MINUTES OF THE NUTRITION COORDINATING COMMITTEE (NCC) MEETING, NATIONAL INSTITUTES OF HEALTH (NIH)
Rockledge 2, Conference Room 9100-9104, Bethesda MD
May 4, 2006 2:00- 4:00 PM

WELCOME

Dr. Pamela Starke-Reed, Deputy Director, Division of Nutrition Research Coordination (DNRC), convened the meeting at 2:00 PM and welcomed participants. Participating via phone were Dr. David Berrigan, NIH NCI; Ms. Jean Charles-Azure, IHS; Dr. Paul Cotton, NIH NINR; Dr. Deborah Galuska, CDC NCCDPHP; Dr. Laurence Grummer-Strawn, CDC NCCDPHP; Dr. Van Hubbard, NIH DNRC; Dr. Molly Kretsch, USDA; Ms. Michele Lawler, HRSA; Dr. Margaret McDowell, CDC NCHS; Dr. Deborah Olster, NIH OBSSR; Dr. Phuang Kim Phan NIH FIC; Dr. Marshall Plaut, NIH NIAID; Dr. Daniel Raiten, NIH NICHD; Dr. Rick Troiano, NIH NCI; Dr. Susan Welsh, USDA CRSEES; and Dr. Amy Yaroch, NIH NCI. The agenda for the meeting is provided as Appendix A, and the list of attendees is provided as Appendix B.

APPROVAL OF MINUTES FROM THE MARCH 10, 2006 NCC MEETING

Minutes from the March 10, 2006 NCC Meeting had previously been sent to NCC members via email. Dr. Starke-Reed asked if there were any other corrections to the minutes. There were none. Dr. Paul Coates, Office of Dietary Supplements (ODS), made a motion to approve the minutes, and Dr. Sharon Ross, National Cancer Institute (NCI), seconded the motion. The minutes were thus approved and will be posted on the DNRC website, http://www.dnrc.nih.gov, along with the minutes from previous NCC Meetings.

BALANCING TOXIC RISKS WITH BENEFITS OF FISH CONSUMPTION: SCIENCE AND POLICY ISSUES

Dr. John Balbus, Senior Scientist and Director of the Health Program for Environmental Defense (ED) presented the NCC with information pertaining to the risks and benefits of fish consumption. In the late 1990s, Environmental Defense, the Monterey Bay Aquarium, and the Audubon Society developed the first sustainable seafood guides. Now there are at least 20 conservation-based guides in circulation as well as numerous health-based guides. There is some discrepancy in these recommendations based on various analyses of sub-populations as well as differences in methodology. Environmental Defense set out to develop a new version of their seafood guide that would standardize the discrepancies in current health-only guides and incorporate both ecological and human health concerns in the same product. The aim of their current guide is to educate consumers so they can use their market choices wisely.

The contaminant methodology used to provide consumption advice is based on mean levels of mercury, PCBs, dioxins and pesticides in commercial fish. Data from more than 75 government databases and scientific studies (mostly for wild-caught fish) are used. Data from media, NGOs, and industry are excluded.

Advisories must be based on 10 or more samples, and data must be from more than one geographic location. Fish are designated a "health concern" if eating them once/week poses an unacceptable health risk according to EPA's National Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories. Advisories are specific to women, men, older children (age 6-12) and younger children (age 0-6) and take into account average weight and portion size.

The current ED guidance is divided into Eco-Best and Eco-Worst choices. The high contaminant species are further highlighted in red. Eating off the "good" list usually makes sense for both environmental and personal health reasons. The ED Eat Smart Website, http://www.oceansalive.org/eat.cfm also has expanded information about almost two-hundred species of fish and shellfish including contaminant and nutritional information. Future goals are to elevate the importance of omega-3 fatty acids in recommendations and to enlist the medical and public health community to help make seafood a more sustainable resource. For more information, Dr. Balbus can be reached at the following address: jbalbus@environmentaldefense.org

WORLD HEALTH ORGANIZATION CHILD GROWTH STANDARDS

Dr. Laurence Grummer-Strawn, CDC, presented the new Child Growth Standards for infants and children aged birth to 5 years. WHO released the growth curves on April 27, 2006. These growth standards were described in greater detail at an NCC meeting in July 2005. In brief, the new WHO charts are designed to describe how children *should* grow rather than simply a description of how children *do* grow in a specific setting and time. Data were collected in Norway, Brazil, India, Ghana, Oman, and the United States. Study sites were selected based on a number of criteria: socio-economic status that would not constrain growth, low altitude, low population mobility, a willingness in the population to follow feeding recommendations of 12 months breastfeeding and 4 months exclusive breastfeeding, existence of a breastfeeding support system, presence of local collaborative institutions, high rate of hospital births, sufficient number of births accessible, feasibility of implementation, and fundability. Consideration was also given to mean birth weight in the target population, maternal height indicating completion of secular trends in height, accessibility to complementary foods, immunization rates, health care utilization, rate of diarrheal disease, and geographic distribution of sites.

The study design included a longitudinal study from birth to 24 months and a cross-sectional study from 18 to 71 months. To be included in the study, infants had to be term, singleton births, with no identified morbidity that would affect growth. Mothers had to be non-smokers and willing to follow the feeding recommendations. For the longitudinal study, the feeding recommendations entailed 4 months of exclusive or predominant breastfeeding, introduction of complementary foods by 6 months, and at least 12 months of continued breastfeeding. For the cross-sectional component, the children had to have been breastfed for at least 3 months. Only children who actually met these feeding

recommendations were included in the actual growth reference. Ultimate sample size was approximately 1700 children in the longitudinal study and 8000 children in the cross-sectional study.

Results of the study are documented in the April 2006 Supplement issue of *Acta Paediatrica*. Perhaps one of the most important results was that the growth patterns across the six sites were remarkably similar, confirming the hypothesis that children from different parts of the world do grow similarly if exposed to similar environmental conditions and recommended feeding patterns.

Statistical comparison between the CDC & WHO curves using NHANES data is underway. An overlay of the two charts is attached as Appendix C. Compared to the CDC 2000 reference, the WHO growth standards show:

H-for-A:	Very similar mean length
	Tighter standard deviation
W-for-A:	Faster growth from birth to 3 months
	Slower growth from 3 to ~18 months
	Mean weight at 5 years nearly identical
	Slightly lighter at -2Z and +2Z
W-for-H:	Generally leaner at all heights, but medians are very close
	Considerably less right skewness, resulting in lower +2Z
BMI-for-A:	Includes BMI-for-A for 0-23 months
	Considerably less right skewness
	At age 2, curves are considerably lower, esp. at +2Z
	At age 5, +1Z and +2Z are not widely different

CDC, NIH and the American Academy of Pediatrics (AAP) will jointly convene an Expert Panel meeting June 29-30 to develop recommendations on the role the new MGRS growth standards should play in the U.S. Options would include using them only for research and international comparison purposes, using them only for breastfed infants, using them only up to a certain age (such as 12 or 24 months), or using them up to 5 years of age. Because the new standards only go up to 5 years, continued use of the CDC 2000 growth reference for school-age children and adolescents will be necessary.

Key agenda items will include presentations on:

- CDC 2000 charts
- WHO charts
- How U.S. children look against each set
- Issues for consideration including
    - Whether a reference or standard is more useful in clinical settings
    - Disjunction in switching to CDC 2000 charts for older children
    - Use of data from other countries
    - Appropriateness of WHO charts for formula-fed infants
    - Whether differences in the curves are large enough to warrant a change

- Use of BMI prior to age 2 years, since the derivation of BMI has previously always used height and not length.

CDC, NIH, and AAP plan to develop a joint position statement as a result of the meeting.

PROPOSAL FOR INITIATIVE OF EVIDENCE-BASED REVIEWS IN DIET AND NUTRITION

Dr. Paul Coates, ODS, and Dr. Rachel Ballard-Barbash, NCI, presented the NIH proposal for the initiation of evidence-based reviews (EBR) in diet and nutrition. The goal of the initiative is to develop and implement a plan for intergrating EBRs into the processes whereby expert scientific groups develop diet/nutrient and health recommendations that are subsequently incorporated into federal agency policies and related applications. Several objectives for addressing the issues surrounding the incorporation of EBRs into diet/nutrition/health scientific evaluations should be addressed:

1. A general approach to evaluate how best to incorporate EBRs into different types of applications and to evaluate areas of commonality and differences involved in incorporating EBRs among several applications.
2. The identification and appropriate understanding of caveats associated with the EBR process
3. A targeted approach to deal with the immediate needs of evaluating how best to incorporate EBRs into the 2010 DG process.

