

**National Institute of Diabetes and Digestive and Kidney Diseases  
National Institutes of Health**

**Network of Minority Research Investigators  
9th Annual Workshop**

**April 21 – 22, 2011  
Bethesda Marriott Hotel at Pooks Hill  
Bethesda, Maryland**

**Summary Report**

**THURSDAY, APRIL 22, 2010**

**INTRODUCTIONS**

*Dr. Sylvia Rosas, Assistant Professor, University of Pennsylvania, Philadelphia, PA, and  
Dr. Lawrence Agodoa, Director, Office of Minority Health Research Coordination (OMHRC),  
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Bethesda, MD*

Dr. Rosas, Chair of the Network of Minority Research Investigators (NMRI) 9th Annual Workshop welcomed participants and asked attendees to introduce themselves and tell why they were attending the workshop. The purpose of this exercise was to let everyone hear the research interests of attendees and what involvement they have had in the NMRI in past years.

After introductions, Dr. Agodoa, Director of NIDDK's OMHRC, welcomed everyone on behalf of Dr. Griffin Rodgers, Director of NIDDK, and said that the mission of the NMRI is to assist in the advancement of the NMRI members in academia, as well as to provide an opportunity to hear from colleagues on the types of high-quality research being conducted by NMRI members around the country. He said that this workshop was a wonderful opportunity for new members to meet those who have been involved in the network for many years, and he encouraged them to network as much as possible over the next two days.

**KEYNOTE ADDRESS**

*Dr. Lynda Szczech, President, National Kidney Foundation, Associate Professor, Division of Nephrology, Department of Medicine, Duke University Medical Center, Durham, NC*

Dr. Szczech provided an overview of her career and the many steps along the way that allowed her to achieve what she sought. A few of the main points she has learned during her career were that you should make sure that if you cannot perform in your job, you tell people before they notice so that your colleagues know you want to do the job but are having difficulties. Also, it helps to have a strong personality; teaching and academic medicine are much like marketing, because you need a patient's attention to promote a message and the patient needs to hear a message that they can understand.

Dr. Szczech provided suggestions based on her experience in career development to which thought should be given thought by young investigators as they plan out their careers. General areas included the following:

- **Choose your topic for research.** When beginning a career, it is imperative to choose a research topic that represents an area that is not overpopulated by current researchers. In her case, Dr. Szczech chose HIV and the kidney because few researchers were involved in this research, although there was a great need to understand the topic better. The topic for research also should be aligned with the patient population you are serving at your institution.
- **Choose good mentors.** This may be one of the most important decisions a young researcher can make. Take time to know what you want in a mentor and select those researchers who compliment your research interests and style. It also is important to have a content mentor and a methodology mentor because both areas will be important to your career.
- **Stack projects logistically.** Begin a project with the power calculation and work backwards toward the question. There must be enough epidemiological information to develop the power calculation; if it does not exist, this is something that must be developed. An advantage of proceeding in a logical manner is that from design to implementation there are many opportunities to publish that will show the logical process. Other advice is that as the project nears the implementation phase, one already should have begun the process of developing another project so there are continual opportunities to publish and move the field forward.
- **Stack projects financially.** A must for any researcher is to know how to develop a budget and know where funds are coming from and what new sources you can seek. In an area of intense financial scrutiny, it is vital that researchers understand what funds can be used for what part of a project. Research is not an individual sport, but a team sport that must be conducted in the interest of the institution. Talk to division chiefs, chairs, or colleagues to gain a better understanding of the budget.
- **Write as much as possible.** Make sure you add to the literature in your research topic at every opportunity. Writing can place you at the center of your topic. Make sure grammar and facts are accurate. The more one writes, the better the writing becomes. Good writers allow readers to focus on the content.
- **Understand what motivates others.** This is especially important depending on the types of funding that motivates individuals or institutions. Many institutions encourage the use of funding from pharmaceutical companies, but some do not. The NIH is most prestigious source of research funding.
- **Stay out of trouble.** It may seem funny to have to say this, but many researchers are not good managers and find themselves having problems in their funding or management of people. Avoid charges of fraud by exercising a high level of oversight in your research. Remember that you will be audited and you must be able to account for time and money.

The regulatory files are probably the most important files to keep organized, and it is best to keep them all in one place. If you deviate from approved plans, it is important that this is documented before the audit.

- **Reach out to national thought leaders.** Do not be afraid to foster relationships with people who are leaders in the chosen field of study. This also will allow you to have name recognition among those in your chosen field of study.

