
21 provide 14 grams of pure alcohol.

22 We'll be looking at the prevalence of

1 binge drinking and frequent binge drinking. So,
2 those are defined here for you. For men, binge
3 drinking is consuming five or more drinks on the
4 same occasion, and that same definition for women
5 is true, with four as the number of drinks.

6 And then frequent binge drinking is
7 binge drinking that occurs on five or more
8 occasions in the previous 30 days.

9 So, this is the analytical framework
10 in terms of the data and the age groupings that
11 we have available to us.

12 So, we'll be looking at dietary
13 intakes relative to alcohol for 20 years and
14 older, alcohol use in terms of underage, the
15 prevalence of underage alcohol consumption from
16 12 to 20 years, adult alcohol consumption, 21 and
17 over, and then pregnant women in our NHANES
18 analysis is 20-44, but because we're using the
19 BRFSS data for pregnancy, that is inclusive of
20 women 18-44.

21 So, when we say exceptions noted,
22 those are largely driven by the way that the data

1 are collected. We have information available to
2 us not only from BRFSS on alcohol, but NSDUH --

3 (Laughter.)

4 MEMBER BAILEY: -- the National Survey
5 of Drug Use and Health -- that has to be my
6 favorite acronym ever NSDUH -- but it is cross-
7 sectional nationally representative survey data
8 on drug use and mental health, including alcohol
9 use.

10 So, as I mentioned, we're looking at
11 the prevalence of alcohol use, binge drinking,
12 and frequent binge drinking. We're interested in
13 how alcohol contributes to energy, caffeine and
14 added sugars specifically, per drink equivalent.
15 And as well as how do alcohol beverages in terms
16 of contribute to a percent of total energy
17 throughout the day, how they contribute to added
18 sugars and caffeine, as well as daily beverage
19 calories.

20 Our next question that I'd like to get
21 your feedback on is the relationship between
22 added sugars and achieving food group and

1 nutrient recommendations.

2 And throughout the last two days we've
3 had the FDA definition of what is an added sugar,
4 so I will not read that to you here, but just a
5 reminder.

6 Our analytical framework includes the
7 usual distribution of added sugars. That is from
8 the two days of intake.

9 The percent of the population that is
10 achieving the current recommendation from the
11 2015 to 2020 Dietary Guidelines, of less than 10%
12 of total energy intake from added sugar, as well
13 as the food category sources of added sugar, and
14 how those contribute to nutrient and food group
15 intakes.

16 And finally, we would like to have
17 some discussion with the Committee today about
18 how we describe and evaluate nutrients of public
19 health concern.

20 We propose that we continue to use the
21 established three-pronged approach to identify
22 nutrients of concern, and that includes nutrient

1 intakes from dietary data, biological end points,
2 and clinical health consequences, when such data
3 are available.

4 So, in terms of defining what is a
5 nutrient of concern, or what I would like to call
6 dietary component of concern, we'll be looking at
7 intakes from food and beverages alone, and from
8 total sources inclusive of dietary supplements.

9 We have the DRI benchmarks for risk of
10 inadequacy and risk of potential excess. So, for
11 all nutrients with an EAR, we will use that as
12 the benchmark of inadequacy.

13 When an EAR is not established, we
14 will utilize the adequate intake and the
15 comparison of the mean intake to the adequate
16 intake.

17 For nutrients with a UL and CDRR, I
18 think currently sodium is the only nutrient for
19 which we have a CDRR, we will look at that
20 percent of the population that exceed that
21 recommended intake threshold.

22 We'll look at calorie intakes outside

1 the acceptable macronutrient distribution range,
2 and then existing guidelines.

3 So, I've mentioned added sugar, but
4 this is also similar for saturated fat. No more
5 than 10% of total energy from saturated fat.

6 So, we'll use that information to
7 inform the dietary component of that three-
8 pronged approach.

9 But in addition to that, we also have
10 to look at what previous guidelines have
11 identified as nutrients or dietary components of
12 public health concern. We will start there with
13 the previously identified.

14 We'll also incorporate information
15 from the National Academy of Science,
16 Engineering, and Medicine report. Specifically,
17 chapter 7 goes into great detail about how having
18 a priori criteria established to be very
19 transparent, and how we identify nutrients of
20 public health concern.

21 We also want to be mindful to dovetail
22 our efforts with the extensive work that FDA has

1 already done on this for the nutrition facts
2 label and the supplement facts label.

3 So, they have done a tremendous amount
4 of work already and, so we want to be
5 complementary to what's already existing.

6 As well as sources of scientific
7 agreement. And, this is particularly for special
8 populations like B to 24, or Pregnancy and
9 Lactation, where nutrients of concern haven't
10 been previously identified, particularly for
11 birth to less than 24 months.

12 So, we'll utilize some of the expert
13 opinions in terms of identifying potential
14 nutrients that way, as well as the three-pronged
15 approach.

16 And then our next steps of course,
17 would be to integrate nutrients from dietary
18 supplements. I mentioned that right now, what we
19 have available is from foods and beverages only.
20 So, the total sources is very important as
21 there's a high prevalence of nutrient containing
22 supplements in the United States.

1 We'll review and summarize the
2 analysis that we already have at our disposal.
3 We will begin to draft some conclusion
4 statements, and then end with some Food Pattern
5 Modeling protocols.

6 So, that is our plan for the moment,
7 and I would greatly welcome committee feedback,
8 input, thoughts, and questions.

9 I'd like to thank our federal support
10 staff that are listed here on the slide, and the
11 members of the Committee.

12 CHAIR SCHNEEMAN: So, Regan, I was
13 wondering if in the subcommittee, have you
14 started to develop proposals?

15 You know, I think from my perspective
16 what you've proposed as the nutrient intake
17 adequacy, you know, what you're looking at and
18 how you're tackling identifying nutrients of
19 public health concern.

20 But if, for example, looking at the
21 EAR cut-point method, have you talked about what
22 percentage of the population falls below, or

1 above, the EAR cut-point?

2 Or with the AI, what kind of
3 discrepancy from the AI would sort of bring a
4 nutrient into looking at it further?

5 MEMBER BAILEY: Yes, so we have
6 started to have some discussions around that with
7 the federal support staff, as well as the
8 committee.

9 Ideally, based on what the
10 recommendations in the NASEM report are, is that
11 we establish a threshold that is consistent and
12 transparent. And, so we've talked about what is
13 that threshold?

14 So, we've done some preliminary
15 analysis looking at nutrients for which 25% or
16 more of the population would be considered
17 inadequate. And, then the next step is that
18 looking at that dietary intake relative to a
19 biomarker.

20 So, I think if we could establish what
21 those thresholds are before we go into the data
22 would be my preference. And that's been informed

1 by the work of FDA, who's done that for the food
2 label for different nutrients.

3 But it varies for different nutrients,
4 and what the severity of low and high intakes
5 are. So, as well as what the DRIs, and the
6 confidence that we have in certain DRIs.

7 And so that's why it's important that
8 we try to link it whenever possible to a
9 biomarker or a clinical end point.

10 So, there's certain nutrients as you
11 know, that there's a very high prevalence of
12 dietary inadequacy. For example, folate.
13 There's up to 25% in certain population groups
14 who by the EAR are considered at risk for folate
15 inadequacy from the diet alone. But when we look
16 to the biomarker, it's less than a half a percent
17 who has low serum or red blood cell folate.

18 So, kind of going through that as an
19 example, then we could eliminate folate as a
20 potential dietary component of concern based on
21 multiple sources of evidence.