The next step is to convene a working group of health-related federal agencies in order to identify and prioritize topics that warrant an EBR approach. Please contact Dr. Coates if you are interested in participating in the working group: coatesp@mail.nih.gov. Please see Appendix D for the full text of the proposal.

UPDATE FROM THE DHHS OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION (ODPHP)

Ms. Kathryn McMurry provided the NCC with several updates from ODPHP:

1. On Monday, May 1st, Secretary Leavitt announced 9 HHS priorities for America's Health Care, which are attached in Appendix E at the end of the minutes. Ms. McMurry directed the attention of the NCC to the obesity prevention priority.
2. The *National Obesity Action Forum* will be held on June 5-6, 2006 at the Hyatt Regency in Bethesda. This meeting is a follow-up to the 2001 *Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity.* It will provide a forum for discussing local actions, including those taken at the state level that have occurred since the Call to Action. More specifically, the forum will serve to identify lessons learned in implementing change at the family and community levels--lessons from the ten conferences that were held in collaboration with the Office of the Regional Health Administrators since the Call to Action was released in December 2001. To register, visit www.outreach.psu.edu/C&I/obesity/default-home.htm

3. D*ietary Reference Intakes Research Synthesis*: The IOM will convene a two-day workshop on issues related to knowledge gaps and research needs in developing and advancing the DRIs. The workshop is scheduled for June 7-8, 2006 at the Keck Center of the National Academies. To register, visit www.iom.edu/DRIresearchWorkshop. See Appendix F for further details.
4. The 4th National Prevention Summit: Prevention, Preparedness, and Promotion will be held on October 26 and 27th at the Hyatt Regency on Capitol Hill. Abstract submissions will be available on the web May 15th. Please see attached flyer for further details (Appendix G).
5. The Presidents Council on Physical Fitness and Sports is celebrating its 50th anniversary this month. The Third HealthierUS Fitness challenge will take place on May 6th at RFK stadium. PCPFS invites you to come out and join the challenge.

NIH OFFICE OF DIETARY SUPPLEMENTS (ODS)

Dr. Paul Coates provided the NCC with several updates from ODS.

1. NIH State-of-the-Science Conference on Multivitamin/mineral Supplements in Chronic Disease Prevention, May 15-17, Natcher Auditorium, NIH Campus. Register at consensus.nih.gov.
2. AHRQ has released the NCCAM/ODS-sponsored evidence report on B-vitamins and berries in neurodegenerative diseases. It can be downloaded from the AHRQ website at: http://www.ahrq.gov/clinic/tp/berrytp.htm#Report
3. The IOM conference on Nutrigenomics will be held at the National Academies of Science on June 1-2, 2006. Co-sponsors include NCI, ODS, and DNRC.
4. NIAAA/ODS sponsored workshop on Alcohol, Zinc, and the Immune System at the American Association of Immunologists meeting in Boston on May 11.
5. ODS reminds ICs that we invite you to submit grant, workshop, and conference applications to be considered for ODS co-funding. While we are prepared to receive these applications at any time during the year, the deadline for receipt in the current cycle is May 22. Please contact Dr. Rebecca Costello in ODS for further information.

UPDATE OF DNRC ACTIVITIES

Nutrition Education Subcommittee (NES).

Dr. Jean Pennington, DNRC, has provided an update of the activities of the NIH NCC NES. For the calendar year 2006, the NES has received 14 documents for review including two from NIH, six from DHHS, and six from USDA. Materials reviewed or under review since the last NCC meeting are:

- *For Woman Website* (DHHS Office of Women's Health)
- *CNPP Height and Weight Additions to MyPyramid.gov* (CNPP, USDA)
- *Trans Fat Fact Sheet* (Food and Nutrition Service, USDA)
- *Nutrition Facts Label* (FDA)

- *Make Your Calories Count* (FDA)

A listing of reviewed and published NIH nutrition education materials is provided on the DNRC website. Needed updates from NCC members should be communicated to the DNRC.

Human Nutrition Research and Information Management (HNRIM) System Update.

Mr. Jim Krebs-Smith, DNRC, announced that the HNRIM data collection process has essentially been completed, and at the next NCC meeting he will have tables showing figures from the 2005 data. Mr. Krebs-Smith will also be giving a presentation at the July NCC meeting on the HNRIM database.

Probiotics

The DNRC is coordinating a probiotics meeting geared toward the production of a "White paper". Since the study of probiotics encompasses various disciplines, we anticipate this meeting will generate a significant amount of trans-NIH interest and therefore the DNRC would like to include all I/C's with an interest in probiotics research. If you would like to be a part of the planning for this meeting, know of someone who would be an asset to this meeting, or have an interest in probiotics research, please contact Dr. Crystal McDade-Ngutter (mcdade-ngutterc@mail.nih.gov).

Office of Portfolio Analysis and Strategic Initiatives (OPASI) Briefing

Dr. Pamela Starke-Reed announced that arrangements have been made for the NIH Deputy Director, Dr. Raynard Kington, to brief us on the status and direction of the new OD office, OPASI (Office of Portfolio Analysis and Strategic Initiatives: http://opasi.nih.gov/). The briefing is scheduled for Friday, June 16th, 11:00 AM – 12:00 PM in Building 31C, Sixth Floor Conference Room 10. Following Dr. Kington's presentation, he will be available for a short question & answer session, so please come prepared with any questions you may have for him.

This is a joint meeting of three trans-NIH committees: the Prevention Research Coordinating Committee (PRCC), the Nutrition Coordinating Committee (NCC), and the Behavioral & Social Sciences Research Coordinating Committee (BSSR-CC). For the latter part of the session, we will discuss how the role of OPASI in overall NIH planning may influence activities of the three committees, and ask members for their thoughts on interactions with the new office.

REPORTS FROM NCC MEMBERS AND LIAISIONS

Dr. Sue Krebs-Smith, NCI, announced that the International Conference on Dietary Assessment Methods (ICDAM) that took place on April 27-29, 2006 was very successful and that they were very thankful for NIH support. This was the first ICDAM to specifically include physical activity assessment methods as a major topic, and Dr. Rick Troiano, NCI, gave a mini-course on the "Statistical Issues in Physical Activity Assessment."

Dr. Daniel Raiten, NICHD, announced a workshop with WHO to develop standards for infants with HIV that will be held May 10th, 11th, and 12th.

NEXT NCC MEETING

There will not be a meeting in June. The next NCC meeting is scheduled for July 6, 2006.

ADJOURNMENT

The meeting was adjourned at 3:38 PM.

LIST OF APPENDICES

Appendix A - NIH NCC Meeting Agenda for May 4, 2006
Appendix B - NCC Meeting Attendees for May 4, 2006
Appendix C - Comparison between the CDC & WHO curves
Appendix D – NIH Proposal for Initiation of Evidence-Based Reviews in Diet and Nutrition
Appendix E – HHS Priorities for America's Health Care
Appendix F – Dietary Reference Intakes Research Synthesis
Appendix G – Save the Date – National Prevention Summit: Prevention, Preparedness and Promotion

APPENDIX A. NIH NCC MEETING AGENDA FOR MAY 4, 2006

2:00-4:00 PM, Rockledge 2, Conference Room 9100-9104, Bethesda MD

1. **Welcome**……..…….……Pam Starke-Reed

2. **Approval of Minutes of March 10, 2006 Meeting**…….…...Pam Starke-Reed

3. **"Balancing Toxic Risks with Benefits of Fish Consumption: Science and Policy Issues**"……...John M. Balbus, MD, MPH
   Senior Scientist and Director of the
   Health Program for Environmental Defense

4. **WHO Child Growth Standards** ……...…Laurence Grummer-Strawn, CDC

5. **Proposal for Initiative of Evidence-Based Reviews In Diet and Nutrition** ……..…Paul Coates, ODS & Rachel Ballard-Barbash, NCI

