Department of Health and Human Services

PUBLIC HEALTH SERVICE

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF MENTAL HEALTH

National Advisory Mental Health Council

Minutes of the 210th Meeting

September 15-16, 2005

Minutes of the 210th Meeting of the National Advisory Mental Health Council

The National Advisory Mental Health Council (NAMHC) convened its 210th meeting in closed session for the purpose of reviewing grant applications at 10:30 a.m. on September 15, 2005, ant the Neuroscience Center in Rockville, Maryland, and adjourned at approximately 3:30 p.m. *(see Appendix A: Review of Applications)*. The NAMHC reconvened the open session at the same location from 4:00 p.m. to 5:00 p.m. and continued the open session on the following day, September 16, 2005, in Building 31C, National Institutes of Health, Bethesda, Maryland, from 8:30 a.m. until adjournment at 12:30 p.m. In accordance with Public Law 92-463, the open policy session was open to the public. Thomas R. Insel, M.D., Director, National Institute of Mental Health (NIMH) chaired the policy meeting.

Council Members Present at the Grant Review and/or Open Policy Session
(see Appendix B: Council Roster):
Sergio A. Aguilar-Gaxiola, M.D., Ph.D.
Jonathan D. Cohen, M.D., Ph.D.
Susan M. Essock, Ph.D.
Faye A. Gary, Ed.D., R.N.
Megan R. Gunnar, Ph.D.
Raquel E. Gur, M.D., Ph.D.
Martha E. Hellander, J.D.
Renata J. Henry
Peter J. Hollenbeck, Ph.D.
Ned H. Kalin, M.D.
Jeffrey A. Kelly, Ph.D.
Helena C. Kraemer, Ph.D.
Eric J. Nestler, M.D., Ph.D.
Charles F. Reynolds, III, M.D.
Peter Salovey, Ph.D.
Suzanne E. Vogel-Scibilia, M.D.
Karen Dineen Wagner, M.D., Ph.D.
Stephen T. Warren, Ph.D.

Chairperson
Thomas R. Insel, M.D.

Executive Secretary
Jane A. Steinberg, Ph.D.

Ex-Officio Council Members Present at the Grant Review and/or Open Policy Sessions:
Robert Freedman, M.D., Department of Veterans Affairs
Douglas A. Waldrep, M.D., Department of Defense
Elias A. Zerhouni, M.D., Director, National Institutes of Health (NIH)

Liaison Representative
Paul Brounstein, Ph.D., for A. Kathryn Power, M.Ed., Center for Mental Health Services, Substance Abuse and Mental Health Services Administration

Others Present:
Ronald Barnett, Social and Scientific Systems, Inc.
Andrea Browning, Society for Research in Child Development
Kwofie Danso, Council on Social Work Education

Martin Gittelman, New York University Medical School
Lynn Grefe, National Eating Disorders Association
Loretta Jones, Healthy African American Families Project
Alan Kraut, American Psychological Society
Kathy Michels, Fogarty International Center
Bill Northey, American Association for Marriage and Family Therapy
Patricia Perkins, Obsessive Compulsive Foundation
Stephanie Reed, American Association for Geriatric Psychiatry
Michelle Rodrigues, SRI International
Angela Sharpe, Consortium of Social Science Associations
Viviana Simon, Society for Women's Health Research
Barbara Solt, Institute for the Advancement of Social Work Research
Tim Tunner, National Association of Social Workers
Barbara Wanchisen, Federation of Behavioral, Psychological & Cognitive Sciences
Kenneth Wells, RAND/UCLA School of Public Health
Sheldon Weinberg, The CDM Group
Karen White, Children and Adults with Attention-Deficit/Hyperactivity Disorder

OPEN POLICY SESSION: CALL TO ORDER AND OPENING REMARKS

Thomas R. Insel, M.D., Director, NIMH, called the open session to order at 4:00 p.m.

NIMH'S RESPONSE TO HURRICANE KATRINA

Dr. Insel explained that our Nation's initial response to Hurricane Katrina focuses on the survival needs of those impacted by the storm. As those needs are met, attention must turn to the immediate and long-term emotional needs of survivors and responders. Dr. Insel said that NIMH's response is being coordinated by NIH in close collaboration with the Department of Health and Human Services (DHHS). NIMH staff members have volunteered and are providing medical and psychological first aid in the impacted areas of Louisiana, Mississippi, and Texas. In addition, space has been made available for those in need at the Clinical Center located on the main NIH campus. NIMH also stands ready to support research on the reactions to traumatic events such as Katrina, and Dr. Insel invited Council comments and guidance on future research directions.

Dr. Aguilar-Gaxiola noted that NIMH's Web site is a critical tool for transmitting information to the public and media concerning NIMH's response to Katrina and for describing the resources that are available to family members, concerned citizens, front-line treatment providers, and others impacted by Katrina. Dr. Wagner reported that the greatest immediate psychiatric need for the victims of Katrina was for renewal of medication prescriptions. She advised that as immediate housing and other physical needs are addressed, attention must be focused on the long-term survivors' psychological and psychiatric issues. She suggested that NIMH participate in an education program for general physicians, teachers, and others outside of traditional mental health treatment pathways concerning the symptoms of and screening instruments for post traumatic stress disorder (PTSD) and depression—illnesses that may develop long after the immediate physical requirements are addressed. Dr. Kelly also urged consideration of the immediate and long-term consequences of the massive life disruptions resultant from Katrina and the types of mental health systems needed to address them.