22 MEMBER NOVOTNY: Rachel Novotny. So,

1 would you say just another couple sentences at a
2 high level about drafting Food Pattern Modeling
3 protocols?

4 Are they -- would these be to address,
5 to identify food patterns to address nutrients of
6 public health concern, or on what kind of basis
7 would the --

8 MEMBER BAILEY: Yes, so the -- and I
9 know it was a long time ago, I don't know if I
10 can skip all the way back there, but the three
11 questions that we have are: are there changes
12 needed to the current recommended patterns to
13 enhance things that are identified in your
14 systematic reviews? So, those are the specific
15 questions.

16 In terms of B to 24, are those food
17 patterns that are existing, are those possible
18 for those two and younger?

19 And then in terms of Food Pattern
20 Modeling related to nutrient adequacy. So,
21 thinking about things like dietary supplements,
22 fortified foods and added sugars.

1 So, those are some of the very
2 specific things that we have as questions for the
3 Food Pattern Modeling sections.

4 CHAIR SCHNEEMAN: I'll ask another
5 question.

6 Because you mentioned the B through 24
7 as a group that hasn't had this defined through
8 the Dietary Guidelines.

9 And, I know that you all are looking
10 at specific nutrients so I'm, I'm just interested
11 to know how did you decide those nutrients, and
12 how does that feed into what this group will look
13 at, or think about how it wants to define
14 nutrients of public health concern for the,
15 particularly the B24, but also pregnancy and
16 lactation?

17 MEMBER DEWEY: I can start and then
18 you.

19 So, for B -- this is Kay Dewey. For
20 B24, we've had some side conversations about in
21 the first year of life, we really have to
22 subdivide between 0 to 6 months, and 6 to 12.

1 So, 0 to 6 because it's all AI values
2 and it's based on the composition of human milk,
3 it's a very different picture.

4 But, from 6 to 12 months, we do have
5 a couple of nutrients where there's an RDA, but
6 most of them are AI values. So, this is another
7 problem.

8 And, in that age group, the likelihood
9 of being below an EAR cut-point for example, is,
10 is very small for infants getting a lot of
11 fortified infant formula. Because they're
12 fortified with all those nutrients.

13 So, that's why stratifying by the
14 human milk fed predominantly, even when they're
15 getting complementary foods, and formula fed
16 infants is so important. And, that's what we're
17 working on.

18 Once that's done, excuse me, based on
19 other evidence and other kinds of modeling, there
20 will most likely be some nutrients that are most
21 problematic or limiting. Iron and zinc, for
22 example, possibly calcium. And, then potentially

1 some vitamins depending.

2 And, so when we start thinking about
3 the food modeling part, I'm, I think we'll have
4 to have a lot of discussion about how that works.
5 Because it would need to include scenarios where
6 it's just the unfortified foods that are getting
7 into the picture, and then option scenarios where
8 fortified foods like baby cereals, et cetera, are
9 in the mix.

10 And, because we've been tackling the
11 issue of our deficiency in infants in the U.S.
12 for decades with fortified infant products. So,
13 those are some initial thoughts.

14 You want to say something about it?

15 MEMBER DONOVAN: Well, I guess in
16 terms of the, I mean obviously in terms of the
17 nutrients that we're focusing on in the
18 systematic reviews were based on the questions we
19 were given, which, you know, identified nutrients
20 or dietary components of concern.

21 But it will be I think very
22 interesting in this process as you go through, to

1 help identify, you know, other. Because we hear
2 a lot about fiber, you know, in children, and
3 fiber in, in the whole U.S. population. But
4 again, we don't have any questions related
5 specifically to that.

6 So, I really see these as, you know,
7 fleshing out some different areas, and, and it's
8 particularly critical I think, in the B24 because
9 we don't know a lot. Particularly with the
10 breast-fed infants.

11 MEMBER MATTES: This may be overkill,
12 but so in your analysis --

13 (Simultaneous speaking.)

14 MEMBER MATTES: But in your analysis
15 of snacks, which will be self-described, will you
16 break it down into snacks early in the day,
17 snacks later in the day? Or snacks will just be
18 a general category?

19 MEMBER BAILEY: I think that we talked
20 about not the specific details of snacking. I
21 think those are some conversations that our
22 committees should have, and have soon.

1 But, I think what we've talked about
2 is early morning eating and late night eating,
3 and how that impacts the frequency of eating and
4 meeting nutrient and food group recommendations.

5 So, and that would vary across the
6 life stages.

7 So, in children, snacks are
8 contributing quite a bit of energy and,
9 potentially for some of the nutrients of concern.

10 But, I think your point is well taken
11 that not only is it an issue of when, but what,
12 that is being called.

13 MEMBER MATTES: Yes, yes.

14 MEMBER BAILEY: Yes, that's a good
15 point. Thank you.

16 MEMBER SABATE: On this slide that is
17 now posted, I mean the questions at the bottom.
18 You relate as far as the frequency of eating,
19 beverage consumption, alcohol intakes, so on and
20 so forth.

21 As far as achieving the food groups
22 and nutrient intakes, I have two questions. One

1 is the food group intake. I mean I think it's
2 one of the issues that this committee, I mean has
3 to come up with guidelines.

4 So, how can your committee works, I
5 mean as trying to compare what the sample
6 population consumes, as far as guidelines that
7 has not been issued yet? I mean that's the first
8 question.

9 MEMBER BAILEY: Yes, so we will
10 utilize the existing food group recommendations
11 from the 2015 to 2020 as a benchmark to inform
12 our report.

13 MEMBER SABATE: Okay. And, as far as
14 the nutrients, as you know, there are many
15 compounds, I mean now considered very helpful
16 that probably are not still yet labeled as
17 nutrients.

18 Are you going to also use those as a
19 benchmark, or these are going to be excluded of
20 your analysis?

21 MEMBER BAILEY: Yes, and I think that
22 is one of the reasons for at least a start to

1 standardize the language to use dietary
2 components rather than nutrients.

3 So, there may very well be strong
4 associations with certain bioactive components in
5 foods. But, if we don't have the requisite
6 database amounts of those bioactives available to
7 analyze our data, and that's oftentimes the
8 limitation.

9 Not only are there not dietary
10 reference intake recommendations for a lot of
11 dietary components, but then we don't have the
12 database information to analyze what current
13 consumption is.

14 And, I think that's something that we
15 will have to document as limitations and areas
16 for future research.

17 MEMBER SABATE: Okay.

18 CHAIR SCHNEEMAN: Other questions or
19 comments from the committee members?

20 I know that this, when we get to that
21 point of trying to integrate based on what you're
22 finding from the literature, being able to see

1 whether we are is going to be a crucial part of
2 actually coming up with recommendations.

3 MEMBER BAILEY: Absolutely.

4 CHAIR SCHNEEMAN: So, I know
5 everyone's anxious to see all the data.

6 MEMBER NOVOTNY: I guess just --
7 Rachel Novotny -- just sort of a general thing
8 I'm thinking about is making a transition from
9 nutrients into foods, and food components or diet
10 components. And, then related to that, trying to
11 address some of the general policy issues that we
12 want to make around foods.

13 Is looking to this group really to
14 help us see patterns of eating and the population
15 in general?

16 I'm thinking that we should spend more
17 time about sort of certain segments of the
18 population that we may want to understand their
19 patterns better in order to go a next step.