6. **ODPHP Update**…….……...……Kathryn McMurry, ODPHP/OS/HHS

7. **ODS Update** ……...….Paul Coates, ODS

8. **Current DNRC Update of Activities**…..…….....…..…..DNRC Staff

   - HNRIM Update…….....…….Jim Krebs-Smith
   - Nutrition Education Subcommittee Update..……..…….Jean Pennington*****
   - International Committee Information…….Pam Starke-Reed/Dan Raiten *****

9. **Reports from NCC Members and Liaisons**…….……..NCC Members

10. **Next Meeting**: July 6, 2006

11. **Old Business**

*** Updates will be included in the minutes of the meeting only**

APPENDIX B. NCC MEETING ATTENDEES FOR MAY 4, 2006

	Members Present	Members Absent	Alternates Present
Chairperson:	V Hubbard		P Starke-Reed
NIH Members:			
NCI		J Milner	S Ross
NHLBI	D Danford		
NIDCR		R Nowjack-Rayner	
NIDDK	C Miles		
NINDS		M Mitler	
NIAID	M Plaut		
NIGMS		S Somers	
NICHD		G Grave	D Raiten
NEI		N Kurinij	
NIEHS		E Maull	
NIA	J Hannah		
NIAMS		J McGowan	
NIDCD		B Wong	
NIMH		P Muehrer	
NIDA		G Lin	
NIAAA	R Breslow		
NINR		Y Bryan	
NCCAM		M Klein	
NCRR	L Yager		
FIC		J Herrington	
NHGRI			
NIH Liaison Members:			
CC	N Sebring		
CIT		J Mahaffey	
CSR	S Kim		N Sheard
NLM		S Phillips	
OBSS	D Olster		
OC		M Stern	
ODS	P Coates		B Costello
OD/ODP	B Portnoy		
OLPA			
ORWH			
PRCC		M Vogel-Taylor	
Agency Liaison Representatives:			
CDC/NCCDPHP	D Galuska		
CDC/NCHS	V Burt		
FDA	K Ellwood		S Blakely
HRSA	M Lawler		
IHS		T Brown	
ODPHP	K McMurry		
USDA	M Kretsch		
DOD		K Friedl	
OPHS		M Terpeluk	

DNRC: R Fisher, W Johnson-Taylor, J Krebs-Smith, C McDade-Ngutter, J Pennington, K Regan, L Somuah

Guests: R Ballard-Barbash (NCI), D Berrigan (NCI), J Charles-Azure (IHS), C Davis (NCI), J Dwyer (ODS), N Emenaker (NCI), J Grof (CC), L Grummer-Strawn, (CDC, NCCDPHP), A. Jerkins (NIH, CSR), C Kaefer (NCI), W Kessel (OPHS), P Kim Phan (NIH, FIC), S Krebs-Smith (NCI), S Lewis (CC), M McDowell (CDC, NCHS), MF Picciano (ODS), J Ritchie (CC), C Salaita (CC), J Slutsky (AHRQ), C Swanson (ODS), C Taylor (FDA), P Thomas (ODS), A Thurn (ODS), R Troiano (NCI), S Welsh (USDA, CRSEES), A Yaroch (NCI), and B Yetley (ODS).

APPENDIX C: Comparison Between the CDC & WHO Curves

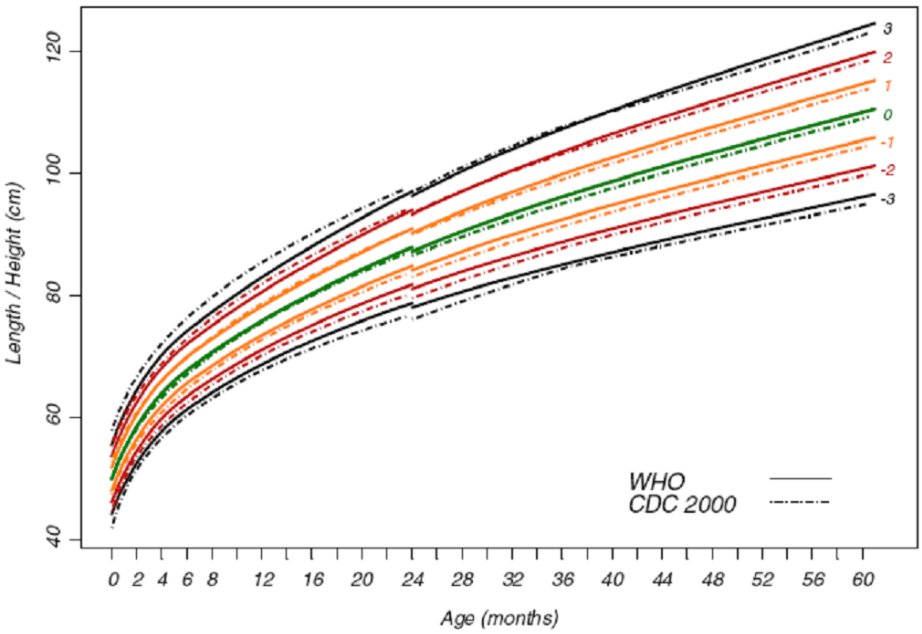

Figure 16 Comparison of WHO with CDC 2000 length/height-for-age z-scores for boys

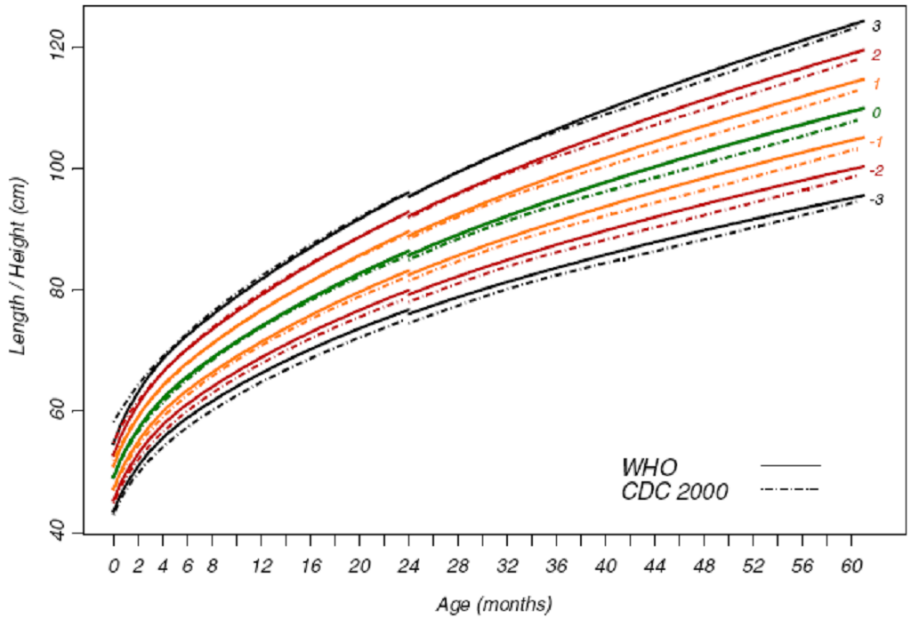

Figure 30 Comparison of WHO with CDC 2000 length/height-for-age z-scores for girls

