MINUTES OF THE NUTRITION COORDINATING COMMITTEE (NCC) MEETING, NATIONAL INSTITUTES OF HEALTH (NIH)
Rockledge 2, Conference Room 9100-1904, Bethesda MD
July 1, 2004, 2:00-4:05 PM

WELCOME

Dr. Van Hubbard, Director, Division of Nutrition Research Coordination (DNRC), convened the NCC Meeting at 2:00 PM and welcomed the participants. The agenda for the meeting is provided as Appendix A, and the list of attendees is provided as Appendix B. Participating via phone were Ms. Mary Lou Valdez, Office of Global Health Affairs, Office of the Secretary, Department of Health and Human Services (DHHS) in Washington DC; Dr. Deborah Olster, NIH Office of Behavioral Sciences and Social Research (OBSSR) in Bethesda, Maryland; Dr. Jenna Seymour, Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia; Dr. Elizabeth Maull, National Institute of Environmental Health Sciences (NIEHS) in Triangle Park, North Carolina; Tammie Brown, Indian Health Service (IHS) in Albuquerque, New Mexico; Dr. Shirley Blakely, Food and Drug Administration on detail in Natick, Massachusetts, and COL Karl Friedl, Department of Defense (DOD) in Natick, Massachusetts.

Dr. Hubbard announced that the DNRC Secretary, Ms. Sharon Frazier, will be retiring at the beginning of September 2004 and noted that a flyer had been distributed about a luncheon in Ms. Frazier's honor to be held on September 1, 2004. Ms. Frazier has been instrumental in organizing and setting up the NCC meetings for the past six years. Please contact Dr. Wendy Johnson-Taylor, DNRC, for more information about the luncheon.

APPROVAL OF MINUTES FROM THE MAY 6, 2004 NCC MEETING

Minutes from the May 6, 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, NIH 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.

NIEHS MEETING ON OBESITY AND THE BUILT ENVIRONMENT

Dr. Elizabeth Maull, NIEHS, provided a report on the *Obesity and the Built Environment Meeting*, which was held in Washington DC on May 24-26, 2004. This meeting was intended as a multidisciplinary conference and focused on how the built environment affects public health in relation to obesity in a variety of settings, including the family; urban, suburban, or rural residential communities; schools; and work sites. Topics discussed included how different environments contributed to obesity via access to food and physical activity, and how environmental health research and interventions can reduce obesity through workplace design, public policy, communication, and education. The goals of the meeting were to develop research and practice agendas to examine the

relationships between the built environment and obesity; to enhance interagency coordination; to provide information to elected officials; and to highlight evidence-based strategies for intervention.

After opening remarks from DHHS Secretary Tommy Thompson, DHHS; Dr. Elias Zerhouni, Director, NIH; Dr. Samuel Wilson, Deputy Director, NIEHS; and Dr. Allen Dearry, Associate Director for Research Coordination, Planning, and Translation, NIEHS, the meeting began with a session titled *Federal Activities Addressing Environment and Obesity* with representatives from the US Environmental Protection Agency, the Federal Highway Administration, the United States Department of Agriculture (USDA), the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, the US Department of Housing and Urban Development, and the NIH (represented by the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK)). Keynote addresses were given by the former Secretary of DHHS, the Honorable Louis Sullivan (*Addressing Health Disparities*); the Former Surgeon General and Assistant Secretary of DHHS, Dr. David Satcher (*Addressing the Overweight/Obesity Epidemic: the Role of the Environment*); and Dr. James Hill (*Addressing the Environment to Reduce Obesity*).

The meeting was structured around three plenary sessions exploring the impact of schools; communities and families; and worksites, employers and employees on obesity. Three break-out sessions discussed the state of the science, setting the research agenda, and developing intervention strategies. A report on the meeting should be available by late August. Additional details may be found at http://www.niehs.nih.gov/drcpt/beoconf/home.htm.

