

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

September 16–17, 2003

The 51st meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, September 16, 2003, at 1:00 p.m. in Conference Room 6, Building 31, National Institutes of Health (NIH), and Bethesda, Maryland. The first day of the meeting was adjourned at approximately 5:15 p.m. The closed session of the meeting, which included consideration of grant applications, continued the next day, September 17, 2003, at 9:00 a.m. until adjournment at 1 PM 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 51st meeting of the NACNR to order, welcoming all Council members, visitors, and staff. She also welcomed Dr. Charlotte Beason, an *ex officio* member of the NACNR representing the Department of Veterans Affairs, following Dr. Pauline Cournoyer's departure from the Council in May.

Conflict of Interest and Confidentiality Statement

Dr. Mary Leveck, NACNR Executive Secretary, 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 National Institute of Nursing Research (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. Leveck 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 May 20–21, 2003, Council meeting by electronic mail. No changes or corrections to the minutes of the May 20–21, 2003, Council meeting were suggested during the September meeting. Comments, corrections, and changes identified after the current meeting should be forwarded to Dr. Grady or Dr. Varricchio. The minutes of each NACNR meeting are posted on the NINR Web Site at (<http://www.nih.gov/ninr>) with the link to the archive of Council minutes found at (<http://www.nih.gov/ninr/about/adv-council.html>).

Dates of Future Council Meetings

Dates of meetings in 2004 and 2005 have been approved and confirmed. Council members should contact Dr. Grady or Dr. Varricchio regarding any conflicts or expected absences.

2004

- ◆ January 27–28 (Tuesday–Wednesday)
- ◆ May 19–20 (Wednesday–Thursday)
- ◆ September 14–15 (Tuesday–Wednesday)

2005

- ◆ January 25–26 (Tuesday–Wednesday)
- ◆ May 17–18 (Tuesday–Wednesday)
- ◆ September 13–14 (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 related to NIH, budget, and NINR.

NIH Updates

The Institute of Medicine (IOM)/National Research Council released its report on NIH organization and infrastructure titled, “Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges,” on July 14, 2003. The report summarizes results of a year-long study of the NIH. Dr. Grady provided testimony on behalf of NINR to the IOM committee on September 10, 2002, along with other current and former NIH leaders, advocates. The report includes 13 recommendations to the NIH; Dr. Grady summarized the report, noting the following four:

- ◆ Centralize management to increase efficiency.
- ◆ Enhance and/or increase trans-NIH strategic planning and funding of projects.

- ◆ Strengthen the Office of the NIH Director, including giving the Office more discretionary money to support special projects and new initiatives.
- ◆ Develop and implement a process to create new offices and programs for the NIH Director.

An executive summary of the report may be found at the National Academy of Sciences Web Site (www.nas.edu), and the link to the report is (<http://books.nap.edu/openbook/0309089670/html/index.html>).

In other news, several departing and incoming NIH Institute and Center (IC) directors have been named since the last Council meeting. Story Landis, PhD., will serve as the new Director of the National Institute of Neurological Disorders and Stroke (NINDS), and Jeremy Berg, PhD., will serve as the new Director of the National Institute of General Medical Sciences. Departing IC directors include Claude Lenfant, MD, who served as the National Heart, Lung, and Blood Institute (NHLBI) Director for 22 years; Kenneth Olden, PhD, who served as Director of the National Institute of Environmental Health Sciences for 12 years; and Ellie Ehrenfeld, PhD, who has led NIH's Center for Scientific Review for the last 5 years.

Regarding NIH Director Dr. Elias Zerhouni's "NIH Roadmap," Dr. Grady reported that the implementation work groups have been re-consolidated into three major areas and themes: New pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise. NINR senior staff serve as members of the implementation groups for Research Teams of the Future and Re-engineering the Clinical Research Enterprise. A roll-out plan for the Roadmap is expected to be delivered at the end of September.

