

**Department of Health and Human Services
National Institutes of Health
National Institute of Nursing Research
Minutes of the National Advisory Council for Nursing Research**

January 25–26, 2005

The 55th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, January 25, 2005, at 1:15 p.m. in Conference Room 6C10, Building 31, National Institutes of Health (NIH), Bethesda, Maryland. The first day of the meeting adjourned at approximately 5:10 p.m., at which time the open session also adjourned. The closed session of the meeting, which included consideration of grant applications, continued the next day, January 26, 2005, at 9:00 a.m., until adjournment at 11:50 am on the same day. Dr. Patricia A. Grady, Chair of the NACNR, presided over both sessions.

OPEN SESSION

**I. CALL TO ORDER, OPENING REMARKS, COUNCIL PROCEDURES, AND
RELATED MATTERS**

Dr. Grady called the 55th meeting of the NACNR to order, welcoming all Council members, visitors, and staff. She noted that the National Institute of Nursing Research (NINR) will turn 20 in 2006 and that plans for a year-long celebration are underway.

Conflict of Interest and Confidentiality Statement

Dr. Claudette Varricchio, NACNR Executive Secretary and Assistant Director, NINR, reminded attendees that the standard rules of conflict of interest applied throughout the Council meeting.

Briefly, all closed session material is privileged, and all communications from investigators to Council members regarding any actions on applications being considered during the Council should be referred to NINR staff. In addition, during either the open or the closed session of the meeting, Council members with a conflict of interest with respect to any topics or any application must excuse themselves from the room and sign a statement attesting to their absence during the discussion of that application. Dr. Varricchio also reminded NACNR members of their status as special Federal employees while serving on the Council, and that the law prohibits the use of any funds to pay the salary or expenses of any Federal employee to influence State legislatures or Congress. Specific policies and procedures were reviewed in more detail at the beginning of the closed session and were available in Council notebooks.

Minutes of Previous Meeting

Council members received a copy of the minutes of the September 14–15, 2004, Council meeting by electronic mail. No changes or corrections to the minutes of the September 2004 Council meeting were suggested during the September meeting. A motion to approve the minutes of the September 2004 Council meeting as circulated was proposed and seconded. Comments, corrections, and changes identified after the current meeting should be forwarded to Dr. Grady. The minutes of each quarterly NACNR meeting are posted on the NINR Web Site (<http://ninr.nih.gov/ninr>).

Dates of Future Council Meetings

Dates of meetings in 2005 and 2006 have been approved and confirmed. Council members should contact Dr. Grady regarding any conflicts or expected absences. Dates for 2007 will be announced at the next Council meeting.

2005

- January 25–26 (Tuesday–Wednesday)
- May 17–18 (Tuesday–Wednesday)
- September 13–14 (Tuesday–Wednesday)

2006

- January 24–25 (Tuesday–Wednesday)
- May 24–25 (Wednesday–Thursday)
- September 26–27 (Tuesday–Wednesday)

II. REPORT OF THE DIRECTOR, NINR (Dr. Patricia Grady, Director, NINR)

The Director's report focused on updates since the last Council meeting and on current and impending activities and initiatives related to the budget, NIH, and NINR.

Budget Updates—The FY2005 budget bill was signed into law on December 8, 2004. It includes a 2.5 percent increase to NINR, compared with a 2.1 percent overall increase to NIH; the increase to NINR also is slightly above the mean for most other Institutes and Centers (ICs). The total allocation to NINR is \$138,054,000. This represents a significant increase since the Institute was established as a Center in 1986 with an annual budget of \$16 million. As Dr. Grady noted, the landscape has changed considerably since 2002, the year that marked the completion of the doubling of the NIH budget. We are now in more of a steady state budget period. An

indication of the FY2006 budget for the Federal government will begin to take shape around the time of the President's State of the Union address in February.

The distribution of NINR's budget is consistent with previous years. Approximately 75 percent of the NINR FY2005 budget will fund extramural research project grants (RPGs); other research (e.g., K awards) comprises 3 percent; and the Centers programs receive approximately 5–6 percent. Research management and support comprises 6 percent; research and development accounts for 2 percent; and the intramural program will receive slightly more than 1 percent. Research training remains at 8 percent, which is approximately twice the NIH average percent of budget allocated for training. Dr. Grady pointed out that NINR is consistently among the top three ICs with the highest percent of budget dedicated to training.

