

**MINUTES OF THE NUTRITION COORDINATING COMMITTEE (NCC)
MEETING, NATIONAL INSTITUTES OF HEALTH (NIH)
Rockledge 2, Conference Room 9112-9116, Bethesda MD
January 6, 2005, 2:00-4:00 PM**

WELCOME

Dr. Van Hubbard, Director, Division of Nutrition Research Coordination (DNRC), convened the meeting at 2:00 PM and welcomed the participants to the first NCC Meeting of 2005. Dr. Hubbard asked the participants to identify themselves and to introduce guests and new attendees. Participating via teleconference were Dr. Joan McGowan, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS); Dr. Elizabeth Maull, National Institute of Environmental Health Sciences (NIEHS); Dr. M Vogel-Taylor, NIH Office of the Director; Dr. Deb Galuska, Centers for Disease Control and Prevention (CDC); Ms. Jennifer Weber and Ms. Kim Stitzel, Department of Health and Human Services (DHHS) Office of Disease Prevention and Health Promotion (ODPHP); Dr. Karl Friedl and Major Lori Sigrist, Department of Defense (DoD); and Dr. Shirley Blakely (Food and Drug Administration (FDA) on detail to the DoD.

The agenda for the meeting is provided as Appendix A, and the list of attendees is provided as Appendix B. Dr. Hubbard made some changes to the order of the agenda items to accommodate several people who wanted to hear the discussion on Vitamin E, but would not be available until 2:30 PM.

APPROVAL OF MINUTES FROM THE NOVEMBER 4, 2004 NCC MEETING

Minutes from the November 4, 2004, NCC Meeting had previously been sent to NCC members via email. Dr. Hubbard asked if there were any corrections to the minutes. There were none. Dr. John Milner, National Cancer Institute (NCI), made a motion to approve the minutes, and Dr. Paul Coates, Office of Dietary Supplements (ODS), 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.

STATUS OF OXYGEN-18 FOR USE IN ENERGY EXPENDITURE AND OTHER MEASURES

Dr. Rick Troiano, NCI, provided information about the availability of oxygen-18 for use in research on energy expenditure and other studies. Dr. Troiano and Dr. Sergei Romashkan from the National Institute of Aging (NIA) met with the US distributor and Israeli marketing manager for Rotem, one of the producers of oxygen-18. This company, which had previously indicated that they would focus on the PET market and had no interest in selling the low-enrichment isotope used for doubly-labeled water studies, is now actively seeking orders for low-enrichment (10%) isotope. Rotem wants researchers to know that the price for the isotope has come down (to roughly \$5-7 per gram, depending on quantity) and that availability is not a problem. Relatively large quantities of the isotope could be delivered within a few months, rather than years, as was the case over the past several years. Smaller amounts appear to be immediately available.

The pricing/availability situation is unlikely to be limited to this producer. Please share this information with other researchers who may be avoiding the use of doubly-labeled water because of concerns about lack of availability.

UPDATE ON FOOD AND DRUG ADMINISTRATION (FDA) HEALTH CLAIMS AND OTHER ISSUES

Dr. Kathy Ellwood, FDA, discussed an article entitled “New Food and Drug Administration Health Claim Requirements Get Mixed Response” by Damon Brown published in the January 2005 Issue of the *Journal of the American Dietetic Association* (Volume 105, Number 1, pages 19-20) and noted that some of the information in the article was not correct. Currently, there is no FDA proposed rule for health claims. The results from some FDA studies about consumer understanding of health claims are being evaluated and will be presented by the FDA Consumer Studies Group at a later date. At the present time, FDA is working under an interim guidance system for health claims. Health claims that are permitted by FDA are listed on the FDA website (<http://www.cfsan.fda.gov/label.html>). FDA issued letters of enforcement discretion for omega-3 fatty acids and coronary heart disease last fall and for monounsaturated fatty acids in olive oil and coronary heart disease last October. Eleven qualified health claims are under review and are listed on the FDA website.