Budget Updates

The proposed fiscal year (FY) 2004 President's and full House budgets include a 3.1 percent increase in the NINR budget, and a 2.5 percent increase in the overall NIH budget. The FY 2004 Senate subcommittee budget recommends 3.9 and 3.7 percent increases in the NINR and NIH budgets, respectively. The President's and House budgets allocate \$134.6 million to NINR, whereas the Senate budget allocates \$135.6 million. The current FY is the final year of the 5-year plan to double the NIH budget; NINR's budget also has doubled during this time, thereby clearly benefitting from the targeted increases to the overall NIH budget. The proposed FY 2004 budgets are forwarded to conference, where differences are negotiated and resolved into one conference bill. This bill is voted upon by both houses of Congress and then is signed into law by the President.

NINR Updates and Outreach

Since the last Council meeting, program staff and NINR grantees have participated in a variety of meetings. One meeting, sponsored by the NRC and titled, "Monitoring the Changing Needs for Biomedical and Behavioral Research Personnel," included a Nursing Panel. Recommendations from prior NRC reports with this focus have focused on increasing the number of postdoctoral training slots and facilitating early entry of students into the research-doctorate pipeline, both of which NINR has addressed and continues to address. The meeting,

which was held on August 5, included panels focused on other health professionals such as dental researchers. The Robert Wood Johnson Foundation held a Leadership Forum on August 4, which addressed the nursing faculty shortage in this country. Intermediate steps and strategies to facilitate the career trajectory were discussed, and more are needed. In another activity, staff were joined by current Council members and former Council members at NINR's annual retreat, which was held off campus on June 5–6, 2003.

NINR has issued several Program Announcements (PAs) and Requests for Applications (RFAs) since the last Council meeting. They include:

- ◆ Biobehavioral Pain Research (PA), which was revised and reissued following the trans-NIH Pain Consortium, supported by several ICs, including the National Institute on Aging (NIA), National Cancer Institute (NCI), and NINR.
- ◆ Chronic Self-Management in Children (PA), which is cosponsored with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Child Health and Human Development (NICHD), and the National Heart, Lung and Blood Institute (NHLBI).
- ◆ Health Promotion Among Racial and Ethnic Minority Males (PA) just released, with the National Center on Minority Health and Health Disparities (NCMHD) as a cosponsor.
- ◆ Minority K01 RFA for career development.
- ◆ K22 RFA, a portable 4- to 5-year award that funds postdoctorates, and that can be carried into academic positions.

NINR currently funds three K22 awardees, and more investigators are encouraged to apply for K01s, minority K01s, and K22s.

Dr. Grady discussed NIH monies, in addition to NINR dollars, that go to schools of nursing (SONs) across the country, and the collaborations that result from such funding. NINR collaborates with most ICs at NIH, and among the many benefits of those collaborations are leadership and mentoring opportunities. FY 2002 data show that NINR provided nearly \$87 million for nursing research, while other ICs awarded approximately \$48 million. The other-IC support has grown over the years and now represents close to one-third of the NIH dollars to schools of nursing.

On-campus events sponsored by NINR since the last Council meeting include the 4th Summer Genetics Institute, which ran in June and July. Twenty students attended the Summer Institute, an intensive, 8-week classroom and laboratory course. NINR will continue to sponsor this course, and updates on the Institute will be given at a future Council meeting. Also, the Working Group to address Moving the Research Agenda Forward for Children with Cancer was held on August 5–6. A summary of the working group meeting will be published in an upcoming issue of the *Journal of Pediatric Oncology*.

Dr. Grady then paid tribute to Doris Bloch, DrPH, RN, FAAN, who passed away on August 10. Dr. Bloch was a pioneer in nursing research and instrumental in the development of Federal programs in nursing science. She was one of the original staff members of the National Center for Nursing Research at the NIH (which later became NINR). She served as Special Assistant to the Director of the NINR, and later founded Windows on Nursing, which celebrates the art of

nursing. She remained active in the nursing research community throughout her life, and her contributions to the field are far-reaching.

Nurse researchers continue to be in the news, and NINR staff compile press releases and articles generated both inside and outside of NINR. Dr. Grady encouraged investigators to contact NINR to publicize their research findings and other news.