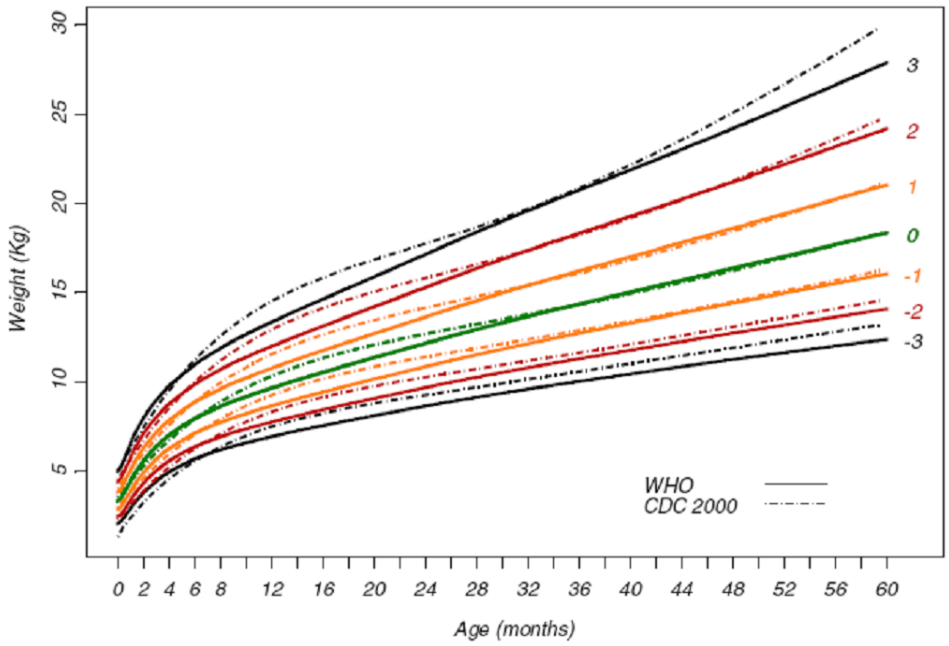

Figure 46 Comparison of WHO with CDC 2000 weight-for-age z-scores for boys

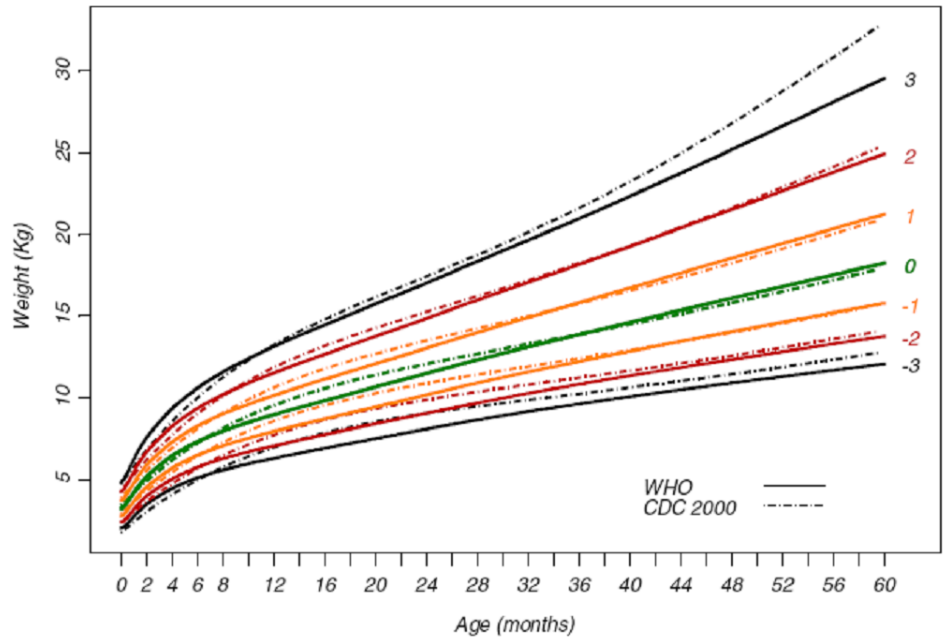

Figure 59 Comparison of WHO with CDC 2000 weight-for-age z-scores for girls

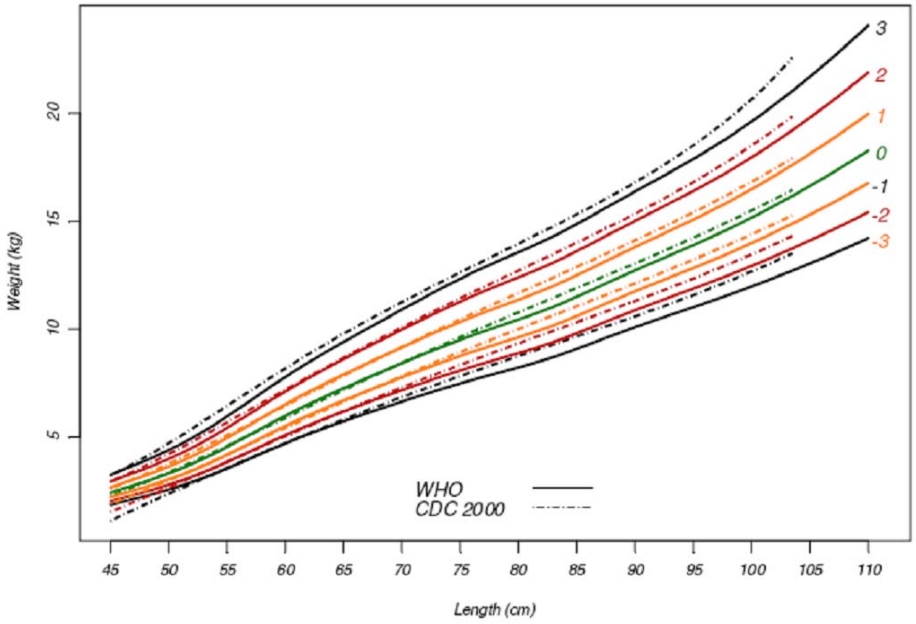

Figure 77 Comparison of WHO with CDC 2000 weight-for-length z-scores for boys

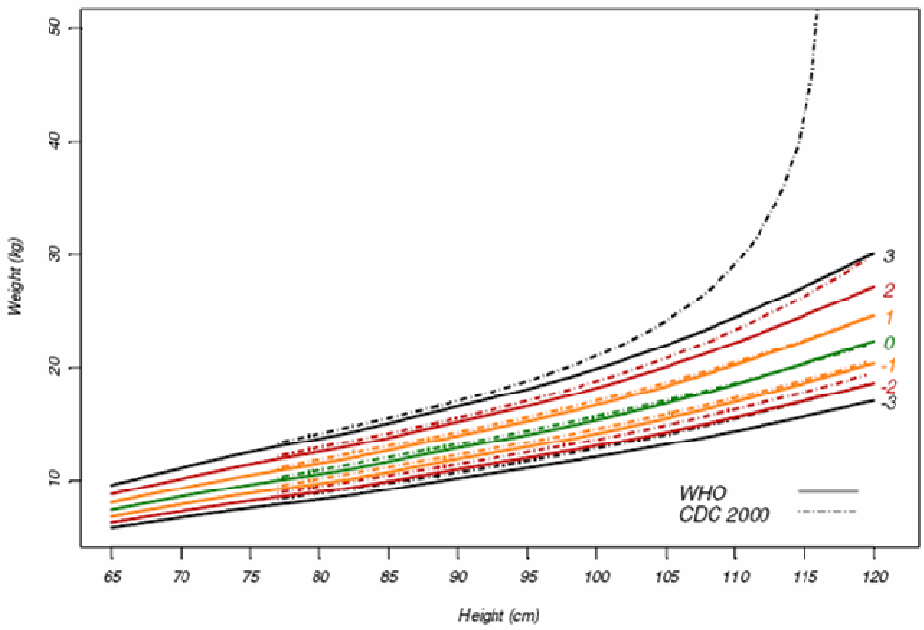

Figure 78 Comparison of WHO with CDC 2000 weight-for-height z-scores for boys

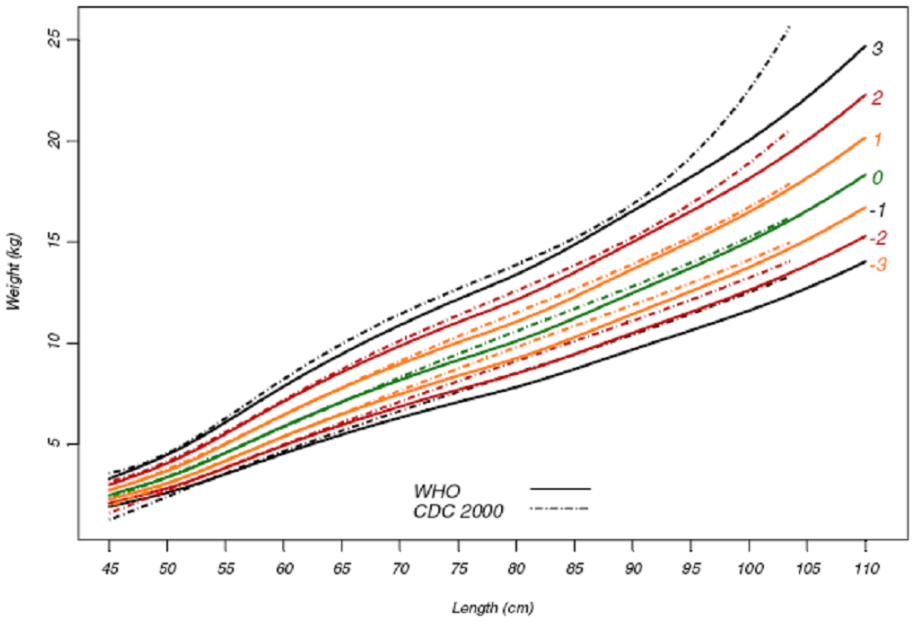

Figure 92 Comparison of WHO with CDC 2000 weight-for-length z-scores for girls

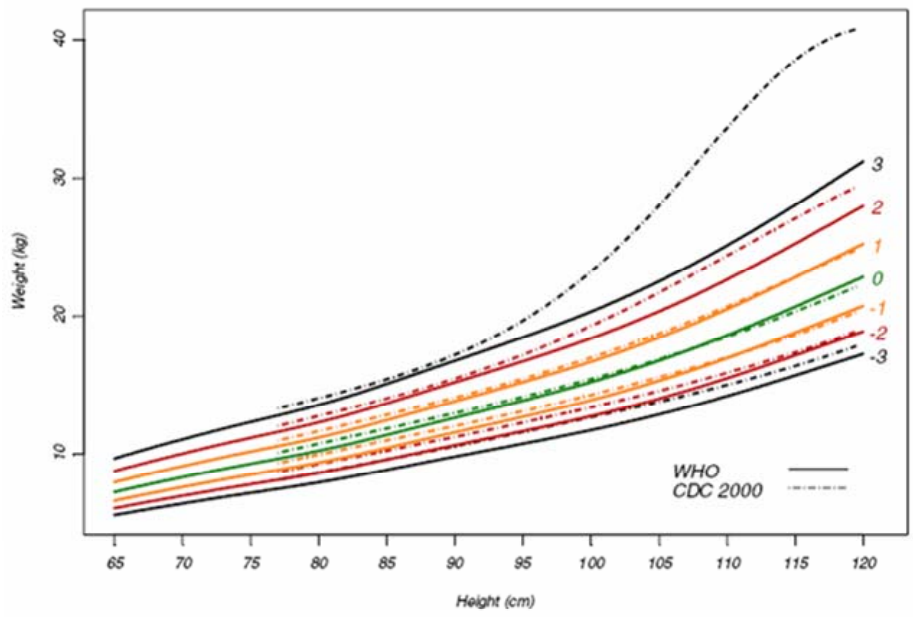

Figure 93 Comparison of WHO with CDC 2000 weight-for-height z-scores for girls

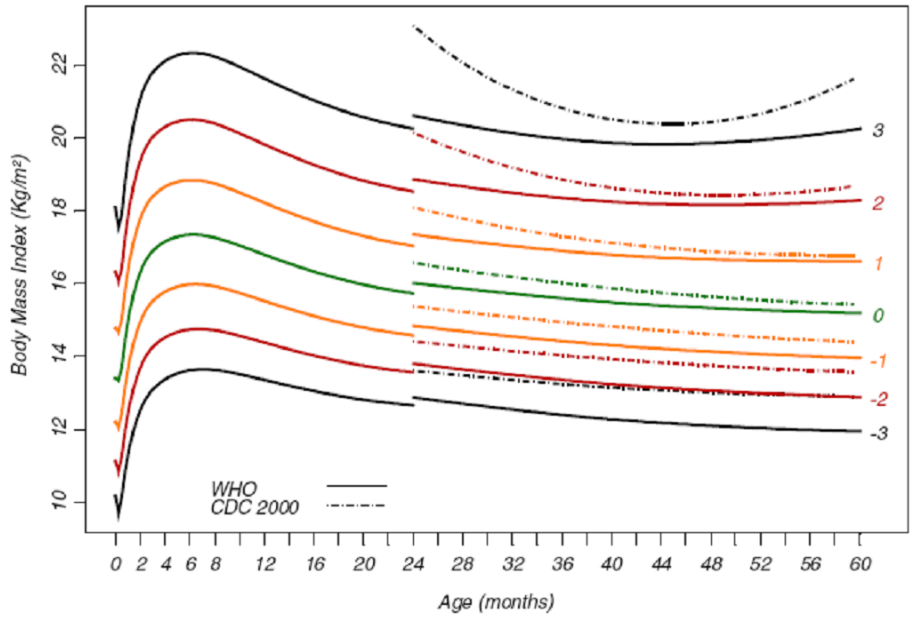

Figure 115 Comparison of WHO with CDC 2000 BMI-for-age z-scores for boys

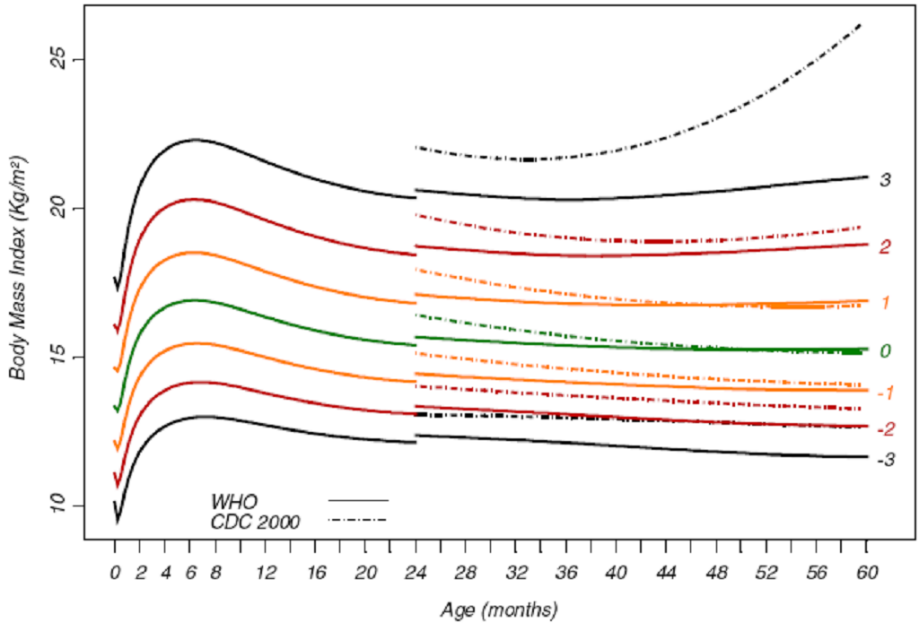

Figure 133 Comparison of WHO with CDC 2000 BMI-for-age z-scores for girls

APPENDIX D:

NIH Proposal for Initiation of Evidence-Based Reviews in Diet and Nutrition

Summary

The National Institutes of Health Nutrition Coordinating Committee (NIH/NCC) proposes to develop and implement a plan for integrating evidence-based reviews (EBRs) into the processes whereby expert scientific groups develop diet/nutrient and health recommendations that are subsequently incorporated into federal agency policies and related applications.

Background