Dr. Gary noted that this is an opportune time for NIMH to connect with educators, health care providers, and members of faith communities who have not been involved previously with NIMH as participants in research. She requested that NIMH strengthen existing ties and establish new ones with institutions in the regions directly impacted by Katrina, including Historically Black Colleges and Universities. These outreach efforts could strengthen the research agenda, lead to better responses for disasters, and promote resilience for vulnerable populations in addressing issues of power, control, helplessness, hopelessness, suicide, depression, anxiety, post traumatic stress, and panic disorder resulting from disasters such as Katrina.

Dr. Kalin commented that trauma impacts individuals to varying degrees depending on individual risk and resilience factors, with potential short-term, intermediate, and long-term effects, including psychopathology and medical outcomes. He continued that the challenge is to structure a response and a research program that address the public health need resultant from traumatic events and help others in the future. He offered his support to the Institute in developing such a response, and other Council members expressed their willingness to support this effort.

Dr. Vogel-Scibilia pointed to the long-term mental health needs of medical and emergency-first responders and suggested that NIMH work with the Department of Veterans Affairs. Dr. Gunnar urged developing materials and training teachers and others to understand the processes that support and impede resiliency and recovery among children. Dr. Essock suggested that Katrina offers an opportunity to conduct formal evaluations of the impact of various interventions, and she urged NIMH to work with the Substance Abuse and Mental Health Services Administration (SAMHSA) as it works to provide funds and other resources to aid the regions impacted by Katrina. Ms. Henry reported that the National Association of State Mental Health Program Directors' (NASMHPD) first actions were to assess the impacted States' abilities to accommodate inpatients who needed to be moved from harm's way. In addition, NASMHPD has been asked to provide disaster response teams to support workers as they recover and identify victims. She stressed that NASMHPD and SAMHSA are natural partners for NIMH in exploring and evaluating culturally competent interventions, resiliency, and response to trauma. She identified the need for mental health professionals to work directly with physicians conducting triage and to develop partnerships with minority researchers and institutions. In particular, she urged NIMH to explore partnerships with Louisiana's Department of Mental Health and with Xavier and Dillard Universities. She also noted the important role that family reunification has in resilience following a disaster.

Ms. Hellander said that in disasters and in war, entire populations are displaced. She asked if rapid response studies are underway to assess survivors' mental health needs and, in particular, if efforts are being made to provide survivors with neuroprotective medications to prevent PTSD. Dr. Insel responded that NIMH supports research on the reactions that occur in response to traumatic events, which has demonstrated that relief workers can promote mental health by creating and sustaining an environment of safety, calm, connectedness to others, self-empowerment, and hopefulness.

Dr. Insel continued that NIMH, through NIH, has responded to Katrina in a number of ways—bed space to accommodate 100 patients as well as family accommodations were made available within hours of Katrina; a nationwide triage system for academic health centers was set up to guide medical mobilization; NIMH staff participated in NIH response teams; NIMH staff participated in relief teams organized by SAMHSA to provide support to frontline workers in the affected area; and NIMH is making ongoing efforts to provide grantees in the area with support to rebuild their projects and reestablish their research projects. Dr. Insel then introduced Dr. Farris Tuma who explained that NIMH's role in disasters is to find ways to disseminate information on mental health learned from prior disasters and to mobilize human, informational, and financial resources. In addition, NIMH supports the evaluation of research to determine helpful practices and works closely with SAMHSA on these matters. He stated that NIMH's Web site posts information that has been offered in the past following disasters. It provides information on expedited applications for pilot-like studies in areas of scientific imperative, for which NIMH now is receiving substantial inquiries. In addition, the Web site offers information on supplemental funding to existing studies that may be situated strategically in the field. NIMH also is engaging in dialogue to ensure that human services and health resources reach the people with the greatest need, taking into consideration the difficult issues surrounding health disparities.

Ms. Henry highlighted the need for research with multifaceted cultural competency to be undertaken—that is, it includes staff and researchers who understand the geographic, ethnic, racial, and socioeconomic issues in working across cultural boundaries. Dr. Tuma responded that the emphasis at NIMH is on projects that involve people representative of the community. Dr. Gary endorsed engaging NIMH-funded researchers likely to have an existing relationship with the individuals who are displaced in order to study short- and long-term effects with the goal of supporting translational research that could inform public policy.

Dr. Insel thanked Council for its helpful advice and noted the importance of cultural competency in disseminating information that is sensitive to the needs of those in the impacted regions. He then introduced Dr. Della Hann, Director, Office of Science Policy, Planning, and Communications, to report on NIMH's communication efforts. She noted the need for a phased communication effort, which began by sending to Louisiana State University 20,000 copies of a publication on helping children deal with trauma. In addition, Dr. Tuma and others are working on resource materials for teachers, parents, and others. The Federal Emergency Management Agency also has requested information, and NIMH has been working with Dr. Grayson Norquist, former NIMH Director of the Division of Services and Intervention Research (DSIR), who now chairs the Department of Psychiatry at the University of Mississippi, to work collaboratively to disseminate information. Dr. Essock suggested tracking the dissemination efforts to learn from current efforts and to strengthen future responses to major traumas.