Per the discussion at the last Council meeting, program staff have fine-tuned and revised proposed NINR research themes based on comments from Council members, advocacy groups, and others. Dr. Grady noted that most comments provided positive feedback, and added support for emerging and growing technologies, such as wireless interventions and bioinformatics; cost effectiveness and cost benefit variables in funded studies; and continued study of patient outcomes from implementation of nursing knowledge. The themes are:

- ◆ Identifying effective strategies to reduce health disparities.
- ◆ Changing lifestyle behaviors for better health.
- ◆ Managing the effects of chronic illness to improve quality of life.
- ◆ Harnessing advanced technologies to serve human needs.
- ◆ Enhancing the end-of-life experience for patients and their families.

Recent NINR activities included cosponsoring the Second Council for Advancement in Nursing Research (CANS) Conference: “Promoting Research Intensive Environments in Clinical Settings” with the American Academy of Nursing, the American Organization of Nurse Executives, the Department of Veterans Affairs and the Mayo Clinic. Approximately 300 persons attended the meeting, which was held on September 12–13 at the Natcher Conference Center on the NIH campus. CANS is a relatively new organization, and the conference focused on developing models for creating opportunities for clinical nursing research.

The Friends of NINR celebrated its annual day of NightinGala events on September 10. This year’s event included a poster session; the Research!America panel of 3 nurse researchers plus representatives from three media organizations, including *JAMA* and *Reader’s Digest*; and the NightinGala dinner, which was attended by about 850 people. Dr. Grady noted that attendees at all of the events expressed enthusiasm and energy for moving nursing research science forward.

Upcoming NINR working groups (WG) include the T32 Directors WG, which will assess the status of institutional training awards and will meet in late 2003, and the Partnership P20 Center Directors WG, which will meet in October to discuss the status and progress of the pairing of research-intensive SONs with minority-serving schools of nursing.

In closing the Director’s Report, Dr. Grady welcomed three new Extramural Program Directors to NINR. Dr. Alexis Bakos is the program director for the Institute’s End-of-Life Research portfolio. Dr. Karen Huss is the program director of the Cardiopulmonary Health and Critical Care portfolio, and Dr. Kathy Mann Koepke is the program director of the Neurofunction and sensory conditions portfolio. Each of the new program directors brings impressive credentials and expertise specific to the portfolios for which they will be responsible.

III. NIH UPDATE: OFFICE OF COMMUNICATIONS AND PUBLIC LIAISON (Mr. John Burklow, Director, OCPL)

The NIH Office of Communications and Public Liaison (OCPL) assists investigators and the ICs in disseminating research results to the larger scientific community and to the public. The Office has taken on new communications activities and challenges to expand this role, as encouraged and supported by NIH Director Dr. Zerhouni and as supported by the IOM, to meet the obligation to let the public know how research affects their lives and how their tax dollars are spent. In response to IOM's charge, the OCPL has developed a strategic communications plan designed to:

- ◆ Convey to policy makers and the general public the relevance of medical research and NIH's leadership role.
- ◆ Demonstrate accountability for the continued investment in medical research.
- ◆ Maximize the impact of NIH by coordinating collective voices of the ICs to communicate medical research discoveries.
- ◆ Reinforce NIH's connection with the Department of Health and Human Services ("One department, one voice").

The objectives of this plan are to:

- ◆ Increase understanding of the relevance of medical research to improving people's health.
- ◆ Increase understanding of NIH's role in supporting and conducting medical research.
- ◆ Increase public awareness of NIH as a trusted, credible source of health and medical information.

The plan includes three key strategies. The first involves working with the Office of the Director and the ICs to develop clear, consistent, and integrated communications (e.g., to identify guidelines for communicating research discoveries). The second strategy focuses on conducting proactive media outreach to communicate NIH messages to the public. The third strategy involves collaborating with scientific, medical, voluntary, and private organizations to engage their members and the interested public.

