UNITED STATES OF AMERICA

DEPARTMENT OF AGRICULTURE
AND
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIETARY GUIDELINES ADVISORY COMMITTEE

FOURTH MEETING

WEDNESDAY, NOVEMBER 4, 2009

The meeting came to order at 1:00 p.m. Dr. Linda Van Horn, Chairperson, presiding.

PRESENT:

LINDA V. VAN HORN, PHD, RD, LD, CHAIR

NAOMI K. FUKAGAWA, MD, PHD, VICE CHAIR

CHERYL ACHTERBERG, PHD, MEMBER

LAWRENCE J. APPEL, MD, MPH, MEMBER

ROGER A. CLEMENS, DRPH, MEMBER

MIRIAM E. NELSON, PHD, MEMBER

SHARON (SHELLY) M. NICKOLS-RICHARDSON, PHD, RD, MEMBER

THOMAS A. PEARSON, MD, PHD, MPH, MEMBER

RAFAEL PEREZ-ESCAMILLA, PHD, MEMBER

XAVIER F. PI-SUNYER, MD, MPH, MEMBER

ERIC B. RIMM, SCD, MEMBER

JOANNE L. SLAVIN, PHD, RD, MEMBER

CHRISTINE L. WILLIAMS, MD, MPH, MEMBER

ALSO PRESENT:

CAROLE DAVIS, MS, RD, CO-EXECUTIVE SECRETARY AND DFO, CNPP, USDA

KATHRYN McMURRY, MS, CO-EXECUTIVE SECRETARY, ODPHP, HHS

SHANTHY BOWMAN, PHD, CO-EXECUTIVE SECRETARY, ARS, USDA

HOLLY McPEAK, MS, CO-EXECUTIVE SECRETARY, ODPHP, HHS

RAJ ANAND, DVM, MPH, EXECUTIVE DIRECTOR, CNPP, USDA

RADM PENELOPE SLADE-SAWYER, PT, MSW, DEPUTY ASSISTANT SECRETARY FOR HEALTH, DPHD, HHS

CAPT SARAH LINDE-FEUCHT, MD, DEPUTY DIRECTOR, ODPHP, HHS

ROBERT POST, PHD, DEPUTY DIRECTOR, CNPP, USDA

AGENDA

Wednesday, November 4, 2009

P R O C E E D I N G S

1:00 p.m.

DR. ANAND: Ladies and gentlemen, good afternoon from Washington. Those of you who have come from off site, luckily we have a nice weather for you. So, if you get a chance, go out.

I am Raj Anand, the Executive Director for USDA's Center of Nutritional Policy and Promotion.

I would also like to welcome people who are on webinar for the fourth meeting of the 2010 Dietary Guideline Advisory Committee.

I would really like to thank the Committee for their contributions, and I want each member to know that their service is highly-appreciated.

I would also like to acknowledge the cooperation between USDA and our partners in the 2010 Dietary Guideline process, the Department of Health and Human Services, the

ARS, the Agricultural Research Service, and the original committee members at the table here today.

We also have some members, and I'll take the liberty of introducing them. On my right is Dr. Robert Post, Deputy Director of the USDA's Center for Nutrition Policy and Promotion.

Next to him is Ms. Carole Davis, Director of Nutrition Guidance and Analysis Division of the CNPP. Carole is a Designated Federal Officer and Co-Executive Secretary of the DGAC and I call her the Queen of Dietary Guidelines. She lives and breathes dietary guidelines, believe me.

On the left also, Rear Admiral Penny Slade-Sawyer, Director of Office of Disease Prevention, Health Promotion, will be joining us later.

But we do have Capt. Sara Linde-Feucht, Deputy Director, Office of Disease Prevention and Health Promotion. And we also

have Ms. Kathryn McMurry, Senior Nutrition Advisor at the Office of Disease Prevention and Health Promotion at the HHS. She also Co-Executive Secretary of the DGAC, which is the Dietary Guideline Advisory Committee.

I would like to take the liberty of reminding the Committee of their charge. Your charge is informing the Secretaries of both departments of the changes to dietary guidelines that are warranted, based on the preponderance of most current scientific and medical evidence, placing their primary focus on the review of scientific evidence published since the last Dietary Guideline Advisory Committee deliberation, emphasizing the development of food-based recommendations, not nutrient-based, preparing and submitting a report of technical recommendation with rationales to the Secretaries of USDA and HHS.

The charge also states that the DGAC does not have the responsibility of translating these recommendations into policy

or communication document.

This committee is governed by the Federal Advisory Committee Act, or otherwise called as FACA. FACA was established to assure that advisory committees, one, provide advice to -- provide advice that's relevant, objective, open to public, they act promptly to complete their work -- Remember, they act promptly to complete their work in time -- comply with reasonable cost controls and keep recordkeeping requirements.

Therefore, each public meeting of this committee has been and will continue to be announced in the Federal Register through a public notice.

As part of the open, transparent process, the meeting -- the full committee are open for observation by the public, and any deliberation that occur between meetings, such as those topic-specific subcommittees are brought back to the full committee at a public meeting, as you will hear today and tomorrow.

During the meeting, all public participants will be in a listen-only mode. The public has opportunities to participate in the process by providing written comments to the committee through our on-line public comments database at www.dietaryguidelines.gov. I repeat, www.dietaryguidelines.gov.

In the recent rules of FACA, I would also like to introduce some rules of engagement for the committee. The Dietary Guideline Advisory Committee Members will refer any individual who contacts them personally to solicit information about their work on the committee, the Dietary Guideline Management Team.

The committee members are not able to speak or give presentation to any individual or outside group regarding the work of the committee, as this would be inconsistent with the Advisory Committee operations, and would preclude the requirement the committee works is transparent to public.

Now, I want to recognize Capt. Sarah Linde-Feucht from HHS, who would make some comments and that will be followed by our Deputy Director, Rob Post. Sarah.

CAPT. LINDE-FEUCHT: Thank you so much, Dr. Anand. Good afternoon, everybody.

As introduced, I am Dr. Sarah Linde-Feucht, and I'm the Deputy Director of the Office of Disease Prevention and Health Promotion. And for those of you who are interested in the shorter name, we call it ODPHP, part of the Department of Health and Human Services.

I'm giving the welcoming remarks on behalf of Rear Admiral Slade-Sawyer, who will be joining us later. She had an engagement that precluded her attendance right at this moment, but she will be joining us just as soon as she can.

On behalf of her and the Department of Health and Human Services, I would like to join Dr. Anand in welcoming the

Committee Members, and also the listening members of the public.

The Department of Health and Human Services deeply appreciates all of the many hours that you have provided in leading your expertise for the very important job of ensuring the Dietary Guidelines for Americans continue to reflect the preponderance of current scientific and medical evidence relating to nutrition and health.

We fully appreciate all of your efforts, the efforts of the USDA staff, as well as the HHS staff to improve the nutritional health of Americans.

So, Dr. Post, I will turn it over to you.

DR. POST: Thank you, Sarah, and than you, Raj.

As one of the Center for Nutrition Policy and Promotions, policy officials, I certainly welcome the committee and look forward to another productive meeting.

We are very excited to be broadcasting this meeting live via the Web. The third meeting was held this past April, and it was the first to be held via Webinar.

And as evident from the WebEx survey feedback, from those participants, this new medium enables us to reach a more varied and larger audience of interested parties. It also provides for recording of the meeting to be archived at, once again, www.dietaryguidelines.gov, for current and future reference by the public.

We have individuals or participants that are registered from across the nation, as well as internationally. We are particularly happy knowing that. In fact, we've got folks registered in Saudi Arabia, Slovenia, Brazil, Iraq, Canada and Greece, to name a few countries.

I would like to review a few technical points for the public, and I guess in a departure from the past, I'm not here to

tell you where the restrooms are. I can, though, tell you that on your screen, for those who have registered, you will see some relevant information.

If you experience technical difficulties, you may contact WebEx technical support, toll free at 1-866-229-3239. This information was also emailed to all registrants, as was a technical assistance number for our international participants.

The event staff here in the room at the committee's meeting will be monitoring an email line, so to speak, where public participants can send notes of any technical difficulties while the meeting proceeds.

Now, as you see on the screen, this email address is tech_issue@yahoo.com. Please note that the event staff will not respond to these emails. It is simply one of the several ways we are monitoring the streaming efficiency of the meeting to the public.

We value your feedback on this Webinar meeting. After the meeting registrants will receive a follow-up survey from WebEx. And, as in the past, a transcript and a written summary of this event will also be posted to our website when available.

Because this meeting is being streamed live to the public, I would like to ask that the committee members clearly state their name before speaking. This is particularly important to facilitate clear deliberations to the public who are following the discussion.

And with that, I'd like to turn back to Dr. Anand.

DR. ANAND: Thank you. I will speak a little more now. I would like to turn the meeting to the Chair of the Dietary Guideline Committee, Dr. Linda Van Horn. Linda, all yours.

CHAIR VAN HORN: Thank you, Dr. Anand. And good afternoon to committee

members and the DGAC support staff, and good afternoon to our public participants who are watching via the Web today.

Since the third meeting of the DGAC in late April, the committee and our support staff have been working very hard to complete many milestones, and I think that's an understatement.

The committee has given much thought to the various research questions that could be asked to help inform dietary guidance for the United States. In so doing, we have developed and extensive list of research questions to be answered.

The detail involved in the work being completed is extraordinary, but necessary, enlightening and also highly relevant. It will provide the information needed to develop a thorough, yet concise advisory report.

The process we are using will strengthen our advisory report, and in turn,

enhance the value of the report to inform the Federal Government, as they develop the 2010 Dietary Guidelines for the American's policy.

The committee has seven subcommittees, each with it's own topics listed on the agenda. In addition to these seven subcommittees, we have also the Science Review Subcommittee whose task is to provide oversight and guidance related to the technical weighing of the evidence.

Among the subcommittees, a number of families of research questions have been developed that encompass roughly 180 subquestions that we'd like to address. We have begun drawing proposed conclusions on the evidence but, due to the volume of work, we will not be presenting all of our conclusions at this meeting.

Today and tomorrow we hope to propose conclusions supported by the evidence, and have discussion for a large number of our research questions. This means that at the

fifth meeting, which will occur in quarter of 2010, the first quarter, we will plan to propose our conclusions for all of the remaining research questions and come to general consensus on the science.

We originally had five meetings planned for our public deliberations, however, to accommodate the large volume of information that needs to be discussed, we will be holding a sixth and final public meeting in the spring of 2010, where we will present and vote on our advisory report.

To help meet our goals for this meeting, our committee members have agreed to keep their presentation succinct. I would like to remind the public that our evidence review will be summarized in our report, however, the details of the evidence review will also be available in an electronic database called the USDA Nutrition Evidence Library or NEL, as you will hear referred to throughout our deliberations.

The NEL is a web-based system set of tools to help support our scientific review process. Having the nutrition evidence library ensures that the details of our scientific review are well-documented, transparent and reproducible.

Our systematic process also reduces reviewer bias and better standardizes the approach used by the various subcommittees. Most questions we will discuss were answered using a NEL systematic review.

To help with the time, I would like to preface an upcoming presentations with some general criteria and information that applies broadly to all our work.

The first step of the evidence review process was to generate research questions that led to the search and sort plans to search the scientific literature.

In general, literature in our review met the following inclusion and exclusion criteria. Inclusion criteria

generally entailed studies with human subjects that are of English language as well as international. Sample sizes with a minimum of ten subjects per study arm and a preference for larger sizes if available.

Drop-out rates less than 20 percent with a preference for smaller drop-out rates and populations of healthy individuals and those with elevated chronic disease risk.

Most questions only considered healthy or at-risk populations, but other populations were included when it was pertinent to the question.

Exclusion criteria generally entailed studies of medical treatment or therapy, disease subjects with -- such as subjects already diagnosed with or a disease related to the study's purpose, hospitalized patients, malnourished or Third-World populations or disease incidences that are not relative to the United States population, such as malaria, animal studies, in vitro studies,

and articles that are not peer reviewed.

Exceptions to this list and additional criteria considered will be noted by each subcommittee during their presentation. In some cases the systematic review of the literature went back to cover literature on infants since potential manifestation of disease in infancy can continue on and across the lifespan.

The Dietary Guidelines themselves, however, provide recommendations for ages two and above. An evidence worksheet was developed to organize the information for each article included in our reviews.

These worksheets were developed by trained evidence abstractors from throughout the country. NEL staff then prepared draft portfolios of evidence worksheets, summaries of each article and overview tables for each research question that we used to review the evidence and draw our conclusions.

The committee is grading the body

of evidence supporting our conclusions using an approach the group has agreed to. You can see the criteria here which takes into account the quality of the studies, consistency of the findings, number of studies supporting the evidence, magnitude of the effect or outcome, and generalized ability.

Based on these criteria the conclusion statement will be given a grade of I, strong; II, moderate; III, limited; IV, expert opinion; and V, grade not assignable.

In addition to NEL reviews, we also use other sources of evidence when appropriate. Thus, it is important to note that only conclusion statements for which there was a formal DGAC NEL review are graded.

After the release of our report, all of the materials, including the committee's evidence summaries, conclusion statements, grades and so forth will be accessible online to the public in addition to our written advisory report to the

Secretaries.

For some questions it was decided that a formal NEL review was not needed. For example, when only a brief update is needed to another substantial source of evidence such as the 2005 Dietary Guideline Report, IOM reports or other sources.

Examples of this approach that are being presented today and tomorrow include assessing, if there's a need for B12 fortification, and answering the question, "What amount of fluid is recommended for health?"

For some questions, we use food pattern modeling. To understand the implications of dietary guidance for Americans, the total diet must be evaluated. We do this by identifying amounts of different foods that could be consumed to achieve various nutrient intakes.

The modeling approach has been developed by USDA's Center for Nutrition

Policy and Promotion and provides an opportunity to answer our "what-if" type questions. Modeling allows evaluation of the amounts of nutrients that would be obtained for consuming various combinations of food to ensure adequate intake.

All modeling analyses are designed to be isocaloric. That is, the changes are made within fixed calorie levels and they also evaluate how the proposed modifications impact moderation goals for the diet.

For example, one question that was evaluated through modeling is: What is the impact on intake of folate and other nutrients if all recommended grain amounts are selected as whole grains, rather than half whole grains and half enriched grains.

The draft report for this question will be presented by the Nutrient Adequacy Subcommittee today.

In addition to modeling, we also have other types of data analyses such as

analyses of dietary intake data from the National Health and Nutrition Examination Surveys.

These data help us answer important questions such as what are the major food sources of sodium in the US diet. So, as you can see, there are many sources of evidence. Often they are used in combination to answer a question.

We have also received about 750 public comments throughout the process already, and each subcommittee is taking these into consideration in the development of their work.

The DGAC has the assistance of staff that help to support this work. All of us are extremely grateful for their assistance and ongoing input. Each subcommittee has a team that includes a lead staff person from the Dietary Guidelines management team who supports the Chair and the Members of their subcommittee in overall project management.

There is a NEL project manager who leads the NEL review for the subcommittee, and also performs quality control measures to ensure the integrity of the evidence-based systems that stay intact.

There is a NEL research librarian who conducts the many literature searches and each team also has other staff support members that contribute in a supportive role similar to those I have just described.

Now that we have reviewed the overall systematic approach being used, we are ready to begin hearing some results. Each subcommittee will present their research questions, propose conclusion statements and then briefly describe the evidence supporting those conclusions.

The proposed conclusions will be presented first, but I'd like to remind the public that the subcommittees began with open-ended questions and conducted extensive surveys of the scientific literature and

graded the evidence before drafting these conclusions.

When appropriate, the recommendations from other national organizations will also be summarized. When there are inadequate data to draw fully the evidence-based conclusions, the DGAC has listed recommended research needed to address these issues.

I'd also like to remind everyone that on everything being presented today and tomorrow, it's in a draft form.

Although, as a committee, we need to come to agreement on many conclusions, as many as possible for some topics, especially those for which there are still puzzle pieces missing or collaborative work between subcommittees planned, additional discussion will be needed after this committee meeting and before a consensus can be formally reached at a later meeting.

Lastly, each committee member

should please remember to announce themselves when speaking to help the public follow along.

With that, I would like to begin our first subcommittee, and we are ready to proceed with the Nutrient Adequacy Subcommittee, chaired by Shelly Nickols-Richardson.

With that, I'll turn it over to you, Shelly.

MEMBER NICKOLS-RICHARDSON: Thank you, Linda. And -- Okay. I just want to start off by recognizing the members of the Nutrient Adequacy Subcommittee. They are listed here on your slide, recognizing the work of Naomi and Cheryl and Joanne and Mim in this committee.

I also want to recognize Trish Britten, our liaison at USDA, as well as Rachel Hayes and Eve Essery at the DHHS. They have been extremely instrumental in helping us complete our work, particularly the modeling analyses that we present today.

So, our subcommittee today will present information about nutrients of concern, folic acid fortification, B12 fortification/supplementation and then move into some food pattern modeling, including the realignment of vegetable subgroups, adequacy of USDA food patterns and then USDA patterns with typical food choices.

And I'll ask that questions be held to the end so that we can move through our information and our proposed conclusions prior to taking those questions.

So, the first question that the subcommittee has been working with is looking at nutrients of concern and when considering nutrients of concern, two basic principles were used to frame this question, and the review of data, as well as guide the decisionmaking process.

The first is that nutrients should come primarily from foods and so population-based dietary intake data were examined to

identify gaps in nutrients, as contained in the usual intakes of individuals residing in the United States.

The second premise is that the Dietary Guidelines for Americans provide guidance regarding means to achieve the most recent Dietary Reference Intakes so that nutrient needs by age and sex groups are achieved.

So, our first question here is "What nutrients are most likely to be consumed by the general public in amounts low enough and are of public health significance to be of concern?"

The process by which nutrients of concern were evaluated included first, the short-fall nutrients were identified. Short-fall nutrients are those nutrients for which a group or groups has or have a high prevalence of inadequate dietary intake based on food consumption data.