NIH Policies for Managing Conflicts of Interest—Last June, NIH Director Dr. Elias Zerhouni gave testimony regarding NIH's Policies for Managing Conflict before Congress' Commerce and Energy Committee. This followed the establishment in January, 2004 of a Blue Ribbon Panel on Conflict of Interest (CoI). The goal of this panel was to review existing NIH regulations and policies regarding (a) compensation or financial benefit from outside sources, including consulting arrangements and outside awards, and (b) requirements for the reporting of NIH staff's financial interests. The Panel's final report, which includes 17 recommendations, was submitted to the Advisory Committee to the NIH Director on May 6, 2004. (The complete report is available at http://www.nih.gov/about/ethics_COI_panelreport.htm.) A key challenge in this process involves striking a balance between maintaining access to NIH's intellectual expertise and protecting all parties while avoiding becoming isolated from outside activities and collaborations that strengthen and complement this expertise. A new NIH Ethics Advisory

Committee, chaired by NIH Deputy Director Dr. Raynard Kington, is reviewing all outside activities of NIH employees. At the time of the Council meeting, NIH employees were under a moratorium for engaging in new activities. NINR is similarly reviewing conflict of interest issues, policies, and requirements within the Institute. Oversight of ethics activities is the responsibility of the NIH Deputy Ethics Counselor, who receives feedback from each IC. The NIH COI Information and Resources Web Site is located at http://www.nih.gov/about/ethics_COI.htm.

The NIH Roadmap—An NIH-wide initiative launched by Dr. Zerhouni, the NIH Roadmap, provides a framework for the priorities the NIH must address to optimize its entire research portfolio (<http://nihroadmap.nih.gov>). The Roadmap is designed to transform the Nation's medical research capabilities, speed the movement of research discoveries from the bench to the bedside, and initiate research from the bedside to the bench. The three main themes of the NIH Roadmap are New Pathways to Discovery, Research Teams of the Future, and Re-Engineering the Clinical Research Enterprise. Associated with each theme is a series of working groups to address specific issues related to that theme. The Roadmap, which is part of a 5-year initiative, just celebrated its 1-year anniversary, and as Dr. Grady pointed out, considerable progress has been made during the past year. The first round of awards has been made, and plans for future activities and research initiatives are underway.

Dr. Grady serves as a co-chair on the Interdisciplinary Research Working Group, which falls under the Research Teams of the Future theme; the other two working groups in this theme focus on high-risk research and public-private partnerships. Interdisciplinary research awards include planning grants for interdisciplinary research centers (P20 Centers) which provide funding for 3

years; innovative training programs which include funding through the postdoctoral level and provide for research plus training in the same vehicle (e.g., the T90); and the development of methodologies aimed at integrating behavioral and social science into interdisciplinary research. The announcement for the P20 Exploratory Centers for Interdisciplinary Research awards was very well received, with more than 300 applications; of these, only 21 were funded. The Centers program was established to lower barriers that impede research, enable scientists to conduct research across disciplines, and create an environment where groups of investigators can more easily establish collaborations. A working group has helped resolve issues as they arise, such as academic promotion and tenure and distribution of overhead funds. One notable outcome of this program is that projects and publications may now have several key investigators rather than just one principal investigator.

NIH Public Trust Initiative—Another new NIH initiative is the NIH Public Trust Initiative, the goal of which is to improve the public health by promoting public trust in biomedical and behavioral research. The initiative is co-chaired by Dr. Grady and Dr. Yvonne Maddox, Deputy Director, National Institute of Child Health and Human Development (NICHD). It interfaces with and extends beyond the NIH Roadmap. The NIH Public Trust Initiative includes two frameworks to house this trust: (1) a research spectrum framework, and (2) an NIH Roadmap framework. The research spectrum framework involves the process of scientific research and the public interface with the research process and spans discovery, communication, dissemination, and translation of research results. The NIH Roadmap framework interfaces with and addresses themes where the public trust can be emphasized and addressed. One of the key activities of this initiative involves working with representatives from the NIH Director's Council of Public Representatives (COPR). One joint effort was the April 2004 meeting titled "Enhancing Public

Input and Transparency in the National Institutes of Health Research Priority-Setting Process.”

More recently, in October 2004, representatives from the NIH Public Trust Initiative joined COPR to sponsor a large group of experts and the public to discuss and identify ways to increase public participation in clinical research by building trust through partnerships. A number of recommendations were identified during the meeting; a summary of the meeting and the recommendations are available online.

HHS and NIH Staff Updates—Michael Leavitt has been nominated to become Secretary of the Department of Health and Human Services (DHHS). Mr. Leavitt is currently serving as Administrator of the Environmental Protection Agency (EPA). Prior to his tenure at EPA, Mr. Leavitt was Governor of Utah. Dr. David Schwartz has been appointed as the new Director of the National Institute of Environmental Health Sciences (NIEHS). He comes to the NIH from Duke University; throughout most of his career, he has studied genetic and environmental influences on various lung diseases. In other news, Dr. David Abrams has been appointed Director of the Office of Behavioral and Social Sciences Research (OBSSR) within the Office of the NIH Director. Dr. Abrams is a clinical psychologist who comes to the NIH from Brown University.