VITAMIN E: RECENT RESEARCH FINDINGS/CURRENT CLINICAL TRIALS

Dr. Maria Sgambati, NCI, and Dr. Paul Coates, ODS, led a discussion with NCC attendees about a paper that appeared in the January 2005 issue of *Annals of Internal Medicine* entitled “Meta-Analysis: High-Dosage Vitamin E Supplementation May Increase All-Cause Mortality” by Edgar R Miller et al. (<http://www.annals.org/cgi/content/full/0000605-200501040-00110v1>). This paper provided the results of a meta-analysis of the dose-response relationship between vitamin E supplementation and total mortality using data from 19 randomized, controlled trials. The paper concluded that high-dosage (≥ 400 IU of vitamin E per day) vitamin E supplements may increase all-cause mortality and should be avoided.

This paper was of particular concern to NIH because of an on-going clinical trial, the SELECT trial, being conducted by NCI and co-sponsored by the National Center for Complementary and Alternative Medicine (NCCAM) several other Institutes and Centers. Dr. Sgambati noted that the SELECT trial is evaluating the effects of selenium, vitamin E, selenium plus vitamin E, and a placebo on the occurrence of prostate cancer. The level of vitamin E used is 400 units of d-alpha-tocopherol acetate. The subjects are men at high risk for prostate cancer and will be in the study for seven to 12 years; the men are currently in the second year of the study. Because the paper generated a lot of attention from the participants, NCI sent letters to them indicating that the level of vitamin E being used in the trial is safe. The trial is still on-going and may be accompanied by more cautious monitoring.

Dr. Coates noted that because meta-analyses allow for the pooling of data, they may demonstrate effects not otherwise seen in the individual studies. There are rules for pooling, and it is not clear exactly how these rules were followed in the paper being discussed. Of particular interest are the differences in the lifestyles and geographic locations of the study participants, the health of the participants, the purpose of the studies, the amount and form of vitamin E that was supplemented, and the complexity caused by interventions other than vitamin E. It is possible that the results of the meta-analysis might have been compromised due to these factors. The paper, which was first made available electronically, has resulted in a number of letters to the editor. Dr. Coates said that the current ODS and Clinical Center fact sheet on vitamin E will be reviewed to determine if any changes are necessary.

Dr. Hubbard said that many NIH researchers might be interested in this vitamin E meta-analysis because there have been 142 NIH-funded studies over the past five years, some of which used vitamin E as an intervention. A number of these studies involved the relationship of vitamin E to cardiovascular risk, Alzheimer's Disease, eye disease, and nonalcoholic steatohepatitis in the obese. When establishing the tolerable upper levels for vitamin E, The Dietary Reference Intake (DRI) review, found no evidence of harm at 1000 units per day. Also of interest is the fact that the requirement for vitamin E cannot be easily achieved by the usual diet; perhaps the DRIs are too high. Also of interest are vitamin E and K interactions and potential implications for bone health.

Dr. Judy Finkelstein, NIA, noted that in two NIA-funded trials using 2000 units of vitamin E per day, no harmful effects were seen. A paper published from one of these studies on Alzheimer's disease and vitamin E found no effect of vitamin E on cognition, but a longer time to nursing home stays. The publication for the second trial is being drafted, but again, it found no effects of vitamin E on cognition.

Dr. Hubbard and the group discussed plans for a vitamin E workshop or conference. Those who want to be involved in the next steps should let Dr. Hubbard know, and he will arrange a conference call.

Recent papers on vitamin E discussed at the meeting include:
Miller ER, et al. Meta-analysis: high-dosage vitamin E supplementation may increase all-cause mortality. *Ann Intern Med* 142:37-46, 2005 (plus accompanying editorial by ER Greenberg, *Ann Intern Med* 142:75-76, 2005).
Vivekananthan DP, et al. Use of antioxidant vitamins for the prevention of cardiovascular disease: Meta-analysis of randomised trials. *Lancet* 361: 2017-2023, 2004.
Knekt P, et al. Antioxidant vitamins and coronary heart disease risk: A pooled analysis of 9 cohorts. *Am J Clin Nutr* 80: 1508-1520, 2004.
US Preventive Services Task Force: Vitamin Supplementation to Prevent Cancer and Cardiovascular Disease - Counseling.
<http://www.ahrq.gov/clinic/uspstf/uspstvita.htm#related>.