20 That's as far as my thinking has
21 gotten, but it's just sort of a general thought.

22 MEMBER BAILEY: Yes, absolutely.

1 Thank you.

2 MEMBER BOUSHEY: You know, in the, in
3 the research space of dietary patterns and then
4 particularly the theoretically driven patterns,
5 but to a certain extent, it also occurs in the
6 hypothetically driven patterns.

7 But so, a pattern is usually made up
8 of a, a number of different groups of foods and
9 we refer to those as dietary components.

10 So, I don't know if that blends with
11 what you have in mind for dietary components.

12 MEMBER BAILEY: I think more or less,
13 to be inclusive of things like added sugar,
14 fiber, caffeine.

15 These are all things that we're
16 interested in broadly, and different questions
17 that we have. But they're not nutrients per se
18 in the -- I mean we all use it colloquially, but
19 you know, not to be overly pedantic, but I'm a
20 big fan of harmonization of terms.

21 Recovering Federal employee. Can't
22 help it.

1 MEMBER MATTES: Do you have particular
2 concerns about the estimates of water intake?

3 (Laughter.)

4 MEMBER BAILEY: I think that is a way
5 of you saying you have particular concerns.

6 (Laughter.)

7 MEMBER BAILEY: Stated differently.

8 Yes, I think there are certain things
9 are notoriously difficult to measure. I think
10 water is one. I think alcohol is one. You know,
11 the serving sizes are provided and, they're very
12 hard.

13 And, I think that we will have to have
14 caveats around that and, in the way that we draft
15 our conclusion statements and in interpreting the
16 data that we have available to us.

17 There is some prompts in the AMPM
18 procedures. We're doing a 24 hour recall to help
19 participants remember to report beverages or
20 forgotten foods that are often, or difficult to
21 measure.

22 So, there are prompts built in to the

1 procedures. But, it remains an issue of concern.

2 CHAIR SCHNEEMAN: Did you have a
3 follow up, or do you?

4 (Laughter.)

5 MEMBER MATTES: He's not willing to
6 risk it.

7 (Laughter.)

8 MEMBER BAILEY: But, I actually cite
9 your paper a lot for that tap water provides
10 about 5% of calcium to diets. And, so it's not -
11 - you know, it's not insignificant.

12 And, so it's an important question and
13 I know that we've been talking through the
14 frequency of eating, but especially, you know,
15 water is an ingestive event because that happens
16 quite regularly for a lot of people.

17 And, so being mindful of that, and the
18 way that we present and think about the data.

19 CHAIR SCHNEEMAN: So, other comments
20 from the committee? Did Beth or Joan, did you
21 have some other comments that you wanted to make
22 or -- okay, go ahead, please.

1 MEMBER MATTES: Can I just make a
2 global?

3 CHAIR SCHNEEMAN: Okay.

4 MEMBER MATTES: Okay, I think things
5 may change as, as we progress along, and that we
6 will be dealing with an adequate number of papers
7 to be worrying about all of the key confounders
8 and then other issues.

9 But, so far, we sort of have a pattern
10 of we start with around 4,000 hits, and we end up
11 with zero, one or four papers. So, it's a moot
12 point that, that we're going to compare across
13 these things.

14 What strikes me is I know that when
15 the NESR group is going through the, the papers,
16 they, they read them. When the see the first
17 disqualifying criteria, they say okay, that one's
18 out. And, I understand completely why you do
19 that.

20 But maybe it would be instructive to
21 know why, which of the criteria in each of these
22 searches actually led to the rejections.

1 It will tell us about where the gaps
2 in the science are. And, so I don't know if we
3 can do it up front because I understand that
4 would be an enormous additional workload on them,
5 but at some point, or some group, that might be a
6 worthwhile exercise.

7 CHAIR SCHNEEMAN: So, I'm going to
8 suggest that you've now started our final
9 discussion for the committee.

10 (Laughter.)

11 CHAIR SCHNEEMAN: And, if we have
12 time, we can as we gather items, if there's some
13 like that, that we may want staff input on we
14 can, we can come at the end and see if there's an
15 opportunity to, to do that.

16 But, since you were last yesterday,
17 you're first today and we'll go to Steve
18 Heymsfield to be.

19 MEMBER HEYMSFIELD: It must be
20 telepathy. I had exactly the same question as
21 Rick.

22 And, you know, I wondered for

1 mortality in our group, Frequency of Eating, we
2 had thousands, 4,000 papers, and none come up at
3 the other end of the line.

4 And, I had thoughts about like, is
5 there an error rate in reviewing these papers?
6 And, if there is, then I assume the public can
7 feed in right, and say you missed this paper, or
8 why didn't you consider this? So, there's some
9 checking mechanisms on our screening process.

10 But also, the same question about is
11 this just bad research or is it unrelated
12 research, or what, what are the underlying
13 rejections due to?

14 Because there are thousands of papers
15 in there that we're not considering. And, it
16 would really help people in future research to
17 know what's really an acceptable, quality study
18 to make an impact.

19 That was my thought as well, yes.
20 Okay, so well, I thought we were going to get
21 around to Heather. Heather rightfully is
22 concerned about our criteria for selecting

1 studies for Frequency of Eating and mortality.

2 And, we set up certain criteria, and
3 there was quite an extensive discussion yesterday
4 about those criteria. Heather, do you want to
5 make a few more comments on that? Is that okay
6 if we go lateral in that direction?

7 CHAIR SCHNEEMAN: Yes, I'd just as
8 soon if it's something where you need the
9 committee input on, it's better to talk about it
10 now.

11 MEMBER LEIDY: So, if you remember
12 yesterday our, we, the Eating Frequency committee
13 had come up with some more, I would say rigorous
14 inclusion/exclusion criteria. Some of those
15 related to sample size, and then how we're
16 including dietary intake.

17 And, so I went back in and had some,
18 you know, one-on-one conversations with folks and
19 then went back in to all the protocols to see if
20 I was missing something across the boards.

21 And, consistently to my knowledge,
22 unless feel free to chime in, none of the

1 subcommittees have established a sample size
2 criteria, whether it's observational studies or
3 experimental.

4 And, so unless I missed it and I
5 apologize, I went through them fairly quickly.

6 And, so it was just something that came up and
7 then the other piece too, was that outside of the
8 NHANES data, there weren't any criteria in terms
9 of how many dietary recalls that should be
10 included, and what to do with food frequency.

11 And, then I also found with the
12 Beverage subcommittee that I'm also on, is that I
13 think that's the only group that established a
14 criteria for study duration of experimental
15 studies of eight weeks. And, that was only
16 applied to those that had body composition
17 outcomes, as well as type-2 diabetes outcomes.

18 And, so I wanted -- that we -- I had
19 a discussion with our Eating Frequency group
20 because I feel like there needs to be a level of
21 consistency among the committee, because a lot of
22 these outcomes are consistent with the

1 subcommittees. And, so it's how do you wrestle
2 with that? And, we've been back and forth.

3 A side note that I didn't bring up,
4 yesterday, I didn't think about it until after
5 the discussion, and Kay had brought it up as far
6 as the number of time points that we were
7 including in the Eating Frequency, so just a
8 comment.

9 When we were talking about the food
10 frequency questionnaires that we include with our
11 eating frequency, just keep in mind we're not
12 really, it's not the standardized food frequency
13 questionnaires that we can include, because we're
14 not dealing with foods, it's the number of eating
15 occasions.

16 And, so a lot of those frequency
17 questionnaires are not validated, which is okay.
18 We don't have that criteria around the board, but
19 a lot of them don't have an established time
20 interval. So, it might just be in general do you
21 skip breakfast or, or whatever. Or maybe it's
22 the past week or past month.