NINR Updates and Outreach—One ongoing activity involves tracking publications of NINR-funded investigators. Staff identified 298 such publications in FY2004, an increase from the prior year that averages about one publication per grant. Staff also assist in the dissemination of NINR-funded research findings through two vehicles; to that end, capsule summaries of NINR-funded research received more than 3,000 hits per month on Medscape, and the Medpulse e-newsletter is sent to 300,000 nurses each week. Dr. Grady highlighted some of the advances in

nursing research that received attention in the media and/or among health care professionals. One body of work that identified gender differences in acute symptoms of heart disease was extensively reported in the popular media to help educate the public about women's symptoms, including shortness of breath, weakness, fatigue, cold sweat, and dizziness, which are distinct from the classic symptoms that men exhibit. Dr. Grady noted that these important findings are now being incorporated into physician training. Results of several other NINR-funded studies were widely disseminated in professional and public journals and media outlets. In looking ahead, the new areas of research opportunity on which NINR will be focused this year include addressing cognitive disorders, studying parenting capacities, improving health outcomes through biobehavioral methods, broadening end-of-life care research issues, and developing a workshop to address important research needs in multicultural research. These topics were reviewed and approved by the Council previously. NINR's Intramural Program Web page has been revised, and the overall NINR Web Site is being updated.

NINR Events and Activities—The 6th annual Summer Genetics Institute is scheduled for June 6–July 29, 2005. The deadline for registration is March 1; the application for the 8-week intensive course on the NIH campus may be downloaded from the NINR Web Site.

Approximately 80 “students” have graduated from the program. In other news, the State of the Science Congress on “Nursing Science: Working Toward a Healthier Nation” was held on October 7-8, 2004; Friends of the NINR (FNINR) events and NightinGala preceded the Congress on October 6, 2004, with keynote speaker Dr. Zerhouni, who spoke on “Nursing Research: The Profession's Commitment to Public Trust.” The events were very well received, with more than 1,200 persons attending the gala and dinner. Staff have been involved in several outreach activities in the past several months, including the Workshop on Increasing Opportunities in

Biobehavioral Research on July 15, 2004; the Cost-Effectiveness Analysis Workshop held on August 4–6, 2004; and the NIH State of the Science Conference on End-of-Life and Palliative Care held in December 2004, which was attended by more than 1,000 persons.

In other news, NINR turns 20 years of age in 2006. Plans for a year-long celebration are underway, with the anniversary kick-off occurring in conjunction with the CANS Conference in October 2005. Updates on events and activities will be posted on the NINR Web Site and announced at Council meetings. Staff will be contacting Council members and others for ideas and suggestions.

Questions/Comments

Regarding the current trend of funding at NIH and NINR, Council members inquired about future funding and how NINR plans to adjust to increasingly limited allocations. Dr. Grady noted that the NIH IC Directors are planning to meet in the near future to discuss budget issues. The goal of the Directors' budget retreat will be to come to some agreement on general principles first and then to specifics. There is some expectation that increased interdisciplinary efforts will improve the sharing of resources, reduce redundancy, and hopefully, expenses. Dr. Grady noted that these issues and trends underscore the importance of the Council's role in guiding NINR in its strategic planning and future research directions. She added that NINR has received reasonable funding levels, given the overall NIH allocation and the budget cuts received by other agencies. Although it is difficult to predict when funding levels might begin to increase again, Dr. Grady pointed out that budgetary profiles do tend to cycle. At this time, however, it is prudent to anticipate similar trends for the near future.

Investigator Awards—Dr. Grady reported that NINR-funded nurse researcher Dr. Linda Aiken was ranked number 10 among Modern Healthcare’s top 100. Dr. Aiken’s work links mortality, complications, and morbidity with nurse-patient ratios. She was quoted as saying that nursing research has “fundamentally changed the way people are thinking about the nursing shortage and its consequences.” Dr. Grady also reported that nurse researcher Dr. Victoria Champion was the recipient of the FNINR 2004 Pathfinder Distinguished Research Award for her work with patients with breast cancer.

NINR Staff Updates and Transitions—Dr. Claudette Varricchio will be departing NINR and NIH at the end of January. Dr. Varricchio has been with NINR for about 4 years and most recently has served as Assistant Director for NINR. Dr. Grady thanked Dr. Varricchio for her service and contributions to the Institute. Dr. Nell Armstrong will be transitioning to NINR’s Office of Science Policy and Public Liaison (OSPPL), where she will be coordinating a number of special projects. Also joining the OSPPL is Mr. Charles Sabatos, who will serve as Chief of OSPPL. Mr. Sabatos previously was with the National Center on Complementary and Alternative Medicine (NCCAM). Dr. Barbara Smothers has recently joined NINR as Chief of the Office of Extramural Programs, where she will be responsible for developing and supporting investigator-initiated applications in all aspects of nursing research consistent with the Institute’s mission. Dr. Smothers joins NINR from the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Another new member of the NINR staff is Dr. Sue Marden, who is a Senior Nurse Specialist with the Intramural Symptom Management Laboratory. Dr. Marden previously had oversight of various research projects at the Clinical Center.