Dr. Insel commented on the importance of expanding our knowledge base in responding to major traumas that will last long after the immediate impact of Katrina. Dr. Gunnar suggested the opportunity to learn about the effects of prenatal stress on neural development—e.g., the possibility of schizophrenia 20 years hence—and the long-term effects of low birth weight and slight prematurity. Dr. Essock suggested that the issues under discussion relate to the research portfolio supported in DSIR and that this might be an appropriate time to consider the research priorities for that Division. Dr. Insel asked for and several Council members agreed to serve on a small working group to consider the services and related clinical epidemiology research supported at NIMH as well as future research directions in these areas.

STRUCTURE OF REVIEW AT NIMH

Dr. Marina Broitman, Scientific Review Administrator, Division of Extramural Activities, NIMH, described NIMH's current review procedures and reported that increased numbers of submitted applications have warranted a reconsideration of the review structure at NIMH. As the number of applications under review has substantially increased, so too has the number of required reviewers and reviewer workload, often leading to less time available for comprehensive discussion of the science at review meetings. In response, a small working group of NIMH review and program staff, with input from grantees and reviewers, proposed a plan for a review committee structure using data from the last six review rounds. The final committee-recommended proposal is for a five-committee review structure, as compared with the two-committee structure currently in operation at NIMH. Three new interventions committees would focus on adult mood and anxiety disorders; schizophrenia spectrum disorders, personality disorders, and dementia in adults; and disorders involving children and their families. Two new mental health services committees would focus on services in mental health specialty settings, including crisis centers, and mental health services in nonspecialty settings, including primary care, schools, criminal justice settings, nursing homes, and shelters, and on large data set analyses. This proposal anticipates reduced workloads for committees and members, fewer reviewers needed in each committee, increased discussion time for individual applications, clear referral guidelines, concentrated reviewer expertise, scientific appropriateness to the interventions and services fields, and more manageable review meetings.

Discussion

Dr. Cohen expressed concern about creating committees that are too specialized, which could limit the opportunity for including new reviewers on the committees, stressing the importance of innovation and exploration as important considerations in evaluating proposed research.
Dr. Broitman responded that these issues were considered in proposing the final committee structure and that both in the initial slate of reviewers and in replacing reviewers as their tenure on a review committee ends would be opportunities to bring new expertise from a broad range of backgrounds to the committees. In addition, she noted that NIMH would sponsor a reviewer workshop on innovation in October. Dr. Gunnar urged that any committee include a developmental focus in evaluating childhood disorders, and Dr. Insel responded that the new structure should be well positioned to evaluate such research. Dr. Salovey suggested inviting experienced investigators who have declined in the past to participate in reviews due to workload issues. Dr. Insel acknowledged the challenge in recruiting experienced investigators, noting a decline in numbers of full professors on the panels. Dr. Gary suggested considering as reviewers researchers who are not yet funded as the review experience could provide valuable lessons on

strategies for submitting successful applications. Dr. Gunnar suggested that NIMH consider workshops for reviewers to convey NIMH's vision for innovative areas of research.

SESSION RECESS

Dr. Insel recessed the initial session of the 210th meeting at 5:20 p.m. The Council reconvened the following morning.

RECONVENING THE OPEN SESSION: CALL TO ORDER AND OPENING REMARKS

Dr. Insel welcomed participants and called the open policy session to order at 8:30 a.m. He introduced new ex-officio Council member Dr. Douglas A. Waldrep, representing the Department of Defense. Dr. Insel announced that Dr. Aguilar-Gaxiola has been named Director of the Center for Reducing Health Disparities at the University of California, Davis School of Medicine, and that Ms. Renata Henry has been named President of NASMHPD's Board of Directors. Dr. Insel presented certificates of service to outgoing Council members Drs. Faye Gary, Megan Gunnar, and Eric Nestler.

Approval of the Minutes for the Previous Council Meeting

The minutes of the May 12-13, 2005, Council meeting were adopted unanimously as presented.

POST-HURRICANE DIRECTION FOR NIMH (continued)

Building on the previous day's discussion of NIMH's future direction in response to Hurricane Katrina, Dr. Insel observed that mental health consequences of Katrina will continue to unfold in the future, and it is here that NIMH can have a critical role. He highlighted Dr. Gary's comments on the need for cultural sensitivity and for connection with clergy and others likely to have the greatest impact on populations most in need and on Dr. Kalin's observation that the public's mental health response to Katrina will be enduring and require a strategically planned response. Dr. Insel reported that several Council members would be working with NIMH to construct an effective, ongoing response that will have the impact needed as the consequences of the trauma unfold. He stated that an NIH-wide response team arrived in Mississippi almost immediately to staff a field hospital and that a second group, together with SAMHSA staff, will provide mental health services for survivors and first responders in New Orleans. NIMH has 41 volunteer physicians, nurses, psychologists, and social workers, many with extensive experience in disaster situations and critical care, who are serving in the impacted areas. Next steps will include input from the Council on how to bring frontline services to people in need, consideration of how NIMH's research mission can best inform the response services and practices to be delivered in culturally diverse populations, and eliciting lessons learned from the disaster.

DIRECTOR'S REPORT

In his Director's Report, Dr. Insel updated the Council on important recent issues and activities (http://www.nimh.nih.gov/council/dirreportsept05.pdf).