1 And, so that was another reason why we
2 felt that having multiple ones of those would be
3 appropriate.

4 With the recalls, the reason we wanted
5 greater than we have three days right now, was
6 just because the eating frequency concept can be
7 different. Primarily, too, when you have, you
8 know, weekdays vs. weekends, there's a different
9 amount of skipping that occurs whether it's a
10 weekday or weekend.

11 And, then intermittent fasting also
12 raises the question that if you are recalling
13 just one day, they may not be eating anything vs.
14 one day where they may be overeating in the
15 context of the given day. And, so that was just
16 some context around that.

17 So, the reason I raised this up is a
18 couple of things that, and I didn't think about
19 it until Barbara brought it up, that, you know,
20 you can identify all studies that generally have
21 this topic and then at the end of the day.

22 So, for example, with our all-cause

1 mortality, there are 18 studies that were
2 identified, and then none met the criteria, only
3 three had the diet intake component.

4 But, you know, is it, this is really
5 a committee decision. Is it appropriate for us
6 to then comment about all of those studies and
7 really have it be that it's really low or poor
8 quality?

9 Or do we establish that there should
10 be potentially, a certain level of rigor that we
11 say well, you know, maybe these studies really
12 shouldn't even meet the criteria to be included?

13 And, you know, another example too,
14 with the duration of -- with weight loss. You
15 know, there are studies that will report weight
16 loss of at two weeks or three weeks, or four
17 weeks. Where do you draw the line that says that
18 it's low quality vs. data that really shouldn't
19 have been included in the body of evidence?

20 And, so that's what we're just trying
21 to figure out if the committee feels that should
22 be a level of consistency, and that maybe our

1 committee is being too rigorous.

2 It is a new research question and so
3 we felt the need that for Eating Frequency,
4 again, I can't document this per se, but the
5 folks that are on the Eating Frequency committee
6 have done research in this area, and there seems
7 to be more variability in the number of eating
8 occasions that we have outside of diet or food
9 choices, or food components.

10 And, so I think that's why we may
11 establish that. But, I think there's just a
12 bigger discussion too, in terms of, you know,
13 when you're dealing with the subcommittees that
14 have outcomes related to body composition, should
15 we collectively establish a certain minimum for
16 experimental studies, and with sample size?

17 Dr. Sabate, you brought up the fact
18 of, you know, observational studies should have a
19 sample size. But, none of us have done that.
20 And, and we did that with experimental evidence,
21 but then nobody else has it.

22 And, I don't think for a sample size

1 question that's not specific to eating frequency.
2 I think that's in general. So, that was very
3 long winded and I apologize.

4 But, I, we thought it was appropriate
5 to bring this up with the committee because I
6 think that really has long lasting implications
7 because our committee made up with various -- a
8 few number of potentially high quality studies
9 that might be appropriate.

10 But then we're not really establishing
11 the level of the quality because it's already
12 higher vs. maybe some of the other committees.

13 So, I, we just wanted to bring that up
14 for comments so, because I feel like at this
15 point moving forward, I think it needs to be a
16 group -- we all decided there should be a group
17 decision how we approach this for all
18 subcommittees. And, then more specifically,
19 comments related to ours.

20 MEMBER SNETSELAAR: I just had one
21 comment related to that. This also relates to a
22 question that Tim had yesterday, which I did not

1 hear very well, on quality of studies. And, then
2 I also had a discussion with Rick.

3 I think in some cases we may have very
4 large randomized controlled trials that have gone
5 on for several years with large populations.

6 And, maybe there won't be a large
7 number of studies related to some of the
8 questions we're answering. But, there may be
9 very seminal kinds of articles that could come to
10 bear on our questions.

11 And, just to make sure that if there
12 are those articles available, and they're of very
13 high quality, that that may answer some of our
14 questions. And, we may not have numerous
15 articles, but we have an extremely high quality
16 type of research that's gone on that does answer
17 questions.

18 MEMBER DEWEY: Kay Dewey.

19 So, I would like to address what you
20 said, Heather, about at what phase do you impose,
21 you know, these judgments.

22 And, in terms of the quality of the

1 exposure assessment, which is what you were
2 talking about in terms of the measurement of
3 frequency of eating, there is a place for that to
4 be done in the risk and bias assessment once the
5 studies have been identified.

6 I don't know how many subcommittees
7 have actually gone through the whole risk and
8 bias thing, but we in Pregnancy and Lactation, a
9 couple of us did this just the other day for one
10 of the outcomes that we didn't talk about yet.

11 And, so there were three types of
12 studies in the evidence base. They were
13 randomized controlled trials, non-randomized
14 control trials, and prospective cohort studies.
15 And, the risk of bias table is different for each
16 type of study.

17 And, so for randomized controlled
18 trials, it includes randomization, deviations
19 from the intended interventions, missing outcome
20 data, outcome measurement, and selection of the
21 report or result.

22 And, then it's a slightly longer list

1 for the non-randomized controlled trials. And,
2 for the prospective cohort studies, it includes
3 confounding, selection of participants, and
4 importantly, classification of exposures.

5 And, that's where I personally would
6 choose to have this criterion around did they
7 assess frequency of eating well enough? Then,
8 they would get a low rating for classification of
9 exposure in that risk of bias table.

10 And, then there's, there are four
11 others. I won't read them all out here, but I
12 think that helps take care of not excluding too
13 many studies, but making sure that their, their
14 flaws are recognized when writing up and making a
15 judgment about the overall grade. Because once
16 these, all these cells are filled in, there's an
17 overall grade assigned to the entire body of
18 evidence.

19 And, this is color coded. It's very,
20 very helpful. You know, green, yellow and
21 orange. And, it's based on external kind of
22 recommendations about how this should be done,

1 and maybe some of the staff members would want to
2 say more.

3 But, I think it's a useful exercise
4 for each subcommittee to have gone through all
5 that to, to think about how it applies.

6 For the power calculation and minimum
7 sample size, I think we have some analytical
8 frameworks where we've done that. Maybe you
9 didn't find them and I could be wrong. But, I
10 seem to recall that we did impose that and, I
11 don't remember which ones.

12 MEMBER LEIDY: So, then I guess the
13 question is should the committee, should all the
14 committee follow that when you're dealing with
15 similar outcomes?

16 And, I would love to have that shared.
17 I just couldn't find it. I apologize. It was, I
18 was trying to do this very short.

19 MEMBER DEWEY: Yes.

20 MEMBER LEIDY: But, for a lot of
21 those, I couldn't find that there was a
22 standardization for the observational, and

1 definitely not for the experimental studies
2 unless it was with ours.

3 And, so I guess as a committee, do we
4 feel that we should, we should have that same
5 level? Or does that go under risk of bias? I
6 mean so it's where do you, I guess it's where do
7 you draw the line then of saying well, you know,
8 this should be.

9 And, it occurred to us that when you
10 put that in the excluded/exclusion criteria,
11 you're excluding studies. You're not even being
12 able to assess risk of bias when you kick them
13 out.

14 So, even the eight weeks for the
15 beverages, I'm wondering if maybe that's
16 something that should be retracted if we
17 collectively feel like they should be in, and
18 then the risk of bias is assessed.

19 So, the same thing I guess with sample
20 size. If we have them, should we keep them and
21 if not, we probably should remove them
22 consistently.

1 CHAIR SCHNEEMAN: So, yes, but I think
2 it would be very helpful to have Julie comment in
3 this.

4 Because the, the other factor is first
5 of all, you, you are looking at the papers. You
6 will receive the papers. So, it's not just the
7 summary. That's part of the assessment is to
8 actually look at the papers.