UPDATE OF THE NIH OFFICE OF DIETARY SUPPLEMENTS (ODS)

Dr. Paul Coates, ODS, announced that the first meeting of a newly-constituted Trans-NIH/Agency Dietary Supplement Liaison Working Group will be held on January 27, 2005 from 1:30-3:00 PM in the Neurosciences Center on Executive Boulevard in Bethesda, Maryland. Under the leadership of Dr. Ken Fisher, ODS, this group consists of liaison members from all NIH Institutes and Centers (ICs), as well as from other agencies of the Federal government with an interest in dietary supplement research.

The need for additional avenues of communication between the ICs and agencies with whom ODS collaborates was identified in the ODS Strategic Plan for 2004-2009. The Trans-NIH/Agency Working Group is being organized as a key mechanism to communicate needs and opportunities for research and to facilitate ODS partnering with ICs and agencies that have common goals related to dietary supplements.

ODS sponsors a monthly seminar series; upcoming speakers include Dr. Tsunenobu Tamura, on sabbatical to ODS from the University of Alabama Birmingham, on January 19, 2005; Dr. Jim Harnly, USDA Agriculture Research Service (ARS), on February 9, 2005; Dr. Irvin Rosenberg, Jean Mayer USDA Human Nutrition Research Center at Tufts University, on March 9, 2005; and Dr. Barry Halliwell, National University of Singapore, on April 13, 2005. Details about topics, times, and locations are attached as Appendix C.

UPDATE OF THE US 2005 DIETARY GUIDELINES FOR AMERICANS

Ms. Jennifer Weber and Ms. Kim Stitzel from the DHHS ODPHP provided a brief update about the publication of the *2005 Dietary Guidelines for Americans*. They noted that the Guidelines will be released in mid-January and that there will be a media advisory two days before the release. There will be an internal briefing after the media advisory. Some consumer materials (being developed by Porter-Novelli) will be released at the same time as the Guidelines policy document. Dr. Hubbard noted that the process for the 2005 Guidelines is different than that from previous years, and that NIH has not formally cleared the policy document.

UPDATE OF DNRC ACTIVITIES

Nutrition Education Subcommittee. Dr. Jean Pennington, DNRC, provided an update of the activities of the NIH Nutrition Education Subcommittee (NES). During 2004, the NES reviewed 31 documents including 14 from NIH, five from USDA, four each from CDC and the Health Research and Services Administration (HRSA), two from DHHS, and one each from the Administration on Aging (AoA) and the DHHS Office of Women's Health. Of the 14 documents from NIH, there were three each from the Weight-control Information Network and NHLBI, two each from NIDDK, NCI, and NICHD, and one each from the Clinical Center and ODS. Documents reviewed or under review since the November 2004 NCC meeting include:

- *Adolescent Nutrition CD-ROM* (Food and Nutrition Service, USDA)
- *Bright Futures for Women's Health and Wellness Materials* (HRSA)

Dr. Pennington requested that NCC members look at the DNRC website (www.dnrc.nih.gov) under "Nutrition Education" to determine if the links and information presented for their IC need to be updated. This information is reviewed yearly, and any updates should be sent to Dr. Pennington.

Dr. Hubbard noted that there would be two presentations during National Nutrition Month (March) from Dr. Brian Wansink, Department of Marketing and Nutritional Science, University of Illinois at Urbana-Champaign, Champaign, Illinois. Dr. Wansink will speak on environmental factors that influence food intake. One presentation will be at the March 3rd NCC Meeting, and the other will be a more general presentation for NIH employees and will be on the NIH Campus.

Subcommittee on International Nutrition Research. Although Dr. Daniel Raiten, National Institute for Child Health and Development (NICHD), was unable to attend the NCC Meeting, he sent a note communicating that the next SCINR meeting will be held on Tuesday, January 18, 2005 from 2:00 to 3:30 PM in the Office of Disease Prevention (ODP) Conference Room, 2B01, 6100 Executive Boulevard, Bethesda, Maryland.