Department of Health and Human Services (DHHS) Update

Dr. Insel noted that 2 years have elapsed since the President's New Freedom Commission on Mental Health released its final report highlighting recovery, patient/family-centered care, and transformation of the Nation's mental health system (see http://www.mentalhealthcommission.gov/). SAMHSA leads the effort to provide mental health services to the Nation, while NIMH provides the research agenda to establish an evidence base for services and to develop new more effective evidence-based interventions. In July 2005, the "Federal Action Agenda" was released, endorsed by all Federal agencies with a stake in mental health, including DHHS, the Departments of Veterans Affairs, Education, Housing and Urban Development, Justice, and Labor, and the Social Security Administration. The agenda includes approximately 70 action items as first steps, and NIMH's role is to provide the science that informs the service—a priority research area at NIMH.

NIH-Wide Issues

Dr. Insel reported that a draft of a reauthorization bill for NIH was the basis for a hearing in the House Energy and Commerce. The draft bill identifies two kinds of Institutes: 14 specific mission-specific Institutes (including NIMH) focused on a disease, organ, or life stage and 10 science-enabling Institutes and Centers that develop resources and tools that could empower or enable research in other Institutes. Rather than continuing the tradition of having a separate appropriation for each Institute, the draft bill calls for four appropriations—the NIH Office of the Director (OD), a new Division of Program Coordination, Planning and Strategic Initiatives located in the OD; all mission-specific Institutes; and all science-enabling Institutes and Centers. The Division will help to ensure consistency across NIH in terms of data analysis, reporting, and disease coding. The Division also will provide cross-NIH coordination in terms of identifying emerging areas of opportunities or public health challenges that could be addressed across NIH, and in launching major initiatives.

Updates on the NIH Roadmap for Research and the NIH Neuroscience Blueprint

Turning to specific trans-NIH initiatives, Dr. Insel explained that the NIH Roadmap for Research (see http://nihroadmap.nih.gov/) now represents 1.1 percent of the NIH budget and is expected to grow to 1.7 percent in 2008. The Roadmap serves as a resource to deepen the understanding of biology, stimulate interdisciplinary research teams, and reshape clinical research to accelerate medical discovery and improve public health. Dr. Insel reported on the importance of one of the activities, the Molecular Libraries and Molecular Imaging Initiative, which is co-led by NIMH and has developed the first network for molecular libraries' screening efforts and a repository of small molecules for screening. The collaborative network will use high-throughput screening methods to identify functional small molecules, which are small organic chemical compounds that can be used as tools for understanding cellular events involved in health and disease and ultimately help identify possible new targets for diagnosis, treatment, and prevention. Other Roadmap initiatives include the Interdisciplinary Health Research and Training announcements targeted at developing a cadre of investigators with expertise in the application of multidisciplinary approaches to complex diseases; the Institutional Clinical and Translational Science Award designed to assist institutions in forging a uniquely transformative, novel, and integrative academic home for clinical and translational science that has consolidated resources; and the Pioneer Award intended to support individual researchers with novel ideas that are potentially groundbreaking—NIMH scientists are recipients of Pioneer Awards in both the first and the second years of these awards.

Turning to the NIH Neuroscience Blueprint (see http://neuroscienceblueprint.nih.gov/), Dr. Insel reported that NIH will contribute $12 million and the NIH Institutes an additional $9 million for the Blueprint in FY2006. Projects that have been proposed for FY 2006 include announcements on training and on developing research tools to support the neuroscience Institutes.

Budget

In discussing the budget, Dr. Insel noted that NIMH's FY 2005 budget was the largest ever at $1.4 billion, with a record or near record number of total grants funded. However, given increased costs of grants and the small increase in the number of submitted applications, fewer new and competing Research Project Grants were issued in FY 2005 compared to FY 2004, with a resultant estimated success rate of 21 percent for competing applications. Dr. Insel commented that because some large non-competing projects will be ending, NIMH should be able to support approximately the same number of competing awards in FY 2006. He also noted that NIMH remains dedicated to support new investigators and to fund studies that are innovative and address priority research areas.

Dr. Insel commented that NIMH has initiated R56 awards to provide 1 year of funding for high-risk and high-priority new applications that fall outside of the payline but show a likelihood of having a real impact. Dr. Insel noted that an internal NIMH Innovation Committee evaluates Program Officer nominations for these awards, with funding in the range of approximately $1.5 million for fiscal years 2005 and 2006.

Discussion

In response to a question from Dr. Salovey, Dr. Insel stated that the ratio of traditional research grants to center grants has changed little. A high priority at NIMH is to bridge basic and clinical science, and given the successes of center programs such as the Conte Centers, the center mechanism was felt to be a useful mechanism to accomplish this goal as the science matures.

To a question from the audience regarding NIMH's response to Hurricane Katrina, Dr. Insel stated that HHS Secretary Michael Leavitt has tasked the Centers for Disease Control and Prevention and SAMHSA with conducting biomedical and mental health needs assessments, respectively, in disaster response and that NIMH will work with these agencies as requested.