9 And, Kay, I'm glad you brought up the
10 risk of bias, because that's really where you
11 start to get in to many of these, these quality
12 factors. But, I think some of these questions
13 relate to the process as it evolves and, that's
14 why I thought it might be useful to have Julie
15 comment.

16 And, Julie, before you do, I can't see
17 you, but Tim, did you have another comment you
18 wanted to add to the discussion?

19 MEMBER NAIMI: Again, Tim Naimi. Just
20 a very brief one. I agree with like, Heather
21 makes some excellent points, but I think Dr.
22 Dewey does as well.

1 I think there's a middle ground. And,
2 I think that for some of these risk of bias
3 assessments, it's going to differ not only on the
4 basis of the type of study, but the type of
5 outcome and the way that the mechanism is
6 expected to work.

7 So, a follow-up period for some
8 outcomes in a randomized trial could be, could be
9 as little as, you know, a day. It just depends
10 on what the expected action is.

11 So, I think we need to be also careful
12 about having blanket decisions about quality
13 criteria applied to all the topics without very
14 careful consideration of that.

15 MEMBER LEIDY: And, just a real quick
16 follow up just to clarify that.

17 I, you know, I think my statement was
18 more about when the outcomes are very similar in
19 nature. So, if you're dealing with a body
20 composition, or type-2 diabetes, or some of
21 those, I think a consistency should be fine.
22 But, they can't be, it can't be a blanket

1 statement across all.

2 MEMBER NOVOTNY: Rachel Novotny. Just
3 thinking that in terms of the process and I mean
4 I know we want to streamline things as much as we
5 can, but I do think that if, if the committee can
6 explain the reasons that, you know, briefly, in
7 terms of sample size or whatever it is, that
8 studies are excluded, that may be of actually a
9 really big service to helping the public
10 understand why all these things they've heard
11 maybe at the end of the day, we're coming up with
12 a different recommendation than perhaps what they
13 might have thought based on some of the more
14 general information out there.

15 So, I guess that would argue towards
16 keeping in more studies and screening them out
17 at the risk of bias level, yes.

18 MEMBER MAYER-DAVIS: If I can chime
19 in, Barbara.

20 CHAIR SCHNEEMAN: Yes.

21 MEMBER MAYER-DAVIS: I was just
22 recalling, at some point in one of our

1 subcommittee calls, we had a lovely table that
2 had been put together by the NESR staff that
3 summarized for, you know, different variables,
4 what would be considered by the different
5 subcommittees for different outcomes as key
6 confounders vs. other factors to be considered.

7 And, that was exceedingly helpful.

8 And there was a reasonable amount of agreement,
9 but then there were some areas of disagreement so
10 that, you know, the subcommittees had opportunity
11 to say oh, well, you know, let me think about
12 that again.

13 A couple things for our subcommittee
14 changed; a lot of things stayed the same.

15 Because for our particular questions, we had a
16 rationale for whatever it was we had decided.

17 So, it might be that while in this
18 moment it might feel like there's, you know,
19 more, you know, inconsistency. There's probably
20 a lot of consistency.

21 But, I think if we could just identify
22 what we are actually trying to compare now more

1 broadly than just key confounders and other
2 variables to be considered.

3 But inclusion, exclusion, some of
4 these other factors that Heather mentioned,
5 whether it's the duration of the experimental
6 study.

7 You know, then we could actually just
8 look at it and the subcommittees could determine
9 relative to their particular set of questions,
10 you know, what their decisions really should be
11 if they're justified in being different or
12 otherwise.

13 And, I think Rachel has a great idea
14 and just document that. Because we're probably
15 closer than at this moment, than potentially
16 feared.

17 CHAIR SCHNEEMAN: So, but you're
18 right. The documentation is important.

19 MEMBER MAYER-DAVIS: Yes.

20 CHAIR SCHNEEMAN: And, my
21 understanding is that the NESR process itself
22 does document reasons for excluding papers.

1 So, Julie, I'll, I'll let you comment.

2 I assume she's down there.

3 DR. OBBAGY: Yes. I'm here.

4 I think a lot of -- is this one?

5 There it goes.

6 I think a lot of the criteria that
7 you're discussing that have come up in terms of
8 inconsistency areas, are ones that we have not
9 historically established NESR standard criteria
10 for some of the exact reasons that you've
11 articulated just now is that there's either not
12 great empirical evidence for why you would select
13 a sample size of 30 vs. 50 vs., you know, 500 vs.
14 1,000 for an observational study.

15 So, that's why we don't have standard
16 NESR criteria because it could depend on the
17 population, it could depend on the question being
18 addressed. And, so we don't have a, you know,
19 very strong rationale for establishing some of
20 those standard criteria. So, that's why we
21 haven't.

22 But, it's certainly within the purview

1 of your role and, your committee to discuss that
2 and come to agreement.

3 And, consistency is always nice but if
4 there's some rationale for doing something
5 differently by question or topic area, you know,
6 that's always acceptable as well.

7 So, that's sort of the point of being
8 able to tailor some of these criteria more
9 specifically to the topics and the populations
10 that you're addressing.

11 So, I think your discussion is all
12 perfectly in line, and we're open to whatever you
13 can come to agreement on as a committee.

14 So, we do, not to switch gears
15 totally, but we do document all of the reasons
16 for exclusion. I think some of the discussion
17 comes from the fact that we document the reason
18 for why a paper is excluded, but we don't go
19 through every paper and document every potential
20 reason for why it was excluded.

21 And, so we can't confidently report
22 exact numbers of X number of studies were

1 excluded based on study design, X, you know,
2 because we sort of capture some of the most
3 easily identifiable ones from the paper and the
4 abstract.

5 So, we can't with 100% confidence
6 report exact numbers on that, but I think what we
7 do provide in terms of the rationale for
8 exclusion, should give you a pretty good sense of
9 what the most common reasons for exclusion are.

10 You know, in the title screening and,
11 I appreciate that it does look like the numbers
12 go from thousands and thousands down to such a
13 little number, but I think if you actually looked
14 at some of the abstracts and titles that come up,
15 you know, the reality is PubMed does not do a
16 very good job with indexing.

17 And, so if you're looking at a
18 frequency of eating review where you've included
19 a search term like fasting, that's going to pick
20 up all papers on fasting blood glucose and things
21 that are not the fasting you're talking about.

22 So, it's that lack of specificity

1 within PubMed that can lead to sort of a lot of
2 noise coming up in the searches, and so that's
3 why the numbers typically look that way.

4 But I think looking from abstract and
5 title screening rationales will give you a pretty
6 good sense of what the reasons for exclusion
7 would be.

8 We come across a lot of cross-
9 sectional studies, for example, so that's a
10 common reason. Or studies conducted in a country
11 not on your HDI criteria. So, I think we can
12 work with you to provide some more details around
13 that.

14 And, then I think just to the points
15 about risk of bias and parts of the process that
16 can address some of these issues that you're sort
17 of uncertain about in terms of how to handle with
18 inclusion/exclusion criteria.

19 I think Kay, you did a great job of
20 talking about exposure assessment being a really
21 critical part of the risk of bias tool for
22 observational studies in particular.

1 So, we do have mechanisms in place to
2 be able to consistently assess some of these
3 limitations across a body if you don't feel
4 comfortable making a criteria.

5 Precision is another place in the
6 grading process where sample size is definitely,
7 you know, part of that assessment for the body of
8 evidence. And, so if you don't establish a
9 sample size criteria, you know, precision in the
10 grading process will allow you to assess that
11 very consistently and transparently.