For many years, federal agencies have used the recommendations of scientific advisory committees to guide nutrition-related policies and programs. For example, the Departments of Health and Human Services (DHHS) and Agriculture (USDA) have used an advisory committee process to update the U.S. Dietary Guidelines (DG) every 5 years. These guidelines, by statute, represent U.S. government policy on diet and health. Additionally, NIH and other federal agencies support efforts by the Food and Nutrition Board of the Institute of Medicine/National Academy of Sciences (FNB/IOM/NAS) to develop Dietary Reference Intakes (DRIs) (e.g., Recommended Daily Allowances, Upper Limits) to serve as reference values for both adequate and safe intakes of nutrients. The DRIs and DG are subsequently used by several federal agencies to develop nutrition/diet policies and by NIH in identifying research needs and in designing and evaluating research studies. Examples of federal agency applications of these science-based recommendations include use by:

- NIH and other federal agencies to ensure that the federal government speaks with a consistent voice on diet/health dietary guidance issues,
- NIH for identifying and prioritizing research needs and for designing and evaluating human studies,
- Food and Drug Administration (FDA) for development of nutrition and supplement labeling policies,
- Department of Defense for evaluation of the nutritional adequacy and safety of military rations and related products, and
- USDA in designing diets and standards for their food stamp, school lunch, and WIC programs.