Dr. Vogel-Scibilia asked what efforts were planned to maintain the populations from the large trials, such as the Clinical Antipsychotic Trials in Intervention Effectiveness (CATIE) and the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD), for further investigation and also about the Institute's position on advancing large research programs targeted at patients with persistent and severe mental illness. Dr. Insel responded that as these large clinical trials reach the end of their contracted periods, plans are underway to maintain the study networks as a platform for new projects, initiated by the community. The success of these networks as resources for other studies and any cost effectiveness of future research that may be realized result as a result of these networks will be evaluated.

Dr. Gunnar suggested the need for conveying to the research community the importance of studies that incorporate developmental processes in understanding pediatric disorders.
Dr. Insel replied that NIMH staff members have been discussing a new center mechanism, similar to the Conte Centers, to bring together the best developmentalists with people interested in child psychiatry to expand work in the pediatric area.

COUNCIL WORKGROUP ON MRI RESEARCH PRACTICES: ACTIVITIES UPDATE

Council member Dr. Jonathan Cohen, Professor of Psychology, and Director, Center for the Study of Brain, Mind, and Behavior at Princeton University, explained that there has been a proliferation of neuroimaging research outside of traditional clinical settings in psychology departments, cognitive neuroscience programs, and independent research institutes. However, accompanying this rapid acceleration of research on human brain function are challenges associated with variability in practices across sites, such as staffing, the frequency of scanning, and the availability of on-site emergency personnel. Although Magnetic Resonance Imaging (MRI) is a safe procedure, there are some potential risks. Once recent issue that has received considerable attention is the risk associated with incidental findings—e.g., the failure to detect a potentially significant finding, as well as the problem of "false positives" that may result in undue anxiety, expense, and unnecessary medical procedures. The Workgroup was convened to consider appropriate safety and ethical issues for the conduct of MRI research that would protect human subjects while allowing research to proceed as efficiently and effectively as possible.

Dr. Cohen noted that there are published standards for the use of neuroimaging in clinical settings (e.g., American College of Radiology, International Society for Magnetic Resonance Research, and the Institute of Magnetic Resonance Safety, Education and Research). However, the Workgroup recognizes that the implementation of these standards may differ depending on the context—i.e., in medical versus university-based research settings. The Workgroup's mission is to develop guidelines that are as congruent as possible with existing ones, yet which address research in non-clinical settings.

Workgroup members include Council members Drs. Gur and Cohen, intramural and extramural researchers who use neuroimaging technologies, radiologists, a legal expert, magnetic resonance physicists, and others. NIMH program staff assisted with the meeting and reports. Liaisons from other Institutes (NICHD, NIDA, and NINDS) also attended. Key issues included MRI screening, staffing and personnel, physical facilities, scanning/subject health variables, university versus clinical settings (uniform or customized guidelines), and the need for additional data and updating the guidelines. The Workgroup discussion yielded several key principles for protecting MRI research subjects, including: (1) informed consent to ensure that subjects understand that they are participating in research and not a clinical study, the potential for incidental findings, and the specific procedures for managing incidental findings in various settings and (2) clear definition by every facility of safety-related procedures, including training and certification of operators, participant screening, and management of incidental findings and emergencies. These and other considerations will be addressed in a written report to be presented to Council at a future meeting.

REPORT ON NORTH AMERICAN PRODROMAL LONGITUDINAL STUDY

Dr. Robert Heinssen, Chief, Schizophrenia Spectrum Disorders Research Program, Division of Adult Translational Research and Treatment Development, NIMH, reported on the first-year accomplishments of the North American Prodromal Longitudinal Study (NAPLS), a consortium of eight NIMH-funded projects that investigate the early pre-psychotic phase of schizophrenia.

As background, Dr. Heinssen noted that the schizophrenia prodrome is defined as the period that marks the onset of illness but precedes the appearance of frank psychotic symptoms. The length of prodrome varies considerably between individuals and can range from several weeks to 3 years prior to the first psychotic episode. Current theories describe a gradual intensification of impairment that begins with subtle difficulties in attention and learning. Behavioral problems such as school failure, interpersonal conflicts, and social withdrawal often follow, along with changes in affect such as anxiety, dysphoria, and irritability. Unusual perceptual experiences or odd beliefs are often observed in the weeks preceding the first psychotic episode. Dr. Heinssen observed that much of what is known today about the early phases of schizophrenia is based on the retrospective accounts by patients diagnosed with schizophrenia who are recruited into studies after the onset of psychosis. Researchers have hypothesized that earlier intervention in schizophrenia may produce dramatically better outcomes, including forestalling psychosis completely. Basic questions regarding prevention constitute the near-term prodromal research agenda including prospective characterization of prodrome, criteria for prodrome onset and progression, more precise risk-prediction models, and strategic targets for early intervention.

Dr. Heinssen acknowledged the seminal contributions of Australian researchers Drs. Patrick McGorry and Alison Yung, who proposed the first objective criteria that described the at-risk mental state in prospective terms. These investigators also pioneered a variety of assessment, treatment, and service-delivery mechanisms for persons in the earliest stage of psychotic illness. Currently 30 prodromal research centers span five continents, almost half of which are in North America. Nine prodromal research programs in North America are supported by NIMH funding.

The NAPLS, conducted by 10 newer and seasoned NIMH investigators, offers some advantages for overcoming current rate-limiting factors in prodromal research. The sites employ an identical strategy for identifying persons at risk for psychosis by using the Structured Interview for Prodromal Syndromes. The multisite approach permits recruitment of a larger sample than would be available at individual sites and allows for combining data, which creates significant gains in the rate of data acquisition and statistical power. The goal of the NAPLS project is to address basic questions concerning the validity of current prodromal definitions, risks associated with certain signs and symptoms, and the course of symptoms over time.