12 MEMBER DEWEY: Kay Dewey. So, thank
13 you so much, Julie.

14 Specific question about the precision
15 criterion. If I remember correctly, that's
16 applied at the level of the entire body of
17 evidence, not study by study. Is that correct?

18 DR. OBBAGY: Not study by study, but
19 I think in order to really assess the body of
20 evidence, you know, you kind of do have to look
21 across the studies. And, so you'll have all of
22 the effect sizes, confidence intervals.

1 MEMBER DEWEY: Yes.

2 DR. OBBAGY: And, looking across that,
3 I think you can make some judgments on a study by
4 study basis, but then bring it up to the body of
5 evidence for.

6 MEMBER DEWEY: That's right. But,
7 what I'm getting at is that the risk of bias
8 assessment by type of study is at the individual
9 study level.

10 And, when I was scanning through those
11 criterion, they're between five and eight or so,
12 depending on the type of studies done, I don't
13 think any of those are specifically around power
14 or sample size, correct?

15 DR. OBBAGY: Correct.

16 MEMBER DEWEY: Yes.

17 DR. OBBAGY: Yes.

18 MEMBER DEWEY: So, what that means is
19 that you wouldn't be, if you don't have an
20 exclusion of studies, of papers based on sample
21 size, it would be at a much later phase when
22 you're looking at the whole body of evidence that

1 the power issues would come up.

2 I was looking at some of the other
3 ones because I could remember that we, we had
4 sample size minimum, and I think and maybe Julie
5 or others can again clarify, but I think we may
6 have inherited some of that language from the
7 previous P-B24 project.

8 Because the one I pulled up was for
9 the human milk and infant formula and other
10 outcomes, and they had a minimum sample size of
11 30 per group.

12 So, Julie, am I right? Is that, did
13 I inherit that?

14 MS. GUNGOR: That's correct. That's
15 inherited from the last project where there was a
16 sample size for the breastfeeding and formula
17 feeding questions that the groups in the study
18 had to have at least 30 per group, or a power
19 analysis that indicated that the sample that they
20 did have was sufficient for the outcome, or the
21 comparison and the outcome of interest that we
22 are interested in.

1 So, sometimes there might be a power
2 analysis in the paper and it might not have been
3 for what we were drawing from the paper. It
4 might have been for a different analysis and
5 maybe what we were drawing from the paper was a
6 secondary analysis of some sort.

7 So, that I guess, is a caveat to maybe
8 mention. Sort of a nuance, but, but that is the
9 sort of complete idea was that it was 30 or power
10 analysis.

11 MEMBER DEWEY: And, I think there's a
12 logistical reason why we might have wanted to
13 inherit that because we -- these are updated. We
14 are updating those reviews and to have to go back
15 and remove that criterion and rescreen and
16 reevaluate everything would be extremely
17 difficult.

18 So, inheriting it was, was
19 logistically the right choice. But that doesn't
20 mean that it has to be imposed across the board
21 for all of the questions that all subcommittees
22 are looking at.

1 MEMBER LEIDY: We were comfortable
2 with ours until the, the committee raised the
3 questions. Because we also have a 30, sample
4 size of 30 for between group, and then 15 were
5 cross-over.

6 And, then the question was made about
7 the observational studies, and I don't think
8 that's in your criteria. It's hard to know
9 whether they were observational or experimental
10 studies.

11 And, so we just felt like after the
12 conversation that it seemed like there were a lot
13 of not red flags, but flags that were raised with
14 our criteria. So, that's why we just wanted to
15 bring it up for the discussion for today.

16 CHAIR SCHNEEMAN: Right. I'm glad you
17 brought it up. I know when we were looking at
18 yours, the fact that you had or a power
19 calculation seemed to open the door that it.
20 It's not that it was set in stone, you, you
21 allowed for the power calculation.

22 What I'm going to propose, and you can

1 disagree or come up with an alternative. Because
2 so many of the subcommittees now are at the point
3 where you're starting to look at the evidence and
4 now really having to think through the risk of
5 bias, which I know you all heard about it before,
6 but haven't necessarily worked with it when you
7 were in the protocol development.

8 My suggestion is within the
9 subcommittees there be a discussion of that risk
10 of bias now that we are at that point of looking
11 at the evidence.

12 Some of the groups have already done
13 it, but to really make sure that your protocol is
14 not duplicating what's in that analysis as far as
15 looking at the, the strength of the evidence for
16 the particular criteria that you've looked at.

17 So, that's a proposal. Do you think
18 that would help to deal with the issue?

19 MEMBER LEIDY: Yes, and our biggest
20 problem is we can't really look at risk of bias
21 because when we have our criteria as an excluded
22 inclusion/exclusion, we don't get the, we don't

1 have the ability to go back and look at those
2 studies for bias.

3 So, I think I, I can't speak for
4 Steve. I feel like our recommendation -- well,
5 we were proposing to do with our subcommittee is
6 to go back and remove the criteria so we can then
7 do a risk of bias.

8 CHAIR SCHNEEMAN: I think look at the,
9 yes, look at the risk of bias to see, yes, the
10 tool, just to see if --

11 MEMBER LEIDY: Right.

12 CHAIR SCHNEEMAN: -- you're
13 duplicating.

14 MEMBER LEIDY: You mean, so you
15 propose we do that before we decide --

16 CHAIR SCHNEEMAN: Yes.

17 MEMBER LEIDY: -- to remove the
18 criteria?

19 CHAIR SCHNEEMAN: Yes.

20 MEMBER LEIDY: So, go back and look at
21 all 18 studies that, that we excluded?

22 CHAIR SCHNEEMAN: No. I'm suggesting

1 you start by looking at the, the criteria that
2 are within the risk of bias.

3 MEMBER LEIDY: Oh, sure.

4 CHAIR SCHNEEMAN: Yes. The tool, to
5 see, okay, did you really factor that in when you
6 set your exclusion criteria?

7 So, rather than just going back and
8 changing criteria, start by looking at did you
9 really factor those in?

10 MEMBER LEIDY: Uh huh.

11 CHAIR SCHNEEMAN: And, if you, if you
12 didn't, then you have a rationale for why you
13 might need to reexamine your exclusion criteria.

14 MEMBER DEWEY: Kay Dewey again. I
15 think that's a great idea. But with that said, I
16 was thinking about the fact that the Pregnancy
17 and Lactation conclusion statement that was made
18 on whether folate intake related to human milk
19 folate, I think all of those studies were less
20 than 30.

21 There were four studies and, I think
22 they were all less than 30 participants, and they

1 would have all got screened out.

2 And, so, I think, I would sort of
3 prefer err on the side of not being too stringent
4 on minimum sample size unless you make a really
5 compelling case. Because there is an opportunity
6 at that final stage of assessment of the quality
7 of the evidence to bring this in to bear.

8 CHAIR SCHNEEMAN: Right. And, I think
9 if you look at some of the statements that were
10 made around the evidence for the seafood, you see
11 that looking at the nature of the study itself in
12 terms of how the committee developed its
13 conclusion.

14 Is that -- are we good with that?
15 Beth, you look like you're ready to say
16 something.

17 MEMBER MAYER-DAVIS: Yes. So, this is
18 on a different topic but I think this was a, a
19 good discussion, so that's great.