Prior to the launch of its new communications plan, from December 2002 through August 2003, the OCPL conducted a situational analysis that included a needs assessment targeting stakeholders and internal audiences; an "environmental scan" to identify communications activities of other agencies and organizations; a media coverage analysis; a web use analysis; consumer focus groups; a public awareness and attitudes survey, and a communications products review of all NIH communications vehicles, which found that only about one-half of these products identify an association with NIH.

Mr. Burklow summarized the results of the consumer focus groups, which included three groups contacted by telephone and three in-person groups, and the public awareness and attitudes survey. Those participating in the consumer focus groups thought medical research was important and that it should be expanded. They also associated personal benefits with medical research, such as improved quality of life and longer, healthier lives. These personal testimonies

signal the importance of translating science into research, and research into practice. When asked to define various terms, consumers described “medical research” as associated with medications and cures for diseases; they had some familiarity with “clinical research” and controlled trials, but they were unfamiliar with the terms “biomedical research” and “basic research.” Awareness of NIH was also low, and was only vaguely familiar to those who were aware of it. This finding was consistent with results of the 2001 Research!America Study, which found that 72 percent of those surveyed did not know that the NIH is the government agency that funds most of the medical research supported by US tax dollars; 22 percent named another organization; and only 6 percent identified NIH. Awareness of the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration was much higher. Consumers identified pharmaceutical companies, universities, hospitals, the American Cancer Society, and the American Lung Association as the primary organizations conducting medical research. Mr. Burklow pointed out, however, that once the focus group members were given information about NIH’s role and mission in the medical research community, they were interested in learning more.

Results of the public awareness and attitudes survey found that 51 percent of those surveyed were interested in information about health or new medical discoveries. About 70 percent were interested in new treatments or cures for specific diseases or conditions, and in practical information on steps to take to stay healthy. However, less than one-half of those surveyed were interested in the research process.

Using the results of the situational analysis, OCPL developed a series of recommendations under five areas of emerging insights focused on awareness, recognition, relevance, benefits, and roles/attributes. The recommendations include strategies to:

- ◆ Increase Awareness—Target the public with outreach efforts that highlight NIH’s role in past, current, and future medical research (e.g., through media plans, speeches, stakeholder relations).
- ◆ Improve Recognition—Develop organizational systems that ensure a consistent linkage to the NIH “entity” (e.g., NIH identity guidelines, coordinated news dissemination).
- ◆ Showcase the Relevance of NIH Research—Use existing communications to demonstrate more effectively how NIH’s work affects lives (e.g., Word on Health, press briefings, stakeholder updates).
- ◆ Highlight Benefits—Use personal, poignant examples in all communication efforts, and target people where they receive information (e.g., local radio, physician offices, consumer magazines).
- ◆ Promote NIH Roles/Attributes—Use information that resonates, consistently communicate NIH’s roles and attributes in all communications efforts, and share learning with ICs and grantees (e.g., research summary guide, cases statement, NIH prototype brochure).

Future steps for OCPL include continuing media outreach, finalizing the communication plan, and implementing an operational plan to achieve the Office’s goals and objectives.

Questions/Comments

Regarding a question about ways in which the communications plan will improve communication with vulnerable populations and address the various myths and negative perceptions of research, Mr. Burklow stated that targeting specific audiences is part of the communications plan; examples of outreach venues include the Spanish-language radio station RadioUnica, community health fairs, and targeted public service announcements (PSAs). He added that the OCPL would be taking over NHLBI's HealthBeat Program, which focuses on important health issues among African Americans.

OCPL also is working to establish more and better linkages with a wider range of news outlets and journalists, and to step up use and dissemination of press releases. Other opportunities being investigated include teaming up with local public television, the Discovery Channel, National Public Radio, C-SPAN, and various government agencies.

IV. RESEARCH ACTIVITIES: HIV/AIDS (Dr. Martha Hare, Program Director, NINR)
An update about NINR's portfolio and activities relating to HIV/AIDS was presented by Dr. Hare.