NAPLS's first-year accomplishments include attaining Institutional Review Board approval for the project, conducting a cross-site reliability study, developing an electronic data entry program, and creating two composite assessment protocols that cover multiple domains of functioning rated at baseline and follow-up evaluations. Future activity includes data recoding, distribution of the integrated pooled database to NAPLS investigators, and planned manuscript submission.

Dr. Heinssen welcomed input on how to structure a collaborative, prospective, multisite study for the future. Features under consideration include broadening the diagnostic focus to include bipolar illness and borderline personality disorder, creating better integration among prodromal and first-episode studies to achieve better longitudinal mapping of illness pathways from risk through the early phases of serious mental illness, and adding expertise in neurobiological, cognitive neuroscience, and imaging methods. The anticipated public health benefits resultant from NAPLS include improved methods of screening, detecting, and diagnosing early serious mental illness; identification of new targets for biological and psychosocial therapies; and indicated prevention for a broad range of mental illnesses, with the expectation of improved outcomes.

Discussion

Dr. Gunnar asked whether the study would track the treatments that patients receive when they are initially identified for NAPLS, noting that several conditions may initially present with some of the same early cognitive features leading to schizophrenia. Dr. Heinssen responded that the sites will catalogue and track the treatments that people receive in an effort to sort out the influence of specific treatments on subsequent course of illness.

Dr. Heinssen responded to questions from Dr. Warren that although NAPLS does not focus on children and young adults with 22Q11 deletion syndrome as a risk factor for psychosis, such a research focus would be welcomed into the collaboration. Dr. Warren highlighted the importance of collaboration on child and adult psychopathology, in terms of both normal development and psychopathology.

Ms. Hellander suggested adding to the collaborative group a patient representative or a parent in the community who has raised a child with psychotic illness, which might enhance recruitment of an expanded group of parents of children with schizophrenia. She also urged that the criterion for entry into NAPLS move to an earlier age than 12 years. Dr. Insel concurred with the suggestion of adding patient representatives, acknowledging parents' unique expertise.

Dr. Aguilar-Gaxiola asked whether NAPLS can offer insights on the accuracy of diagnosis for minority groups. Dr. Heinssen responded that every project has developed a plan for recruiting ethnic and racial minority study participants and that combining samples across sites should permit statistical analysis with meaningful findings.

NIH DIRECTOR'S REPORT

Dr. Elias Zerhouni, Director, NIH, indicated that as science rapidly advances, NIH must be positioned to embrace that change and translate scientific innovations into health gains for the Nation. The NIH Roadmap for Medical Research was designed to meet that challenge by identifying areas of emerging opportunities to develop areas of science and by understanding and rapidly evaluating the potential for scientific breakthroughs. Citing neuroprotection as an example, Dr. Zerhouni asserted that the mechanisms of dysfunction on the neuronal level must be addressed in a multidisciplinary fashion at multiple levels to achieve real progress and that the NIH Roadmap would provide such an opportunity.

Regarding Hurricane Katrina, Dr. Zerhouni noted that although NIH's initial response was to address the immediate medical needs of those impacted by the disaster, it became clear that pressing mental health issues also required immediate attention. NIMH responded by sending volunteers to the field and by working with SAMHSA to address those needs.

Dr. Zerhouni noted his pride in serving as NIH Director as NIH mobilized on multiple fronts to meet the challenges. He recognized that not only must NIH concern itself with mental health as a disease burden, but also it must consider the immediate and long-term mental health issues in the context of national response to events, including September 11, the war in Iraq, and natural disasters. He stressed that health disparities remain a challenging problem that must be addressed and that an essential component of this effort is to provide for a diverse workforce and diversity among researchers, particularly in mental health, to conduct research in a culturally sensitive manner.

In thanking Council members for their contributions to NIMH's mission, Dr. Zerhouni noted that NIH relies on 21,000 scientists and leaders who serve on peer review sections, advisory councils, task forces, boards of scientific counselors, and other bodies. He reaffirmed the value of peer review and the need to support a multifaceted research agenda that fosters adaptability, flexibility, and innovation.

Turning to the NIH budget, Dr. Zerhouni emphasized that the budget represents an investment in scientific discovery for improving the public's health. He asserted the criticality of accelerating the pace of translating findings into medical and public health practices and the urgency to continue to defend the Nation's investment in fundamental research and development. The current budget represents 1.5 percent of health care costs per individual in the United States and an investment of $96 per American per year. NIMH's budget translates into a $4.70 per person investment. He indicated that we are living in tough times with touch choices, and the challenge is to invest wisely in an effort to address unmet health needs and, in particular, the health disparities that exist today. Dr. Zerhouni also indicated that steps are necessary to avoid losing a generation of young scientists. The average age of first-time NIH grantees is considerably higher than it was 30 years ago, and Dr. Zerhouni stressed the importance of supporting new investigators, particularly in light of the large percentage of the scientific workforce preparing to retire. In closing, Dr. Zerhouni expressed his pride in NIH's scientists, administrators, and leaders in working toward the common goal of improving public health.