The NIEHS currently has a *Draft Request for Applications (RFA) for Obesity and the Built Environment*. This RFA was submitted to ENS several weeks ago and is planned for release this month. The initiative will support both R01s and R21s related to the built environment and obesity. Special requirements call for interdisciplinary partnerships consisting, at a minimum, of a scientist with expertise in health research, a clinical specialist, and an expert on planning, design, or transportation. Participating organizations include NCI, the National Institute for Child Health and Development (NICHD), and OBSSR. The participating institutes intend to commit approximately $4.35 M in fiscal Year 2005 to fund 10 to 12 new and/or competitive continuation grants. The RO1 mechanism may request a project period of up to five years and a budget for direct costs of up to $500,000 per year. The R21s are restricted to a two-year period with a combined budget for direct costs of up to $275,000.

WHO GLOBAL STRATEGY ON DIET, PHYSICAL ACTIVITY, AND HEALTH (MAY 2004 WORLD HEALTH ASSEMBLY)

Ms. Mary Lou Valdez, DHHS Office of Global Health Affairs, Office of the Secretary, discussed the World Health Assembly (WHA) Global Strategy on Diet, Physical Activity and Health. The 57th WHA, which was held in May 2004, adopted resolution 57.17 which endorsed the World Health Organization's Global strategy on diet, physical activity and health, and annexed the Strategy to the resolution as a package, to avoid negotiation of the Strategy itself by Member

States. Leading up to the 57th WHA, the US played a critical role (1) by providing a technical review of *Report of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases* (Report 916) which was published by WHO and FAO in April 2003 and which served as one of several process inputs into the development of the Global Strategy; and (2) in advocating for additional time for Member States to review and provide comments to the draft version of the Global Strategy presented to the WHO Executive Board in January 2004, to be considered for a second draft version which would be submitted for subsequent consideration by WHA. Interest was high with approximately 68 Member States providing interventions on the agenda item. Negotiations on the resolution spanned over a two-day period. The US was viewed as an honest broker between developed and developing countries, seeking balance on a range of concerns while keeping public health at the forefront of the discussion.

UPDATE OF THE NIH OFFICE OF DIETARY SUPPLEMENTS (ODS)

Dr. Paul Coates, Director ODS, provided the following information. ODS is taking the lead for an NIH State-of-the-Science Conference on the role of multivitamins/multiminerals in the prevention of chronic disease, under the auspices of the Office of Medical Applications of Research (OMAR). A number of NIH Institutes and Centers (ICs) have already participated or have expressed interest in participating in the process, including the National Institute on Aging (NIA), NIDDK, National Institute of Mental Health (NIMH), National Institute of Child Health and Human Development (NICHD), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Center for Complementary and Alternative Medicine (NCCAM), National Institute of Neurological Disorders and Stroke (NINDS), National Eye Institute (NEI), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), as well as DNRC. Dr. Michael McGinnis, former DHHS Deputy Assistant Secretary of Health, has agreed to chair the independent panel for the Conference. OMAR is in the process of setting up a planning meeting for the Conference this fall. Planning meeting participants will decide on questions to be addressed in an AHRQ evidence-based review, expert speakers for the Conference, as well as panel members. It is anticipated that the State-of-the-Science Conference will be held in the fall of 2005.

On June 28 and 29, 2004, a workshop was held by ODS and the National Center for Health Statistics (NCHS) to assess the potential impact of changes in methodology for folate and vitamin B-12 monitoring in the National Health and Nutrition Examination Survey (NHANES) and to develop a strategy for transition to replacement methods. The method currently employed for folate and vitamin B-12 monitoring (Bio-Rad QuantaPhase II radioassay) will be available through 2006, but the length of its availability after that time is uncertain. Data needs were identified to facilitate the eventual change in methodology, including comparison studies and additional evaluation of data from NHANES III and NHANES 1999-2000. A report will be prepared and made available. Copies of

the Agenda and List of Participants are attached to these minutes as Appendices C and D, respectively.

ODS, NCCAM, and NIEHS recently issued an RFA for re-competition of their Botanical Research Centers Program. In response to the RFA, 22 applications were received in June 2004. They will be peer-reviewed by NCCAM's Office of Review in October-November 2004 and be presented to Council in January 2005 with funding of successful Centers possibly in April 2005. Other ICs and Offices are welcome to participate in this program. In the past, both the National Institute of General Medical Sciences (NIGMS) and the Office of Research on Women's Health (ORWH) contributed significant funding for these Centers. For further information about the program, please contact Dr. Christine Swanson in ODS.