Second, biochemical indices, when

available and/or disease prevalence data were evaluated for short-fall nutrients to consider the public health significance of all or any short-fall nutrients.

And third, the likelihood of a short-fall nutrient being met by achieving food intake guidelines was also considered.

So, to identify short-fall nutrients, usual intake data from several sources were examined. The 2005, What We Eat in America Report included 24 nutrients from NHANES 2001 through 2002 data.

The 2008 Food and Nutrition Service reports on the diet quality of Americans by Food Stamp participation status, the diet quality of American young children by WIC participation status, and the diet quality of American school-aged children by school lunch participation status included 18 nutrients from NHANES 1999 through 2004 data.

The 2009 What We Eat in America Report for 25 nutrients from NHANES 2005/2006,

for one-day intakes, and then the 2009 What We Eat in America Report for usual intake of four nutrients, including vitamin D, calcium, phosphorus and magnesium from 2005/2006 data were also evaluated.

The 2008 Centers for Disease Control and Prevention Report titled National Report on Biochemical Indicators of Diet and Nutrition in the US Population, 1999 through 2002, was used to evaluate blood or urine concentrations of relevant biochemical indicators of diet and nutrition.

Specimens were from the NHANES 1999 through 2002 survey, and then additional peer reviewed studies were used to supplement this report for nutrients not included in the report, and disease prevalence data were considered for nutrients without biochemical indicators to reflect nutritional status.

The likelihood of achieving the DRI for nutrient was also considered. Food intake patterns using the 2005 USDA Dietary

Guidelines for Americans within set caloric levels were modeled and the ability to consume nutrients in adequate amounts were examined using nutrient-dense food choices from food item clusters for food groups.

A review of the dietary intake evidence indicates that short-fall nutrients for adults and children include vitamins A, C, D and E, and calcium, magnesium, potassium and dietary fiber.

For adults, short-fall nutrients also include vitamin K and choline and for children, phosphorus is a short-fall nutrient among adolescent females.

A review of biochemical evidence indicates that less than five percent of the US population has low serum concentrations of retinol and alpha tocopherol, and the CDC has also reported from 2003 to 2004 NHANES data, a very low prevalence of poor serum vitamin C concentration in the US.

And Booth and Al Rajabe in 2008,

reported that vitamin K deficiency is very rare in the United States.

One report also indicated that more than 55 percent of individuals residing in lower latitudes in the United States had serum 25 hydroxy vitamin D concentration less than 25 nanograms per ml or 63.5 nanamoles per liter during the wintertime.

And I'll just note here that this particular information is pointed out specifically for lower latitudes because these individuals do have more year-round exposure to sunlight compared to those living in the higher latitudes.

The IOM defines serum 25 OHD concentration of less than 12 nanograms per ml or approximately 30 nanamoles per ml for adults and less than 11 nanograms per ml, or 27.5 nanamoles per liter, excuse me, for infants and young children.

So, using the IOM cutoff values, only about ten percent of non-Hispanic whites

over the age of 60 years have a 25 OHD concentration of less than 11 nanograms per ml, with a proportion of older adults having vitamin D deficiency increasing as the cutoff values increase.

And so, minor changes in that cutoff point do increase somewhat significantly the number of individuals with lower or inadequate vitamin D concentrations, 25 OHD concentration.

These cut points will be reviewed when we review vitamin D more thoroughly and potentially present that at the next meeting.

Data from NHANES 2005-2006 indicated that ten percent of women and two percent of men over age 50 years had osteoporosis of the femoral neck and many more older women and men have osteopenia.

Nearly 100 million men and women have prehypertension and hypertension, and it's also known that increased potassium consumption in foods can lower systolic and

diastolic blood pressure in individuals with normal and elevated blood pressure.

Dietary fiber is considered in light of risk reduction of coronary heart disease, which is the leading cause of death in the US.

And food pattern modeling indicates that DRI's for vitamins A, C, and K can be easily achieved by meeting recommendations for fruit and vegetable intakes, although vitamin E is less readily consumed in the typical diets of individuals in the US, biochemical data and disease prevalence data do not suggest that vitamin E nutriture is problematic for Americans.

Choline and phosphorus represent nutrients that may be possible -- of possible concern for some subgroups of individuals in the US and these nutrients are addressed in a separate question by the Nutrient Adequacy Subcommittee looking at particular nutrients of concern for subgroups of individuals.

So, after evaluating dietary intakes of Americans, biochemical data, disease prevalence and potential ability to meet nutrient recommendations by consumption of a variety of foods, the nutrients of concern for children and adults include vitamin D and calcium, magnesium, potassium and dietary fiber.

Evidence for magnesium is still under review, and for certain subgroups, vitamins B12, folate, choline, iron and phosphorus require attention. Potassium will be and is thoroughly addressed in the sodium, potassium and water group. I believe that's in future discussions, and not presented today.

And then dietary fiber will be addressed in upcoming meetings and discussions in the carbohydrate and protein group.

Questions related to folate and vitamin B12 will be presented today and to start with folic acid fortification, I'll turn

it over to Mim to discuss fortification and questions related to folic acid.

MEMBER NELSON: Hi. This is Mim Nelson. Are we going to -- we aren't going to do questions within each piece, as we go, or are we going to wait till the very end? Okay. Okay. That's fine.

So, I am presenting on a series of questions related to folic acid fortification. So, what is the relationship between folic acid intake in the US post fortification era related to serum, plasma and red blood cell folate status, neural tube defects, CVD and stroke.

I should say CHD and stroke, colon cancer and folic acid supplementation, risk of CHD and folic acid supplementation risk of stroke.

You will recall that in mandatory compliance in the United States for folic acid fortification began in January 1998, with voluntary starting in '96, and in Canada, full

compliance was by 1998. All of this as a result of an FDA authorization -- or rather the United States Public Health Service recommendation that all women of childbearing age should be consuming 400 micrograms of folic acid daily to reduce the risk of neural tube defects.

So, we had our basic inclusion criteria with the NEL was research published between 1999 and February 2009. January 2004, and February of 2009, regarding colon cancer, looking at healthy human subjects for the most part and some that have elevated chronic disease risk, peer-reviewed in the English language.

So, one of the first questions that we wanted to look at was "Has there been an increase in folic acid in serum plasma and red blood cells as a result of the fortification?" and our draft conclusion with the Grade I evidence is that there's clear and consistent evidence that serum plasma and red

blood cell folic concentrations increased in the United States and Canada following mandatory folate fortification.

This is from eleven different cross-sectional studies, eight in the United States, three in Canada, five, which were nationally represented in the United States using NHANES data, and one with high-risk Mexican-American population that was on the border between Mexico and America.

And serum folate more than doubled between pre and postfortification periods. Red blood cell folate increased approximately 57 percent. There still is a very small group of women of childbearing years that do have -- or are still at risk for low folate concentrations.

The second question, "What impact has mandatory folic acid fortification had on the incidence of neural tube defects?" The proposed conclusion with the Grade I evidence is that there is clear and consistent evidence

that the incidence of children born with neural tube defects has been reduced following mandatory folic acid grain fortification in the United States and Canada.

This is from 13 different studies, three cohort, one longitudinal, one CDC report, one cross-sectional and seven trend studies. Of the nationally-represented studies in the United States, it showed that there was about a 23 to 54 percent reduction in spina bifida incidence and about 11 to 16 percent reduction in anencephaly incidents.

One Canadian national study reported a similar 53 percent reduction in spina bifida and a 31 percent reduction in anencephaly incidents.

So, moving along, "What impact has mandatory folic acid fortification had on the incidence of stroke?" The proposed conclusion with a Grade of III is that there is limited evidence.

This is mostly because there's not

much evidence, but there is some that stroke mortality has declined in the US and Canada following folic acid fortification policy.

There is one population-based cohort study that was conducted in the United States and Canada, and with controls against England and Wales, ongoing decline in stroke mortality in the US and Canada between comparing 1990 to 1997 to 1998 to 2002 showed an increasing reduction going from minus 3.3 percent to minus 2.9 percent per year in the US and going from one percent per year, minus 1 percent to minus 5.4 percent per year in Canada, whereas the stroke mortality in England and Wales did not change significantly between 1990 and 2002. So, a small but significant difference.

So, "What impact has mandatory folic acid fortification had on the incidence of colon cancer? We gave this a Grade of III, that there's limited evidence that mandatory folic acid fortification has resulted in a

transient increase in the incidence of colon cancer in the US and Canada.

This comes from two studies, one that was done in the United States and Canada, and one that was done in Chile. Absolute rates of colorectal cancer began to increase in 1996.

This is when voluntary fortification began, or 1997 in Canada and peaked in 1998 or 2000 in Canada, and it represents a signification transient deviation from prior folate fortification in the US by about four to six additional cases per hundred thousand individuals.

There is some evidence that the rate of incidence is back to where it was before, and that this is a -- the reason for the transient is that there was a shift for several years during the time, and if we need to, I can get into some of the biological plausibility, but I'd rather not, because we did that before in an earlier meeting.

Rates -- an interesting study that was done in Chile looked at the rates of hospital discharge due to colorectal cancer in Chile before their fortification, which was looking between 1992 and '96, and after 2001 to 2004, after their mandatory folic acid fortification, and they saw an increase by a rate ratio of 2.6 in adults age 45 to 64, and 2.9 in adults age 65 to 70.

So, further evidence in another country that went through folate fortification of this bump up in colorectal cancer.

So next, we wanted to look at -- to sort of complete the full question, looking at folic acid supplementation, so, "What effect does folic acid supplementation with or without additional B vitamin supplementation have on risk of stroke and those with or without existing -- preexisting vascular disease.

We give this a Grade III, that there's inconsistent evidence that

supplementation with folic acid reduces risk of stroke in adults. This comes from two meta-analyses, one that 12 RCT's in the US, Canada in Europe and another that had eight RCT's from US, Canada, China, Australia, New Zealand and Europe.

In the first there was an overall relative risk for patients treated with folic acid supplementation compared to controls, was nonsignificant. For cardiovascular diseases, CHD, stroke and all-cause mortality -- and I'll get to CHD further in the next question.

And in the other trial, folic acid supplementation, in that meta-analysis did significantly reduce risk of stroke by about 18 percent, but should be noted that the relative risk for those trials that were in regions with fortified grain was nonsignificant.

The final question was, "What effect does folic acid supplementation, again, with or without additional B vitamin

supplementation, have on the risk of CHD, in those with or without preexisting vascular disease?"

And we give this a Grade I, that folic acid supplementation does not appear to reduce risk of CHD, particularly in countries with folic acid fortification.

This comes from two large randomized control trials, and one meta-analysis that -- that also -- that contained 12 RCT's.

One of the randomized trials was done in Norway. There was no effect of folic acid, B12 or B6, total mortality or cardiovascular events. This is in people with preexisting disease.

The other was also looking at folic acid, B12 and B6, and also did not reduce cardiovascular events. That trial also was in people with preexisting disease.

And then the meta-analysis, folic acid supplementation did not reduce risk of

cardiovascular disease or all-cause mortality in persons with prior history of disease.

So, Eve, do you have -- is there -- I see you're wandering around in there.

MS. ESSERY: I am going to pass it along.

MEMBER NELSON: Oh, okay. Okay. Sorry.

So, in summary, the overarching question which we will summarize this into really one answer, but the overarching question really is, "What is the relationship between folic acid intake in the US and Canada postfortification era and health outcomes?"

And the overarching is that there is a substantial reduction in neural tube defects. There may be a very small decrease, but significant decrease in stroke. There may also be -- and it may have been transient -- we'll have to see with further data as we get further along after these dietary guidelines are out, but that there may be a transient

increase in colon cancer.

So, it's mixed, but I would say the overall -- the overarching is that the benefit of the neural tube defects is very much there.

MEMBER FUKAGAWA: This is Naomi Fukagawa who will now address the question -- another overarching question, namely -- why am I not going forward? Ah. Here we go. -- about special nutrient recommendations needed for certain subgroups.

And this is somewhat of a different nutrient, in that we did not conduct a full NEL review of the literature for this specific nutrient.

As many of you know, the 2005 Dietary Guidelines for Americans did address the concern about groups at risk for pernicious anemia or neurological deficits related to vitamin B12 deficiency, and these were largely pregnant women and those who are over the age of 50.

Instead of a full NEL review, we chose to update the literature review since 2005, since there weren't significant new randomized control trials done on these particular nutrients, and we also included a review of the NHANES intake data for 2005 to 2006 in order to draft a conclusion.

So, my presentation this morning is -- or this afternoon, will actually be a little bit different from what Mim has just done, in that I'll present the evidence before proposed conclusion.

So, on this next slide, we can see that, based on the NHANES 2005 to 2006 data, the mean daily vitamin B12 intake from foods was above the recommended dietary allowance, which is approximately 2.4 micrograms per day, for all ages and all gender groups.

And furthermore, vitamin B12 deficiency, which was found in -- was found in less than three percent of the population based on serum B12 concentrations, but this

was also in combination with serum homocysteine concentrations greater than 10 micromoles per liter.

We did find in this particular report that the supplement, the use of supplements or fortification for B12 did reduce this prevalence to less than .5 percent in the older at-risk population.

So therefore, our proposed conclusion is that individuals over the age of 50 appear to be meeting their RDA for vitamin B12 and should continue to do so by eating foods naturally rich in vitamin B12 and consume fortified foods with -- foods that are fortified with vitamin B12 or by taking the crystalline form of vitamin B12. Thank you.

CHAIR VAN HORN: Before we move into the food modeling discussion, I think perhaps it would be valuable for the committee to discuss a little bit of what was presented so far in terms of the nutrient issues.

So, Shelly, if you want to maybe

kick off the discussion, that would be great.

MEMBER NICKOLS-RICHARDSON: Well, I'll open it for questions or comments.

MEMBER CLEMENS: This is Rog. Thank you very much, Naomi, for that insight on vitamin B12 status, in particular. I can remember a number of years ago we're looking at the elderly population and I found that in that particular case we see that a number of those individuals have challenges with the intrinsic factor.

Do we have any data that these individuals are able to maintain an adequate status other than what you indicate here in terms of absorption, other than what you indicated on serum status?

MEMBER FUKAGAWA: That's more of a problem. This is Naomi Fukagawa. More of a problem with the naturally-occurring vitamin B12. But if one -- the absorption of the crystalline vitamin B12 is really quite good in the elderly individuals.

And so therefore, if one looks at adequacy and intake, at least across the age groups, they certainly are receiving sufficient -- or it appears that they are receiving sufficient B12.

MEMBER RIMM: This is Eric Rimm. I just wanted to add onto that comment, because I know I've seen some, I believe, preliminary data, or if not published data, probably published data by now, from the Premium Heart Study, suggesting that measuring serum B12 and homocysteine doesn't actually capture deficiency, that looking at methylmalonic acid, which really is a marker of vitamin B12 activity, you capture much more of the deficiency state, and there actually was cognitive function associated with methylmalonic acid.

So, I wonder if there's -- maybe this data set doesn't have that, and I wonder if there's a way to try to incorporate that, because I do worry that this may be an

underestimate of the population that's getting sufficient amounts of B12 that's actively incorporated.

MEMBER FUKAGAWA: This is Naomi again. At least in the data and the studies that I've reviewed, there wasn't an association, even looking at methylmalonic acid concentrations with change -- functional changes such as cognitive decline and so forth, but that's a point well-taken, yes.

MEMBER APPEL: Larry Appel. I have a question for Mim about the folic acid supplementation. The -- it looks like for coronary heart disease you gave Grade I. There's no relationship, and yet for stroke, it seems like you're -- you might be trying to leave the door open, and I was wondering whether, you know, the conclusion should be no apparent benefit as opposed to inconsistent evidence that it reduced.

It looks like one of the -- the bigger of the two meta-analyses -- and granted

I don't have it in front of me, showed no relationship. So --

MEMBER NELSON: Yes. This is Mim Nelson. Inconsistent. I'm -- I'm a little nervous about sort of providing much strength to either of those in terms of -- so you're talking about with the stroke one in particular?

MEMBER APPEL: Well, actually, I think we might be on the same wavelength here.

MEMBER NELSON: Yes.

MEMBER APPEL: Your conclusion, proposed conclusion for CHD was -- does not appear to reduce --

MEMBER NELSON: That's right.

MEMBER APPEL: -- say, risk Grade I, okay, so it's basically you don't see a relationship, good evidence, and yet for stroke you say inconsistent evidence of -- of a relationship --

MEMBER NELSON: Because --

MEMBER APPEL: -- with Grade III.

MEMBER NELSON: Because one of the meta-analyses did show an improvement and the other didn't, but I think that the key with that was that in the folate-fortified countries, there was no reduction.

So, it's inconsistent. Do you think it should be a different grade?

MEMBER APPEL: Well, it's two points. I was wondering whether it should be there is no apparent relationship, which is probably --

MEMBER NELSON: So, what do I do with the other meta-analysis, then?

MEMBER APPEL: Well, I'm not -- is the one with the 12 RCT's -- I know it has more numbers, but is it a -- you know, meta-analyses get updated, and so --

MEMBER NELSON: Right.

MEMBER APPEL: -- the general is you accumulate more evidence, you believe the last one rather than using the first one to keep a hypothesis alive that might not be

worthy of being alive.

MEMBER NELSON: Yes, I'm just looking.

MEMBER APPEL: Part of the reason I say this is --

MEMBER NELSON: Yes.

MEMBER APPEL: -- somebody's going to look at this and say, yes, it's a reasonable hypothesis, we need to do another--

MEMBER NELSON: Yes --

MEMBER APPEL: -- study.

MEMBER NELSON: I don't think -- one of my researcher -- I'm not sure that we need any more research here.

MEMBER APPEL: Yes.

MEMBER NELSON: I think I'd be -- I don't know, Eric, you had just reviewed this, you said also. So, can we go back, can I just go back?

MEMBER APPEL: This is the kind of --

MEMBER NELSON: Yes.

MEMBER APPEL: -- maybe it's worth

either a committee coming back and --

MEMBER NELSON: Yes, and taking a look.

MEMBER APPEL: Because you have two frames --

MEMBER NELSON: So, it's with this one -- it's this one, because there's inconsistent evidence.