20 And, that is thinking about, you know,
21 dietary patterns, food groups, foods, nutrients.

22 It occurred to me this morning, and we

1 had some conversation about it, that for the B24
2 and Pregnancy and Lactation groups'
3 subcommittees, there's attention being paid to
4 looking explicitly at supplements whereas for
5 Beverages and Added Sugars, for example, you
6 know, we at some point decided not to deal with
7 supplements looking at FDA, you know, definition.

8 And, it was partly because as a matter
9 of scope and likely available data when you think
10 about, you know, various supplements broadly
11 defined that find themselves in smoothies these
12 days, you know, that that was just not something
13 that we, you know, reasonably could address.

14 But, I'm just wondering, you know,
15 Barbara and Ron, what your thoughts are and maybe
16 what discussion we might have as far as, you
17 know, thinking about supplements that may be
18 important to include for specific nutrients of
19 public health concern, for example. Maybe
20 certain, you know, stages in life course, B24,
21 Pregnancy and Lactation.

22 Then again, we thought well, you know,

1 in the elderly this can be an issue, too. So,
2 some, I think maybe some general conversation
3 might be helpful in terms of supplements as
4 relates to our work for Dietary Guidelines.

5 CHAIR SCHNEEMAN: Okay, so I think the
6 first place I might go is to look at what we're
7 going to learn from the data analysis in terms of
8 with and without supplements.

9 (Laughter.)

10 VICE CHAIR KLEINMAN: Bye, Tim.

11 (Laughter.)

12 CHAIR SCHNEEMAN: So, with that
13 introduction.

14 MEMBER BAILEY: Yes, bye Tim.

15 (Laughter.)

16 MEMBER BAILEY: I think that's why
17 it's an advantage at this point that we don't
18 have the dietary supplement data. Because I
19 think it's important that you look at nutrients
20 from foods and beverages alone, and then in the
21 context of, particularly in pregnancy where more
22 than 70% of pregnant women are using

1 micronutrient containing supplements.

2 So, I don't know if that addresses
3 what you're talking about. I think you're
4 talking more about in all of those, the other
5 subcommittees?

6 MEMBER MAYER-DAVIS: Well, there's
7 another layer to it, which really has to do with
8 focus on nutrients vs. foods. And, so we've
9 really thought in our subcommittee anyway, about
10 beverage as foods.

11 MEMBER BAILEY: Uh huh.

12 MEMBER MAYER-DAVIS: And, you know,
13 added sugars as a matter of foods, you know, and
14 so forth, rather than a focus on nutrients and
15 that it is not, in our view, particularly in our
16 remit, to really focus on nutrients that might be
17 contained in say, beverages, with respect to
18 particular outcomes.

19 So, we're actually not looking at
20 trying to come up with what are the nutrient, or
21 what are the dietary components that might
22 explain an association, for example, between

1 beverage intake and, you know, type-2 diabetes.
2 We're staying at the food level, essentially.

3 MEMBER BAILEY: Yes.

4 MEMBER MAYER-DAVIS: And, that was
5 part of the philosophy around not getting into
6 supplements, because that drives you to a
7 nutrient focus rather than a food focus.

8 MEMBER BAILEY: Yes.

9 MEMBER MAYER-DAVIS: So, that was
10 really some of the back drop of our thinking.

11 MEMBER BAILEY: And, I think that's
12 actually an advantage because the approaches that
13 we're taking complement each other in a lot of
14 ways.

15 And, we're also taking an approach
16 where we're looking at foods, food category
17 sources of nutrients, and then nutrients in and
18 of themselves.

19 So, you have like three different
20 levels of data that will inform the Federal
21 government on how to interpret that into
22 actionable guidelines for Americans.

1 MEMBER MAYER-DAVIS: So, that makes
2 sense as between Beverages and Added Sugar
3 subcommittee, and the work of your committee.

4 I'm still not quite sure how that fits
5 with the B24 Pregnancy Lactation that does have a
6 specific focus on supplements, which I don't have
7 any personal objection to. I'm just trying to
8 make sure that, you know, you know, we have an
9 understanding about really what the scope is.

10 MEMBER DEWEY: This is Kay Dewey
11 again.

12 Well, you know, we were given those
13 questions and, it was just intake from
14 supplements or fortified foods. So, it wasn't
15 the foods, and then did they happen to have
16 something in them as well.

17 So, and it is because certainly
18 pregnancy is a period with heavy supplement use.
19 And, then there are questions around whether
20 supplements are needed for infants.

21 MEMBER MAYER-DAVIS: So, that's just
22 a function of the very specific questions given.

1 Okay, so as long as we're all in agreement that
2 we're sometimes looking at supplements for those,
3 for that reason and sometimes not.

4 MEMBER BOUSHEY: Liz, in these papers
5 that you've looked at, do they even provide that
6 information? I mean what happens is when you go
7 into different spheres of research questions,
8 it's rare that a paper might even put in
9 supplements.

10 And, so I don't, you know, so that's
11 a risk if you start adding them, then.

12 MEMBER MAYER-DAVIS: Yes, and we're
13 not planning on adding them.

14 MEMBER BOUSHEY: Right.

15 MEMBER MAYER-DAVIS: I just wanted to
16 make sure that we were all in good communication
17 about what we were doing. So, yes.

18 MEMBER BOUSHEY: Yes.

19 MEMBER NOVOTNY: Yes, no, I appreciate
20 the question. I've been struggling with that,
21 too, because I mean I'm, we're the Dietary
22 Guidelines Committee and, but I also sit on the

1 subcommittee.

2 So, those were the questions given to
3 us. It does beg the question, I don't know if
4 again, it's going to depend on the papers. Maybe
5 we can kind of as a philosophy, try to articulate
6 sort of the relative role of food and supplements
7 in the outcome if it's there, just to keep the
8 emphasis on food.

9 CHAIR SCHNEEMAN: I think this is very
10 helpful to have the subcommittees identify if
11 there are additional issues where they really
12 need the input from the full committee, to make
13 sure that you can make great progress between now
14 and the, our next meeting.

15 So, our time is getting short so I'm
16 just going to sort of quickly go around and see
17 if there's anything else that needs to be brought
18 up along those lines from.

19 So, Steve, you, you did your thing.

20 MEMBER HEYMSFIELD: I think I'm good.

21 CHAIR SCHNEEMAN: Yes.

22 MEMBER BOUSHEY: I'm good.

1 CHAIR SCHNEEMAN: Okay, great.

2 MEMBER BOUSHEY: Thank you.

3 CHAIR SCHNEEMAN: Kay?

4 MEMBER DEWEY: I have no further
5 comment.

6 CHAIR SCHNEEMAN: Okay.

7 MEMBER DONOVAN: No.

8 MEMBER STANG: Me, neither.

9 MEMBER BAILEY: I guess this is not
10 specific to the Committee, but a plea for people
11 who are doing funding, reviewing, and publishing
12 research, that you include or demand that details
13 of the methods are so critical in their
14 applicability to our purposes.

15 So, if you are a journal editor, if
16 you are a researcher, if you are funding
17 research, the devil is in the details, and those
18 details need to be published. And, a lot of
19 times, you're limited by word count, or, or
20 things like that.

21 But, just be mindful that in order for
22 your research to be impactful and interpretable

1 to committees like this, you have to have the
2 details.

3 MEMBER NOVOTNY: Pass.

4 MEMBER SABATE: And, I just appreciate
5 the conversation we had, the last one as far as
6 the clarification between the measured emphasis
7 of this group on nutrient vs. foods and food
8 patterns.