Dr. Grady also announced the appointment of Dr. Mary E. Kerr as NINR's new Deputy Director. Dr. Kerr comes to NINR from the University of Pittsburgh Medical Center (UPMC), where she served most recently as UPMC Health System Chair in Nursing Science in the School of Nursing. During her career, Dr. Kerr has focused her research on preventing cerebral ischemia and maximizing cerebral perfusion in critically ill patients with neurologic conditions. She is particularly interested in identifying early biomarkers or physiologic parameters that help nurses identify individuals at risk for cerebral ischemia, including genetic-specific variation in an individual's response to and recovery from an acute neurologic condition such as traumatic brain injury or a ruptured cerebral aneurysm. As the NINR Deputy Director, Dr. Kerr will partner with Dr. Grady in planning, directing, and managing the programs and resources of the Institute. Dr. Kerr joins NINR on February 7.

The search for Scientific Director of the Division of Intramural Research is underway. Those seeking further information or interested in nominating a candidate for the position were referred to Dr. Mindy Tinkle and Dr. Joan Austin. Interested parties also may access the following Web page: <http://ninr.nih.gov/ninr/about/employment.html>. The current search is open through early March.

Dr. Grady noted that the NINR Intramural Program and clinical staff have moved into their new space in the Mark O. Hatfield Clinical Research Center. A tour of the offices and Center will be planned for a future Council meeting.

III. REPORT OF NINR ACTIVITIES IN SUPPORT OF RESEARCH ON ISSUES AT THE END OF LIFE (Dr. Alexis Bakos, NINR)

NINR has been the lead NIH institute on end-of-life issues since 1997. In this leadership role, NINR has encouraged the establishment of collaborative and multidisciplinary research efforts, which culminated in the State of the Science Conference on Improving Life Care on December 6–8, 2004, that was attended by nearly 1,000 registrants. The road to this conference began with the 1997 Workshop on Symptoms in Terminal Illness. This workshop, sponsored by NINR with additional support from the then Office of Alternative Medicine (OAM), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), and others, considered the status of research and clinical practice regarding symptoms and their treatment among persons with terminal illnesses. The major symptoms (pain, nausea, dyspnea, and cognitive effects) and their management were assessed. An outcome of the workshop was a Program Announcement (PA) titled “Management of Symptoms at End of Life” and a subsequent Request for Applications (RFA).

As part of its commitment to advancing and increasing awareness about end-of-life research and its applications, NINR’s outreach efforts have been extended not only to investigators and clinicians but also to patients and their families, policymakers, and the general public. One such effort was NINR’s involvement, in collaboration with other organizations and agencies, in a postproduction panel discussion of the play, “W;t,” about a woman’s journey from being diagnosed with cancer, through treatment, and then facing the end of her life. NINR established a trans-NIH special interest group (SIG) on end-of-life issues. The SIG sponsored a Town Hall Meeting “The End of Our Lives,” which was open to the public and highlighted clinical and

public health issues around end of life. In conjunction with the American Association of the Colleges of Nursing (AACN) and other professional organizations, NINR helped to develop a video training series titled “End-of-Life Care” for nurse educators and investigators that translated research into practice. <http://www.aacn.nche.edu/elnec>.

The Institute of Medicine (IOM) has taken a strong interest and active role in investigating the status of a range of issues involving end of life, and NINR had an important role in these reports. NINR was the major sponsor of “When Children Die: Improving Palliative and End-of-Life Care for Children and Their Families” (2003); these reports have shaped end-of-life care and research, and they include strong recommendations to health professionals to improve palliative care.¹

Examples of research areas in this portfolio include studies on end-of-life in premature infants, homeless persons, and trajectories associated with terminal illnesses. One example of NINR-funded research is Tilden’s study of advanced care planning, decedent symptoms, and caregiver burden associated with out-of-hospital death. The results of this study, published in 2004 in the *Journal of the American Geriatric Society*, impact clinical care skill and practice. Another study by Phipps and colleagues investigated the attitudes, preferences, and behaviors of African American and Caucasian patients and their families near the end of life. This study, which included patients without living wills, was published in 2003 in the *Journal of Clinical Oncology*. In *JAMA*, 2003, Lunney described the results of her study on the patterns of

¹ “When Children Die Improving Palliative and End-Of-Life Care for Children and Their Families”. Field, Marilyn J. and Richard E. Behrman, Ed. Institute Of Medicine of The National Academies, The National Academies Press Washington, D.C. 2003.

functional decline and activities of daily life at the end of life in frail persons as compared with persons who die suddenly. McClain and colleagues' study of the effects of spiritual well-being on end-of-life despair in cancer patients with less than 3 months to live was published in *The Lancet* in 2003.