MEMBER APPEL: And you said that a Grade III, but your larger meta-analysis would, I think, support a Grade I, no relationship.

MEMBER NELSON: That's right.

MEMBER APPEL: You know, and I don't know if --

MEMBER NELSON: Or at least a Grade II, yes.

MEMBER APPEL: Or whatever, yes.

MEMBER NELSON: Yes, okay.

MEMBER APPEL: And then the CHD one is --

MEMBER NELSON: Pretty strong.

MEMBER APPEL: It's stronger in the Grade I. So, I'm just trying to look for parallels here.

MEMBER NELSON: More, because they're -- yes, okay. Yes. Let me go back and look at this, but I'm inclined at least to go with a Grade II on this instead of Grade III, because I agree.

MEMBER APPEL: Yes.

MEMBER NELSON: The trickier part is the one is actually with the folate fortification, in seeing this small -- both in Canada and the United States, and is there anything else going on that may have caused that -- I don't think so. I think it's the folate.

Or, what do you think, because this right here, this is -- this is, again, it's just one -- it's one population-based cohort study with stroke. And this is just --

MEMBER APPEL: Yes.

MEMBER NELSON: -- similar to the

neural tube defects. I mean, it's a similar design. It's basically looking at the decline -- stroke mortality has been going down, so it's looking at the percent reduction.

MEMBER APPEL: Yes.

MEMBER NELSON: It's very small.

MEMBER APPEL: Yes. I mean, I think you, in order to make a strong statement, you need to know what's happening with blood pressure levels and control rates--

MEMBER NELSON: There's so many other things going on.

MEMBER APPEL: -- such as -- I mean, blood pressure is probably the strongest determinative of stroke that we know.

MEMBER NELSON: That's right.

MEMBER APPEL: So, if you're not out --

MEMBER NELSON: So that's why -- I mean, it's only -- we'll never have another study because this is the data and it's only one time only, but I give it -- do you think

this is fair?

I mean, given this is the one, you know, it was US and Canada versus England and Wales.

MEMBER RIMM: Larry, what are you saying? Are you saying we should -- I mean, the conclusion is that there may be some benefit for folate and stroke, and you want to make that a stronger grade?

MEMBER APPEL: No, no. No.

MEMBER NELSON: No.

MEMBER APPEL: I mean, I was --

MEMBER NELSON: I brought up this --

MEMBER APPEL: -- brought up the issue, and I was explaining that it's hard to --

MEMBER NELSON: It is very hard.

MEMBER RIMM: I mean, the challenge is that a lot of these studies are among people -- this is Eric Rimm, sorry. A lot of these studies are among people with

preexisting disease, so the question really is, for primary prevention, it's more challenging because most of the trials for stroke also are among people with preexisting disease.

MEMBER NELSON: No, but this is -- no, this is not the trial.

MEMBER APPEL: This just looks like vital statistics --

MEMBER RIMM: Oh, sorry. Yes, this aspect of it, yes.

MEMBER NELSON: This aspect.

MEMBER APPEL: So it can be very hard. This is ecologic data, I believe.

MEMBER RIMM: Yes. Okay. I mean, I think there are a few prospective studies from a long time ago also that would suggest that there's benefit of folate in stroke that are observational, that are not just ecological --

MEMBER NELSON: But this is --

MEMBER RIMM: -- that's not

fortification.

MEMBER NELSON: This is about fortification.

MEMBER APPEL: Right.

MEMBER NELSON: This is prefortification and post. I mean, I -- I -- so, Larry, you're saying -- and Tom, I'm looking at you, too, you're okay with this as a Grade III, and it's limited evidence and we leave it because we'll never know, is basically it?

MEMBER RIMM: No, we may know. There's a lot of countries that have fortified with folate.

MEMBER NELSON: Right.

MEMBER RIMM: There may be 30 or 40 studies that can be done like this.

MEMBER NELSON: Come up.

MEMBER RIMM: Yes, that come up where there's a -- you know, change in stroke rates over time.

MEMBER NELSON: Okay.

MEMBER APPEL: Yes, the -- it just will have to have better data because, you know, also there are big pushes now to achieve better blood pressure control in a lot of different countries.

MEMBER NELSON: Right. There's so many. And that's the same issue, I think, with these -- sorry, with the questions about folate supplementation. It's the same issue.

These people with preexisting disease, most of them are on statins or blood pressure medication. There's so many other things that are going on that it's problematic.

But, Larry, we'll revisit this one on stroke and probably upgrade it to II.

Yes, Tom.

MEMBER PEARSON: This is Tom Pearson. You know, I think the 1990 to 1997 actually was in somewhat of an odd sequence of years ago, to stroke incidents, which it actually had been going down, flattened off

for about seven years, and then proceeded to go down again, so that the decline in stroke on fortification looks like pre-prefortification levels.

And I think it's just entirely ecologic, and probably the declines had to do more with an awareness that the stroke rates weren't going down and blood pressure control --

MEMBER NELSON: Yes.

MEMBER PEARSON: -- had kicked in at that point. I think the other thing is that you have ecologic data that's influencing your Grade III, and you have randomized control trial data that usually, in the course of things, you go with a high-risk group, you do your randomized trials and then put all the evidence together, but it's the randomized trial data that I think really is the most direct here.

MEMBER NELSON: It is.

MEMBER PEARSON: So, I think the--

I think the Grade III for this particular conclusion is adequate, because it's -- ecologic data has many, many other explanations.

MEMBER NELSON: Right. For this one. For the fortification one, but we may, for the actual supplementation one, upgrade this to a II, this one. There's two different ones around the stroke. Does that make sense? Okay. Okay. Thank you.

MEMBER PEREZ-ESCAMILLA: Can I --

MEMBER NELSON: Yes. Sorry.

MEMBER PEREZ-ESCAMILLA: I have a follow-up question on folic acid fortification, and -- this is Rafael. -- and what you are calling a transient increase in a colon cancer, and my understanding, based on the biological plausibility that you shared with that committee before, that these may be related to people that have precancerous lesions to begin with.

MEMBER NELSON: Yes.

MEMBER PEREZ-ESCAMILLA: But my question is why it would be transient and not continue.

MEMBER NELSON: Well, the folate hypothesis here with cancer is that it may be -- it may be actually protective, chemoprotective in terms of if somebody does not already have cancer, it may reduce their risk.

But, if they actually have precancerous polyps, then the replication of the cancerous cells may be up-regulated with the folate, and so that may speed up the incidents of full-blown cancer, colorectal cancer.

So, it could be -- if you don't already have polyps, it's protective. If you do have them, it may speed it up. So, there is this sort of a hypothesis that, you know, maybe over time colon cancer rates may go down, but we popped up that group that -- no pun intended, but already had polyps, so to

speak.

So, I guess that's the best way I can simply sort of describe this.

MEMBER PEARSON: I have a couple of questions. This is Tom Pearson again on -- for Mim on the folic acid fortification. One of the charges was to look at cardiovascular disease and fortification.

MEMBER NELSON: Oh, yes.

MEMBER PEARSON: I would like to expand that to congenital coronary -- congenital heart disease --

MEMBER NELSON: Okay.

MEMBER PEARSON: -- because I know that your search was focused on neural tube defects, but I thought there was some evidence that might influence on a quantitative basis your recommendations coming from the congenital heart disease data, I think in the Canadian study, particularly about the conotruncal abnormalities, ventricular septal defects and a single ventricle disorder.

MEMBER NELSON: Yes.

MEMBER PEARSON: So, I was -- I was wondering if, because relative to where the neural tube defect activity is going, it should also affect the closure of the structures of the heart on an embryologic basis.

MEMBER NELSON: Yes.

MEMBER PEARSON: So, I think --

MEMBER NELSON: I think that will --

MEMBER PEARSON: -- will influence some of your decisions about the, say, the quantity of the fortification, which is my second question, is is it -- I would agree with your conclusions that the fortification has been a success.

The question is, there seems to be a lingering discussion of should we go further, so it becomes not a qualitative one, whether or not this has been good, but a quantitative one about should the

fortification be even more. Would you comment on that.

MEMBER NELSON: Boy, I'm hesitant to really answer that question because I don't think that we, as a committee, might be the right committee to answer that.

One of the things that we know happened with the -- right at the mandatory folate fortification time is that, in fact, it was probably double to triple or somewhere -- it was very high levels of fortification, because the manufacturers were worried they were going to not meet the targets.

And then, in fact, if you look at serial blood, there are a couple of these -- when looking at the blood levels, there are a couple of studies that actually looked at just before, just during the first couple of years, and then after, you see an increase and then you actually see a coming down. So the highest levels were within those two years.

I'm hesitant to answer that

question, whether there should be more. My bias reading this would be at the moment, I'm always worried about the risk/benefit ratio, and I would say probably not.

But one of the things I should say, one question that we attempted to answer was actually -- which I don't have here, was the impact of folate fortification on coronary heart disease, and there were no -- there were no data. So, we didn't answer it.

But, I will take a look at what you're talking about before.

MEMBER FUKAGAWA: Mim, I'd like to make a comment addressing Tom's concern about congenital heart disease.

MEMBER NELSON: Yes.

MEMBER FUKAGAWA: But one of the other considerations we have to think about are the epigenetic changes that might be induced by higher methyl group intake in the form of folate.

And I think that's a question

that's not yet answered. It certainly has been investigated in animal studies, and would be a consideration.

MEMBER NELSON: Yes. But, I don't know, Tom, maybe I should ask you. Do you think -- I mean, do you know anything I don't know about whether we should actually be fortifying with more folate?

MEMBER PEARSON: Well, around the time there had been, relative to some population-based folate levels, I believe, some consideration of a further reduction from the -- say 50 percent or so reduction in neural tube defects and anencephaly, even further.

MEMBER NELSON: Right.

MEMBER PEARSON: Because the randomized control trials, I think, of high-risk groups, you know, the folate story is absolutely textbook, a case of causal --

MEMBER NELSON: Right.

MEMBER PEARSON: -- inference.

All the pieces are there.

MEMBER NELSON: Yes.

MEMBER PEARSON: And even though there is a public health piece, the epidemiologic, ecologic piece there, the question still remains whether you could get down to the levels of folate that you get with a supplementation strategy with women who are planning childbirth --

MEMBER NELSON: Right.

MEMBER PEARSON: -- in which you get very large reductions in neural tube defects, whether or not you're achieving that with a fortification policy.

MEMBER NELSON: Yes.

MEMBER PEARSON: And I think this is --

MEMBER NELSON: Yes.

MEMBER PEARSON: -- so it's not a scientific --

MEMBER NELSON: Right.

MEMBER PEARSON: -- question, it's

almost an implementation issue about should be supplementing more, as part of our charge looking at the American diet.

MEMBER NELSON: Yes. I think it's worthy to continue doing research on the impact. There's different ways to look at this, but to look at it before we change it, there's -- it wasn't -- it was -- the initial -- the monitoring research projects were not well-designed before the fortification went into play, and so -- which is unfortunate, because this was something -- we're going into a national experiment, and all of these should have been set up better, and I think we need to -- you know, there's still more work that needs to be done on the existing fortification.

Larry.

MEMBER APPEL: Yes. Hi. I'll take you off the hot seat. I want to -- Shelly, I have a question for you, and it has nothing to do with nutrient adequacy, even

though that's the name of your -- phosphate and phosphorous -- I mean -- phosphorous.

It seems that -- is there a public health issue that is lurking that we haven't really dealt with, which is that not inadequate, but excessive intakes -- you know, I think, you know, we'll come to this in electrolyte, but sodium, you know, phosphate is now being added to a lot of meats, and we have a, you know, kidney disease epidemic, and with a lot of people consuming large amounts of, you know, phosphorous that they might not be aware of.

I don't know, did that -- was there a -- you listed it more as a possible short-fall in children, but I'm thinking of it more as a potential serious -- a potential but unknown -- I'll put that "unknown" health problem in the adult population.

MEMBER NICKOLS-RICHARDSON: This is Shelly Nickols-Richardson. In response to that from our dietary intake data, it is just

that one adolescent female group that there appears to be, you know, a short-fall nutrient related to phosphorous.

So, I don't think it's a large concern. I don't think that there's a public health concern in relation to a positive health outcome.

We will be looking at abundance nutrients next. That's one of our next steps, and I don't know that we had really thought about phosphorous as maybe in light of abundance-type nutrient in relation to health outcomes, but I think we could add it to the list of those that we consider and take a look at it from that perspective.

MEMBER APPEL: I guess that if you do that, too, you -- just my own experience is that nutrient databases are pretty inadequate, and you might get a misleading result that you think it's not a problem because it all adds up, and it seems to be relatively low, but there are so many missing values when we try

to attempt to understand our diets and our feeding studies, that it might appear normal or low, but really actually be quite high when you take into account all sources.

MEMBER NICKOLS-RICHARDSON: Shelly, again, and that's a great point. I think when we consider, you know, much of the dietary intake data, that there are some limitations to that, putting them in the context of what are the -- I'm not sure that they are biochemical data to support this, but what are the other public health issues of concern, and maybe doing an exploratory search that would lead us toward making some decisions about that, but it's certainly something we could take a look at.

CHAIR VAN HORN: Shelly -- this is Linda Van Horn. I think the other topic that came up during discussions within this subcommittee related to the whole issue of supplement use, indiscriminate, I guess I should say, supplement use, especially among

certain segments of the population, and in this case, particularly the elderly who, of course, are at higher risk for development of something like colon cancer.

And I think it was certainly a telling moment to me, personally, but I would imagine we all would want to continue to keep in mind that what perhaps we used to think of as a kind of benign activity, i.e., taking vitamin, mineral supplements individually or, you know, complex, may not necessarily be as benign as we think in the context of food fortification, and there may be reason to consider studying those kinds of questions to make sure that we're not overnourishing certain segments of the population, and then placing them at risk.

So, I think, as this group continues to go forward and as the studies move ahead, we should continue to keep that very important question in mind, and plan our studies to be specific about assessing not

only diet, but also supplement use so we can take a look at that.

MEMBER NELSON: Linda, if I could just comment on that. This is Mim Nelson. During our Webinars that we had in helping us to inform our work on the folic acid supplementation, fortification, et cetera, all of our experts, it seemed to me, and those that were on the call can hopefully agree or disagree with me, but that, in fact, multivitamin B supplement, supplementation for older adults was not advised, specifically because that's where the problems come in, not with the fortification, not with basic folate that's in the foods, but the problem is much more with actual B vitamin supplementation, and in the very high levels.

So, I think what you -- you reminded me about that, and I'll make note of that.

MEMBER NICKOLS-RICHARDSON: Okay. And we will move on with the rest of the

nutrient adequacy information. Let's get to our appropriate slide here.

Okay. So now we're going to shift to questions that were investigated by food pattern modeling, because these questions were more appropriately addressed by modeling scenarios, rather than through literature searches.

And in the next three modeling questions that we discussed, for each of these modeling analyses, there was a specific methodology that was developed and approved by the subcommittee.

So, as we go through these different -- these three different modeling analyses, you'll see that there were very different approaches taken for them.

Cheryl's going to begin with the first question related to the vegetable subgroups.

MEMBER ACHTERBERG: Thank you, Shelly. Cheryl Achterberg here. This is a

very different kind of research question, where we're actually investigating whether or not the current food group patterning or categories is effective, and what would it look like if we made some adjustments.

So, the first food pattern modeling question was designed to address the vegetable subgroups and current patterns of intake, and more specifically the question is "What revisions to the vegetable subgroups, such as including tomatoes with orange vegetables and leafy lettuce with dark green vegetables may help to highlight vegetables of importance and allow recommendations for intake levels that are achievable -- that's by the general public -- without compromising the nutrient adequacy of the patterns themselves.

This current concern -- I'm sorry. I went the wrong way there. This current concern is that the other vegetable subgroup contributes the greatest proportion to overall vegetable intake in the US diet, but the

recommendation for orange vegetables is much greater than consumption.

For example, the recommendations are nine times greater for girls and 14 times greater for boys than median intakes. Orange vegetables currently count for four percent of vegetable consumption, while the, quote, "other vegetable" subgroup accounts for 55 percent. And tomatoes, alone account for 22.3 percent of total vegetable consumption.

Giving more recognition to tomatoes will make vegetable consumption recommendations more realistic and highlight a good source of specific short-fall nutrients.

Therefore, the rationale for examining potential changes in the vegetable subgroups structure is four-fold: to decrease the wide discrepancy between the largest vegetable subgroup, "other vegetables," and the smallest vegetable subgroup, orange vegetables; to provide more focus on tomatoes,

now part of the "other vegetable" group, orange vegetable group, as a vegetable choice in recognition of their nutrient contributions.

Did I skip something?

MEMBER NICKOLS-RICHARDSON: Just go back one.

MEMBER ACHTERBERG: Yes, I'm sorry. To facilitate development -- we'll call this number three for now -- to facilitate development of food intake patterns that meet nutritional recommendations, within calorie needs and are realistic and similar to proportions selected by consumers.

And the forth rationale, to encourage increased vegetable consumption and selection of a variety of vegetables to meet nutrient needs through guidance that is both understood and achievable by consumers.

To cut to the chase, the vegetable subgroups were realigned. The results are that the food item clusters changed somewhat.

And, as you can see, orange shifted now to red-orange vegetables, subgroup emerged.

Butterhead lettuce and bok choy shifted to the dark green subgroup, and the consumption of orange-red vegetables, when tomatoes are included substantially increases.

So, red-orange vegetables, when tomatoes are included, is a new subgroup we have introduced and consumption is substantially increased in that particular group.

The overall vegetable recommendation does not change. That is two and a half cup equivalents per day. With the realignment, the new recommendations are within the 95th percentile of usual intake for almost all age, sex categories, while still a large increase above the median, the change required may be more achievable than the change required for meeting current targets.

In terms of nutrient adequacy, the overall nutrient adequacy of the new patterns

is essentially the same as the old patterns.

Shifting now to conclusions. The proposed revision of the vegetable subgroups results in expanding to the new red-orange vegetable subgroup with only minor changes in the dark-green, leafy and broccoli subgroup.