UPDATE OF THE DIETARY GUIDELINES ADVISORY COMMITTEE

Ms. Kathryn McMurry, DHHS Office of Disease Prevention and Health Promotion (ODPHP), and Dr. Eric Hentges, USDA Center for Nutrition Policy and Promotion (CNPP), provided an update on activities relating to the *2005 Dietary Guidelines for Americans*. The Dietary Guidelines Advisory Committee (DGAC) had their fourth meeting on May 26-27, 2004 at the Holiday Inn in Bethesda, Maryland. The fifth meeting of the DGAC will be held on August 11 (location not yet known), and the final draft DGAC report is due by the end of August 2004. The report will be reviewed by agencies within DHHS and USDA during September 2004, and public release is still scheduled for early 2005. After the release of the DGAC report, there will be a 30-day public comment period. Staff members from DHHS and USDA will develop a policy document from the DGAC report, and this policy document will be peer reviewed by a small group of DHHS and USDA representatives.

Ms. McMurry gave an overview of the general directions of the DGAC report, which include a greater emphasis on consumption of fruits, vegetables, whole grains and fish; greater emphasis on energy balance and physical activity; emphasis on limiting trans fat as well as saturated fat and cholesterol; and decreased consumption of sodium/salt. It appears there may be a separate recommendation concerning sugar consumption. There are likely no major changes from the 2000 Dietary Guidelines with regard to recommendations regarding alcohol or food safety. Dr. Hubbard noted two specific issues (1) much of the data used for the DGAC report is from group/population data; however, the guidelines are intended for individuals; and (2) consumers do not understand how to keep their calorie intake within their calorie limit.

Ms. Chris Dobday, ODPHP, provided an overview of the development of the nutrition education materials for the new Dietary Guidelines. She noted that her staff will be working closely with USDA and also with the Dietary Guidelines Workgroup. The communication materials will be developed by a contractor; the award is to be made in July 2004. Some education materials will be provided with the January 2005 launch of the DGAC report.

UPDATE OF THE US FOOD GUIDANCE SYSTEM

Dr. Hentges provided an overview of the work being done by CNPP is revising the USDA food guidance system. A *Federal Register* notice, released in September 2003, provided the technical basis for the food groups. CNPP received 255 comments on this notice. Clearance on a second *Federal Register* notice is pending, and it should be published within the next two weeks. This notice will ask for comments regarding the communication and education of food guidance information as well as potential changes to the food guidance graphic. There will be a 45-day comment period for this notice and a public meeting in Washington DC. The comments will be posted on the CNPP website. The development of the new food guidance material is closely tied to the Dietary Guidelines policy document and the communication materials, and it is essential that they all be harmonized.

PROCESS FOR DEVELOPMENT OF POLICY AND PUBLIC DOCUMENTS

Ms. McMurry and Dr. Hubbard briefly reviewed the Congressional mandate and process for the review of DHHS and USDA nutrition education materials with reference to consistency with the Dietary Guidelines. A 2002 publication in the *Journal of Nutrition Education* (volume 34, pages 53-58) describes the NIH and DHHS/USDA review of nutrition education materials and is available, on request, from the DNRC Office.

UPDATE OF DNRC ACTIVITIES

Nutrition Education Subcommittee. Dr. Jean Pennington, DNRC, provided an update of the activities of the NIH Nutrition Education Subcommittee (NES). The NES has a new member, Karen Regan, DNRC. For 2004, the NES has received 18 documents for review (ten from NIH, two from CDC, one from the Administration on Aging (AOA), two from Health Research and Services Administration (HRSA), one from the DHHS, and two from USDA). Documents reviewed or under review since the last NCC meeting include:

- Healthy Women Build Healthy Communities Brochures (HRSA)
- Holiday Calendar Message (CDC)
- 5 A Day Quiz for Men's Health Month (NCI)
- Facts About Postmenopausal Hormone Therapy (NHLBI)
- Small Steps Ideas (DHHS)

Human Nutrition Research Information Management (HNRIM) System.