Discussion

Dr. Aguilar-Gaxiola praised Dr. Zerhouni's efforts to inspire young scientists.

Dr. Salovey supported Dr. Zerhouni's position on the importance of the peer review process to ensure the quality of science. Dr. Salovey asked how Council might be helpful in reaffirming the value of the peer review process and the NIH science that results. Dr. Zerhouni responded that he welcomes the input and advice of Council members, members of the extramural community, and constituency groups in conveying to the public the importance of basic research and its relevance to public health. Dr. Kelly described his own efforts in working with his congressional delegation about the significance of his AIDS research and noted the importance of educating the media as well—another important vehicle for conveying the value of research.

Ms. Hellander noted that disasters can catalyze people to make positive changes in their lives, and she suggested engaging survivors in underserved Gulf Coast communities in the scientific enterprise through education about the signs, symptoms, and treatments available for mental illness, as well as the role of research. Ms. Henry urged Dr. Zerhouni to encourage all Institutes to appoint advisory boards that reflect the face of the disease or disorders addressed by a specific Institute. She further urged NIH to respond to Katrina with commitments and connections with communities requiring mental health assistance in a way that will make a difference and that will support the elimination of disparities. Dr. Zerhouni noted that because it is difficult to recruit the needed study populations without a community presence, NIH's Clinical Research Associate Corps Program is evaluating the feasibility of organizing 50,000 community-based providers who would be credentialed and connected to information systems and become active participants in research.

COMMUNITY PARTNERSHIP IN RESEARCH: PUTTING THE PUBLIC IN THE PURPOSE

Dr. Kenneth Wells, Senior Scientist, RAND, Professor of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine, and Professor of Health Services, UCLA School of Public Health, and Ms. Loretta Jones, Executive Director, Healthy African American Families, Los Angeles, California, described their experiences with the community participatory partnered research (CPPR) model of community engagement.

Prior to launching into the discussion, Dr. Wells described his work with Ms. Jones in responding to hurricane survivors and displaced families, which included initiating daily supportive conference calls for Los Angeles service providers and community members to discuss care for 3,500 displaced families in the areas affected by the hurricane. He said that fellows and residents in psychiatry were the first responders in the field trying desperately to pull together services where none existed and that a number of them contacted him to ask for mentoring advice about how to provide needed care. He shared several e-mails from these workers in the field and concluded by noting that although there is great task ahead, he welcomed and valued his partnership with Ms. Jones in providing a new perspective on the parameters for responding and combining science, community knowledge, and partnership in an area so geographically damaged.

Ms. Jones introduced CPPR as a model designed to engage communities in mental health research in ways that are enduring and that build capacity in the community. Dr. Wells explained that underserved communities face disparities and typically have little voice in research and programs that affect their own health. He noted that community participatory research is a recommended approach to health disparities but that it had not been evaluated in studies of mental illness—would the model increase public trust, support for, participation in, and uses of the findings of research? Ms. Jones described the Witness for Wellness Program as an example of CPPR. The Healthy African American Families Program, developed in 1992, demonstrated that communities want an active role in activities that affect them. Although the project was intended to focus on preterm delivery, the community asked for a whole health approach—advice that the program adopted. The Circle of Influence Model for Collaborative Research includes the community as the outer ring of the circle, with the next ring composed of resident experts who have expertise and connections to what is happening in the community or "Ph.D.s of the sidewalk" and community partners as the inner ring. Essential ingredients of CPPR include joint goal setting, a planning process that is equal and level, community responsibility and authority for implementation, and sharing results with the community in lay language.

Ms. Jones described the limitations of "community involvement" in traditional research as being one step removed from community centered and driven, with reports back to funders rather than to community members, and as being "for" and not "with" the community. By contrast, CPPR builds sustained capacity to engage a community over time; builds trust and ownership over time; develops shared agendas, action plans, and methods with the community; and places ownership of the research with the community, which results in the community having a sense of ownership of the interventions under evaluation and a stake in removing disparities, thus building sustainable capacity in the community.

Dr. Wells described the Partners in Care program, an NIMH-funded study of evidence-based care for depression in primary care practices. An important study question is the evaluation of the interventions for typically underserved populations. The quality improvement interventions included opportunities for information, resources, and supports to promote better decision making by doctors and patients and demonstrated improved rates of care over the first year when compared to treatment as usual. Over 2 years, participants in the intervention group experienced fewer symptoms of depression (about 1-2 months symptom free), $450 more in health care costs, and 1 additional month of employment. Five-year follow-up evaluations showed a lasting main health effect that was even more pronounced among African American and Latino families than in Caucasian families. The results suggest lasting behavioral changes as a result of the intervention and raise the question of how to achieve this promise in traditionally underserved communities.

Dr. Wells explained that he contacted Ms. Jones to pursue a joint project designed to give information back to the community. As a result of this initiative, a community conference was held, and the community's response was much larger than anticipated, with more than 500 participants meeting to engage in a dialogue on the community's view of depression, available resources, and advocacy. The Witness for Wellness project emerged, guided by principles of trust, respect, participation, knowledge, and experience that drive the partnership. At present, 160 community people and 40 scientists work together to develop and conduct surveys and conduct data analysis; thus science and community expertise are convened to enable communities to continue the research. The overarching goal of Witness to Wellness is to reduce the burden of depression in traditionally underserved populations in Los Angeles. The implementation phase of the program has been ongoing since September 2004, and a unique team of community and community researchers has coauthored a special issue of *Ethnicity and Disease* (January 2006) that describes this and other related research projects.