Dr. Bakos provided highlights of the State of the Science Conference on Improving Life Care, which evaluated the current state of the science to determine future directions for end-of-life research. Conference co-sponsors included NCI, National Center for Complementary and Alternative Medicine (NCCAM), National Institute on Aging (NIA), National Institute of Mental Health (NIMH), Centers for Disease Control and Prevention (CDC), and others. The panel of experts charged with this assessment worked from the following set of questions: What defines the transition to the end of life? What outcomes are indicators of quality of life for the dying person, the caretakers, and family members? What factors are associated with outcomes, and do those factors improve or worsen outcomes? What processes are associated with outcomes? What future directions should end-of-life research take? The key recommendations of the panel were to: (1) develop a research infrastructure to enhance research resources; (2) refine standardized definitions of end-of-life care, palliative care, hospice care in the context of the research enterprise, and other relevant terms; (3) enhance communication across research components and communities; (4) recruit underrepresented populations in sufficient numbers to provide the power to detect subgroup differences; and (5) create and support research networks and patient cohorts to foster multisite studies. A draft summary report of the conference has been produced, and the final report will be available through the NINR Web Site.

In summary, NINR supports a wide range of research in its end-of-life portfolio. This support is consistent with the overall shift in clinical research from studying acute disease to chronic and terminal illnesses as our Nation's population ages. NINR's commitment and leadership in this area will continue, and proposed concepts are slated for review this spring.

Questions/Comments

Council members were very supportive of NINR's leadership role in end-of-life and palliative care research and noted the growing interest and participation in the field as the need increases.

IV. RESEARCH INITIATIVES FOR FY07 (Council members as lead discussants)

Physical Activity and Comorbidities in Mobility-Limiting Disorders (Dr. Joan Austin, Council Discussant)

A wide variety of chronic conditions contribute to the activity limitations of approximately 35 million Americans. Of these conditions, 38 percent, or more than 13 million persons, have mobility-limiting conditions, which span all socioeconomic, cultural, racial, gender, and age groups within the United States population. Reduced physical activity, in turn, is associated with obesity, and studies over the past decade indicate a growing increase in the disparity in the proportion of overweight persons with disabilities as compared with those without disabilities. This initiative is designed to stimulate research that focuses on physical activity and the associated risk and protective factors contributing to obesity and other comorbidities in persons with mobility disorders. The focus will be on prevention strategies that intervene at all levels, and that address relevant cultural and belief systems.

Discussion/Comments

Council members agreed that this is an important area of research to pursue, that it fits well with NINR's mission, and expands and builds on NINR's research priorities. Suggestions and comments included:

- Distinguish more clearly between mobility-limiting disorders and disabilities, and focus the language in the initiative so that it is more consistent with mobility-limiting disorders.
- Prevention should be a focal point of the research objectives and goals. Early interventions targeting obesity also should be added.
- Identify how this initiative is unique and also how it builds on existing PAs on disabilities and on obesity. Should the initiative focus on sequelae other than obesity? Dr. Mann Koepke noted that although the emphasis is on obesity, other factors and outcomes are included (e.g., osteoporosis).

Reducing Health Disparities Among Children (Dr. Dolores Sands, Council Discussant)

Recent census data show that 16.7 percent of children in the United States live in poverty and that there are more poor children than in any other segment of the population. Moreover, the population of children is becoming increasingly more ethnically and racially diverse, and current census predictions are that racial and ethnic minority groups will comprise the majority by 2050. There is an urgent need for research focused on the elimination or reduction of health disparities

among children to thwart potentially significant burdens on individuals in the health care system, and society as a whole. This initiative is designed to stimulate research that targets the reduction of health disparities among children (0–18 years old) who have limited access to resources and privileges that impact their health. The initiative focuses on ethnic and racial minority children and medically underserved children. It includes children from low literacy, rural, and low-income populations; geographically isolated children; hearing and visually impaired children; physically or mentally impaired children; children of migrant workers; children from immigrant and refugee families; and non-English-speaking children. The primary purpose of the initiative is to solicit intervention studies in these groups of children and to delineate further mechanisms of disparities that will inform the development of interventions. Proposals incorporating a multilevel approach (individual, health systems, community, societal) will be encouraged.

Discussion/Comments

Council members considered this to be a timely and very important initiative, especially with respect to the limited access to health care facing many persons and groups, including children in racially and ethnically underserved populations, those living in rural areas, and those who are members of immigrant and non-English-speaking families. These factors tend to place the youngest children (0-10 years old) at greatest risk.

This area of research also could be strengthened through clarification of underlying mechanisms for health disparities and health problems in children; the initiative could be framed to understand the factors that contribute to special populations. The objectives also should include studies that evaluate how gender and legal/immigrant status affect access to health care and

health disparities. Another objective might be to identify and study novel ways to ensure continuity of care among children whose families move frequently, who live in shelters, and other similar situations. Another area to explore to a greater extent is the influence of families and familial cultural beliefs and values on access to care and health, nutrition, and lifestyle/activity level.