Ms. Karen Regan, DNRC, indicated that the collection and review of HNRIM data for Fiscal Year 2003 were nearly complete and that ODS has completed its review of dietary supplement coding for the HNRIM projects. Most of the ICs have responded to the ODS code requests; those that have not provided data will receive a notice next week.

SubCommittee on International Nutrition Research (SCINR). Dr. Daniel Raiten, NICHD and Dr. Rachel Nugent, Fogerty International Center (FIC), shared plans for a workshop on the international implications of obesity. The proposed focus

of this workshop would be on the measurement of body mass index/body composition and relative implications for health across international settings.

REPORTS FROM NCC MEMBERS AND LIAISIONS

Dr. Sue Krebs-Smith, NCI, announced that she was working with Dr. Paul Sorlie of the National Heart, Lung and Blood Institute (NHLBI) to develop a Community NHANES-like project. They will have an extensive baseline on four groups of Hispanic individuals (4,000 in each group) and will follow them over time. There will be a large nutrition component for this project. Dr. Hubbard will provide information to NCC members as the work progress. Appendix E provides a description of this NHLBI Initiative, "Epidemiologic Research in Hispanic Populations." Those interested in this activity may contact Dr. Sorlie or Dr. Krebs-Smith.

Dr. Vishnudutt Purohit, NIAAA, announced that the proceedings from a meeting on alcohol and fatty liver will be published in September 2004 and that there is an upcoming meeting on alcohol and cancer on October 6-7, 2004. A number of ICs are involved (ODS, NCI, NIDDK, NIDA). The meeting will include discussion of the role of nutrient supplementation with respect to cancer as well as chronic effects of alcohol on the upper GI tract. International speakers have been invited. Dr. Sharon Ross, NCI, is a co-organizer of the conference.

Dr. Raiten, NICHD, noted that two recent news articles in the *Washington Post* and the *New York Times* discuss a recent paper in the *New England Journal of Medicine* on nutrition and HIV. He urged NCC members to read the articles and expressed concern about policy being made from one study. Dr. Nugent, FIC, provided copies of the newspaper articles to NCC members. Contact Drs. Raiten or Nugent if you would like to have further discussion on this topic.

Dr. Cindy Davis, NCI, announced a workshop on the Merits of Lycopene which is scheduled for March 2005. Several NIH ICs are involved (NCI, ODS) as well as USDA.

Dr. Wayne Wolf, ARS/USDA, said that there would be a new and permanent ARS liaison to the NCC after August 2004.

Ms. McMurry, ODPHP, announced that ODPHP was moving to the Tower Building in Rockville, Maryland.

NEXT NCC MEETING

There will not be a NCC Meeting in August; the next NCC Meeting is scheduled for September 2, 2004. Dr. Karl Friedl, DOD, will provide a presentation at the next NCC meeting on DOD nutrition research and interaction with NIH.

ADJOURNMENT

The meeting was adjourned at 4:05 PM.

LIST OF APPENDICES

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APPENDIX A. NIH NCC MEETING AGENDA FOR JULY 1, 2004

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

1. **Welcome**……Van Hubbard
2. **Approval of May 6, 2004 NCC Meeting Minutes**……Van Hubbard
3. **NIEHS Meeting on Obesity and the Built Environment**…….Elizabeth Maull
4. **WHO Global Strategy on Diet, Physical Activity, and Health (May 2004 World Health Assembly)**……..Mary Lou Valdez
5. **Office Dietary Supplements Update**……..……...Paul Coates
6. **Update of the Dietary Guidelines Advisory Committee**….Kathryn McMurry, Eric Hentges, and Chris Dobday
7. **Update of the US Food Guidance System**……...Eric Hentges
8. **Process for Development of Policy and Public Documents**……Kathryn McMurry and Van Hubbard
9. **DNRC Activities Update**
   - Nutrition Education Subcommittee…….……..…….. ..Jean Pennington
   - HNRIM Update…….…… …Karen Regan
   - Subcommittee on International Nutrition Research……..Daniel Raiten
10. **Reports from NCC Members and Liaisons**……..……..NCC Members
11. **Next Meeting:** tentatively September 2, 2004……..……Van Hubbard
12. **Adjournment**……...Van Hubbard