Council members viewed brief video clips of the community conference highlights, and Dr. Wells explained that one theme coded by community members from the conference's discussion groups was "depression is everybody's business." Dr. Wells commented on the openness of conference participants to discuss their personal experiences with depression and how cultural values and spirituality affect both resilience and seeking treatment.

Another video clip demonstrated the project's orientation and training of academic and community co-leaders, emergence of leadership, and a preliminary, lay-language presentation to the community of the action plans. Ms. Jones emphasized the necessity of knowing, and of earning trust in, communities by investing time and effort. She noted that each workgroup is jointly led by one academic and two community partners.

In conclusion, Ms. Jones reported that depression is being discussed in the community; leaders have emerged; community groups are doing active research and that the groups are growing in number; the academic community is learning and changing; partnerships are clearly important; and the Witness for Wellness Program serves as an example for other diseases. She emphasized that CPPR stimulates community enthusiasm and promotes rigorous research, generates substantial minority participation in research, requires real community resources and power sharing with the community, and requires evaluation strategies that support action and build community capacity.

Discussion

Dr. Kelly concurred with the presenters about the need to engage the community as a partner in developing programs, as opposed to "doing" programs in a community. He noted that community-as-partner requires shared decision making and vision. He suggested educating peer review groups on that importance of community participatory research.

Dr. Gary observed that the CPPR model provides a mechanism to explore best practices. She noted the need for education of new scientists to allow them to be participants in this model as a mainstream process. She revisited the opportunity for hurricane survivors to learn about the research process and for them to teach about their lives, for the process to be captured and integrated into service models, and to develop new theories about how people seek help.
Ms. Jones responded that her organization works in communities with Robert Wood Johnson's (RWJ) clinical scholars and minority medical students from multiple institutions to acquire first-hand knowledge and mentorship to help support research. Dr. Wells added that this is a major activity for the RWJ Clinical Scholars Program.

Dr. Cohen asked how the scope of the approach might be broadened, perhaps by engaging institutions that house many research studies rather than engaging with the community on a project-by-project basis. Ms. Jones suggested pilot testing centers of excellence in communities. This approach would offer opportunities to build relationships with community partners and provide a legacy for the community. She asserted that communities must be able to trust that the research is good and suggested using centers as models for long-term research. Dr. Insel stated that a Roadmap initiative focuses on this issue to build capacity by empowering 50,000 clinicians and other participants around the country from diverse communities to develop a community of academic health centers. Dr. Aguilar-Gaxiola remarked that this presentation reflects Council's concerns and noted the importance of remaining mindful of the ultimate beneficiaries of NIMH's endeavors. He acknowledged the difficulty in changing the paradigm in the research profession. Dr. Insel emphasized that translation occurs in two directions and that the presented model of community engagement highlights the importance of increasing the relevancy of the Institute's research program to the end-users of that research.

Dr. Salovey discussed the need for researchers to be aware of the extended time required for community engagement in participatory research. He noted the value of being available to advise and to stay engaged with the community on issues—and not just about the research project itself. He also noted the value of researchers living in the communities where they are establishing partnerships. Finally, turning to the need for research training, he suggested that NIMH consider expanding training opportunities for basic science by building in training and community-based participatory research in training programs, and Dr. Insel replied that the services research portfolio is addressing this issue. Dr. Gur noted her experience in partnering with an ethnic and minority community and the need for a special approach to engage the community as a partner in research, including opening medical centers and improving access to best care, talking to schools, and otherwise making an effort to be real partners. An added benefit might be better recruitment in studies. Dr. Insel noted that a small Council workgroup would be reviewing the data on ethnic and minority participation in clinical trials. He suggested that that group also might consider strategies to embrace and nurture community partnerships for training, clinical trials, or other research. Drs. Nakamura and Insel expressed appreciation to the presenters for their work and its implications for future research.

PUBLIC COMMENT

Dr. Martin Gittelman, New York University Medical School, noted his experience with the provision of mental health services following disasters. He asserted that because the science is poor for this type of response, NIMH has a role to play in examining the evidence base and in disseminating findings to providers in the field, including religious organizations. Dr. Insel noted that in addition to the activities noted earlier that day, NIMH provided more than 20,000 pamphlets that capitalize on lessons learned from prior disasters to agencies in the Gulf Coast region. He acknowledged the value of educating volunteers and first responders on the use of evidence-based practices.

Dr. Barbara Solt, Institute for the Advancement of Social Work Research, suggested that lessons can be learned from the extensive literature on refugee resettlement as it may apply to the victims of Katrina. Turning to another topic, she noted that her organization convened a symposium on enhancing the health and well-being of lesbian, gay, bisexual, and transgender individuals, families, and communities and for building a related social work agenda. Dr. Nakamura served as a discussant on the state-of-the-science panel, and she noted that a report is to be issued on that meeting (see http://www.iaswresearch.org/).

ADJOURNMENT

Dr. Insel adjourned the 210th meeting of the NAMHC at 12:30 p.m. on September 16, 2005.

I hereby certify that, to the best of my knowledge,
the foregoing minutes are accurate and complete.

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Thomas R. Insel, M.D., Chairperson

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