And these proposed new amounts are more achievable than existing recommendations while meeting nutrient adequacy and staying within an individual's calorie needs.

MEMBER NICKOLS-RICHARDSON: Okay. Thank you, Cheryl. This is Shelly Nickols-Richardson again. Our second question related to modeling, dealt with "How well do USDA food intake patterns using updated food intake and nutrient data meet DRI's and potential 2010 Dietary Guideline nutrient recommendations.

And part of the reason for conducting the vegetable subgroup modeling first was to be able to use those patterns within this next step. So, this was the next logical question after that realigning

vegetable subgroups, and then looking at how well do these patterns, based on the USDA Dietary Guidelines meet requirements.

This modeling analysis was actually conducted in 2005 as well for the Dietary Guidelines, and the approach to the modeling analysis was that appropriate energy levels for food intake patterns were identified based on the DRI formulas for estimated energy requirements.

Next step was that nutritional goals for these patterns were set for nine vitamins, eight minerals, six macronutrients, and the acceptable macronutrient distribution range for five macronutrients, and then based on age, sex groups.

Food groups were established in amounts of nutrients obtained by consuming various combinations of foods were determined and nutrient levels in each pattern were evaluated against nutritional goals.

To update this modeling analysis

for the 2010 Dietary Guidelines, more recent and detailed food consumption and nutrient content data were used. All foods reported consumed from the 2003-2004 NHANES were assigned to appropriate food item clusters and an ideal -- ideal being a nutrient-dense form representative food was selected for each item cluster. Nutrient profiles for each food group or subgroup were then calculated.

The vegetable subgroup realignment analysis was used again, and calories and nutrients provided by each pattern from the nutrient profiles and recommended intake data were calculated, and finally, nutritional goals that were or were not met were identified.

For all food patterns, when using the nutrients and calories from ideal representative foods, again, those are foods that are in their nutrient-dense forms. The sum of the calories from recommended amounts of each food group in oils, which are

considered essential calories, was less than the caloric goal for the pattern.

The remaining calories were assigned to the discretionary calorie allowance.

So, the 12 USDA food patterns meet almost all of their nutritional goals for adequacy. Many nutrients in the patterns are well above the RDA or AI, such as protein, selenium, riboflavin, copper and vitamin B12.

Some nutrients are within 90 to 110 percent of the RDA or AI, such as iron for women age 19 to 50 years of age, or calcium for adolescent girls.

Three nutrient adequacy goals are not met, including vitamin E and choline as well as potassium in patterns at the lower calorie levels. However, these patterns meet almost all nutrient goals for moderation.

As an example, the USDA food pattern for 1400 calories includes 1,255 essential calories based on the ideal

representative food pattern modeling analysis with 145 discretionary calories.

This example highlights that consumption of nutrient-dense foods within the guidance of the USDA food patterns can meet the vast majority of nutrient requirements with some discretionary calories available so that further nutrient-dense foods or other food items can also contribute to nutrient goals.

So the proposed conclusion here is that nutrient needs can be met by consuming the USDA pattern of eating that includes a defined energy intake level for an individual.

Then, the next food pattern modeling question that is of interest is, "What is the impact on caloric and nutrient intake, if the USDA food patterns are followed, but typical, rather than the ideal representative choices are made?"

So, this question then looks at what are Americans currently doing and how

does that compare to these ideal food choices.

As with the USDA food patterns, modeling analysis, all foods reported consumed from the 2003-2004 NHANES were assigned to appropriate food item clusters, and the typical food consumed, which was usually the top contributor to intake from each item cluster was selected as the typical representative food.

Nutrient profiles for each food group or subgroup or were calculated. Calorie, sodium, cholesterol and saturated fatty acid levels for nutrient profiles using ideal and typical food choices were compared, and excesses and deficiencies in the typical choices pattern compared to ideal choices in the standard were identified.

Calories, sodium and saturated fatty acids in most food groups increased when typical versus ideal food choices were included in the model.

Typical food choices that

contributed to these higher levels included foods from all food groups, so across all of our food groups, these typical choices contributed to the higher levels.

Must of these higher levels of calories, sodium and saturated fatty acids had to do with selection of processed foods, methods of preparation, such as frying of foods or inclusion of added sugar and whole fat foods.

Calorie levels per cup or ounce equivalent were up to 50 calories higher when typical rather than ideal food choices were made. So, if typical food choices were continually made, moderation goals for calories, total fat, saturated fat, cholesterol and sodium would not be met.

So, a proposed conclusion is that typical food choices do not substantially affect nutrient adequacy goals, so nutrient requirements are met with typical foods, however typical foods tend to be higher,

again, in calories, total fat, saturated fat, sodium and cholesterol, compared to the ideal nutrient-dense food selected for the USDA food pattern models.

For example, the 2000 calorie pattern contains over 2400, or about 400 more calories if all food choices are typical food choices rather than nutrient-dense food choices as modeled in the USDA food intake pattern.

I'm going to go ahead and go on to our next -- next step slide, knowing that we'll come back for discussion on the modeling question. So, next steps for nutrient adequacy subcommittee include now moving into food groups of concern.

We've looked at the nutrients and we'll continue some work with the nutrients of concern, but we want to move into those food groups. We'll also be looking at abundance foods or nutrients of concern and can keep some of the comments in mind from today.

Vitamin D will be a specific question, and we're moving forward with that. Breakfast intake and meeting nutrient needs is part of a larger question that's being addressed by several subcommittees.

Looking at the question of nutrient supplements was sort of our fundamental premise of foods first, then taking a look at nutrient supplements only for specific intake patterns and age, gender groups and looking at this in light of nutrients for specific age groups.

We have some more modeling work to be done looking at substituting whole grains for enriched grains and Linda did mention we would present that today, but we're holding that until the next meeting to have some other pieces that go along with that from other subcommittees.

Then, also looking at vegan patterns, milk and milk products, nutrients from starchy vegetables compared to grains and

additional food patterns and nutrient adequacy. So, some additional modeling that needs to be done.

So, I'll open the discussion up for questions related to the modeling.

MEMBER PEREZ-ESCAMILLA: I have a question for Cheryl or -- Cheryl, and thank you very much for a very nice presentation.

And this question is related to the issue of adding tomatoes to the orange-red group because I think it is important to have an understanding of the food products that are contributing the most to tomato intake in different age groups in the US, because if we allow for catsup and processed pasta sauces and so on that are very high in sodium, do we count it?

I'm not sure if we did a benefit-risk analysis how that would come out.

MEMBER ACHTERBERG: Thank you for the question. I feel confident in staying that catsup is not a huge contributor to this

food group, but we have been doing the modeling and looking specifically at the particular foods, and I think, in fact, in the typical diet modeling study, we have the specific info on what tomato products are consumed.

Marinara sauce is high in that respect. If you were wondering about a tomato sauce, and we have separated plain tomato sauce from the marinara sauce which also, incidentally, contains added fats, but be that as it may, we have all of those data and we can speak to those data.

But the first modeling question was what difference would it make if we restructured the way that vegetables were categorized so that we could speak more directly to the public about the consumption of those vegetables.

MEMBER RIMM: This is Eric Rimm. I mean, just to add to that comment, Rafael, I think it is a really important point, but I

think it needs to be taken in the context of all the guidelines.

If we have guidelines saying that sodium should be reduced and the fat that's in the food should be monosaturated tomato, then you could make a tomato sauce that contributes to the red vegetables, contributes to low sodium and contributes to monounsaturated fats. So, in defense of tomato sauce.

CHAIR VAN HORN: I would just like to congratulate the group on the work done so far, recognizing just how complex all these questions are. But I also would like to just sort of remind ourselves as we go forward with this discussion today, tomorrow, that we'll repeatedly remind ourselves of the obesity epidemic that we have currently underway.

And I think everything that Shelly and her group has done in regard to recognizing that lower energy intake is lower to be necessary for the majority of the American public as we go ahead.

The value of energy density becomes even more apparent because making proper selections within each of those food groups really becomes essential in a reduced calorie environment, and so the food modeling that is going on, and all of the effort to try to come up with recommendations at various calorie levels will be just really invaluable, I would think, for the public as they try to work their way through these choices and still meet all their nutrient goals.

So, you know, the point that Eric just made about, you know, pasta sauce that makes a lot of different contributions in one felled swoop will become more and more important because meeting those nutrient needs within a limited calorie intake will become something that everyone in this country should be more conscious of.

MEMBER ACHTERBERG: This is Cheryl, if I could add to that. And, thank you, Linda.

I think this may be the first committee that's really taking in hand to what the realities of average intakes as they are in trying to figure how to move them in the direction that's desired.

And that was the impetus behind a lot of this food modeling. Acknowledging what exists, where it is, and then trying to figure out how do we shift it in the direction that we think is desirable.

MEMBER PEARSON: Cheryl, this is a directed view of maybe the entire committee, and we've had a number of issues from the fatty acid group relative to the probability that some of our models may not show adequacy in choline, and it looks like you've had that kind of across the board in many instances.

I guess it would certainly be helpful to us in our fatty acid committee to get an idea of really the significance of the choline recommendation, how definite those are.

I had been led to believe that these were perhaps still a little bit sketchy in terms of compared to the nutrient adequacy data we have for many other things, and that would be very helpful for us to know that so that we don't basically have kind of the tail wag the dog here in terms of the -- a relatively minor issue, actually starting to control something that -- such as saturated fat or cholesterol content, which obviously are big issues.

MEMBER ACHTERBERG: Yes, thanks Tom, for the question. It looks like I am going to punt to Shelly.

MEMBER NICKOLS-RICHARDSON: Well, I am not sure that I am receiving that ball yet but I will say -- this is Shelly -- that when we look at choline, obviously, there's a particular food source that is abundant in choline. That presents a problem for cholesterol.

That when we look at this as being

a nutrient of concern for certain subgroups, we're probably looking at women of childbearing age, and then potentially an older population.

So, it will not likely fall across the entire population of all age ranges.

MEMBER PEARSON: And the evidence for those concerns are strong enough to --

MEMBER NICKOLS-RICHARDSON: This is Shelly again. The evidence for those concerns is not at the same level of -- I don't think we have the ability to conduct a NEL search at this point. We have done some soft searches, if you will, some exploratory searches, and the evidence that is there is not as robust as what we have been able to do for some of the other questions.

So, I -- we don't plan at this point to have a NEL process to go along with that, but it's more a cautionary note for certain subgroups.

MEMBER SLAVIN: This is Joanne

here. I just wanted to mention, it's an adequate intake for choline, so it isn't -- you know, it's not -- so I think we do want to acknowledge that, so it's similar to fiber where we have and adequate intake as far as the DRI, so I think we need to make sure that if we're not meeting it, that we address it.

MEMBER APPEL: Yes, Larry Appel. That was great. I -- in terms of just one comment, could dark-green be just plain green vegetables, you know, because I think you're now moving some other --

MEMBER ACHTERBERG: Okay. The perennial problem. This is Cheryl. The perennial problem with green beans. Their nutrient profile doesn't align with the other dark-green vegetables.

MEMBER APPEL: So what are you going to put, like lettuce? Is that --

MEMBER ACHTERBERG: It's not dark-green, either, although the dark-green leafy lettuces are good. So, so the iceberg lettuce

has fewer nutrients of interest here. It's basically water, but some of the darker-green leafy lettuces grouped in the dark-green leafy vegetable group do have the nutrients of interest.

MEMBER APPEL: You know, it might be helpful to see sort of side-by-side, you know, old system, new system to understand, you know, how these sorted out, and I think there is a -- I mean, I just -- I'm having a little bit of difficulty understanding it myself, as somebody who doesn't really understand --

MEMBER ACHTERBERG: Sure.

MEMBER APPEL: -- where all the greens --

MEMBER ACHTERBERG: We actually have, in essence a white paper written, and I think the suggestion is that these papers would be attached as appendices in the report.

MEMBER NELSON: Sorry, this is Mim. I agree. I agree. I think it might be

helpful to very succinctly and clearly sort of describe the old and the new system and what things fit in, but which would -- I'm assuming would be done anyway.

So, beyond just a white paper, but actually in the question -- yes, just to clarify. But, as long as I have the speaker for a second, I just want to really commend Trish. The typical diet modeling, I think, you know, I echo some other voices around here.

I think it was incredibly helpful because what it really, really showed, and I think we've got to hammer it home, is that when people are meeting their nutrient needs, the typical American, the way that they're meeting them to get these food groups is they're, for a 2000 calorie diet they're getting 2400 calories, which is significant, and I just -- it's really -- I think it's really important that we highlight this.

MEMBER APPEL: Yes, to tell you --

this is Larry Appel again. Actually, this was the main question I was going to raise, is that when I looked at the -- what at least the summary here is the substitution between ideal and typical was not meant to be isocaloric, which I think is a key issue, you know.

And so, the question that I would have -- I mean, you're changing -- your doing two things. One, you're letting the type of food change, but also the total caloric intake.

You know, so then saturated fat, sodium and cholesterol will go up, as well as actually the nutrients. A possibility.

So, I'm just wondering what -- you know, this gets at the heart of what the type of modeling should be. Should it be isocaloric, or should it be, you know, let it float a little bit, you know, and I really --

MEMBER NELSON: But my sense is -- my sense is the ideal was we can design, or we -- as in the modeling, the global "we" can --

this is Mim Nelson again -- that you can design with ideal foods really nutrient-dense wonderful diet.

So, it's -- and they were done at different caloric levels, and that's what Shelly presented. And I think that the -- what we wanted to see was, okay, well, these are ideal and these are great and we actually can and we should be able to meet our nutrient needs with eating real foods.

But what are Americans actually eating, and how does that -- if you put that screen over it, what does it look like for these food groups to -- I think that that is the right -- if you -- the other thing is, without a doubt, if you then did it isocalorically, I'm assuming by just the math, if you do it isocalorically, you're going to be deficient in the food groups because you'd be eating a lot less of each of the things in order to make that calorie.

MEMBER APPEL: But I guess I'm --

and I don't want to be a devil's -- I actually don't think it's being a devil's advocate. I think that, in reality people are eating those typical foods, but it's not -- I don't know the extent of the calorie, how many more calories, but the likelihood, you know, if people are just, you know, for the obesity, given the obesity epidemic, that's probably only like 50 to 100 calories, you know, on average that's contributed.

MEMBER NELSON: No.

MEMBER APPEL: So, if that's the case -- per day. So if that's the case, then do we, you know, how many calories more per day --

MEMBER NELSON: Over 400.

MEMBER APPEL: Over 400. That's impossible. It's impossible. So, I think --

MEMBER NELSON: But Trish is shaking -- Trish is shaking her head. Maybe --

MEMBER ACHTERBERG: Could I --

this is Cheryl. Could I speak, please. Because I think it has not been widely recognized that when the food guide pyramid was put together, and the recommendations made, they were made on the basis of a so-called representative food items, which were the most extreme, the most nutrient-dense choices within each of those food groups.

So, comparing the most nutrient-dense food item choices to the typical intake is that gives us that 400-calorie spread on a daily basis on a 2000 calorie diet.

So, the exercise to evaluate the typical intake, I think was extremely important to show us, in essence, what the gap is, and to help us consider, as we are framing or reframing advice what we need to be giving our attention most to.

Does that make any more sense?

MEMBER APPEL: I understand but, you know, neither is realistic. That's the problem. And to have 400 calories more, I

just don't -- I mean, I think if you did modeling where you somehow ratcheted the calorie -- because I just, for the life of me, cannot believe that, you know, people are consuming 400 calories more in real life.

And that's what I think you're trying to model, closer to real life. So, you might want to say, okay, well, it's not isocaloric, but maybe it's a hundred calories more on average when they make bad selections.

MEMBER ACHTERBERG: It's not intake data.

MEMBER APPEL: No, I realize that.

MEMBER ACHTERBERG: Yes.

MEMBER APPEL: You're trying to model what would likely be happening if people were consuming, you know, the typical choices --

MEMBER NICKOLS-RICHARDSON: The top typical choices all the time. So, it's one extreme to the other extreme. So, the reality is probably somewhere in that 400

calories.

Let me have Trish speak now. Trish is going to say a few comments.

MS. BRITTEN: Hi. I think the confusion about the extra 400 calories is that the way we approach the modeling from the staff perspective was what if Americans actually followed all the advice about how much to eat from every food group so that they are actually are eating two and a half cups of vegetables a day, they actually are eating two cups of fruit a day, the three cups of milk, et cetera.

But, they didn't get the second half of the message, which is they have to be in nutrient-dense forms. So, we know right now that Americans are not eating two and a half cups of vegetables. They are eating more like a cup to a cup and a half, and about a cup of -- you know, less than two cups of fruit by a long shot, and less than three cups of milk by a long shot.

So, that 400-calorie level is the -- I'm sorry. I'm reminded to say that this is Trish Britten from USDA.

So, that 400-calorie difference isn't a difference that actually would happen unless you had a person who said, okay, I'm now -- I'm going to -- I haven't been following this, I'm going to follow it, I'm going to eat all of these food groups as recommended, but they are still eating fried chicken and they're still drinking whole milk or two percent milk, and not listening to the rest of the message.

So, that's where that difference is. We just wanted to make sure that -- that we identified the extent of the problem of not getting the whole complete message about following the food patterns.

MEMBER ACHTERBERG: So, in essence it establishes both the floor and the ceiling.

MS. BRITTEN: Yes.

MEMBER ACHTERBERG: Through this

modeling. But what people actually do is going to be somewhere in between.

MEMBER APPEL: Yes. The problem is that you're using the term "typical foods," but it's not a typical total intake. And if you made typical foods plus typical intake, you probably would get a better idea of -- of what would be happening, you know, in the real world if somebody was --

MEMBER ACHTERBERG: Point taken.

MS. BRITTEN: Well, we have taken data. This is Trish again. We do have intake data from NHANES. We have -- we know what people are eating, and so that's one point of departure.

But this is another point of departure, looking at what if we're following these recommendations that would, in fact, be nutrient adequacy.