APPENDIX B. NCC MEETING ATTENDEES FOR JULY 1, 2004

	Members Present	Members Absent	Alternates Present
Chairperson:	V Hubbard		
NIH Members:			
NCI	J Milner		
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 Finkelstein	
NIAMS		J McGowan	
NIDCD		B Wong	
NIMH		P Muehrer	
NIDA		G Lin	
NIAAA	V Purohit		
NINR		K Helmers	
NCCAM		M Klein	
NCRR		F Taylor	
FIC		N Tomitch	
NCHGR		K Hudson	
NIH Liaison Members:			
OD/ODP	B Portnoy		
CC		N Sebring	
CIT		J Mahaffey	
CSR	S Kim		
OLPA			
NLM		S Phillips	
OC		M Stern	
ODS	P Coates		
PRCC		M Vogel-Taylor	
OBSSR	D Olster		
Agency Liaison Representatives:			
FDA			S Blakely
CDC/NCHS		M McDowell	
CDC/NCCDPHP		S Kuester	
HRSA		M Lawler	
HIS	T Brown		
ODPHP	K McMurry		
USDA		T Kramer	
DOD	K Friedl		

DNRC: S Frazier, W Johnson-Taylor, J Pennington, K Regan, P Starke-Reed

Guests: R Ballard-Barbash (NCI), P Bocek (NIAID), C Davis (NCI), C Dobday (ODPHP), E Hentges (CNPP, USDA), D Howard (FDA on detail to ODPHP), S Kayar (NCRR), W Kessel (ODPHP), Y Kim (NCI), K Kolsky (NIA), S Krebs-Smith (NCI), R Nugent (FIC), E Rodas (NIDCD), S Ross (NCI), J Seymour (CDC), K Stitzel (ODPHP), R Trioano (NCI), D Vafiadis, (CNPP, USDA), J Webber (ODPHP), W Wolf (ARS, USDA)

APPENDIX C – AGENDA FOR THE NHANES FOLATE AND VITAMIN B-12 ASSESSMENT WORKSHOP

Folate and Vitamin B-12 Assessment Workshop
Doubletree Hotel
1750 Rockville Pike
Rockville, MD, US 20852.
June 28th and 29th, 2004

Brief Background

Folate and vitamin B-12 nutritional status are evaluated in the National Health and Nutrition Examination Survey (NHANES) from measures of intakes (foods and dietary supplements) and various analytes (serum and red blood cell folates, serum vitamin B-12, plasma homocysteine and methylmalonic acid).

Currently, NHANES employs the Bio-Rad QuantaPhase II radioassay (Bio-Rad Laboratories, Hercules, CA). for measurement of serum and red cell folates. This assay also permits the simultaneous measurement of serum B-12. According to the manufacturer, the Bio-Rad QuantaPhase II radioassay will be available through 2005. This means that a replacement assay may be needed in 2006 and beyond.

NHANES provides data for folate and vitamin B-12 status on a continuous basis for a representative sample of non-institutionalized citizens of the US (approximately 5,000/year). Thus, data from folate and B-12 assays must be interpretable in a manner consistent with previously collected folate and B-12 data from the methodologies used in previous NHANES. To this end, an appropriate strategy must be developed to permit continued valid interpretability of folate and B-12 nutritional status for both insufficiencies and excesses.

Nutritional monitoring for folate status post folic acid fortification remains exceedingly important not only for women of reproductive age but also for children and persons of all ages to assess the possibility of unsafe levels of intake. Nutritional monitoring for vitamin B-12 status, particularly among the elderly, is similarly important. An important corollary issue is the dietary source of folate and B-12(foods, fortified foods and dietary supplements) within population subgroups.

Fundamental Purpose of the Workshop

The Office of Dietary Supplements (ODS) is seeking additional information on which to base its decision about supporting collection and analyses of these nutritional biochemistries in future NHANES and their usefulness in evaluating public health issues related to these nutrients. The major factor influencing ODS's decision is the extent to which methodological changes may impact the ability to interpret time trend data for public health purposes.

Goal of the Workshop

Provide a basis for meaningful evaluation of folate and vitamin B-12 status in continuous NHANES and to continue to track changes over time since NHANES II.