Human Nutrition Research and Information Management (HNRIM) System Update. Mr. Jim Krebs-Smith, DNRC, provided a status report of the HNRIM System. He noted that the request for Fiscal Year 2004 data for HNRIM will be issued to NIH ICs within the next few weeks. NCC representatives were asked to carefully review their IC complete research portfolio - including contracts and intramural research - to identify all relevant nutrition research, based on the Interagency Committee on Human Nutrition Research (ICHNR) Definition for Human Nutrition Research (<http://hnrnim.nih.gov/pdf/codesdefins.pdf>). Any questions regarding data preparation, coding, or submission of the IC report should be directed to Mr. Krebs-Smith or Ms. Karen Regan via email or telephone.

The NIH is working to develop an automated Knowledge Management (KM) system to provide a consistent method across IC's to centrally code research projects by subject area and dollar amounts. In 2004, NIH conducted a pilot project looking at R01s in seven ICs for 12 disease/area categories. Nutrition was one of the categories examined. The new KM system identified less than 100 nutrition-related projects, but an examination of HNRIM records identified over 700 R01 nutrition records, for the same ICs, in the same time period. The pilot project is complete, and each IC has been asked to designate a representative to the KM Committee to discuss the manner in which this system will be implemented and to develop definitions for all disease/area categories. The DNRC is in contact with the NIDDK representative to the KM Committee, and hopes to be closely involved with the development of the nutrition definition. Each NIH NCC representative is encourage to make contact with their respective IC representative to the KM Committee to make him/her aware of the existence of the HNRIM system that is used by all federal government agencies to code for

nutrition research activities and to indicate that staff from the DNRC are willing to discuss information about the system with them.

REPORTS FROM NCC MEMBERS AND LIAISONS

Dr. John Milner, NCI, noted that one of the *Stars in Nutrition Seminars* will be held on March 21, 2005 in the Lipsett Amphitheater on NIH Campus from 3:00-5:00 PM with a presentation by Dr. Paul Talalay from the John Hopkins University School of Medicine, who will speak on *Protection Against Cancer: Edible Plants, Genes, and Enzymes*.

Dr. Cindy Davis, NCI, mentioned the workshop on *Promise and Perils of Lycopene/Tomato Supplementation and Cancer Prevention* to be held February 17-18, 2005 in Bethesda, Maryland. Contact Dr. Davis (301 594-9692; davisci@mail.nih.gov) for more information.

Dr. Elizabeth Maull, NIEHS, noted a conference on *Research Needs in Infants Fed Soy Formula* on February 16-17, 2005 on the NIEHS Main Campus, Rodbell C in Research Triangle Park, North Carolina. The contact person for this event is Dr. Janet Archer, NIEHS (919 941-9344, ex 334; archer2@niehs.nih.gov). The meeting will be in a small room, so please contact Dr. Archer regarding space availability.

Dr. Sue Percival, NCI, mentioned a one-day workshop entitled *Immunonutrition: Enhancing Tumoricidal Cell Activity* on March 23, 2005 in North Bethesda, Maryland. Contact Dr. Percival for more information.

NEXT NCC MEETING

Next NCC meeting – The next NCC Meeting is scheduled for February 3, 2005.

ADJOURNMENT

Dr. Hubbard made a motion to adjourn the meeting, and Dr. Milner seconded the motion. The meeting was adjourned at 3:55 pm.

LIST OF APPENDICES

Appendix A - NIH NCC Meeting Agenda for January 6, 2005

Appendix B - NCC Meeting Attendees for January 6, 2005

Appendix C - Office of Dietary Supplements 2005 Spring Seminar Schedule

17February2005draftjp

APPENDIX A. NIH NCC MEETING AGENDA FOR JANUARY 6, 2005
2:00-4:00 PM, Rockledge 2, Conference Room 9112-9116, Bethesda MD