Transitions in the Pediatric Cancer Trajectory (Dr. Sandra Underwood, Council Discussant)

Significant advances in pediatric cancer treatment and outcomes have been made in the past 25 years. Collaborative, multi-center research has transformed cancer in children from an almost universally fatal disease to one that is curable in greater than 75 percent of patients. However, much more can be done with respect to: developmental stage of the child, particularly when cancer is first diagnosed in adolescence or young adulthood; transition of younger patients and survivors into the teen years; the impact of risk-taking behaviors in adolescence; and appropriate support for families at different stages of development and age at diagnosis. The purpose of this initiative is to integrate a developmental approach (child, adolescent, and young adult) with the cancer trajectory to develop a body of science that will improve pediatric oncology outcomes and to prepare young people and their families for long-term survivorship.

Discussion/Comments

Staff should consider placing greater emphasis on studying trajectories in culturally, racially, and ethnically diverse populations and on assessing the state of the science of mechanisms of effective psychosocial and behavioral interventions. Other transition points for children that might be considered for further study are the day of diagnosis and the last treatment day, both of which are viewed as among the “worst” days for adult cancer patients. Additional focus areas

include continuity of care and cancer survivorship. One key objective to add to the initiative is to identify and develop quality indicators for effective transition.

Biotechnology in Self-Management and Informal Caregiving (Dr. Jacqueline Dunbar-Jacob, Council Discussant)

Chronic diseases such as heart disease, cancer, and diabetes are the leading causes of death and disability in the United States, affecting the quality of life of 90 million Americans today and an estimated 150 million Americans by 2030. Self-management of chronic diseases is becoming increasingly complex and more time consuming for patients, in large part because of the requirements for monitoring signs and symptoms, numerous and sophisticated medication regimens, lifestyle behavior demands, decision-making, and problem-solving related to effective management. Self-management of chronic disease increasingly involves biotech and information systems to monitor physiological and other data about the patient and the disease. In the area of informal caregiving, “smart devices” that can “think” for themselves, wearable devices, wireless Internet-linked systems, and internet support groups (professional and personal) are being targeted toward the delivery of intelligent health care in the home. The growing demand for personal technology assistance is coming from patients, health care providers, and producers of technologies. This initiative is designed to stimulate advances in research on use of information and communications technology and biotechnology aimed at two areas: self-management and informal caregiving. Opportunities include: (1) studies to show how effectively, accurately, and safely biotechnology systems can be integrated into self-management and caregiving; (2) research investigations to determine the benefits of emerging self-management and caregiving; and (3) describing the potential for information and biotechnologies

related to individual patient/family capabilities and the environment, and the user-friendliness of technologies.

Discussion/Comments

Considering the very rapid development of technologies entering or poised to enter the health care arena, it is advisable that nursing be on the forefront of moving these technologies into practice and disease management.

The initiative is well targeted with respect to self-management, and it is consistent with NINR priorities on self-management and long-term care. The initiative also is consistent with NIH Roadmap themes and offers opportunities for partnerships within and outside of the NIH.

The total evaluation seems to be missing some key outcomes associated with use of specific technologies, including outcomes for caregivers and impact on number of lost working days. Thus, it may provide information to encourage studies that identify and monitor outcomes that give added benefits to the workplace, increase cost-effectiveness, decrease health disparities in underserved populations, and reduce health care costs. Council members cautioned, however, that staff ensure that the initiative includes a focus on quality indices and does not drift toward doing “company” studies.

Providing End-of-Life and Palliative Care in Rural and Frontier Areas (Dr. Anna Alt-White, Council Discussant)

Although many urban settings offer end-of-life programs with options to ease the suffering of terminally ill patients, very few if any options exist for those who live in rural communities as they face the end of life. Several factors contribute to this gap in care. People living in frontier and rural areas are often isolated and have poor access to basic facilities such as markets, hospitals, and health care providers. In addition to geographic barriers, several other factors, such as higher unemployment, lower literacy, and fewer types of services including end-of-life and palliative care programs, contribute to gaps in providing a continuum of health care to remote communities and, consequently, to health disparities at the end-of-life between residents of rural and metropolitan areas. The proportion of elderly in rural areas also raises concerns regarding availability and adequacy of end-of-life care. Data indicate that about 25 percent of the total elderly population in the United States resides in nonmetropolitan areas, accounting for about 15 percent of the rural population. This initiative seeks to identify the end-of-life experience in rural and frontier areas and to examine appropriate interventions that seek to improve the quality of life at the end of life for those who reside in these areas. It dovetails with NINR's research theme of enhancing the end-of-life experience for patients and their families.

Discussion/Comments

This is a timely and challenging area of opportunity consistent with NINR's research goals and priorities. The objectives, which focus on intervention, care delivery, and descriptive studies (e.g., merits of technology for these populations) are well matched to NINR's efforts toward building a comprehensive health disparities portfolio that includes rural and underserved areas.