MEMBER FUKAGAWA: This is Naomi. I have a question for either Trish or Cheryl. With respect to making the change that you've

made with respect to going to red-orange, certainly the other food groups changed, because you're within a finite.

And what impact does that have with the movement around between vegetables, starches, starchy vegetables, grains, et cetera.

MS. BRITTEN: The biggest change was in -- it really kind of equalized the amount of vegetables and the amount of consumption that came from each one of the subgroups, because the other -- the, quote, "other vegetable" subgroup in the old system represented over half of all vegetables consumed and it was kind of a mish-mash of different vegetables.

But pulling the tomatoes out, that was the only really big change that was made. All the others are minor. I would call them housekeeping.

What you've done is, you've established a red-orange group that is about,

I think it's 30 percent of vegetable consumption, but I don't have the numbers in front of me, and a, quote, "other vegetable" group that's about 30 percent.

So, things are spread out. The starchy vegetables, the legumes, were not changed at all in this modeling, and the dark-green only changed by finding a couple of dark-green leaves that are similar to the other dark-green leaves, which were the butterhead lettuce and bok choy, putting them in where they belonged, along with the romaine lettuce and the spinach and the collard greens and those things.

So, that was more of a housekeeping issue. But the big change was that -- that all of the intake of tomatoes kind of got lost and we had this focus, if you look at our vegetable subgroups of orange vegetables, a real focus on essentially four vegetables which only one has any kind of major consumption, and that's carrots.

MEMBER FUKAGAWA: But the actual amounts that they would be consuming did change.

MS. BRITTEN: The total -- we kept that constant, because the question really was realigning the vegetable subgroups, not increasing total vegetable consumption above what's now currently recommended. We just shifted the amounts around.

MEMBER ACHTERBERG: Cheryl Achterberg. So, these calculations were done in cup equivalents.

MEMBER FUKAGAWA: If they were they did change from 2005 for other things, such as peas, dried beans and peas would have gone down.

MEMBER ACHTERBERG: Actually, they didn't, but we have all of the data in this white paper. I have the numbers all in front of me. You probably don't want me to sit and read them to you, but -- but what we kept constant was the volume of vegetables, and all

we did was sort them differently.

MEMBER PEREZ-ESCAMILLA: Cheryl, I have a question about -- are you going to be able to model -- and this is Rafael -- for families or individuals on a limited budget, the types of food selections that they could make to meet nutrient requirements and stay within caloric requirements and budgetary constraints?

MS. BRITTEN: This is Trish. We actually, at USDA have a whole other -- other set of food plans. They are designed specifically to look at lower income. I think there was a presentation in April or January by -- by Andi Carlson of our office, and the most famous of our food plans is the Thrifty Food Plan, which is the basis for Food Stamp allotments.

It actually used the same food grouping system as -- as our -- the patterns you're looking at that are the basis for MyPyramid.

And she does a computerized simulation to identify how to put -- meet all the constraints of the amounts that are recommended from each food group and all the nutrient constraints and what foods come up with -- with meeting that at the lowest cost.

And so, that's what ends up being the Thrifty Food Plan. So, essentially, yes, we do it, and that is updated on a regular basis as well.

So, presumably, after these guidelines are out, that will be updated again, and so people will be able to see foods that are at minimum cost that meet all of the constraints of nutrient adequacy and food group recommendations.

MEMBER ACHTERBERG: And perhaps just for the sake of clarification -- this is Cheryl again -- I'll share a few numbers just to give you a picture of this.

So, dark-green vegetables, 5.38 percent, red-orange, rounding it now to 27

percent, legumes six percent, starchy, 30 percent, other, 32 percent. Whereas, the "other" used to be over 50 percent.

So, the shift is really out of the "other" and into red-orange. And as Trish described it, almost everything else is margins, on the margins and housekeeping.

CHAIR VAN HORN: Okay. Other questions or comments in regard to this?

MEMBER ACHTERBERG: I just have one. I'm sorry. Go ahead, Xav.

MEMBER PI-SUNYER: I just wanted to clarify, is this a done deal?

MEMBER ACHTERBERG: Cheryl. Everything we're presenting today, in the spirit of everything else we're presenting today, I guess are provisional, but it was the basis from which all things flow in terms of our other modeling.

So, all of our other modeling exercises did so with this regrouping.

MEMBER NELSON: So, -- this is Mim

-- a little bit of the same follow-up question. What if we, after, you know, April, that we say that actually it's not, you know, three vegetables a day or whatever the number is, that it should be five or six, does then -- do we sort of update the modeling process? Is that sort of -- okay.

Because, I think we ought to be a little careful, because there may be evidence why we want more fruits and vegetables.

MEMBER ACHTERBERG: I don't think this would get in the way at all. Rather, you know, our preexisting organization, if you wanted people to eat more fruits and vegetables, it was very hard to steer them into anything except other vegetables.

But, the choices in that other category essentially equate cucumbers and iceberg lettuce to tomatoes, but from a nutritional point of view, they are very, very different in terms of contributions to the diet. And that's what we were trying to take

into account.

MEMBER NICKOLS-RICHARDSON: And this is Shelly. Just for the record, we were nodding head. The answer to Mim's question is yes.

MEMBER NELSON: Okay.

CHAIR VAN HORN: And maybe just to kind of summarize the discussion that we just had, I'm looking again at your slide, talking about the nutrients of concern, and the short-fall nutrients which in both adults and children, you know, A, C, D, E, K, you know, calcium, magnesium, potassium and dietary fiber.

Well, obviously, very many of those would be accommodated if there was a greater intake of fruits and vegetables across the entire population. So, as we continue to go forward and as Trish continues to do her modeling, I think, once again, in an obese environment, we're looking at ways to enhance nutrient density without increasing calories.

And so, you know, making choices within this new configuration is more likely to result in nutrient adequacy where these nutrients are concerned.

And in addition, you know, initiating that, I think is really where we would like to see people go. There's no question that the kinds of things we'll be recommending mean some differences, mean some changes that we're advocating here that people, children, families, policies, we'll need to make, not only to meet those nutrients, but also to address the obesity problem.

So, I believe that what we're describing here is the essence of that, and as we continue, you know, we'll simply continue to add further to how that ideal eating pattern should look, and hope that, you know, we can come up with practical and cost-effective ways to make that happen.

Other questions, comments on this

very important subcommittee?

(No response.)

CHAIR VAN HORN: All right. With that, I think I would like to adjourn for ten minutes just a postponement, or a break for everyone, and we'll resume promptly at three o'clock eastern time. Thank you.

(Whereupon, a short recess was taken from 2:49 p.m. until 3:00 p.m.)

CHAIR VAN HORN: Welcome back. We are ready to get started for the second presentation of the group this afternoon, which will be chaired by Joanne Slavin on carbohydrate and proteins, and we have a rich discussion in store. Thank you.

MEMBER SLAVIN: Thanks, Linda. Yes, we're the carbohydrate and protein subcommittee, and I'd like to acknowledge my other members listed here, Dr. Cheryl Achterberg, Dr. Pi-Sunyer and Dr. Van Horn.

I would also like to acknowledge the wonderful staff that works with us, Jan

Adams, Eve Essery, all the NEL people, the librarians. It's been a ton of literature searches we're going to go through today and had a lot of help with that.

The topics we're going through today are all NEL searches, and the way we structured our work at the end we'll give you a list of all of the things that are also on the committee's plate to do.

But everything that we're going to talk about today are NEL searches. And they are listed in the next slide. Glycemic load and glycemic index by Dr. Pi-Sunyer.

I'll talk about dietary protein patterns and then we will get into our food groups discussions, fruit and vegetables. Cheryl will talk about and I will cover milk and milk products, and then dried beans and peas.

So, I'm going to turn it over to Dr. Pi-Sunyer. Thanks, Eve.

MEMBER PI-SUNYER: Thank you,

Joanne. So this first presentation is a review of glycemic index and glycemic load, and we asked the following questions: What is the relationship between glycemic index and glycemic load, and body weight, cancer, type II diabetes and cardiovascular disease?

First of all, I want to go through some definitions. Glycemic index is a classification proposed to qualify the relevant blood glucose response to consuming carbohydrate-containing foods.

Operationally, it is the area under the curve for the increase in blood glucose after the ingestion of a set amount of carbohydrate in a food, generally 50 grams during the two-hour postprandial period relative to the same amount of carbohydrate from a reference food, white bread or glucose, tested in the same individual under the same conditions, and using the initial blood glucose concentration as a baseline.

Glycemic load is an indicator of

the glucose response or insulin demand that is induced by total carbohydrate intake. It is calculated by multiplying the weighted mean of the dietary glycemic index of the diet of an individual by the percentage of total energy from carbohydrate.

And the glycemic response is the effects of carbohydrate-containing foods, the effects that they have on blood glucose concentration during the time course of digestion.

With regard to the search strategy that we used, we used -- we looked at any references that were available from June 2004 to March 2009 for body weight and cancer.

When we did that for cardiovascular disease and type II diabetes, we found very few references, so we went back and looked at the time range from January 2000.

We considered incident disease as outcomes. Neoplasm was the search term used

for cancer and all types of cancer were included. We excluded all systematic reviews and meta-analysis and reviewed only original research articles.

The first question, then, is what is the relationship between glycemic index and load and body weight. The proposed conclusion with a grade of strong, is that GI and GL are not associated with weight and do not lead to greater weight loss or better weight maintenance.

There was no difference between high versus low GI and GL diets of greater than eight-week durations in facilitating weight loss.

The review of the evidence, we found 22 articles relating to this, 13 randomized clinical trials, two prospective cohort studies and seven cross-sectional studies.

The randomized control trials overwhelmingly show no difference between high

and low GI diets in achieving weight loss or maintenance. Data on glycemic load were less numerous, but show the same results. And observational studies validate this finding from RCT's.

The second question is: What is the relationship between glycemic index and load and cancer? Again, the proposed conclusion grade is strong. The evidence is strong that the epidemiological evidence for an association between glycemic index or glycemic load and cancer is overwhelmingly negative.

The review of the evidence, we found 26 articles, 19 prospective longitudinal observational studies, one cross-sectional, observational study, five case control and one case cohort study.

Seventeen prospective studies examined the association between GI and cancer, one showed a very weak positive association for total cancer, 15 found no

association, and you can see the different cancers that were involved, endometrial, pancreatic, breast, stomach and colorectal, and one found an inverse association for colorectal cancer.

With regard to glycemic load, 19 prospective studies examined the association between glycemic load and cancer. One, again, showed a very weak positive association for total cancer. Sixteen found no association with endometrial, pancreatic, breast, stomach and colorectal cancer, and one found an inverse association for colorectal cancer.

No other associations were observed except in the case control reports. In the case control reports, three found GI to be significantly associated with cancer. One for prostate and one for gastric and one for thyroid, and similarly for glycemic load.

With regard to type II diabetes, the question is: What is the relationship between glycemic index and load and type II

diabetes?

For glycemic index, the proposed conclusion with a Grade of II, or moderate, is that there is mixed evidence as to whether there is an association between a high GI and type II diabetes.

With regard to glycemic load, the proposed conclusion with a Grade I of strong, is that there is little evidence to suggest that a high glycemic load is associated with type II diabetes.

The review of the evidence shows ten longitudinal prospective observational studies. With regard to the glycemic index, five reports found a positive association, two were from the same cohort, four found no association, and one found an inverse association.

With regard to glycemic load, one report found a positive association, seven found no relationship, and two found an inverse association.

With regard to cardiovascular disease, the proposed conclusion is Grade III, very limited data, and the conclusion is the evidence for an association between high GI or high GL and cardiovascular disease is more negative than positive, but the evidence available is inadequate, really, to come to a firm conclusion regarding this question.

The review of the evidence with regard to cardiovascular disease, we found eight articles. Seven were longitudinal prospective observational studies, and one was a case control study.

The relationships between GI and GL and cardiovascular disease outcomes were inconsistent. Three studies reported a relationship between GI and GL and cardiovascular outcome in women with a BMI greater than 23 or 25, but not in those with lower BMI.

So, overall, if we put the questions together and say what is the

relationship between GI, GL and weight, type II diabetes, cardiovascular disease and cancer, I think the overall conclusion is strong with a Grade of I.

Current evidence predominantly shows no relationship of GI and weight or cancer, and no relationship of GL and weight type II diabetes and cancer.

The evidence for GI and type II diabetes is mixed, but more strongly negative than positive. The evidence for the relationship of either GI or GL in cardiovascular disease is inadequate to come to any conclusion.

Thank you very much.

MEMBER SLAVIN: I think what we'd like to do is, since our different questions don't relate, if anyone has a question now on glycemic index, glycemic load, please ask.

MEMBER APPEL: Yes. Xav, a question. I notice that you didn't include systematic reviews and meta-analyses, and I

think that a lot of other groups are using those, so I was just sort of curious what the rationale was, because I think -- I was hoping -- I wasn't quite sure.

MEMBER PI-SUNYER: Well, we thought it was better to go to the original literature rather than look at the reviews. So, we went to the original publications.

MEMBER APPEL: But sometime -- I mean, but then there's the -- I realize that, that's useful going to the originals, but then to synthesize -- I guess if it's a consistently null, and you know, you aggregate and you get point estimates that are null, then that reinforces the overall conclusion.

But sometimes, you know, things that tend -- you know, where there's inadequate statistical power, of course, and you aggregate, you might get a result.

MEMBER PI-SUNYER: Well, we could go back and do that. We felt that we had enough data -- I don't think that we could

resolve the cardiovascular one if we went back and looked at the review ones, and I think the other would probably stay pretty much the same.

But, we could certainly do that if the committee wants us to go back.

The only advantage I could see to that would be that the reviews would probably go back beyond 2005, and so would include some studies that were not included here, because our window has been between 2005 and 2009, except for diabetes and cardiovascular disease, where we didn't have enough -- we didn't feel we had enough data from 2005 to 2009 to come to any conclusions.

MEMBER NELSON: This is Mim. I had sort of a similar question, because I think that -- that I sure would feel more comfortable if there were systematic review or meta-analysis that sort of corroborated this and went back, because I'm concerned about some of our questions where there may have

been really good trials that were done before our cutoff, were sort of -- not that we're in a vacuum, but we're not necessarily reviewing those, and I think that that's where a meta-analysis or review can sort of corroborate and we feel solid.

I think it might be really helpful, because if it doesn't say anything different, it's more, you know, confirmatory and it does go back further in history, which I think can be helpful.

MEMBER PI-SUNYER: Well, we can certainly do that if the subcommittee wishes. Tom.

MEMBER PEARSON: This is Tom Pearson. It seems in the lipid, in the fatty acid group we were coming across a number of times an end point that was not related to a nutrient, except in the subgroup with diabetes, or metabolic syndrome, and I was wondering if you got any signal since, you know, seven or eight percent of Americans now

are diabetic, and probably another 25 percent are pre-diabetic.

Did you get any possible subgroup signals of the glycemic load index, et cetera, that would suggest that as a subgroup that might have some -- a different conclusion than you're drawing?

MEMBER PI-SUNYER: I think it's possible that a diabetic group would have a different result with regard to this. Our -- I think when we started our deliberations we -- we agreed that we wouldn't do diseases, that we would do it essentially we're talking to healthy nonchronic disease Americans.

If we branch out and do diabetes and cardiovascular disease and so forth, we could do that, but then that would greatly change the whole -- the whole inspection of the evidence.

One of the problems with the diabetes ones, I think, if you look at them as most of them are very short-term, you know, we

generally said that we would only look at those that went longer than eight weeks.

There are a lot of single-meal or short -- very short-term studies with diabetic patients. There aren't many long-term studies. There are some, but not very many.

MEMBER PEARSON: No, I agree. We did the same thing, but these came up in the course of looking at other papers where the authors looked at the subgroup and said that, but it didn't look like the diabetics were acting the same way as the healthy groups. I just wondered if that was a signal you got.

MEMBER PEREZ-ESCAMILLA: Xavier, this Rafael. My understanding is that there is quite a large intra individual variability in glycemic measures. And if that is the case, could that explain why it is so difficult to find association with any of the outcomes or do you think it's just a poor biomarker for predicting chronic disease?

MEMBER PI-SUNYER: Well, I think

it's probably both. I think it's certainly true, there is an enormous variation from time to time. We know that even from a glucose load for a two-hour glucose tolerance curve.

You know, one day a person could be normal and the other day abnormal. It's created a bit of havoc with diagnosis. So, we know there is this variation that's very strong, but I think, you know, whether it's -- that it's a biomarker effect, there could be some of that, too.

MEMBER SLAVIN: I am going to cut in if that's okay, unless there's a pressing question, just to keep on our schedule. Appreciate that -- the glycemic index load was an example of one that was reviewed in 2005, so then we took the NEL approach.

We're going to move on to something that is new to this committee, so we had nothing to start from, so we -- what is the association between consumption of various dietary patterns, plant-based, animal based

and vegan, and health outcomes.

And in trying to put this question together, these are the ways we came up to phrase them. "How did the health outcomes of a plant-based diet compare to that of an animal-based diet?"

"How did the health outcomes differ between those who follow a vegan, non-animal protein diet, and those who consume animal products?"

Definitions were a problem, just we came up with these, and this is the way we searched, and this is -- and at the end you will see that this is a limitation of this field.

We define the animal-based diet as a dietary pattern that includes regular consumption of animal products, a plant-based diet, as a dietary pattern that includes occasional consumption of animal products with most dietary intake coming from plant foods, and a vegan diet as a dietary pattern that

does not include animal products.

We went back, trying to figure out how far to search. Our date range, January 2000 to June 2009. Children and adults, two years and older, and specific health outcomes were not identified in the search, so we wanted to go fairly broad in this search.

First question: How do the health outcomes of a plant-based diet compare to that of an animal-based diet, and our conclusion is a Grade III limited.

Using the current NEL process, intake of a plant-based diet is associated with lower BMI and blood pressure, no protective properties of vegetarian diets against cancers were found in the EPIC-Oxford cohort, and a little bit of a disclaimer here is that the differences in eating patterns among countries are great and affect the results of this question.