HIV/AIDS is an international and domestic problem that is exacerbated by socioeconomic status (SES) disparities. An estimated 42 million adults and children were living with HIV/AIDS worldwide at the end of 2002. With India and Brazil now producing anti-HIV/AIDS medications, prevention and survival in poorer nations are expected to improve. In the United States, approximately 360,000 persons were living with HIV/AIDS at the end of 2001. Approximately 79 percent of affected Americans are males, but with increased heterosexual exposure to the virus, the proportion of affected women, particularly poor women and African-American women, is increasing. Data show that 65 percent of women in this country are infected through heterosexual transmission.

Thus, individuals are not just living longer with HIV/AIDS; the number of persons infected also is increasing. In the last few years, the total number of infected, non-Hispanic blacks surpassed the number of infected, non-Hispanic whites, although the number of affected persons in each of those groups has increased steadily in the last decade. A similar trend is seen for Hispanics, as reported by the CDC. The epidemic is growing most rapidly in the South and in rural areas. The average ages at which most individuals in the United States are first diagnosed with HIV are 30 and 39 years old (38 percent of all new cases), followed by 20 and 29 years old (30 percent), and 40 to 49 years old (19 percent).

The NINR response to HIV/AIDS has increased as the epidemic has grown; similarly, the NIH Office of AIDS Research (OAR) each year renews, revises, and identifies new goals, activities, and strategies in response to the latest trends in this field. Overarching HIV-related research areas supported by NIH/OAR include natural history and epidemiology, etiology and pathogenesis, therapeutics, vaccines, behavioral research, training, infrastructure and capacity building, and information dissemination.

NINR's HIV/AIDS research portfolio focuses primarily on behavioral research. The portfolio has grown from approximately \$6.2 million in FY 1999 to an estimated \$12 million in FY 2004. Funds for HIV/AIDS research are awarded separately from the rest of each IC's budget. A range of grant mechanisms is available, including R01s, R15s, R03s, F and K series awards, D43s (co-funded through the Fogarty Institute), and P20s to study minority health disparities. As the portfolio has grown, NINR has increased both the number of grants and the average size of each grant. Dr. Hare encouraged Council members to share information about the portfolio and the various grants available to investigators at their institutions.

The NINR HIV/AIDS research portfolio is characterized by seven major categories, including:

- ◆ Biobehavioral and Sociocultural Research in HIV Prevention and Intervention. This area cross-cuts other categories in the portfolio and focuses on theory-based research, methodological studies and the meta-synthesis of qualitative research that can be used to develop appropriate instrumentation and interventions, and cultural sensitivity in the United States and elsewhere.
- ◆ Risk Reduction. Research projects funded in this category have examined outreach to women cared for in STD clinics in Chicago, and the impact of including partners of young adolescent mothers in prevention interventions in Los Angeles. This category also has a focus on Latinos, including immigrants, and outreach to rural populations, domestically and abroad.
- ◆ Interventions to Improve Adherence (to Drug Regimens). This rapidly growing portfolio has supported research to develop tailored interventions for individuals and specific populations in various communities across the country, and to manage symptoms of HIV/AIDS (e.g., the impact of exercise and nutrition to ease symptoms associated with Highly Active Antiretrovirals (HAART)).
- ◆ End of Life Care. NINR has been the lead IC at NIH in this area of research. One newly funded study explores care preferences and life priorities of people with AIDS who are near death. This descriptive study collects data from providers, informal caregivers, and patients in an urban setting; it includes a focus on ethnic and racial minorities.
- ◆ Symptoms. Another field of research for which NINR has a leadership role, this category recognizes symptom management as an ongoing concern for persons with HIV/AIDS. One recently completed study examined the effectiveness of a nutritional intervention for diarrhea. New studies focus on co-morbidities, such as co-infection with the hepatitis C virus, and the identification of symptom clusters, which was a 2005 area of opportunity recommended by the Council.
- ◆ Shifting Trends. With guidance from the Council, NINR pays close attention to specific issues and shifting trends in research. One overarching research area that has shifted in the last decade is formal and informal caregiving. For example, hospital and home care studies were a large part of the NINR portfolio in the 1990s. Today, community-based studies emphasizing adherence and symptom management are more common.