Multicultural Issues in HIV Research (Dr. Frances Munet-Vilaro, Council Discussant)

This initiative will be based on the results of a workshop titled “Research Issues in a Multicultural Society: HIV/AIDS as a Case Study,” to be held on the NIH campus in August 2005. The topic grows out of needs identified in the nursing, behavioral, and social science research communities that the concept of cultural competence is underdeveloped regarding health behavior research. Not all sectors of the HIV/AIDS population are enjoying the benefits of new treatments, in part because of issues related to cultural diversity. The topic addresses concerns about the design and conduct of research that is sensitive to, or appropriate for, our culturally diverse society and global community. The workshop will examine what has been learned about conducting health behavior research, as applied to HIV/AIDS, in a multicultural society; identify the gaps in our knowledge base; and recommend next steps. The workshop and the subsequent initiative build on the leadership role of nurse scientists in the identification of the relevance of culture to optimal care of patients, families, and communities.

Discussion/Comments

This initiative is timely and challenging and will provide much-needed research on the role of cultural appropriateness and diversity on treatment, behaviors, and quality of life among persons with HIV/AIDS. This initiative is additionally important given the increasingly multicultural makeup of the United States population, and it will help build trust with culturally diverse communities. It builds on NINR’s leadership role in several areas, fosters cultural competency, and is congruent with the NIH Roadmap goal of fostering multidisciplinary research teams.

Staff were asked to consider adding an objective to study the influence or interaction of geopolitical and religious “cultures” on behavioral and lifestyle decisions in association with HIV/AIDS.

Opportunities for Research in Environmental Health (Dr. Joan Shaver, Council Discussant)

Using estimates of global disease burden, some 30 percent of disease occurrence is attributable to environmental exposures. In the United States, approximately 1 million children exceed the current threshold for blood lead levels; asthma prevalence in children has increased 58 percent since 1980, while mortality increased by 78 percent. Approximately 3 percent of developmental and neurological deficits in children can be attributed to known toxins, and as many as 1.4 billion urban residents breathe air that does not meet World Health Organization air quality guidelines. Evidence now suggests that the development of most chronic diseases is the result of complex interactions involving genes, environmental factors, age, behavior, and random events associated with endogenous metabolism that influence the timing of gene expression and susceptibility to environmental toxins. This initiative is designed to foster research in environmental health, ranging from biological and behavioral investigations to clinical and population studies. The focus is on human responses to detrimental environmental factors and targeted approaches to risk reduction, psychological coping, and management of complications and side effects of environmental exposures. Research on the influence of environmental hazards and research that identifies and reduces exposure to precursors of illnesses and conditions is encouraged.

Discussion/Comments

There was some question regarding whether the involvement of nurse researchers in this area will duplicate much of what public health investigators study. In response, it was noted that this is a newer, grassroots area of investigation in the nursing research community and that the initiative focuses on collaborative investigations.

Comments for further consideration included studying environmental exposures on a day-to-day activity basis (e.g., through outdoor exercise programs), unsafe environments versus exposures to specific chemical and biological toxins, and geomapping/geographical influences on environmental exposures and health.

V. REPORT OF THE WORKING GROUP ON PROMOTING RESEARCH ON FOCAL COGNITIVE DEFICITS (Dr. Joan Austin, Council Member)

The NINR Working Group on Promoting Research on Focal Cognitive Deficits in Non-Dementing Disorders met on October 12, 2004; the meeting was organized and funded by NINR with support from the NIH Office of Rare Diseases. Refer to: <http://ninr.nih.gov/assets/Documents/CognitiveDeficitsinNon-DementingDisorders.doc>. The purpose of the working group was to assist NINR staff in considering an area of research opportunity related to improving health and quality-of-life outcomes for persons with brain disorders, and developing effective interventions that will reduce cognitive deficits and promote better health behaviors and health decision-making for persons with brain disorders. The conditions under consideration included those in which persons have significant cognitive

reserves, unlike progressive dementing cognitive disorders.

The group found that progress is slow in this area of research in large part because of methodological limitations. Gaps were identified and recommendations made by the group.

VI. REPORT OF THE WORKING GROUP ON THE SCIENCE OF SELF-MANAGEMENT IN CHRONIC DISEASES (Dr. Louis Burgio, Council Member)

The Working Group on the Science of Self-Management in Chronic Disease convened December 9–10, 2004, to assist NINR staff in the consideration of a research agenda with three key aims: (1) improve health and quality-of-life outcomes for individuals with chronic disease; (2) advance the science of chronic disease self-management through research in diverse populations, through the lifespan, and across chronic disease conditions; and (3) promote research to address gaps and unresolved questions in the area of self-management. To that end, working group participants were charged with highlighting current knowledge of self-management research, determining current research gaps in the knowledge base, and defining challenges and emerging opportunities for research in this area.