1. **Welcome**.....Van Hubbard
2. **Approval of November 4, 2004 NCC Meeting Minutes**.....Van Hubbard
3. **Vitamin E: Recent Research Findings/Current Clinical Trials**.....
Paul Coates, ODS; Margaret Chesney, NCCMA; Maria Sgambati, NCI;
NCC Members
4. **Update on FDA Health Claims and Other Issues**.....Kathy Ellwood, FDA
5. **Status of O18 for Use in Energy Expenditure and Other Measures**.....
Rick Troiano, NCI
6. **Update from the NIH Office of Dietary Supplements**.....Paul Coates
7. **Update of the 2005 Dietary Guidelines for Americans**...DHHS/USDA Staff
8. **DNRC Activities Update**
Nutrition Education Subcommittee.....Jean Pennington
Subcommittee on International Nutrition Research... ..Daniel Raiten
HNRIMJim Krebs-Smith
9. **Reports from NCC Members and Liaisons**.....NCC Members
10. **Next Meeting: February 3, 2005**.....Van Hubbard
11. **Adjournment**.....Van Hubbard

APPENDIX B. NCC MEETING ATTENDEES FOR JANUARY 6, 2005

Members Present Members Absent Alternates Present

Chairperson: V Hubbard

NIH Members:

NCI	J Milner		
NHLBI	D Danford		
NIDCR		R Nowjack-Rayner	
NIDDK	C Miles		R Kuczmarski
NINDS		M Mitler	
NIAID	M Plaut		
NIGMS		S Somers	
NICHD		G Grave	
NEI		N Kurinij	
NIEHS	E Maull		
NIA	J Finkelstein		
NIAMS	J McGowan		
NIDCD		B Wong	
NIMH		P Muehrer	
NIDA		G Lin	
NIAAA		V Purohit	R Breslow
NINR	Y Bryan		
NCCAM	M Klein		
NCRR	S Kayar		
FIC		N Tomitch	
NCHGR		K DeLeon	

NIH Liaison Members:

CC	N Sebring		
CIT		J Mahaffey	
CSR		S Kim	
NLM		S Phillips	
OBSSR		D Olster	
OC		M Stern	
ODS	P Coates		
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		D Klurfeld
DoD		K Friedl	

DNRC: W Johnson-Taylor, S Jennels, J Krebs-Smith, J Pennington, K Regan, L Somuah, P Starke-Reed

Guests: R Ballard-Barbash (NCI), W Barouch (NHLBI), B Bowman (CDC), TA Collins (NCI), C Davis (NCI), J Dwyer (ODS), A Ershow (NHLBI), S Krebs-Smith (NCI), S Perceval (NCI), MF Picciano (ODS), S Ross (NCI), H Seifried (NCI), M Sgambati (NCI), K Stitzel, T Tamura (U AL), R Troiano (NCI), J Weber (ODPHP), A Yaroch (NCI)

APPENDIX C. OFFICE OF DIETARY SUPPLEMENTS 2005 SPRING SEMINAR SCHEDULE

11:00 AM to 12:00 Noon

January 19, 2005

Tsunenobu Tamura, M.D.

Professor, Department of Nutritional Sciences

Visiting Scientist from the University of Alabama Birmingham

Office of Dietary Supplements

National Institutes of Health

Topic: Prenatal Zinc Supplementation, Fetal Growth and Neurodevelopment in Early Childhood

Location: 6100 Executive Blvd., Room 2B03

February 9, 2005

James Harnly, Ph. D.

Research Leader, Food Composition Laboratory

Beltsville Human Nutrition Research Center

Agricultural Research Service

US Department of Agriculture

Topic: Flavonoid Analysis: The Bitter and the Sweet

Location: 6100 Executive Blvd., Room 2B03

March 9, 2005

Irvin H. Rosenberg, M.D.

Senior Scientist and Director, Nutrition and Neurocognition Laboratory

Jean Mayer USDA HNRCA at Tufts University

Topic: Vitamin B-12, Folate and Cognitive Performance

Location: Neurosciences Building, Room TBD

April 13, 2005

Barry Halliwell, Ph. D.

Director, Graduate School of Integrative Science and Engineering

The National University of Singapore

Topic: The Antioxidant Paradox: Implications for use of Dietary Supplements

Location: Neurosciences Building, Room TBD

May 11 or 18, 2005

Speaker: TBD

Topic: TBD