The studies that came in to the NEL review: 18 observational studies, 15

longitudinal cohort, two-case controls, 11 cross-sectional studies. They represented data from nine different countries, and six articles were actually from the same EPIC-Oxford cohort in the UK.

They've made an attempt to include vegetarian, so it was one of the few cohort studies that has enough vegetarians. Some of the limitations of this, small sample sizes of those consuming plant-based compared to animal-based diets in these cohorts, and that's particularly true of vegans.

But even people that are more plant-based, there is a small number, and this all inconsistent classification of plant-based diets, that in most studies there's not a way that this gets sorted out, that people go into these categories.

So, I think the Oxford study that -- the reason that we have data from that is that they made an attempt to do that. Most other studies, the numbers in these groups are

very small, and they are not easily classified.

Question: How did the health outcomes differ between those who follow a vegan, non-animal protein diet, and those who consume animal products? Our Grade III, limited for a conclusion, there are very few studies that compare vegan diets to animal-based diets.

So, any types of study, perspective, interventions, there just aren't studies out there that have been published in this area to go from. There is some limited data that vegans have lower body mass index than meat-eaters. There is some data that vegans may have lower blood pressure than meat-eaters.

There's -- in looking at nutrient data in these studies, vegans have significantly lower intakes of calcium than meat-eaters. So there's some data that a vegan eating pattern may improve certain

biomarkers, but can also be associated with lower intakes of some nutrients, and particularly calcium coming out here.

Dietary protein patterns, review of the evidence, five observational studies, two longitudinal cohorts, three cross-sectional. Again, four were based on this EPIC-Oxford cohort, and the limitations of very small number of vegans and semi-vegetarians in this cohort.

We have a big section on research recommendations on this just because this area, even though there's a lot of interest, a lot of public comments, and we really wanted to do a nice job of reviewing this and seeing what's out there, but there are really a need for well-defined cohort studies of populations where we have people consuming plant-based diets compared to animal-based diets.

Some of the potential limitations of plant-based diets for key nutrients come out: calcium, iron, B12, protein quality,

especially in children and the elderly, and some of these can be done with a modeling. We'll talk more about that as potential ways to get at that.

Better assessment tools to classify vegetarian dietary patterns in epidemiologic studies. Most of the studies, there's very few people in these categories, anyway, and they're not well-classified.

A need to identify and follow cohorts that include a significant number of vegan subjects on US diets compared to matched protein eaters. I mentioned most of the data is in other countries, or hardly any US data at all. A lot of variation between the -- among all these different countries and the results.

And then there are -- essentially, I could find -- we could find really no intervention studies where people were actually given vegan diets compared to other non-vegan diets, and looked at biomarkers,

weight loss, anything like that. There's just no real studies out there that make those comparisons.

All right. Any questions about animal protein patterns?

MEMBER FUKAGAWA: I do. This is Naomi Fukagawa.

MEMBER SLAVIN: Yes.

MEMBER FUKAGAWA: Presumably into the category of protein quality, you are implying that it's the amino acid distribution within vegetable versus animal proteins? Because there are definite differences that will occur based on some of the essential amino acids, and therefore, it could have an impact on health outcomes.

MEMBER SLAVIN: Well, the way this search was -- the questions were put together was just animal versus plant, so we didn't talk about all the differences that potentially would be in those diets, whether -- you know, because absolutely protein

quality, there would be big differences there.

MEMBER FUKAGAWA: So that's what you mean by protein quality in that research areas, or research recommendations?

MEMBER SLAVIN: Okay.

MEMBER FUKAGAWA: Looking at that, that was the question.

MEMBER SLAVIN: Okay. Yes.

MEMBER FUKAGAWA: And a follow-up question to that is, another important consideration is whether it's total protein intake or really the type of protein that induces some of the, you know, negative health, or whatever health outcomes you may be concerned about, because there are some sort of prospective sort of, you know, studies and clinical research centers, et cetera, that might suggest that it's the total protein intake, not really the type of protein that could be associated with physiologic changes that lead to negative health outcomes.

MEMBER SLAVIN: Right. In some of

our other areas we're going to look at with the macronutrient distribution of carbohydrates, proteins and fats in weight loss and relation to biomarkers will get at that more than this question will.

This question was really just set up of, if we look at protein source, plant versus animal, and ask that question straight-out, what kind of differences do we see?

MEMBER PEREZ-ESCAMILLA: Joanne, this is Rafael. You know, the difference in lifestyles between vegetarians and non-vegetarians have been well-documented for a number of risk factors, others than diet, and I'm assuming that, you know, these studies probably control for a number of those, but still, you know, without a randomized trial, this is an area where it's, I think, very difficult to interpret the differences.

MEMBER SLAVIN: We looked at some information on just number of vegetarians and vegans in the US and I think it's like 2.3 and

1.4, so it's a very small number.

So these large studies, typically we don't get very many people -- and people do go, you know, from category to category. They become vegans and then they, you know, stop being vegans.

So, I think we wanted to ask this question because of all the public comments we got to see what -- what information is out there and to -- I think the research recommendations would say there's a real need to generate more research in this area to answer a lot of the questions that we have.

Mim.

MEMBER NELSON: Well, I have a question because -- this is Mim Nelson. I also wonder, the reality, seeing that there's less than, let's say, three percent of the population that is vegan or even vegetarian, isn't the more relevant question on the range -- like high, abundant meat-eaters, versus, you know, like along the spectrum so that -- I

mean, isn't there some data that, you know, people that eat meat, you know, three times a day, that they may not have as great health outcomes as people that eat, you know, meat, twice a week kind of thing.

So, it's on the spectrum, not in the categorical, but more as a continuous variable, I guess, is what I'm getting at.

MEMBER SLAVIN: We are asking a question on animal protein later on, and I think that would get at that as far as more of a quantity.

I think there's this kind of perception, though, that there would be a huge difference in health outcomes if you separate it out, you know, vegetarians versus meat-eaters.

And with the data we have, that we can't -- that data doesn't exist. Now, whether, if you had -- I don't know, I think it would be good to study people and have more information.

But even like, meat-eating -- you know, Cheryl wants to chime in. Help me out here.

MEMBER ACHTERBERG: I think my perception of going through the literature is that somewhere along the line we, as a nutrition community, stopped investigating vegetarian diets, vegans or plant-based foods.

There were a lot more studies done about 20 years ago, but the diets that people consumed then about 20 years ago are quite different, I think, than the plant-based vegetarian diets today.

So, I think, in general, all we can say is there was a big hole in the literature that needs to be filled, and it's very hard for us to speculate beyond that.

MEMBER SLAVIN: Tom.

MEMBER PEARSON: Were the -- this is Tom Pearson. Were the blood pressure changes explained by the BMI changes in the vegans versus the meat-eater?

MEMBER SLAVIN: I think they were, because that's the same study that information came from. So, yes.

MEMBER PEARSON: So all of that, there's no other pathways to look like we're acting --

MEMBER SLAVIN: Not reported.

MEMBER APPEL: This is Larry Appel. I have a little bit of perspective on this because actually the rationale for the DASH Diet was a vegetarian diets lower blood pressure and if you go to the RFA that was part of it.

So, the fact that the literature search was clipped, what was it -- ten years, is a problem because the two major study -- there are clinical trials of vegetarian diets and blood pressure, and they both showed about a five millimeter reduction in blood pressure, one and hypertensive and one in nonhypertensive.

So -- and I grant you, there are

not a lot of clinical trials in this, so it won't be -- get a rating of I, but there are clinical trials out there, and it was just before your point in time. So, that's one thing.

And then, just to get to Cheryl's point, I actually wanted to do a clinical trial. It didn't have the menus for DASH Diet versus a vegetarian version of the DASH Diet, could not get it funded, couldn't even get approval to submit the application.

So, the reality is that, you know, that when you try to even do the studies and you have a good design and an infrastructure to do these things, you might not be able to get it done.

MEMBER NELSON: But -- this is Mim Nelson. I mean, I think we have to, with all these questions, be careful about clipping the data at a certain time point because a lot of times -- we have to be cognizant of previous research because otherwise, some of the best

research may have been done earlier. We just have to be very careful about it.

MEMBER APPEL: Yes. I don't know what the solution is, though. If you just say, you know, how do you deal with this if, you know, if you -- the last ten years when your best studies are done 30 years ago or 25 years ago and they were trials.

MEMBER SLAVIN: Well, I also think just the diet has changed at that point, that with soy and some of the -- yes, some of the newer things that people are consuming, it would be nice to have more current studies on that.

CHAIR VAN HORN: The other thing we were discussing earlier on this subject -- this is Linda Van Horn -- is the fact that what we do have are data that suggest that people who eat more vegetable protein versus animal protein -- in other words, not necessarily pure vegans or vegetarians, even, but rather do consume a diet that is more

vegetable plant-based, those data exist in greater abundance.

And so, you know, sometimes it's a matter of looking at the data through those eyes and being able to tweak and filter out those answers from data that were not necessarily collected to answer that question.

And I think this group has done a great job of trying to do that, and I believe we'll probably go forward a little bit more on that -- that level.

Despite what Joanne said about the very small estimate of vegans, less than two percent in the population, I suspect, and I think we already know that there are more people who eat relatively less animal protein and more vegetable protein, and that population is somewhat greater, which would allow us to look at some of those relationships.

So, I think that's kind of the direction we're more likely to head, rather

than an all-out randomized control trial, looking at, you know, one versus the other.

MEMBER SLAVIN: I wanted to follow up on Naomi's point, too, just about protein quality because, as we talk about people eating less, I think protein quality becomes a more important variable.

MEMBER NELSON: Linda -- this Mim. Shouldn't we make sure that some of the studies that you're referring to are -- it seems that they would be appropriate in this search category that we -- that Joanne just reviewed, that we should make sure that those papers are in there because sometimes these search terms can really cut out a whole category of studies that should be considered.

CHAIR VAN HORN: Yes. To share with those who are listening and may know specifically. Hello. Linda Van Horn. To share with those who are listening and may not know this specifically about the kind of search that we're doing and the use of the

NEL, et cetera, it's only as good as the search terms that are applied.

And I'm not suggesting that they're not good. They're absolutely wonderful, and this is the closest we've ever come, I think, to doing a thorough evidence-based analysis.

But without a doubt, even in our deliberations earlier today we recognized that there were certain studies, certain papers, certain topic areas that, for whatever reason, were simply not captured by that search that we now need to go back and work with our librarian staff and group to try to make sure that we've done justice to the availability of some of those data, even if it's a hand search to try to be sure we incorporate some of that.

So, you know, it's not a perfect world and some things will, you know, simply fall out, but I think the goal now is to look at whatever was provided on a standardized approach and make sure we're not missing

anything by going back over it with some of these other studies.

MEMBER SLAVIN: I wanted to mention -- this is Joanne again, Linda, that we are looking at animal protein products as another one of our searches. So, this is not -- we're not done with protein. So, there is -- yes, we're just starting.

So, any other protein questions before we go to food groups?

Roger?

MEMBER CLEMENS: Yes. Rog. A number of years ago there were a number of studies that looked at protein in excess. If you are to reexamine to Larry's comment, go back another ten, 20 years, would your group look at the potential issues associated with excess protein intake.

I think the current USDA data indicate we're taking about two times the amount of animal protein than we do in terms of plant protein. I just throw that out, and

it piggy-backs also on Naomi's comment.

MEMBER SLAVIN: Yes, and I think if you look at DRI, it's anywhere from ten to 35 percent of our calories are from protein, and there's no UL for protein, so I think for DRI, as calories go down, percentage of calories from protein have to go up.

MEMBER FUKAGAWA: This is Naomi. I did want to make one more comment that, you know, we've placed a lot of emphasis, perhaps, on the EPIC-Oxford Study, and I just checked, and their BMI's were largely from self-report.

They did obtain real weights in only about 5,000 of the cohort, but we all know the difficulties we have with self-report of height and weight. So, we'd have to look, interpret that data with some caution, I think.

MEMBER SLAVIN: And I think that that comes up because they did try to recruit vegetarians, so they have -- and a lot of that obviously is self-reported in there, too, just

the way the diets are described.

All right. Other questions before we move to our food groups?

We're going to go through fruits and vegetables, milk and dried beans and peas, and Cheryl is going to take us through fruits and vegetables.

MEMBER ACHTERBERG: Okay. I think as I go through this, a lot of the same themes will emerge once again, so you might want to consider contextual factors here.

Our first question here is, the general question: Was the relationship between the intake of fruits and vegetables and body weight. In one case cardiovascular outcomes, in another, future presentations, we'll be looking at diabetes type II, and cancer.

Our search strategy, I want to emphasize the date range here. June 2004 to June 2009. As we began this, and we looked at the charge to the committee it said to

emphasize the last five years.

We were trusting that we would be building on the work that had been done in the former Dietary Guideline Advisory Committee work.

The studies here were restricted to adults 19 years and older, and that's because another subcommittee is looking at what happens in a pediatric population.

The search included individual studies as well as systematic reviews and meta-analyses, and we looked at the intake of all fruits and vegetables, but did not consider juices.

So, for the first question, a relationship between the intake of fruits and vegetables and body weight. The proposed conclusion here is Grade III, limited.

Using the current NEL search process, the evidence for an association between increased fruit and vegetable intake and lower body weight is modest, with a trend

towards decreased weight gain over five or more years in middle adulthood.

No conclusions can be drawn from the evidence on the efficacy of increased fruit and vegetable consumption in weight loss diets.

So, for the review of the evidence, there were 11 studies, three RCT's, three prospective cohort studies, one case control and four cross-sectional studies.

In the RCT's, a small weight loss that was usually one to two kilograms were observed over short time periods of less than six weeks. All prospective cohort studies showed a weak inverse relationship between fruit and vegetable consumption and weight gain that was long term, from approximately six to 12 years.

There was also an inverse relationship reported in the cross-sectional studies except for one study from China where we didn't see any significant effect, but

again, I think the baseline there had higher fruit and vegetable intakes.

Limitations, most of the limitations that were described in the previous section are here as well. It's also very difficult to quantify the amount of fruits and vegetables in any given study because of the various differences in methodology.

Shifting to the second question: What is the relationship between the intake of fruits and vegetables and cardiovascular disease?

The proposed conclusion in this case is a Grade II, moderate. Using the current NEL search process, there is moderate to strong evidence supporting an inverse relationship between fruit and vegetable consumption and cardiovascular coronary heart disease in the US, in US populations, with larger effects noted above, five fruit and vegetable servings per day.

Looking at the evidence, then, there were ten studies, two meta-analyses, six prospective cohort studies and two case control.

The meta-analyses showed increased vegetable intake and increased fruit intakes are independently associated with decreased risk of CVD mortality when the total consumption was over five servings a day.

Four prospective cohort studies found positive relationships between fruit and vegetable intake and a decrease in CVD in extreme quintiles -- that's the highest versus the lowest consumption there, and the case control studies showed similar results.

Turning now to blood pressure. What is the relationship between the intake of fruits and vegetables and blood pressure?

In this case we're proposing a conclusion Grade III, limited. There were very few data. So, using the current NEL search process, there's limited evidence to

suggest any association between fruit and vegetable intake and blood pressure.

What did we look at? There were four studies, one prospective cohort study and three cross-sectional studies. The prospective cohort study found no association between the intake of fruits, vegetables, or fruits and vegetables combined and hypertension.

Cross-sectional studies provided mixed results. I think all of these are international. One study reported no relationship where that average intake was over five and a half servings per day.

One reported an inverse relationship for fruit and vegetable intake and blood pressure. One reported a positive association between fruit and vegetable intake and lower risk of home measured hypertension.

Continuing now, blood cholesterol. What is the relationship between the intake of fruits and vegetables and blood

cholesterol? Once again, the proposed conclusion is a Grade III, limited.

Using the current NEL search process, the evidence for relationship between fruits and vegetable intake and blood lipids is limited, but appears to show a trend between increased consumption of fruits and vegetables, with lower total and LDL blood cholesterol levels.

Review of the evidence. There were only three studies, one trial and two cross-sectional studies. The trial added three servings of cherries per day for 28 days, and the impact on plasma lipids.

Cross-sectional studies found an inverse association between fruit and vegetable consumption and, as I said before, with total and LDL cholesterol between extreme quintiles.

Implications. I think this work is still under review. There are a lot of questions. I think we now want to look

farther back in terms of what the research literature has to offer us, take a longer long-range perspective on that.

So, what we've presented today represents what evidence has been collected and reviewed for the last five years.

Any questions?

MEMBER NICKOLS-RICHARDSON: This is Shelly. Just a quick question just for clarification. In these studies "servings" is related to --

MEMBER ACHTERBERG: Cup equivalent.

MEMBER NICKOLS-RICHARDSON: Cup equivalents. What are the servings?

MEMBER ACHTERBERG: You raise one of the major limitations. I really struggled with this because different studies approach it different ways.

Europe tends to approach vegetable intake according to weight measures by gram. Here in this country we're using cup measures.

Some of the Asian studies -- it's something different again.

So, a serving does not equal a serving, does not equal a serving as you're trying to compare studies one to another. So, that's one of several limitations here.

Other limitations go with the difference in diets altogether. For example, one study from Serbia, the main vegetable consumed were onions. In Asia, it's a different set of vegetables. In the US, another set of vegetables.

So, I think one of the major research questions and implications are whether, as we consider higher intakes of fruit and vegetables whatever effects are found, is that due to a replacement?

In other words, the question is: Are fruits and vegetables acting as an asset or out of a deficit model, that if there's more of something, there's less of something, and we see an effect that way.

Or, are the fruits and vegetables, in and of themselves, contributing something. And I might add there, are they contributing something independent of fiber, because another confounding factor here, as we look at the evidence, is oftentimes those two terms are used interchangeably, and clearly fruits and vegetables are more than fiber packages.

So, it ultimately gets down to food matrix questions, or perhaps even diet matrix question.

CHAIR VAN HORN: Eric.

MEMBER RIMM: I wonder -- this is Eric Rimm. This is one of those cases where you had to make tough decisions at the beginning of this in terms of which questions to ask.