To date, nutrition-related policies and programs have been guided by recommendations made by advisory committees that have relied primarily on expert narrative reviews of the scientific evidence by committee members in order to develop their conclusions. However, for some topics, these types of narrative reviews have significant limitations, including the incomplete inclusion of all relevant scientific data and the lack of systematic, methodologically rigorous, and transparent approaches to the process. As a result, traditional expert opinion review approaches are increasingly being augmented

with use of EBRs conducted independently according to rigorous methodologic standards. Addition of an EBR approach for selected topics would have an advantage in that EBRs systematically and comprehensively evaluate the existing literature relative to the framework questions. They also can be used to identify research needs that may assist future evaluation activities of advisory committees, such as those required for the DG. Principles of EBR that have made it attractive for the purpose of developing health-related recommendations and guidance include:

- Transparency of the process,
- Independent evaluation of relevant literature, and
- Systematic review: comprehensive, reproducible, credible, quantitative assessment of the evidence.

An example of widely used and scientifically accepted EBRs are those performed by the Agency for Healthcare Research and Quality (AHRQ)-supported Evidence-Based Practice Center (EPC) program. These EBRs have been extensively used by NIH and other federal agencies on a wide range of topics. Some of these EBRs have focused on diet/nutrition and health relationships to meet several different types of agency needs (Appendix 1). These examples of AHRQ EBRs exhibit wide flexibility in the types of questions that were used to frame the review, the types of studies that were included, and the results that were reported.

Despite its appeal, there are challenges associated with augmenting narrative reviews with EBRs. The experiences and concerns of several diet/nutrition and health-related advisory committee/expert panel activities underscore the complexities, challenges, and controversies:

- U.S. Dietary Guidelines: An initial attempt to incorporate EBR procedures into the 2005 U.S. DGAC deliberations was limited because of inadequate resource and time constraints that precluded formal incorporation of outside EBRs. Moreover, the recent acquisition by USDA of the American Dietetic Association's (ADA) "ADA Evidence Analysis" software for possible use in the next revisions of the U.S. Dietary Guidelines has raised questions among some NIH collaborators about the relative merits of internal vs. external, independent, expert EBRs for purposes of updating the Guidelines (see page 4).

- Nutrient Risk Assessments: A recent Food and Agricultural Organization/World Health Organization consultation considered the integration of EBRs into the Nutrient Risk Assessment process. The consultation concluded that some modifications from EBR approaches as used for other types of applications would likely be necessary if EBRs were to be successfully integrated into nutrient risk assessment procedures.

- Integration of EBRs into future FNB/IOM/NAS DRI activities is one of the controversial topics currently under discussion by the DHHS/Office of Disease Prevention and Health Promotion-led Federal Steering Committee for DRIs.

Recommendation by the NIH Nutrition Coordinating Committee (NCC)

The NIH NCC recommends a two-step process for addressing the issues surrounding the incorporation of EBRs into diet/nutrition/health scientific evaluations:

1. A general approach to evaluate how best to incorporate EBRs into different types of applications and to evaluate areas of commonality and differences involved in incorporating EBRs among several applications.

2. A targeted approach to deal with the immediate needs of evaluating how best to incorporate EBRs into the 2010 DG process.

General:

The NIH NCC recommends that EBRs for the purpose of informing science-based nutrition guidance applications be critically evaluated to determine how best to integrate EBRs into the full range of types of science-based diet/nutrition/health applications and the differing conceptual models and processes used to derive these expert positions.

It further recommends that this evaluation begin with a workshop(s) to gain input from relevant communities – scientists and policymakers in the government, academia, professional societies, and industry – about the design and conduct of EBRs, the types of scientific input needed to inform the decision-making processes involved in developing nutrition recommendations, and the needs and challenges of user communities of the EBRs and advisory committee recommendations. For example, one question that needs to be addressed is whether each scientific type of application (e.g., Dietary Guidelines, DRIs) requires unique EBRs to address their particular sets of questions and different analytic frameworks or whether a given EBR can be flexible enough to address the information needs of multiple applications. In all cases, a key question is how best to incorporate EBRs to ensure the quality and transparency of the scientific evaluation while ensuring that such reviews can be well utilized by nutrition-related advisory committees. Because other groups have also identified similar questions, it would be important to collaborate with them in this effort (e.g., DRI interim process).

The NIH NCC recommends that once the basic framework for integrating EBR with nutrition applications is agreed upon, EBR for the purpose of informing nutrition guidance recommendations be performed by an independent group of experts well trained and experienced in the principles and the practice of EBR rather than by sponsoring government staff (e.g., NIH, USDA). These processes cannot be taught in a short time; in fact, most credible EBRs are performed by individuals with advanced degrees in biomedical fields and with years of training and experience in EBR methodology. Instead, sponsoring government staff – as well as scientists from the

academic and private sectors – can be available for continued consultation as questions from the EBR experts arise. Furthermore, for NIH-sponsored, nutrition-related EBRs we recommend that the NIH NCC serve as the coordinating group for such reviews to identify the specific topics that will undergo review, the relevant framework questions, and the types of results needed from the EBR.

Based on the topics selected and applications for which the EBR is being conducted, NIH ICs that are members of the NCC would contribute to a joint fund to support agreed-upon EBRs and aid in the development of framework questions, the provision of IC technical federal experts as needed by the EBR group, and in review of draft final reports for adherence to the EBR Task Order. The NIH NCC recommends a budget of $1,000,000/year for EBRs in this program, with contributions coming from multiple NIH ICs. This would allow roughly 3 reviews per year and would require only a modest commitment from an individual IC.

Specific to the 2010 Dietary Guidelines:

Consideration of the integration of EBRs into the process for developing the DG for 2010 requires immediate attention before the next DGAC is convened. The DG form the basis of science-based dietary recommendations for the U.S. public. They have been provided by the government since 1980 and are revisited, by Congressional mandate, every 5 years by DHHS and USDA. The joint effort includes convening a DGAC to review new scientific literature (obtained since the previous DGAC meeting) that may lead to changes in the DG. For the DG 2005 effort, an initial attempt was made to introduce the strategies and principles of EBR into the process. However, limited resource and time constraints precluded both the use of an outside evidence-based review center and the ability to achieve the full potential of this process for updates to the 2005 DG process. NIH believes that this process must be further developed and expanded so the best approach can be adopted for use in current (2010) and future DGAC deliberations.

While the leadership of the DGAC effort is jointly shared by DHHS and USDA, the secretariat and organizing functions alternate between the agencies for each 5-year cycle. The USDA has responsibility for the secretariat functions of the DGAC in the current cycle leading up to the 2010 DGs, although both agencies will continue as co-sponsors of the DG process and final documents. NIH commends USDA for recognizing the need to move forward quickly with setting up the mechanism for performing EBRs in advance of the DGAC being formed. However, NIH is concerned that the process chosen by USDA may not fit the current standards for EBRs and may result in reviews that are not considered credible, standardized or objective, thereby lessening the credibility and utility of such reviews. We recognize that USDA has already contracted with the ADA to use their "ADA Evidence Analysis" software. The NIH NCC recommends that the best way to use EBRs for the next DGAC should be open to discussion and that the approach on which USDA has embarked be reconsidered.

Appendix 2 is a draft of a step-wise approach to the incorporation of EBR into nutrition policy-making processes. It follows the standard approach employed by AHRQ's EPC program, and attempts to recognize the importance of placing EBR in the context of nutrition policymaking. It should be noted, however, that that is a starting point and is subject to further discussion among interested parties.

To address the issues and controversies identified above, the NIH NCC proposes the following process to meet the short-term needs for EBRs for the 2010 DG revision.