Objectives of the Workshop

1. To identify potential replacement methods for biochemical assessment of folate and vitamin B-12 status and to assess their relative strengths and weaknesses. Evaluation criteria to include collection and management issues (sample size, handling and storage conditions, sample stability, cost, number of samples that can be analyzed per unit of time, etc.) and methodological issues (robustness, specificity, validity, accuracy, reproducibility, etc.).

2. To determine interpretability and address issues of comparability among various methods used in NHANES over time and across a range of values.

3. To develop a strategy for transition to candidate replacement methods (data needs).

4. To identify research needs and strategies to improve interpretation and strengthen ability to link monitoring data to functional/health outcomes.

5. To identify collaborative and confirmatory measures in addition to serum and red cell folates and serum B-12 that are essential for accurate determination of deficiency/toxicity. Candidate measures to include but are not limited to homocysteine, methylmalonic acid and creatinine.

Tentative Program

Monday, June 28th

8:15-8: 30	Welcome and brief overview of the purpose of the workshop Mary Frances Picciano
8: 30-8:45	Charge to the workshop Kenneth Fisher, Chair
8:45-8:55	Development of databases for dietary supplement Ingredients Johanna Dwyer
8:55-9:00	Q and A
9:00-9:20	History and evolution of folate and B-12 methodology in NHANES Barbara Bowman/Elaine Gunter
9:20-9:30	Q and A
9:30-10:20	Validation as a process Richard A. Grazzini
10:20-10:30	Q and A
10:30-10-45	Coffee break
10:45-11:15	Development of a new *Standard Reference Material* for homocysteine and folate in human serum Michael J. Welch
11:15-11:25	Q and A
11:25-11:35	What we have learned from folate and vitamin B-12 monitoring in NHANES: A review of the literature Susan Pilch
11:35-11:45	Q and A
11:45- 1:00	Lunch
1:00-1:15	Available methods for assay of folates in serum and red blood cells and selected characteristics T. Tamura
1:15-1:25	Q and A

1:25-1:40 Available methods for serum vitamin B-12 and selected characteristics
Donald W. Jacobsen

1:40-1:50 Q and A

1:50-3:00 Summary of Centers for Disease Control and Prevention/ National Center for Environmental Health/ Division of Laboratory Sciences recommendations for folate and vitamin B-12 methods for NHANES 2005-2006 and review of evidence to support recommendations
Christine Pfeiffer

1) NHANES 1999-2000 data:
Population distributions and references ranges for folate, vitamin B12, homocysteine, and methylmalonic acid as well as a comparison between post- and pre-fortification data for folate and vitamin B12.

2) Folate/vitamin B12:

CDC isotope-dilution LC/MS/MS method for serum folates
CDC isotope-dilution automated LC/MS/MS method for serum and whole blood folates

- Summary of experiments on whole blood folate extraction, Method comparison between CDC LC/MS/MS, microbiological assay and BioRad assay for serum and whole blood based on ~100 NHANES samples,
- Comparison of CDC LC/MS/MS folate results to results obtained by NIST LC/MS/MS method for preliminary serum SRM material,
- Characteristics of CDC LC/MS/MS method, microbiological assay and BioRad assay with regard to NHANES 2005-2006 or research projects (cost, throughput, reportable range).

3:00-3:30 Coffee break

3:30- 4:30 Continued discussion of CDC data

4:30-5:00 Summary Remarks

Tuesday, June 30th

8:30-8:45	Charge for the day Kenneth Fisher
8:45-10:15	Discussion of questions associated with each objective
10:15-10:30	Coffee Break
10:30-12:00	Continued discussion of questions associated with each objective
12:00-1:00	Lunch
1:00-2:00	Tentative conclusions
2:00-3:00	Workshop summary and next steps
3:00	Adjournment

Questions to be addressed by Workshop Participants (DRAFT 6/14/04)

Obj # 1

1. What, other than the issue of availablility in 2005-2006, are the strengths and weaknesses of the BioRad kit in terms of 1) folate measurement; 2) B12 measurement?

2. Assuming the grids developed and reviewed yesterday identified needed evaluation criteria in two sets, sample management and methodology, is there agreement on the definition of the terms used to define the factors in the criteria?