You obviously did not ask fruits and vegetables and cancer because there's a recent report on it that you can probably point to.

But I wonder if it's, at this

point, now that you've gone through some of this is that you may want to trim your questions, is that the fruits and vegetables and blood pressure, maybe there's not enough new, and we need to just sort of fall back on what was there and say what was there is -- there's not -- you know, there's not enough new, and maybe the weight change is also because it's so difficult to measure weight change and the new data are not substantially greater than what's there, and maybe, instead of making it seem a little bit more vague and confusing, we should just fall back on the ones where the answers are the strongest.

MEMBER ACHTERBERG: Well, I think we still have to look at that literature before we decide that for sure, but the curious thing is these results don't necessarily align with some of the older results.

MEMBER RIMM: Yes. This is Larry Appel. Yes, this is one where the prior data

are going to have an impact. I mean, most people -- the DASH clinical trial again, there was a third arm that was fruits and vegetables, and that significantly reduced blood pressure, well-controlled study, 150 people, you know, versus control.

So, you know that -- and then there was another study, I believe, by John's -- the reason I know this is I was in your position five years ago. I reviewed the fruit and vegetable literature, so I'm glad --

So, I think that -- but, you know, there are not a huge number of studies, so you're not going to push this up to -- I mean, I think there is a reasonable argument, but it's also in the context of potassium, the reality, because you have supplement trials, then you have some food group trials, and together the argument is reasonable, though.

But in terms of the other issue that I wanted to raise, I think you need to divide cardiovascular into stroke and CHD

because if I remember correctly when I did this, the evidence on stroke was actually pretty decent with almost all of the co -- not all, but most of the cohort studies showing a, you know, an inverse relationship.

You know, I just looked it up. It was like seven or eight out of ten cohort studies of higher fruits and vegetables associated with reduced stroke and again, it's consistent with this blood pressure-potassium hypothesis.

For CHD, it only comes out when you do the meta-analysis, you know, there might be one or two studies, but more then tend to be, you know, negative. So, I think you need to -- they are -- they're different, I think.

MEMBER ACHTERBERG: I wanted to follow up, too, Eric, because cancer and type II is still being done, so it's not like we're not -- yes, so they will be done.

And also, I wanted to just

mention, Larry, just this -- when we start with this process, the NEL process, I think it really, you know, deciding how far to go back is a real problem.

You know, and because -- and the other thing I worry about is sometimes in these studies, unless somebody keyworded fruits and vegetables, they won't come up unless you know them. They are not going to get onto this review because that's not how they were keyworded.

So, that's a concern, that there might be data out there that we don't pick up in this type of a search unless somebody, you know, knows about it and brings it forward.

MEMBER APPEL: The one thing that we might do, and I don't know if the NEL people do this, is that there are, you know, seminal studies, you know, so you can, you know, with the fruit and vegetable area say, okay, most people really do know about these one or two studies, and if you do like, you

know, linked -- linked, you know, related articles or something like that, you might be able to pull up some of the ones that you just described that wouldn't, you know, be captured in your search.

MEMBER NELSON: This is Mim. I agree. I'm concerned, because the DASH study didn't make it into the search, and so --

MEMBER ACHTERBERG: The date -- the date would not --

MEMBER NELSON: Because of the date. And so, again, it's a time issue, and we've got to be careful that we're -- we can't come up with an implement -- you know, a conclusion and grade based on just a certain number of years when there's been good data beforehand that's not being considered.

And we -- just it's a -- we have to be very careful. I think that would be erroneous.

MEMBER ACHTERBERG: I just want to thrown in hindsight is 20/20. I think this

was a careful, systematic review following the guidelines we as a committee all agreed on.

In hindsight, because these results didn't necessarily align with earlier results, now questions are being raised. Now it's being asked should we go back for a longer-term review.

But let's be clear about where we are, why we're there, and the quality of the work that got us here.

MEMBER RIMM: I don't -- this is Eric Rimm. I don't think anybody would question what you've done and that this is a thorough job.

I think the issue is that, for all of our things, I think ultimately what we're doing, we're trying to summarize, we're essentially bean-counting the number of studies -- excuse the pun but, I mean, the blood pressure is -- you have four studies, one's prospective and three are cross-sectional.

So, you have three cross-sectional studies where people are diagnosed with high blood pressure. They may change their diet, so they compare that result with, you know, the many, many studies that came before.

It's not -- it shouldn't be just a matter of bean-counting. We have to look at the quality and decide if it really should impact our decision based on the new evidence. New studies are not always the best.

MEMBER ACHTERBERG: Absolutely. And we also need to ensure that we maintain a systematic approach. That's what I'm trying to say.

MEMBER PI-SUNYER: Yes, that's the -- this is Xavier. That's the danger of your suggestion, Larry, that if you go back and you know two studies, that's not systematic.

MEMBER APPEL: No, no, no. That wasn't what I was saying. I was saying you do the systematic, but that gets you only part of the package. I mean, most systematic reviews

actually have, you know, you search multiple databases, but then you also have seminal studies and you use those to either reference check or use those as related articles to identify ones that weren't captured. It's not only -- it's more global.

MEMBER NELSON: Yes, and it helps come up with different search terms that you haven't thought about --

MEMBER APPEL: Well, yes.

MEMBER NELSON: -- which is the key, and then you're systematic. I mean, we've done that with some other questions. You know, we've come up with why didn't it pick up these couple studies, and then you realize because of a couple of search terms or a date.

CHAIR VAN HORN: There is another issue that relates to the assessment methodology, and we're all aware of the, you know, limitations of diet assessment, not only in terms of the method used, i.e., food

frequency, questionnaires, they tend to group things together which, of course, limits, you know, what you can do with those data.

But, also the fact earlier studies were more nutrient-focused and it's only been more recently that we started looking at food groups or foods themselves and food patterns and things of that sort.

So I think, you know, we're trying to, you know, synergies all of these different factors and maximize the benefit of current as well as previous studies that allow us to perhaps look at some of these questions using new approaches, but not, you know, forget that some of those were not created or developed in a way that allows us to have perfect assessment ability and, you know, the method used may not allow that. So, we just have to be careful.

MEMBER SLAVIN: Other fruit and vegetable questions before we move to milk? And I appreciate your comments, Linda, because

it's like when we did this, these searches, we decided to go with the food groups pretty much early on because we thought they would create some discussion.

And the studies weren't really designed to do that. So, we're looking for milk, milk products, fruits and vegetables, this is what comes up.

So, background on milk and milk products. We know they are a source of many nutrients. They vary from fat-free to full fat. Calorie content is going to vary. You know, fat-free -- or get rid of saturated fat, but you have protein, calcium.

The relationship between milk intake and body weight is controversial. The role of calcium intake in obesity and adiposity has also been debated, so there's a lot of literature in this area.

It does tend to fall out, is it food, milk -- food-related, or is it nutrient-related. Calcium, we're going to talk about

bone health, the importance of milk and milk products as calcium-rich foods.

Cardiovascular disease and saturated fat, we kind of move over into that area just because most of the searches we did on just dairy -- milk and dairy products, milk products, so fat is typically not controlled in our searching here.

So, low-fat dairy products included in the DASH Diet, here are some examples of where different dairy products are included in diets and I'm not sure we're going to always pick those things up.

So, our question has to do with what is the relationship between intake of milk and milk products and these end points, body weight, bone health, cardiovascular outcomes, metabolic syndrome, type II diabetes.

We did go back to 2004 and this was because in Section 6 of 2005 Dietary Guidelines there was a search on milk and milk

products. So, we did not go past. Just like the fruit and vegetable which was also in the 2005, we went back, started 2004 to July 2009.

For children two to 18, for all outcomes except body weight, and this is looked at in another subcommittee, so we're not going to include that, and then adults 19 and older for all other outcomes we're talking about.

In this case we -- this is what's hard in our literature that when you include systematic review or meta-analysis, you don't want to double count them. So, trying to figure out what's already been counted, in this we included individual studies as well as systematic reviews and meta-analyses, and then if it was already counted in a meta-analysis, we tried to exclude it. So, that was really difficult to do.

And I can see like for Xav, the nice thing about excluding the meta-analysis and the systematic reviews is you can, you

know, do all your own analysis and not be worried about double counting.

First question: What's the relationship between the intake of milk and milk products and body weight? It's a Grade I, strong. There is little convincing evidence that milk and milk products have any unique role in regulation of body weight and body adiposity.

So, we'll go through the review of the evidence. Eighteen studies, one systematic review, one randomized control trial, four prospective cohort studies, eight cross-sectional, three studies with energy intake as an outcome and one study in pregnancy, and this conclusion is supported by the systematic review and intervention study and four prospective cohort trials.

Any questions on body weight? There's been a lot of interest in it, calcium, milk as, you know, particularly linked to lower body weights, but I think the literature

is quite clear, there's nothing uniquely calcium or dairy product, milk product that has any difference there.

Bone health --

MEMBER CLEMENS: This is Rog. Just real quick.

MEMBER SLAVIN: Sure.

MEMBER CLEMENS: This is rather intriguing, frankly, because there have been a lot of studies on fractions of milk relative to body weight and weight management, and obviously in this type of research, if you look at the full food to your comment, Linda, that that relationship doesn't pop up in the most recent information.

MEMBER SLAVIN: Yes. There are, you know, a lot of components for sure. There are studies that people have looked at that, and it doesn't -- in this approach we're looking at milk and milk products.

So, what is the relationship between the intake of milk and milk products

and bone health? This is a -- we had a big discussion on this. This is a very top area.

Proposed conclusion, intake of milk and milk products is associated with improvements in bone health in children, and we've given it a moderate, Grade II.

Adults, the results in adult trials are more mixed and there's inconsistency. There's an inconsistent support for the role of milk and milk products on bone health.

We've struggled with this grade right now. It's -- we think it's a moderate, because -- well, we can go through the literature and we're going to have more discussion about this.

Review of the evidence, nine articles, one systematic review to meta-analysis, three trials, one longitudinal, one case control, one cross-sectional study.

A study reported that children who are milk avoiders have poorer markers of bone

health. There is a meta-analysis of this question in adult populations that's less clear.

There are some concerns about just measures of bone health, so we can go down that path and talk about that, but one review concluded that there is weak evidence of a protective capacity of milk and milk products on bone health.

Another meta-analysis concluded that a low intake of calcium, as judged by intake of milk does not confer a substantial increase in fracture risk, and the intervention studies are supportive of a role for milk and milk products in bone health. So, there are quite a few intervention studies that show a role.

I guess we want to -- we'll go through all the milk, and then we'll take questions. Milk and milk products, cardiovascular disease, what's the relationship between intake of milk and milk

products and cardiovascular disease, and a Grade II, moderate.

Recent studies find that intake of milk and milk products is protective against cardiovascular disease. This is based on three articles, one systematic review, one systematic review with a meta-analysis, and one case control study.

Some of the outcomes that were reported, stroke, myocardial infarction, ischemic heart disease, acute coronary syndrome, an inverse association was consistently reported.

Metabolic syndrome, what's the relationship between intake of milk and milk products and metabolic syndrome, Grade III, limited milk and milk product consumption is not generally linked to metabolic syndrome and may even be protective in certain population groups.

Evidence, five articles, one systematic review, one prospective cohort

study and three cross-sectionals. The meta-analysis showed a reduction in risk associated with the highest level of milk consumption.

Dairy consumption was not associated with any metabolic variables in an elderly Dutch population.

In a French study, intake of dairy products was associated with lower probability of insulin resistance and NHANES data, looking at that data set that they found that each serving of dairy products increased risk of metabolic syndrome by eight percent among men, no significant associations between whole milk, low-fat milk or skim milk and metabolic syndrome were observed.

Blood pressure. What's the relationship between milk and milk products and blood pressure? Grade III, limited. Using the current NEL search process, there is limited evidence that supports a relationship between intake of milk and milk products and blood pressure.

This 13 articles, one systematic review, one trial, six prospective cohort studies, five cross-sectional. The systematic review concluded there is an inverse association between intake of dairy products and hypertension.

The results from the six prospective studies reviewed suggest a more mixed result with four not reporting a relationship. And this area is complicated by types of milk products consumed, confounding with calcium intake, relationship of blood pressure to weight loss.

Blood cholesterol. What's the relationship between intake of milk and milk products and blood cholesterol? Grade II, moderate. Intake of milk and milk products in recent studies does not show increases in total blood cholesterol, but may be linked to increased HDL cholesterol.

Three articles, one randomized trial, one prospective, cross-sectional. In

the dairy product feeding study intakes of milk product was associated with lower blood cholesterol, but that was also associated with weight loss in the study.

The Dutch elderly study, baseline dairy consumption was not associated with change in lipid levels over 6.4 years, and NHANES data set found that in women more frequent cheese consumption was associated with higher HDL cholesterol, lower LDL, while in men more frequent cheese consumption was associated with higher BMI, waist circumference, HDL and LDL cholesterol.

Diabetes. What's the relationship between intake of milk and milk products and type II diabetes. Grade II, moderate. Recent systematic review with a meta-analysis relative risk for type II diabetes was estimated to be ten percent lower in people who had a high milk intake.

One systematic review with meta-analysis -- meta-analysis included four

prospective cohort studies and this relative risk was estimated to be ten percent lower in people with high milk intake.

All right. Milk and milk product questions. Comments.

Eric.

MEMBER RIMM: Hi. This is Eric Rimm. I mean, again, I don't know the studies that have led to this, but the fact that there's Grade II evidence that higher milk consumption is associated with potentially increased HDL cholesterol worries me.

Is that -- I don't know if that's driven by just the fact that this is only data from the last five years, or that we've -- it does not take into account different types of fat, but obviously, if you can compare it to what's going on in the fat subcommittee where we're looking at different types of fat and how they impact HDL or LDL cholesterol, I guess this would be an opposite conclusion.

MEMBER SLAVIN: Well, I think you

have got to remember, too, we're asking the food group question here. Milk and milk products. So -- and it's a broad milk and milk product question, so we don't get --

MEMBER RIMM: So that -- well, can I make -- okay. Well, maybe the question is, is the Grade II based on -- is Grade II -- that's a pretty strong statement. It's strong enough to have a single trial and a single prospective cohort study to make that statement.

The prospective study was not associated with -- I don't want to challenge you. You guys obviously know this stuff much more than I do. It just struck me as -- this is very different from what we have been talking about in the fat subcommittee.

I know, I realize it's fat, and milk and milk products are different things. The cross-sectional studies from NHANES, which is based on a single 24-hour recall of milk.

MEMBER SLAVIN: Yes. Yes, I think

the NHANES -- right.

MEMBER RIMM: Which would trouble me, if you're going to base a Grade II conclusion on a single 24-hour recall where you're equating it with a biomarker. I don't know the trial, so I guess the issues is, if the trial is a fantastic trial and it's proven it's long-term and it's NIH-funded, then I would be very happy with that conclusion.

But I would be worried about where this could go. If this is such a strong conclusion, this would lead to a Guideline that -- to increase HDL cholesterol, the strongest thing to do would be to increase milk consumption and milk products.

MEMBER SLAVIN: Well, you know, -- yes. Each -- you see, there's a lot of questions on milk and milk products with different end points. So, you know, in doing the search, that's what came up, because that's what we were looking for.

And so we're searching milk and

milk products, and then these different search criteria that came in. So, I think that the rating with this is difficult.

MEMBER RIMM: Yes. No, I agree.

MEMBER SLAVIN: You know, and deciding what's a II or a III with the food groups now. So, I think we could discuss that for sure.

MEMBER PI-SUNYER: This is Xavier. I wonder if this is -- you know, it's -- what this is bring up is that five years aren't enough, and we're running into trouble here with a lot of them, you know, where you have one RCT or no RCT and three cross-sectional, and we're trying to come to conclusions on the basis of very little evidence.

MEMBER ACHTERBERG: And it's a changing food supply. And we need to be careful about that. The milk and milk products is another example. So, as you're looking at the relationship between certain lipids derived from milk and milk products,

the profile of what people have been consuming has changed pretty dramatically.

And people have decreased, a total decrease in milk and milk products, but people who are using them, many, many more are using nonfat, low-fat, fluid milk, yogurts, and other kinds of milk products.

So, I think it is useful to have the longer perspective but at the same time we have to be very careful to balance that longer view against changes in the food supply.

MEMBER APPEL: Just a question -- just to follow up on that, the -- we say milk products. There actually have been sort of a -- several studies dealing with sort of products that have peptides from dairy. Was that what you mean by milk products or are you thinking about yogurt?

MEMBER SLAVIN: No. We're just thinking about foods. So, we didn't get into --

MEMBER APPEL: No, but those are

actually -- I mean, I think some of them actually --

(Off-mic comment.)

MEMBER SLAVIN: Yes. We like whey protein, milk peptides. We did not -- that would not --

MEMBER APPEL: So, that's not included, okay.

MEMBER SLAVIN: -- that would not come up in the search.

MEMBER PEREZ-ESCAMILLA: This is Rafael. Have you looked at the dietary patterns comparing high versus medium versus low dairy consumers? Because, I think, you know, it's -- I understand why you are looking at a food group, but the food group falls within a dietary pattern, and it's really difficult, I think, for me at least, to make sense of all of these massive work that you have done without understanding more what are the characteristics in terms of the rest of the diet of those.

MEMBER SLAVIN: Linda, go ahead.

CHAIR VAN HORN: Right. I think that the point you're raising, Rafael, is something that we talked about earlier today also as being one of those cross-cutting issues that go back to the discussion we just had about modeling.

For example, we know that in individuals, both adults and children who consume more dairy products, more milk products, their intakes of not only calcium but magnesium and vitamin D and a variety of other nutrients that are concerns, are enhanced because of the nature of the food that they are consuming.

I suspect that, you know, as we continue through this -- and again, this is all preliminary, so just to remind our listening audience as well as everybody here, you know, we're raising this today to reveal the level of discussion that we have going on, but there are absolutely no confirmatory

statements being made here yet.