Convene a working group of health-related federal agencies (e.g., NIH, FDA, USDA, Centers for Disease Control and Prevention) to:

- **Identify topics** for the 2010 DG that would benefit from currently available EBRs or for which new EBRs done through AHRQs EPC program would be useful,
- **Prioritize** these needs, define the DGAC questions which lend themselves to EBRs, and to the extent possible, initiate EBRs through AHRQ to meet this need,
- Develop a process to ensure that adequate attention is given to the:
  - **Development of framework questions** through an awareness of the types of science-based decisions for which the Dietary Guidelines advisory committee needs scientific information,
  - **Iterative process** between the sponsoring agencies and the EBR methodologists and technical experts to ensure that the framework questions meet the information needs of the committee, and
- Evaluate the questions surrounding how best to incorporate EBRs into the 2010 DGAC process.

This activity needs to be started immediately as the available time to prepare for the 2010 updates is currently very limited. It should also be recognized that this should be an ongoing process. Thus, an evaluation of the successes and challenges encountered for the 2010 Dietary Guideline process should be documented to improve future DG efforts.

Appendix 1. Examples of EBR in Nutrition-Related Settings

AHRQ-sponsored EBR in the process of preparation for all NIH Consensus Development Conferences:

MVM and Health Outcomes
For the NIH State-of-the-Science Conference on Multivitamin/Mineral Supplements and the Prevention of Chronic Disease

AHRQ-sponsored EBRs for use by NIH in setting research agendas:

Antioxidant Supplements, Prevention and Treatment of Cancer
Abstract / Summary (October 2003)
Evidence Report (PDF File)

Antioxidant Supplements, Prevention and Treatment of Cardiovascular Disease
Abstract / Summary (July 2003)
Evidence Report (PDF File)

Garlic, Cardiovascular Disease
Abstract / Summary (October 2000)
Evidence Report

Omega-3 Fatty Acids, Effects on Arrhythmogenic Mechanisms in Culture Studies
Abstract / Summary (March 2004)
Evidence Report (PDF Files)

Omega-3 Fatty Acids, Effects on Asthma
Abstract / Summary (March 2004)
Evidence Report (PDF File)

Omega-3 Fatty Acids, Effects on Cancer
Abstract / Summary (February 2005)
Evidence Report (PDF File)

Omega-3 Fatty Acids, Effects on Cardiovascular Disease
Abstract / Summary (March 2004)
Evidence Report (PDF File)

Omega-3 Fatty Acids Effects on Cardiovascular Risk Factors
Abstract / Summary (March 2004)
Evidence Report (PDF File)

Omega-3 Fatty Acids, Effects on Child and Maternal Health
Abstract / Summary (August 2005)
Evidence Report (PDF File)

Omega-3 Fatty Acids, Effects on Cognitive Functions
Abstract / Summary (February 2005)
Evidence Report (PDF File)

Omega-3 Fatty Acids, Effects on Eye Health
Abstract / Summary (July 2005)
Evidence Report (PDF File)

Omega-3 Fatty Acids, Effects in Type II Diabetes, Rheumatoid Arthritis, and Other Diseases
Abstract / Summary (March 2004)
Evidence Report (PDF File)

Omega-3 Fatty Acids, Effects on Mental Health
Abstract / Summary (July 2005)
Evidence Report (PDF File)

Omega-3 Fatty Acids, Effects on Organ Transplantation
Abstract / Summary (February 2005)
Evidence Report (PDF File)

Soy, Effects on Health Outcomes
Abstract / Summary (August 2005)
Evidence Report (PDF Files Download)

Vitamin D and Health Outcomes Report due: Spring 2006

B Vitamins and Berries and Age-Related Neurodegenerative Disorders Report due: Spring 2006

AHRQ-sponsored reports used by United States Preventive Health Services Task Force in developing clinical practice guidelines:

Vitamin Supplementation to Prevent Cancer and Coronary Heart Disease: Counseling (June 2003)

AHRQ-sponsored reports for use by FDA in evaluating Qualified Health Claims:

Chromium Picolinate and Diabetes

FDA Docket # 2004Q-0144

Lutein and eye disease

FDA Docket # 2004Q-0180

Appendix 2

1. Steps in EBR for Use in Development of DGs
   - Define the questions: Perhaps the most crucial step in the process is for the agencies sponsoring/requesting the EBR to define the questions for which scientific evaluation is needed in order to best inform the decision-making processes involved in development of the DGs.

i. Prioritize topics based on reasoned assessment of the state of the current literature; for example, what has changed since the last iteration of DG.
ii. Frame the questions and types of results for the EBR
iii. Clarify populations, interventions, comparisons, outcomes of interest.

- Recruit a Technical Expert Panel (TEP) comprised of subject matter federal experts from sponsoring agencies to work with the sponsoring agencies in an iterative process to refine the preliminary questions set by the sponsoring agencies, to serve as a resource to the EBR team of methodologists, and to review drafts.
- Determine the strategy to obtain evidence: language(s), databases, inclusion and exclusion criteria for studies and, if needed, additional quality factors for rating the scientific quality and relevance of individual studies included in the review.
- Conduct a systematic review of the relevant literature and select, using pre-determined criteria, which will be included in the final synthesis.
- Evaluate the quality of evidence, for both individual studies and the body of evidence that pertains to each question.
- Synthesize the evidence, and analyze using appropriate analytical tools (e.g., meta-analysis, meta-regression) as warranted.
- Prepare a draft evidence report that describes the approach taken and the results of the synthesis.
- Submit draft evidence report for peer review by the TEP and possibly others.
- Prepare a final version of the evidence report, including review comments, to effectively and efficiently communicate the findings, in this case to the sponsoring agencies for transfer to the DGAC.

2. <u>What is the Role of the Government, the EBR Team, and the DGAC?</u>
   - The sponsoring government agencies identify the questions and the types of results needed. Subject-matter specific requirements may also need to be agreed upon before the EBR begins (e.g., subject-matter relevant quality factors for evaluating individual study quality and relevance).
   - The sponsoring agencies form the TEP from federal subject matter experts to review the EBR. The final EBRs are generally published in peer-reviewed journals and could be provided to the DGAC in this form, or not yet published EBRs would be provided to the DGAC in a pre-publication format.
   - The EBR team, composed of experts in systematic review methodology, provides the framework for conducting EBR, works with government to refine and finalize the questions, systematically reviews and transparently documents the relevant literature, and provides independent evaluation of the results of that literature review to the sponsoring agencies. The EBR team provides the final EBR to the sponsoring agency and ensures its publication. The sponsoring agency will ensure that the DGAC has access to all published EBRs and final EBRs not yet published as part of the literature provided to the DGAC in performing its review.

- The DGAC and sponsoring agencies should **not** be responsible for selecting the relevant literature and conducting their own EBRs. Not only do these groups lack expertise in EBRs, but the DGAC also lacks the time and resources to adequately conduct such reviews. It is the DGAC's responsibility to interpret the conclusions of EBR and consider these results in the context of other factors relevant to the process in making its recommendations to the sponsoring government agencies.
- The sponsoring and/or responsible government agencies will then make policy decisions based on the recommendations for the DGAC, taking into account other prevailing circumstances.

3. Who Should Do the NIH sponsored Evidence-Based Review?
   - NIH recommends the same process that is done by well established and credible EBR centers/groups as noted on the first page and repeated here. The review should be performed by an independent group of experts well trained and experienced in the principles and the practice of EBR. Scientists lacking formal EBR credentials and experience cannot be taught the processes in a short time; in fact, most credible EBRs are performed by doctoral and masters level individuals with years of training and experience in EBR methodology.
   - NIH recommends that as much consistency as possible be maintained across agencies and nutrition policy applications in how EBR reviews are conducted.
   - As an example, the DHHS Agency for Healthcare Research and Quality (AHRQ) contracts with 13 Evidence-Based Practice Centers (EPCs) in the United States and Canada to carry out EBR of topics that range across the spectrum of health – from Medicare coverage of emerging medical devices (for the Centers for Medicare and Medicaid Services [CMS]), to clinical practice guideline development, to biomedical research agenda setting. The EPCs operate under contract to AHRQ; other agencies (such as CMS and NIH) sponsor evidence reports at arm's length from the actual process of EBR.
   - The NIH NCC notes the current standard of credible, objective EBRs cannot involve a process that has agency staff performing the review. However, the role of agency staff in identifying the relevant questions, ensuring comprehensive identification of relevant literature and review of draft reviews has been summarized above.