Dr. Hare closed her presentation by noting that nursing research is at the forefront of HIV/AIDS here and abroad. For instance, nurse investigators have been highly competitive in seeking funding through the World AIDS Foundation. Nurse researchers also have established extensive collaborations, and will continue to partner with ICs across NIH, and with national and

international agencies and organizations. These collaborations will produce new research initiatives that are expected to have an impact on the worldwide HIV/AIDS pandemic.

Questions/Comments

Regarding NINR's efforts to help stem the significant numbers of persons affected worldwide as well as the growing domestic problem, Dr. Hare noted that NINR's HIV/AIDS research portfolio has a small but growing international component. NINR also is focusing on collaborative efforts with other national and international ICs such as the Fogarty International Center. In addition, NINR supports prevention and treatment research, which have the potential of impacting various groups and populations around the world. Another area where NINR affects HIV/AIDS is through the training of nurse investigators in basic, clinical, and behavioral science research. NINR currently supports 40 grants in the HIV/AIDS research area.

V. RESEARCH PRESENTATION: HIV RISK REDUCTION AMONG LATINAS (Dr. Nilda Peragallo, Dean, University of Miami School of Nursing)

Dr. Peragallo provided highlights of "Project SEPA (Salud/Education/Prevention/Autocuidado)," a study on HIV risk reduction in Latinas. The project, funded by an R01 grant from NINR, is in its last year. The goal of the project is to test the effectiveness of a culturally specific HIV/AIDS intervention to increase HIV prevention behaviors in low-income, inner-city Mexican and Puerto-Rican women. The initial component of the study involved identifying issues associated with HIV/AIDS that were important to women in the specific target community, and then developing the intervention based on those issues and concerns.

The study followed a randomized pre-test/post-test HIV comparison design and followup assessments at baseline, 6 weeks, and 3 and 6 months. Subjects were recruited using a variety of venues, including radio and local television; many women also learned about the study through word of mouth. Participants included 657 sexually active Latinas, between 18 and 44 years old, who were assigned to either an intervention group, which consisted of six weekly interventions, or a control group. All participants were given HIV pre-test counseling, and they received \$20 to \$40 compensation for each interview (baseline through 6 months post-test). Childcare was provided at each session. A total of 422 women completed the entire study.

The six weekly intervention sessions lasted 2 hours, and included instruction and discussion topics on knowing the male and female body; skills training in the use of male and female condoms, in sexual communication and negotiation, and in conflict management and violence prevention; risk awareness and management; and peer support for change. Through these sessions, the investigators discovered that the participants preferred receiving information from bilingual/bicultural experts of the same ethnic background. The sessions focused on skills training in sexual communication and negotiation, and those that included role modeling were especially successful. Skills training in conflict management and violence prevention also was critical, with approximately 20 percent of women in violent/abusive relationships.

The investigators used a series of validated tools in HIV/AIDS research that were modified as needed to measure condom use, HIV behavior knowledge, protective sexual communication,

safer sex peer norms, perceived barriers to condom use, and risk reduction behavioral intention. Outcomes measured included bidimensional acculturation for Hispanics, HIV knowledge, depression, self-efficacy, substance abuse, communication with partners, intimacy between partners, conflict management, and conversations with male partners about condoms and HIV/AIDS concerns, and condom use. Findings showed that Project SEPA was highly successful in increasing condom use, HIV health communication, and HIV knowledge, and in decreasing risk behaviors among low-income, primarily Spanish-speaking Latinas. Results also indicated that the cohort had a high rate of depression. As Dr. Peragallo noted, the cohort comprised a vulnerable, isolated, largely monolingual population that had not been reached regarding critical information and education on HIV/AIDS and related issues.

The study also provided evidence that HIV/AIDS prevention interventions must be culturally tailored to the targeted population of the intended program. Dr. Peragallo pointed out that the development and subsequent success of Project SEPA was based in large part on focus groups, which helped to identify key issues of concern, gaps in knowledge, and needs of the study cohort. The same strategies and delivery system may not necessarily be replicated “as is” in another group. However, some components of Project SEPA may be generalizable to other intervention programs, or modified on an as-needed basis for a more general Latina population. Further, Dr. Peragallo noted, certain elements, such as the sessions on knowing one’s body, have implications for clinical practice.