9 And, I am in full agreement that, or
10 at least that was my understanding that, the main
11 purpose of, of this task force is to relate foods
12 and, and food patterns, and with the health
13 outcomes. And, I think that was a very useful
14 conversation as far as understanding the role.

15 And, we know that these were
16 questions that were asked as far as a specific
17 nutrient supplements.

18 But in general, I think we have to
19 continue trying to see the connection that exists
20 between foods and food patterns, and health
21 outcomes.

22 CHAIR SCHNEEMAN: Thank you.

1 You already had a turn.

2 (Laughter.)

3 CHAIR SCHNEEMAN: So, Ron, do you want
4 to?

5 VICE CHAIR KLEINMAN: No, I have
6 nothing to add. I'm just glad that we were able
7 to come together. I think we really do
8 accomplish a lot when we're seeing each other
9 face-to-face.

10 Something to be said for staying home
11 and doing it over the phone, but it is great to
12 be able to talk these things through, so thank
13 you all.

14 CHAIR SCHNEEMAN: Okay, and so I know
15 that I believe Eve has to officially adjourn the
16 meeting, so I won't do that.

17 But, I will remind you that we, the
18 Committee takes -- as long as the Committee is
19 meeting, public comments can come in. But, if
20 anyone has specific comments on the protocols
21 that, particularly the new protocols that have
22 been discussed, those will be most useful to the

1 Committee if we receive them by November 7.

2 So, I will turn it over to Eve.

3 DR. STODY: Thank you, Dr. Schneeman,
4 and to the Committee. And, we do just have a few
5 closing remarks before we adjourn for today.

6 I did want to just make a quick
7 comment regarding the supplement conversation.

8 Historically, the Dietary Guidelines
9 that have focused on 2 years and older, it has
10 been a focus on meeting nutrient recommendations
11 through foods.

12 But, as Kay and Regan kind of both
13 noted for these new populations, for, you know,
14 for Birth to 24 months and Pregnancy and
15 Lactation, there were just questions around
16 should there be a recommendation at the
17 population level for supplements in addition to
18 like, a typical diet?

19 So, that's where those questions came
20 from. So, that's why there's not specific
21 questions related to supplements for the kind of
22 2-year and older population, but for the Birth to

1 24 and Pregnancy. So, just a few comments there.

2 Okay, so thank you for joining us for
3 meeting three of the 2020 Dietary Guidelines
4 Advisory Committee.

5 I do want to note that materials from
6 this meeting, as always, will be posted at
7 DietaryGuidelines.gov, so that'll include
8 recordings of all of the presentations. There
9 will be transcripts, meeting minutes, all of the
10 slides.

11 It does take a little bit of time to
12 get the transcripts and all of that stuff
13 finalized. So, please allow about one month for
14 those materials to be posted. But as always, our
15 LISTSERV is the way that we communicate.

16 So, if you're signed up for a
17 LISTSERV, as soon as those materials are posted,
18 we will send out an announcement so you can come
19 back and view the discussion again.

20 Okay, did want to spend just a minute
21 talking about meeting four, because it is in a
22 different location.

1 And, meeting four will be held in
2 Houston, Texas, and who knew when we were setting
3 our meeting locations we were predicting the
4 World Series, so stay tuned for the next round, I
5 guess.

6 (Laughter.)

7 DR. STODY: So, yes, our next meeting
8 is in Houston on January 23 and 24 at USDA's
9 Children Nutrition Research Center. And, the
10 meeting will be held from 9:00 a.m. to 4:30 p.m.
11 each day, if that helps with your planning
12 purposes.

13 And, as we talked about yesterday,
14 meeting four will include an opportunity for oral
15 comments to the Committee from the public. This
16 will be essentially exactly the same as it was
17 last time.

18 The public will be able to provide up
19 to three minutes of oral comments to the
20 Committee, and that will be registration is
21 expected to open for that in early January, so
22 registration is not yet open.

1 Registration will be confirmed on a
2 first come, first served basis and, as with the
3 last time, we ask that we keep it to one
4 representative per organization.

5 So, watch for an announcement through
6 our LISTSERV for registration. The registration
7 does fill up pretty quickly. I think it filled
8 up in the first day for the last meeting, so stay
9 tuned for that. Be ready.

10 Similar to last time, when you go to
11 register for oral comments, we do ask for a high
12 level outline of the items you plan to discuss so
13 you can be at the ready when that announcement
14 comes through.

15 In the meantime, you can follow the
16 work of the Committee at DietaryGuidelines.gov.
17 You can view progress on the scientific
18 questions. As we go, protocols will be updated
19 so between now and the public meeting, we do
20 expect to do an update on the website.

21 You can also read subcommittee
22 updates, there's a section on the website with

1 subcommittees, and there's brief updates provided
2 on the work that they've done at various points.

3 We typically do both of those pieces
4 -- we do it all at once. So, for all of the
5 subcommittees, we'll update the protocols and the
6 subcommittee updates all at once. And, this is
7 another thing. When we do that, we'll send an
8 announcement through our LISTSERV.

9 So, if you're interested in kind of
10 following the process, be sure to sign up for our
11 LISTSERV.

12 At DietaryGuidelines.gov, you can also
13 see a link to Regulations.gov, and there you can
14 go as Barbara noted, to submit comments to the
15 Committee. Comments anytime throughout their
16 process. Again, for the comments specific to new
17 protocols, the 19 new protocols, those are asked
18 for by two weeks, November 7.

19 You can also read all of the written
20 comments that have been submitted to date.

21 You can check our recently updated
22 most popular questions page. We do update this

1 page based on the questions that we are
2 receiving. So, that is something that we try to
3 keep updated based on questions that are coming
4 in and that we're hearing.

5 And you can also learn about
6 continuing professional education credits for
7 viewing the meetings.

8 Now, as has been discussed by Barbara
9 and others, this is really, it's an independent
10 committee and, their findings are their findings.
11 But it does take a lot of staff to support the
12 process. And, this is staff from across USDA and
13 HHS who support this process in some way.

14 So, for example, supporting the
15 Committee's scientific review through the
16 systematic reviews, data analysis and food
17 pattern modeling, managing all of the web
18 updates, processing public comments, coordinating
19 the actual meetings and more. And, so really,
20 just thank you to all of the staff for that
21 support.

22 I do want to pause for just a second

1 and acknowledge a specific staff member who is
2 retiring next week.

3 (Laughter.)

4 DR. STOODY: And, that is Colette
5 Rihane, who is very mad at me right now.

6 (Laughter.)

7 (Applause.)

8 DR. STOODY: So, Colette has supported
9 the Dietary -- four different Dietary Guidelines
10 Advisory Committees.

11 She's the Director of the Office of
12 Nutrition, Guidance and Analysis at USDA Center
13 for Nutrition Policy and Promotion. And, I just
14 want to say, you know, she has had just huge
15 dedication to this process, just worked so hard
16 and committed so much.

17 So, thanks for your contributions to
18 this process, and to the Dietary Guidelines, and
19 for your 33 years of service.

20 So, thank you.

21 (Applause.)

22 DR. STOODY: So, with that, we will

1 adjourn for today. Thank you again for joining
2 us and we look forward to seeing you in Houston
3 in January.

4 Oh, and I should note that that
5 meeting will be in person and by webcast. We're
6 bringing our YouTube team. So, if you can't make
7 it to Houston, you can always join online.

8 So, thank you.

9 (Whereupon, the above-entitled matter
10 went off the record at 12:17 p.m.)

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In the matter of: Public Meeting

Before: Dietary Guidelines Advisory Committee

Date: 10-25-19

Place: Washington, DC

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