VII. REVIEW OF COUNCIL DOCUMENTS (Dr. Claudette Varricchio, NACNR Executive Secretary and Assistant Director, NINR)

NINR's biennial report on inclusion of women and minorities in clinical trials in FY2003 and 2004 was presented to Council. NINR supports a limited number of Phase III clinical trials, and persons enrolled in those trials are monitored and documented in accordance with designated procedures. NINR has been keeping up with its targets and remains committed to the inclusion of women in clinical studies, as evidenced by data showing that more than one-half of participants in NINR-supported studies are women. NINR also is committed to inclusion of minorities in clinical studies, and the establishment and growth of minority partnerships through NINR-funded mechanisms that support this commitment such as the NIH's Research on Women's Health Report. A few protocols continue to report information on enrollees using 1977 standards. In the past 2 years of tracking human subjects concerns, NINR reported a peak of 13 administrative actions in September 2003 that was concomitant with centers beginning to report enrollment data. Since that time, there has been a steady decline in human subject and gender and minority administrative actions, with nine, six, and one reports in January, May, and September 2004, respectively.

Comparison of NINR data with NIH data is underway, and findings of this analysis will be included in NINR's report to the NIH Office of Research on Women's Health (ORWH) in March; ORWH, in turn, reports the findings of all NIH ICs. NINR's gender and minority enrollment data compare favorably with other ICs, and the Institute's record on recruiting women to clinical trials exceeds that of many ICs.

Following this presentation, Dr. Grady thanked participants and attendees, with special recognition to outgoing Council members, Drs. Dunbar-Jacob, Naylor, Shaver and Ward, for their time, interest, and contributions during their tenure. Dr. Grady adjourned the open session of the meeting.

CLOSED SESSION

This portion of the meeting was closed to the public in accordance with the determination that this session was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, US Code, and Section 10(d) of the Federal Advisory Committee Act, as amended (5, USC Appendix 2).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

REVIEW OF APPLICATIONS

The members of the NACNR considered 83 research and training grant applications on which NINR was the primary Institute; these applications requested a total of \$18,031,402 (direct costs year 01). Council also considered 65 applications on which another Institute/Center was primary and NINR was secondary; these applications requested a total of \$18,006,266 (direct costs year 01). The Council concurred with the IRG recommendations on these 148 grant applications.

ADJOURNMENT

The 55th meeting of the NACNR was adjourned at 11:50 am on January 26, 2005

CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete.

Patricia A. Grady, Ph.D., R.N., F.A.A.N
Chair
National Advisory Council for Nursing
Research

Claudette Varricchio, D.S.N., R.N., F.A.A.N.
Executive Secretary
National Advisory Council for Nursing
Research

MEMBERS PRESENT

Dr. Patricia A. Grady, Chair
Dr. Claudette Varricchio, Executive Secretary
Dr. Joan Austin
Dr. Peter Buerhaus
Dr. Louis Burgio
Mrs. Rosemary Crisp
Dr. Kathleen Dracup
Dr. Jacqueline Dunbar-Jacob
Dr. Sandra Millon-Underwood
Dr. Gary Morrow
Dr. Frances Munet-Vilaro
Dr. Mary Naylor
Dr. Dolores Sands
Dr. Joan Shaver
Dr. Anna Alt-White, *Ex Officio*
Dr. Catherine Schempp, *Ex Officio*

MEMBERS OF THE PUBLIC PRESENT

Carolyn Branson, Constella Group
Jennifer Casavant, UVA
Mary Cerny, SCG, Inc.
Mary Gleason, UVA
Kimberly Hemphill, UVA
HeeJung Jang, UVA
Mary Kerr, U Pitt
Jureerat Kijrompon, UVA
Barbara Parker, UVA
Eileen Resnik, The Society for Women's Health Research
Karen Rose, UVA
Althea Rowlands, UVA
Audrey Snyder, UVA
Lisa Zerull, UVA

FEDERAL EMPLOYEES PRESENT

Dr. Nell Armstrong, NINR/NIH
Dr. Lauren Aaronson, NINR/NIH
Dr. Alexis Bakos, NINR/NIH
Ms. Diane Bernal, NINR/NIH
Mr. Ray Bingham, NINR/NIH
Dr. Yvonne Bryan, NINR/NIH
Ms. Diane Drew, NINR/NIH
Ms. Ana Ferreira, NINR/NIH
Mr. Lawrence Haller, NINR/NIH
Dr. Martha Hare, NINR/NIH
Dr. Karin Helmers, NINR/NIH
Ms. Lisa Horton, NHLBI/NIH
Dr. Karen Huss, NINR/NIH
Ms. Samantha Jarvis, NINR/NIH
Dr. Ruth Kirschstein, OD/NIH
Dr. Kathy Mann Koepke, NINR/NIH
Dr. Sue Marden, NINR/NIH
Mr. Kevin Laser, NINR/NIH
Dr. Trudi McFarland, CSR/NIH
Ms. Jacqueline McKissic, NINR/NIH
Ms. Mary Miers, NINR/NIH
Ms. Tara Mowery, NINR/NIH
Mr. Lanny Newman, NINR/NIH
Mr. Chuck Sabatos, NINR/NIH
Ms. Arlene Simmons, NINR/NIH
Dr. Barbara Smothers, NINR/NIH
Ms. Allisen Stewart, NINR/NIH
Dr. Mindy Tinkle, NINR/NIH
Mr. Mark Waldo, NINR/NIH