Questions/Comments

In response to followup questions, Dr. Peragallo stated that intermediate outcomes at the 3-month mark showed an effect from the interventions, suggesting that a longer term intervention is not necessarily required for sustainable, positive behavioral changes in this cohort (and perhaps others). The investigators also found that the 6-week intervention could be done in a shorter period of time (e.g., over 4 weeks), with the same impact.

VI. NINR HIGH BUDGET APPLICATIONS (Council Discussants: Drs. Peter Buerhaus and Joan Shaver)

Dr. Grady provided background for this discussion. For NINR, high-budget applications are for awards funding at least \$350,000 in direct costs, with R01s comprising most competing high-budget awards. In FY 2002, NINR ranked sixth among the ICs for average R01 cost. During that year, NINR funded 66 competitive R01s averaging \$378,000; the overall NIH average R01 award was \$342,000. ICs ranking close to NINR included the National Institute on Drug Abuse (NIDA) and the National Institute of Aging (NIA), which fund research similar to NINR’s. Several of the ICs ranked closest to the NIH average, such as the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and National Institute of Child Health and Human Development (NICHD) also fund research similar to the types of research NINR funds. In contrast, the fourth-ranked IC, the National Center for Research Resources, funds large infrastructure grants. Overall, as a small institute, Dr. Grady noted, NINR ranks high on a cost-per-grant basis. The relative high cost of NINR grants is in large part because the majority of the awards are for clinical research, which is

more personnel-intensive than bench work. In addition, nursing research has evolved from more descriptive investigations to more costly quantitative and complex studies.

The average size of competing R01s has increased in the past few FYs, with NIH averages increasing steadily by 4 to 8 percent annually, and NINR following a more cyclic trend, with an overall increase of 7 percent between FY 1999 and FY 2002. With the ending in FY2003 of the NIH budget doubling period, however, growth in IC budgets is expected to slow, which in turn translates into a reduction of additional funding available to award. As Dr. Grady explained, approximately 75 percent of the proposed NINR budget is already promised, because of the four year average length of most awards, leaving approximately \$1.25 million in new funds to be awarded in FY 2004 (i.e., 25 percent of the proposed \$5 million increase).

Given this background, Council members were asked to identify and discuss possible strategies that NINR may consider to moderate the growth of R01 budgets. Many other ICs have initiated stop-gap measures to address increases in application budgets in conjunction with slowed growth in funding. NINR is seeking innovative and creative alternatives that balance the range of factors that contribute to research budgets, and that recognize the role of budget as a potential rate-limiting step in the review, approval, and funding process. Among the issues and strategies discussed by the Council were:

- ◆ Funding is based in part on innovations in science and their translation into practice. Clinical studies, particularly those targeting populations that require culturally knowledgeable and sensitive staff, translations, and recruitment efforts, are highly staff and cost intensive. The discussion focused on the merits of moderating the cost of R01s, versus consideration of the impact on public health, despite the high cost, as justification for approval of an application with a high budget.
- ◆ Should NINR/Council members focus more on the rate of increase, and on strategies to moderate NINR's rate of cost increase?
- ◆ Expand research collaborations with investigators at other ICs and through centers of excellence, and cost-share funding, particularly on clinical studies (e.g., through co-funding agreements). Consider partnering with outside sources such as professional advocacy groups and pharmaceutical companies. Dr. Grady noted that NINR could suggest reassignment of applications to other ICs, as appropriate.
- ◆ Reach more investigators by expanding the number of smaller research projects funded.
- ◆ Many high-budget studies run for 5 years, which could be amended. For example, program staff could promote a shift in the focus from final outcomes to interim outcomes, which would lessen not only the length of many studies, but also the cost. Longer studies also could be broken down into smaller, shorter, outcome-driven studies.
- ◆ Consider increasing the funding ceiling for high-budget applications to NINR.
- ◆ Consult with other ICs on their strategies to contain increasing costs. For example, high-budget applications (i.e., \geq \$500,000) submitted to NIA and NHLBI must be preapproved, or they go into negotiations. NINDS encourages applicants to submit proposals through its pilot grant program.
- ◆ Educate the scientific and medical research communities about the type of research that NINR supports; develop messages to clarify that funding focuses on clinical interventions and public outcomes.