APPENDIX E

HHS Priorities
for America's Health Care

Health Care Value Incentives

Health Information Technology

Medicare Rx

Medicaid Modernization

New Orleans Health System

Personalized Health Care

Obesity Prevention

Pandemic Preparedness

Emergency Response & Commissioned Corps Renewal

Health Care Value Incentives: The growth of health care costs is restrained because consumers know the comparative costs and quality of their health care — and they have a financial incentive to care. Consumers gain control of their health care and have the knowledge to make informed health care decisions.

Health Information Technology: The medical clipboard becomes a thing of the past. Secure interoperable electronic records are available to patients and their doctors anytime, anywhere. Immediate access to accurate information reduces dangerous medical errors and helps control health care costs.

Medicare Rx: Every senior has access to affordable prescription drugs. Consumers will inspire plans to provide better benefits at lower cost. Medicare Part D is streamlined and improved to better connect people with their benefits. Pay for Performance methodologies act to increase health care quality.

Medicaid Modernization: Sustainable Medicaid programs help provide coverage for millions of people who are not covered now. People in differing economic situations are helped through flexible benefits and incentives tailored to meet their needs. People with disabilities have access to care in their homes and communities.

New Orleans Health System: Adversity turns to advantage. The New Orleans health system of antiquated, inefficient emergency room care becomes a place where every citizen has a medical home that is prevention-centered, neighborhood-located and electronically-connected.

Personalized Health Care: Health care is tailored to the individual. Prevention is emphasized. Propensities for disease are identified and addressed through preemptive intervention. Discovery and innovation move drugs to the market and to medical practice faster and at lower cost.

Obesity Prevention: The risk of many diseases and health conditions are reduced through actions that prevent obesity. A culture of wellness deters or diminishes debilitating and costly health events. Individual health care is built on a foundation of responsibility for personal wellness.

Pandemic Preparedness: The United States is better prepared for an influenza pandemic. Rapid vaccine production capacity is increased, national stockpiles and distribution systems are in place, disease monitoring and communication systems are expanded and local preparedness has been dramatically enhanced. Planning and preparedness encompasses all levels of government and society.

Emergency Response and Commissioned Corps Renewal: We have learned from the past and are better prepared for the future. There is an ethic of preparedness at HHS and throughout our Nation. We have a Commissioned Corps that is bigger, better trained, and deployable.

APPENDIX F

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Food and Nutrition Board

DIETARY REFERENCE INTAKES RESEARCH SYNTHESIS

Project Overview

Background—The Institute of Medicine (IOM) under the aegis of the Food and Nutrition Board developed the Dietary Reference Intakes (DRIs), published as a series of eight reports (IOM, 1997-2005). The DRIs are quantitative reference values for recommended intakes and safe upper levels of intake of nutrients. The DRI reports implement an approach that (a) reviews nutrients for their role in elimination of nutritional deficiencies and reduction of risk of chronic diseases and (b) uses a risk assessment model to evaluate the extent to which excess consumption may lead to health problems. Knowledge gaps and research needs were also identified and prioritized.

Objective—This project will provide avenues for the synthesis and dissemination of the research recommendations identified in the DRI reports. The DRIs are used in a number of food- and nutrition-related program and policy activities in the United States and Canada. Given the broad use of the DRIs, it is important that knowledge gaps and research needs be clearly articulated so that mechanisms to fill them can be developed. The sponsoring agencies are interested in promoting a clear understanding of knowledge gaps and research needs and have asked the IOM to organize a workshop to develop and discuss important aspects of the research recommendations and to develop a searchable database of the research recommendations.

Workshop—The IOM will convene a two-day workshop to engage expert research scientists and nutrition practitioners from government, academia, and industry, and others in discussion on issues related to knowledge gaps and research needs in developing and advancing the DRIs. The workshop will provide a venue for hearing and discussing experts' perspectives on the research recommendations identified in the DRI reports. The workshop is scheduled for June 7-8, 2006, at the Keck Center of the National Academies, 500 Fifth Street NW, Washington, DC; register at www.iom.edu/DRIresearchWorkshop. Release of a summary of the workshop is anticipated in September 2006.

Workshop Planning Group:

John W. Suttie, Ph.D. (Chair), University of Wisconsin, Madison
John W. Erdman, Jr., Ph.D., University of Illinois—Urbana-Champaign
Suzanne P. Murphy, Ph.D., R.D., University of Hawaii, Honolulu
Robert M. Russell, M.D., Tufts University, Boston, MA
Susan J. Whiting, Ph.D., R.D., University of Saskatchewan, Saskatoon, SK, Canada

Database—The IOM will develop a database to provide ready access to the research recommendations from the DRI reports. The searchable electronic database is being developed in consultation with a number of scientific and technical experts. The database was released on April 1 in preliminary form for public comment; download the files at www.iom.edu/DRIresearch2006. The database will be discussed at the workshop and released in final form in September 2006.

Sponsors

This project is supported by the U.S. Department of Health and Human Services (Office of Disease Prevention and Health Promotion; the Division of Nutrition Research Coordination and the Office of Dietary Supplements, National Institutes of Health); the U.S. Department of Agriculture (Agricultural Research Service); and the Canadian Institutes of Health Research (Institute of Nutrition, Metabolism, and Diabetes). Support from Health Canada is anticipated.

For more information, contact the Study Director, Janice Okita, as indicated below.

USDA

CIHR IRSC

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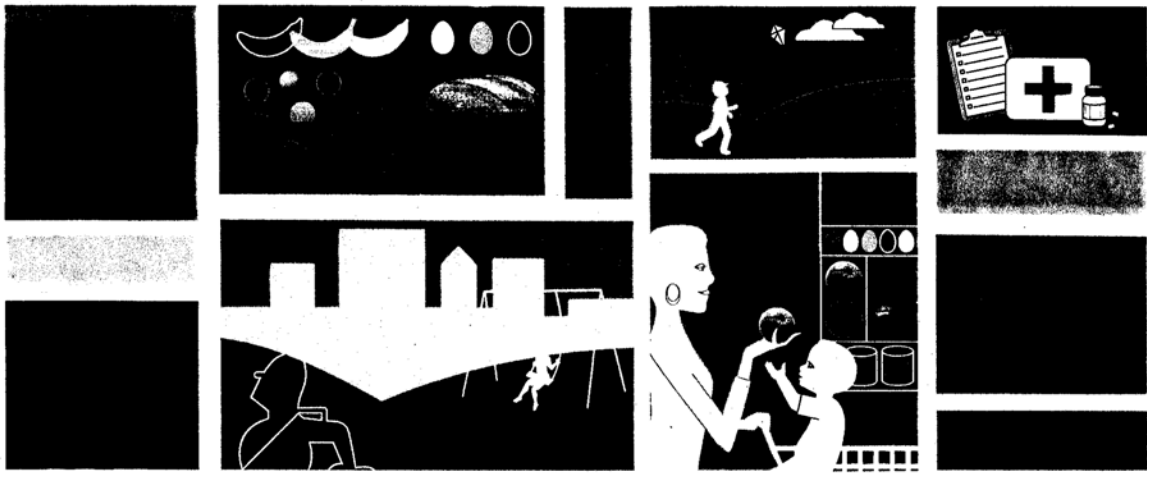
APPENDIX G



SAVE THE DATE

National Prevention Summit: Prevention, Preparedness, and Promotion

October 26 and 27, 2006

Hyatt Regency on Capitol Hill
Washington, D.C.

Building on last year's Third National Prevention Summit, the upcoming 2006 National Prevention Summit will focus on disease prevention, health preparedness, and health promotion and will feature innovative programs that are making a difference in communities across the country to build a HealthierUS. These programs are focused on healthy lifestyle choices—eating a nutritious diet, being physically active, making healthy choices, and getting preventive screenings—to help prevent major health threats and burdens such as obesity, diabetes, asthma, cancer, heart disease, and stroke. One special emphasis this year will be the prevention of childhood overweight and obesity. Another emphasis will be on preparing for public health emergencies, such as avian influenza.

Abstracts will be accepted for oral and poster presentations at the Summit. Please watch for additional announcements about the call for abstracts and registration.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Disease Prevention and Health Promotion