3. Based upon the grids themselves, which of the methods that might be considered should be those considered in the highest tier of priority and why?

Obj # 2

1. What are the advantages and limitations to interpretability of each of the methods identified as those in the highest tier of priority?

2. What are the factors that need to be considered when comparing the interpretability of data among methods? Are these the same or are there other factors related to intrepretability over time?

Obj# 3

1. Assuming a change in method is justified for 2005-2006, what needs to be done, or what are the data needs to establish validity, and interpretability of data among past, current, and future assays of folate and B12 status?

2. Outline the sequence of the steps of the strategy in regard to how they can be accomplished.

3. Identify the specific studies or data that are needed, and then the statisical approaches to evaluation of these studies and data sets? What criteria should be used to establish if and when the goals of the strategy have been met?

Obj# 4

1. Focusing on the public health aspects of folate and B12 status, what functional outcomes should be considered as critical in assessing the impact (influence) of folate or B12 biochemical indices? Identify the data that establish or indicate linkage; or, in the absence of adequate data, what studies are needed to strengthen interpretabilitty and linkage?

Obj# 5

1. What additional analytes and/or other parameters should measured separately to enhance interpretability of measures of folate and vitamin B-12 status in the context of public health monitoring?
   a. other serum factors
   b. other RBC factors
   c. possible functional/health outcomes?
   d. etc.

and then their separate relationships to 1) serum folate 2) RBC folate and 3) serum B12, and clinical states of deficiency, adequacy and toxicity.

APPENDIX D. PARTICIPANT LIST FOR THE NHANES FOLATE AND VITAMIN B-12 ASSESSMENT WORKSHOP

NHANES: Folate and Vitamin B_{12} Assessment Workshop

June 28-29, 2004

Doubletree Hotel

1750 Rockville Pike
Rockville, MD

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APPENDIX E. DESCRIPTION OF THE NHLBI INITIATIVE "EPIDEMIOLOGIC RESEARCH IN HISPANIC POPULATIONS"

Initiative: Epidemiologic Research in Hispanic Populations

Primary Institute: NHLBI
Other Institutes: NCI, NIDCR, NIDDK, NIAMS, OD/ODS, NCHS

Introduction In response to a working group held in July, 2003, the NHLBI is developing an initiative to study the risk of cardiovascular and lung diseases in diverse Hispanic populations. A prospective cohort study in communities of Hispanics would permit estimation of both the prevalence of disease and risk factors, but also allow investigation of unique risk factors for development of disease.

Rationale The Hispanic population is now the largest minority population in the US with a projected growth of three fold by 2050. It is influenced by factors which are not found in other US population groups including changes in diet, activity, stress, community support, working conditions, and health care access associated with immigration from different cultural settings and physical environments. It is experiencing increasing obesity, higher risks of diabetes, and changes in social and behavioral factors with large potential impact on disease.

Design To achieve the goals of the NHLBI, the current proposal recommends studying 4,000 men and women, age 45-74, in each of four major Hispanic groups (Mexican Americans, Puerto Ricans, Cubans, and Central/South Americans) resulting in a total of 16,000 participants. The current proposal recommends one comprehensive examination, and subsequent follow-up for incidence of CVD. If recommended for continuation, a repeat examination would be proposed six years after the initial examination to assess changes in risk factors and behaviors over time. Baseline data to be collected will include standard CV risk factors; a comprehensive nutritional assessment; blood stored for future studies; measures of acculturation, behavior, and physical activity; and anthropometry.

Collaboration Since this proposed study encompasses research goals of many Institutes, a consortium of interested Institutes, Centers and Offices has come together to discuss potential collaboration. This consortium has discussed aspects of study design and ways that this study could achieve the research goals of each participating organization. For example, the study could be expanded to younger ages, could include other components (e.g. a dental examination, arthritis examination), could include other questionnaires for specific research goals (e.g. a detailed dietary supplement questionnaire), and could include other detailed laboratory measurements.

Implementation If multiple partners expressed a commitment to this research, the NHLBI could coordinate the issuance of an RFP with collaboration and support from these other Institutes, Centers and Offices. At this time, all plans are still tentative, but because of many shared interests, collaboration with additional Institutes is encouraged.

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