- ◆ Identify ways that investigators can streamline various costs (e.g., types of staffing, laboratory space, instrumentation). For example, master's-prepared research assistants, instead of nurse practitioners, could serve as study coordinators. Student researchers could be research assistants as part of their training programs. NINR staff can assist investigators in identifying value-added resources, and in promoting collaborations and cost/resource sharing.
- ◆ Encourage investigators submitting applications with budgets approaching the \$350,000 cap to identify budget components that could be trimmed or reduced significantly.

Following this discussion, Dr. Grady adjourned the open session of the meeting and thanked those in attendance for their participation.

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 303 research and training grant applications requesting \$72,731,889 in direct costs (Data obtained from IMPACII//QVR on September 9, 2003; includes all primary and dual applications and excludes F31, F32, F33, R03, and L series applications.)

OTHER ITEMS FOR CLOSED SESSION: EXECUTIVE SESSION

ADJOURNMENT

The 51st meeting of the NACNR was adjourned at 1 p.m. on September 17, 2003.

CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete

Patricia A. Grady, PhD, RN, FAAN
Chair
National Advisory Council for Nursing
Research

Claudette Varricchio, DSN, RN, FAAN
National Institute of Nursing Research

MEMBERS PRESENT

Dr. Patricia A. Grady, Chair
Dr. Mary Leveck, Executive Secretary
Dr. Peter Buerhaus
Ms. Rosemary Crisp
Dr. Joyce Giger
Dr. Margaret Grey
Dr. David Hanley
Dr. Roseanne Harrigan
Dr. Frances Munet-Vilaro
Dr. Mary Naylor
Dr. Dorothy Powell
Dr. Dolores Sands
Dr. Joan Shaver
Dr. Charlotte Beason, *Ex Officio*
Dr. Catherine Schempp, *Ex Officio*

MEMBERS OF THE PUBLIC PRESENT

Ms. Michelle Armstrong, VCU
Mr. Joseph Camphor, Howard University
Ms. Mary Cerny, SCG, Inc.
Mr. Jim Doyle, VCU
Dr. Elissa Emerson, Howard University
Dr. Mary Jo Grap, VCU
Ms. Janet Herr, VCU
Ms. Karen Holliday, VCU
Ms. Carline Jean-Gilles, VCU
Ms. Cindy Little, VCU
Ms. Tonya McGill, Howard University
Dr. Cindy Munro, VCU
Dr. Rita Pickler, VCU
Ms. Kathleen Porter, VCU
Ms. Graciela Rodriguez-Santos, Howard University
Ms. Inez Tuck, VCU
Ms. Tiffani Wilson, Howard University

FEDERAL EMPLOYEES PRESENT

Dr. Nell Armstrong, NINR/NIH
Dr. Alexis Bakos, NINR/NIH
Mr. Ray Bingham, NINR/NIH
Ms. Kim Brinson, NHLBI/NIH
Mr. John Burklow, OCPL/NIH
Ms. Linda Cook, NINR/NIH

Ms. Janet Craigie, NHLBI/NIH
Dr. Genevieve de Almeida-Morris, NINR/NIH
Dr. Martha Hare, NINR/NIH
Dr. Carole Hudgings, NINR/NIH
Ms. Samantha Jarvis, NINR/NIH
Dr. June Lunney, NINR/NIH
Mr. Daniel O'Neal, NINR/NIH
Mr. Eddie Rivera, NINR/NIH
Ms. Arlene Simmons, NINR/NIH
Ms. Allisen Stewart, NINR/NIH
Dr. Mindy Tinkle, NINR/NIH
Dr. Claudette Varricchio, NINR/NIH