I think the other thing to recall is, even a study like DASH, for example, which did involve low-fat dairy products and including that as far as its relationship to blood pressure being a risk factor for cardiovascular disease, I think some of these issues really need further deliberation in terms of, you know, is it a cause and effect or is it an association, is it a substitution effect, what is it that we're actually looking at here.

But, you know, without a doubt, we won't have the answers to some of these questions on the basis of hard evidence because the studies were not designed that way.

Again, we're trying to make implications out of data that exists and try to tease, you know, those kinds of issues apart.

Mim.

MEMBER NELSON: This is Mim. One following up on that, I really think that we have to be careful as a committee with these single food group and nutrient sort of outcomes because I think where we have moved to, thanks to a lot of research over the last five to ten years is more of the patterns.

And I think that -- that we're going to -- we may stumble on each other, with our different committees, different questions, because we're going to come up with one thing when you look at it one way, but you're going to look at it another, if you look at the pattern.

And I think that there may be reasons to tone down the single food group piece and talk more, you know, beef up -- no pun -- well, I shouldn't use "beef up," but you know, strengthen the food pattern piece and the modeling piece because of the obvious -- it's -- whether it's the deficit model or the addition model, we don't know, because

diet is a funny thing.

And I just wouldn't -- I mean, it's just sort of an overall -- I'm nervous about the single food group piece. And to that end, in terms of bone, having done a lot of research in the area of milk and dairy products and bone, I think one of the issues that we have weaker evidence is just because in the last -- all the best studies were done in the Eighties and Nineties around this, and all of the really new stuff on milk and milk intake has been more in the, you know, the lipids and, you know, it's like there's a lot more work that's happening, so you have stronger evidence just because of the nature of the trials that have been done.

And, you know, they're classic trials. And I, you know, just reading over again, looking at the guidelines that were before we should update -- I think, I really feel like we should be updating the literature searches here, not necessarily coming up with

different conclusions because -- anyway, I just think we have to be careful, because the bone data, even though the diets change, it's pretty strong on the RCT's, and I know there's sort of a bi-modal approach to bone and calcium, but anyway --

MEMBER SLAVIN: Other dairy, milk and milk product questions?

I completely agree with you, Mim. You know, and I think last time these questions were done last, and we decided to do them first because we wanted to do them with the NEL process.

So, I think they will have to circle back and come back together and not be in conflict.

All right. Our next group of questions are dried beans and peas. We know they are important sources of protein, fiber, minerals and vitamins in the US diet.

I want to mention that these were not done in 2005, so we were starting from no

review in the Dietary Guidelines book.

Typically, when you look at consumers, they don't consume much beans and peas in the daily diet in the US. We have good data on fiber linking to lower body weight, so we might think that intake of beans and peas might also be linked to lower body weight.

We also know that dried beans and peas are concentrated sources of soluble fiber which is known to lower serum lipids. Vegetable protein from legumes are stated that it also lowers serum lipids. We have an existing health claim in the US for soy protein and lowering serum lipids.

And a little bit on soluble fiber slowing absorption of carbohydrates and lower glycemic index of foods, and in the original studies on glycemic index, intake of legumes was associated with the lowest glucose response.

So, it's possible that dried beans

and peas could show promise for use in blood glucose control.

So, that's the background. So, the questions we asked: What is the relationship between intake of dried beans and peas and body weight, cardiovascular outcomes and type II diabetes.

We, in this -- since this was not searched in the 2005 Dietary Guidelines, we went back to January of 2000 and, as we've discussed today, that may not be back far enough, but that's where we started.

Ages, children and adults, two years and older. What we did in this, we looked at individual studies and then we also looked at systematic reviews and meta-analyses were included in the review. And then if the individual study was included in the meta-analysis, then we did not review it twice.

First question: What is the relationship between intake of dried beans and peas and body weight? Grade III, limited.

There's very little data that intake of dried beans and peas is related to body weight.

The evidence that we reviewed, nine articles, one meta-analysis, two systematic reviews, four trials, one prospective cohort study, one cross-sectional study.

In the randomized trials diet treatments with beans and peas are generally no more successful in weight loss than the controller, the comparison treatment. So, the studies that were done, they didn't -- beans and peas did not look to be uniquely better at weight loss.

The cross-sectional analyses suggest that bean-consumers had better overall nutrient intakes and lower body weights and waist circumference. So, there is some data, cross-sectional data that suggests that people that consume more beans, dried beans and peas, are lower body weights, but in general, there's hardly any intake of beans and peas in

the US prospective cohort trials.

So, it's difficult to see if it's linked to disease outcomes, because intake is so minor.

Cardiovascular: What's the relationship between intake of dried beans and peas and cardiovascular. Also a Grade III, limited.

Soluble fiber content of beans contributes to lipid lowering benefits. There is limited evidence that dried beans and peas have any unique abilities to lower serum lipids, so there's a theoretical, but there's not much there.

Thirteen articles, one meta-analysis, six trials, three prospective cohort studies, one longitudinal, one case control and one cross-sectional.

In intervention studies, dried beans and peas lowered serum lipids, as expected, based on their soluble fiber content. So, in these studies they are

typically fed, and the predicted amount of lipid-lowering is seen based on their high content of soluble fiber.

Soy studies. Soy may lower lipids in subjects -- hypercholesterolemic subjects, but doesn't lower serum lipids in subjects with normal serum cholesterol.

Then just this -- if you look at the prospective cohort studies, the intake of dried beans and peas is -- and soy all are really low.

And as we go through this I want to mention that we did separate out soy in these studies, just because there's a lot of research with soy that has been done since 2000.

Dried beans and peas, type II, what's the relationship between intake of dried beans and peas and type II diabetes, limited. Their consumption of legumes may be inversely associated with risk of type II diabetes.

There's very little data, one prospective cohort study, total legume consumption and consumption of soybeans and other legumes were each associated with decreased risk in type II diabetes.

So, any beans and peas questions before we move to a list of other things that we are working on?

Yes, Tom.

MEMBER PEARSON: As a major source of protein for vegans, is this confounded by this group being overrepresented in the consumer groups?

MEMBER SLAVIN: Ask me that again. I'm confused.

MEMBER PEARSON: I would imagine the highest consumption of dried -- the highest consumers of dried peas and beans, I would imagine, as a protein source, would be from vegetarians or vegans.

I'm just wondering if there was a confounding of the relationship with some of

these with that group that had a lot of other things going on.

MEMBER SLAVIN: Yes, and I think there is such low consumptions in the prospective studies that you have hardly anybody. You know, if you look at protein quality of beans and legumes, even though they have fairly high protein content, their net protein utilization is actually pretty low.

It's one of the least digestible proteins, depending on how you cook it, but -- I think we wanted to include this just because, trying to be responsive of interest in more vegetarian eating patterns and to see what kind of data is out there on health benefits.

Cheryl.

MEMBER ACHTERBERG: But I'm glad you mentioned that we did this analysis separating the soy from the beans and peas because the earlier comments we had about dietary patterns, people who eat a lot of soy

don't necessarily eat dried beans and peas, and a lot of the folks who eat a lot of dried beans and peas don't eat soy.

And they may work quite differently. And certainly the way they are used in the diet are -- you know, it's a different pattern of usage.

So, I think that distinction is important, although it's still hard for us to draw very many conclusions.

CHAIR VAN HORN: Rafael.

MEMBER PEREZ-ESCAMILLA: This is Rafael. In terms of the soybean studies, did you -- and lipid profiles, did you identify randomized control trials?

MEMBER SLAVIN: Yes.

MEMBER PEREZ-ESCAMILLA: Okay. And did they actually use soybean foods or did they use soy protein isolates?

MEMBER SLAVIN: Yes. Most of them used soy protein isolates.

MEMBER PEREZ-ESCAMILLA: And my

understanding is that when you translate that concentration into the actual food intake, into actual soy intake, that people would have -- would need to have, it's pretty large. Right?

MEMBER SLAVIN: Yes. It's like 25 grams of soy protein to significantly lower cholesterol. So, to get a health claim, you have to have 6.25 grams in your -- but, you know, tofu, there's a lot of things, soy flour, that can get there.

So, you know, there are foods out there but, you're right. Most of the studies that were done on concentrated soy proteins. In hyperlipidemics, yes.

Larry.

MEMBER APPEL: Yes. These are more questions -- I mean, comments, questions that are generic rather than to your group, but I listened to you and I'm getting sleepless trying to figure out how you're going to get all this done plus update the thing.

And then I also take that in the context of -- I mean, there are 11 more, and each of those is actually in multiple parts. And then earlier on we had a discussion that in February we're supposed to go through all our conclusions and we said there are 180 questions.

That means that if we have 16 hours, we're going to finalize every hour 11 conclusions. And I just think that we have to really trim our sails and focus on the things that are most likely to affect the Guidelines, and I'm worried that -- and I think I mentioned this before, that I'm really worried that we are -- some of these questions, I mean, are just not going to change the Guidelines, because we, you know, we might be relying on gut instinct, but we know that the literature isn't there to support something major, and so why are we, you know, wasting staff time, our time on this. So, the narrowing it, I think is really important.

The second thing has to do with, I think, come out, and I don't -- I think that you've done a great job. I don't think it's sort of shooting the messenger to say this issue about how to deal with truncating the literature searches is huge, and affects all the committees.

And I think we're not dealing with it in a systematic way, and I think that unless -- I think we can't leave this meeting unless we, you know, have guidance for you, for my -- for our group.

I think we dealt with it differently, how to deal with, you know, the pre -- you know, before this NEL process, and because it could also, again, waste your time.

And I'm wondering how we do this because, you know, I look at our schedule and it's -- you know, it's dense with subcommittee presentations, and yet we really need a very, you know, procedure-oriented discussion about how to deal with this evidence and grade it,

and at least have tentative conclusions.

So, I'm just -- you know, maybe we should -- some of us should just stay here and just think about the options and come back tomorrow, you know. Better use -- you know, better -- I don't know. I'm just throwing that out.

MEMBER SLAVIN: I think, took, that we want everything to be documented, so that's why we used the NEL process. If we bring in papers from before, if the 2005 Dietary Guidelines, if that's in there, we can build on that, and then just say from this point on.

But if we're bringing in new things, then we want to make sure that it's been presented and it's -- people can get it from the library, so it's all, you know, available for everybody to see where the data is and what we based our conclusions on.

So, I agree with you that we want to make sure that that's done systematically

so people --

MEMBER APPEL: And consistently.

CHAIR VAN HORN: There's another thing to keep in mind, I think, as we've discussed in terms of some of our sub -- scientific review committee calls, that one of the beauties of this approach is that each of the subcommittees has a committed, dedicated group of experts deliberating on these questions.

And we, as a total team, rely on the expertise of these individuals to make some of those investigations and determine whether preexisting data are so solid and so complete that the idea of going back over them, just to say that we did, really, as you said, Larry, is not necessarily the best use of our time because, you know, there are such concrete, you know, data, suggesting that this is solid evidence, that we need to move ahead.

Whereas, in other cases, as we've just discussed today, and especially things

that have come up since the 2005 Guidelines, once again, you know, there are some subcommittees that are dealing with that.

So, even though I think we all recognize the value of trying to standardize our approaches to this, there will be variability, subcommittee-to-subcommittee because of the data that exists, because of technology that has changed since then, perhaps, where there are perhaps more objective data now to be able to look at that didn't exist prior.

You know, it's all those kinds of questions, but if we all deliberated on every one of these collectively, we would be here until 2020.

So, I think we have to, you know, while I agree totally that we should do as much as we can to standardize, we also have to use some judgment here in making some of those decisions within subcommittees, and then prioritize those factors.

MEMBER APPEL: Yes. I think that -- this is Larry again. I think the main thing I'm finding, really concerned about, is this grades of evidence where you do a five-year search and you give a Grade III when the best studies were done, you know, 15, 20 years ago, and we know that, you know.

And that really worries me. And we had, I think, some discussion in the electrolytes committee that we would apply the grades of evidence only to the ones where we did a NEL search, plus there was some systematic review.

And I -- it might be worthwhile to say, okay, well, does everybody buy into this, and if so, then to try to follow this to the extent possible. And if you're not following that NEL process, you never give a numeric grade, I, II, III, you just give some qualitative, but it's not -- it's not, you know, an official --

Now, there are probably other ways

to do it, but I think we just need to make sure we are all sort of --

MEMBER SLAVIN: I want to mention to Larry, if you look at our remaining research topics, we started with our NEL searches. So most of those up there are not going to be NEL searches, the things that are still, you know, in the process.

So, I agree with you that I don't think we can -- we can't give them a grade, so they won't be graded.

MEMBER APPEL: Even though some of these might be your stronger relationships, or some of them.

MEMBER NELSON: This is Mim. But I also wonder, again, as procedural is, thinking about in particular some of the ones that you've presented and also, you know, looking at the Dietary Guidelines book, if there is -- it's the trimming of the sails.

At some point I think we're not going to be able to fully answer all 180 of

these questions, and I think that we need to do some pretty quick triaging within our subcommittees to say all we need to do is update a few references in the 2005 Dietary Guidelines.

We did it pretty well, we did a search, but things haven't really changed in terms of what we would recommend, because it's a whole process when we do this NEL search and the way we present it.

And I really think within our subcommittees we should do some -- maybe in our next individual subcommittee calls, do a pretty quick triage on what we need to trim, also based on what we hear over the next couple of days, because 180 questions is -- I think it's actually ridiculous.

And especially when the focus should be more on the patterns, caloric intake, obesity. I mean, I just sort of am echoing what Linda has said, but I think we need to do some really quick trimming.

MEMBER ACHTERBERG: I have a suggestion to offer. This is Cheryl. I think, as we've listened to the work we've presented so far today, one of the major outcomes of all our effort here is to identify what the research gaps are.

And, very quickly, as we were looking at whatever individual question we're focused on, I think we can come to some conclusions whether there needs to be a lot more research, or whether there doesn't need to be a lot more research, and that might help us do this triage.

You know, to focus on those areas where we know we need to look. Well, if we know we can't answer the question and more research has to happen, let's say that, and then move on and focus more of our attention, our time in those areas where we think there's enough evidence that we can come to a more precise answer.

MEMBER PI-SUNYER: I do think --

this is Xavier -- that some of the subcommittees will have an easier time than others. I think this has been a particularly difficult one, and it will continue to be.

I think things like ethanol and fluids and electrolytes and food safety, I think we can -- won't have this kind of difficulty.

So, it's not across the board. It's just some particular subcommittees have a much more difficult job.

MEMBER ACHTERBERG: And might I mention, this is a small subcommittee.

MEMBER PEREZ-ESCAMILLA: But it's bigger than the food safety subcommittee.

MEMBER SLAVIN: I just wanted to -- just the remaining research topics that we have up there, and some of these obviously are in progress, they're just not completed, so we're not going to present them today, but the food groups, whole grains and also animal protein products where we're asking questions

about different animal protein and if there are health relationships with that.

Vegetable protein, animal versus vegetable. Fiber, carbohydrate type, which is a large -- and some of this is background that's already in the Dietary Guidelines and it will be expanded. There's not a lot of new research.

Liquids versus solids, a very large area. Noncaloric sweeteners, also a large area. Satiety and then some of the modeling questions that are related to our subcommittee, we appreciate.

Adjusting percent of animal and plant protein intake, if we do -- you know, since there isn't a ton of data on vegans versus vegetarians versus animal product protein-eaters, if we can just model that and see if we do the modeling, what type of nutrient deficiencies, problems we run into, if any.

And then macronutrient proportions

and nutrient adequacy is also on our committee's plate.

CHAIR VAN HORN: Okay. Other comments or questions, either related to this subcommittee or other topics that go along the line of what Larry was saying?

One thing I would also add, based on just kind of following up to what Cheryl said, there may be some lightbulbs that go on, you know, as we continue with this over tomorrow.

I mean, we've heard -- we've heard some amazing, you know, and very comprehensive reports today. But they are only the beginning, and we have several more that are going to take place tomorrow.

And since I've had the opportunity sit in on several of the subcommittees, I would venture that the energy balance group and the discussion again -- you know, I sound like a broken record, but our focus is on obesity and the epidemic we're facing, or that

we have currently in our country and I think that in many ways if we had to pick one priority area, we're sort of charged with that one, because we've already, you know, recognized and identified that that is public enemy number one at this point.

So, I think that we will want to keep that in mind as we go forward. I think that we have spoken over and over again, and we haven't even begun to talk about this yet, but we will tomorrow, about primary prevention of obesity which, of course, will, without a doubt, address children, and the need to look at children, growth, even gestational weight gain that we discussed earlier today in some of our smaller group sessions.

So, you know, I think that as we go forward, some of these questions, not all of them, I'm sure, but some of them may fall into place, and into rank order as far as what we should be addressing first and foremost in order to, you know, really stay true to our

goals that were identified up front.

Other topics along that line or other things that anybody in the group would like to raise?

MEMBER FUKAGAWA: This is Naomi Fukagawa. I agree with you, Linda, and I do think that in some ways we're somewhat strapped by the fact that we've been grouped into nutrient categories.

And really, what we want is an integrated view on the diet that will affect the health and well-being of the population. So perhaps we don't need, as Larry was saying, to continue to, you know, try to whittle away at some of the more sort of specific types of questions, but perhaps put our energies towards a more global, integrated view, or at least that's my thought.

CHAIR VAN HORN: Other topics?

MEMBER NICKOLS-RICHARDSON: This is Shelly. I don't have a question, but just a comment, that Joanne and your committee, I

very much appreciate this analysis that you have done, because I think now when nutrient adequacy goes to look at the food intake and look at patterns, this will help support if we find gaps in food intake, that there are health outcomes, health consequences of that.

So, in terms of connecting pieces, this is going to be very helpful for our committee in informing us on what those gaps mean.

CHAIR VAN HORN: All right. Well, I think we have really covered the territory. I think for those listening in, the group here is still bright and eager, but clearly has seen a busy day, and is ready, perhaps for a little rest, and maybe you are, too.

We appreciate everybody's interest and attention, and we will adjourn for today and reconvene tomorrow morning at eight a.m., Eastern Time. Thank you all very much.

(Whereupon, at 4:38 p.m., the meeting concluded for the day.)

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