Dr. Szczech provided a brief overview of the science she has pursued since beginning her research career. At the time she began, there were few researchers working in the field of HIV and the kidney (e.g., ESRD), and in fact, the incidence of HIV-related kidney disease was declining. Still, very little was known about why the risk and mortality were declining. The decline became the question for her research. Working with collaborators, they were able to develop a model to explain the decline—the use of protease inhibitors—that also predicted that the rise may begin again because of the increase in the number of people living longer with HIV.

In developing her project, Dr. Szczech looked for databases that did not have nephrologists associated with them but had collected renal data, such as the Womens Interagency HIV Study (WIHS). Analyses of these data found that risk factors for proteinuria were a low CDC4 count, high viral load, race, and the hepatitis C antibody. This led her to speculate that these risks also were risks for kidney disease, which led to additional research on HIV-associated nephropathy (HIVAN). This, in turn, led to her observations that in membranous glomerulopathy not associated with HIVAN, deposits in the glomerulus were one of the characterizations of the condition. Speculation, later confirmed by colleagues, was that this condition might respond to the same anti-retroviral treatment as used in HIVAN. A small, informal consortium was formed to pull together biopsies from patients with kidney diseases; this resulted in the finding that patients with HIVAN received a benefit from anti-retroviral therapy that was not seen in patients without HIVAN. This supported the idea that a biopsy is not needed to confirm HIVAN, but is needed to confirm the patient does not have HIVAN, and help direct treatment.

Other findings from the WIHS data indicated that albuminuria is a predictor of proteinuria in HIVAN patients. Next steps in this research include developing aims and objectives needed to better define the clinical landscape of the disease, including HIVAN, identifying markers for cardiovascular disease, and identifying biomarkers for prevention of the disease.

In summary, Dr. Szczech asked attendees to remember that your passion may not “pay the bills,” so you may have to have other areas of research interest. It also is important to volunteer for administrative roles during times of fiscal shortages. In addition, the following are clichés to live by:

- If you are not afraid that something will slip through the cracks, you are not doing enough.
- Get it off your desk.
- If you don’t get one rejection letter, you won’t know whether you are shooting high enough.
- Throw 10 darts at the dart board and hope one of them sticks.
- Don’t take it personally; they can’t all be gold.

Finally, remember what is really important in your life: the science, your patients, your family, and your self-esteem, and that what is not so important are the images others have of you.

### ***Discussion***

One point that must be stressed is that promotion policies are different at each institution. One must know the rules going into the promotion process and follow them according to what is expected from the institution.

Many institutions encourage collaborations, but do not value collaborations in promotion policies, for example, giving little value to middle authors on publications. Unfortunately, being a first or last author is more valued.

One challenge for young or middle-age researchers is the potential lack of longevity at institutions. Skipping from one job to another may be practical for an individual, but this often leads to a sense that there is a lack of commitment to specific areas of research. This is an individual choice and it is really dependent on the needs of the individual.

### **NATIONAL INSTITUTES OF HEALTH (NIH) MINORITY HEALTH AND HEALTH DISPARITIES**

*Dr. Joyce Hunter, Deputy Director, National Institute on Minority Health and Health Disparities (NIMHD), NIH, Bethesda, MD*

The NIMHD became an NIH Institute in the past year, emerging from the former National Center on Minority Health and Health Disparities (NCMHD). Dr. Hunter presented an overview of the NIMHD and the mission, which includes leading, coordinating, supporting, and assessing the NIH effort to reduce, and ultimately eliminate, health disparities. NIMHD meets its mission by conducting and supporting basic, clinical, behavioral, and social science research; promoting the development of research infrastructure and training; implementing outreach programs and public communication to minority and other health-disparity communities; and fostering emerging programs.

Dr. Hunter highlighted various NIMHD programs of interest to NMRI members. The Institute is trans-NIH and works in all diseases or conditions that affect minority or underserved populations. The NIMHD Centers of Excellence offer support for smaller institutions through P20 mechanisms, and larger institutions through the P60. NIMHD also is unique among NIH Institutes and Centers in accepting endowments to endow institutional chairs, support curriculum development, and to support fellowships for students and faculty.

Other programs of NIMHD include the Loan Repayment Program (LRP), which will be discussed later, the Community-Based Participatory Research (CBPR) program supported by R24 funding, and a program for Building Research Infrastructure and Capacity (BRIC), supported by the P20 mechanism.

The CBPR program is the only 11-year program at the NIH. It includes a 3-year planning phase, a 5-year intervention phase, and a 3-year data dissemination phase. The program supports

interventions in the community, using CBPR methods, for any disease or condition that is important to that community. During the planning phase, researchers have to go to the community to plan the intervention through collaborations with community programs. It is expected that the intervention can be sustained after the intervention and data dissemination phases are completed.

NIMHD also supports the NIH's Small Business Innovation Research (SBIR) program (R43), the Small Business Technology Transfer (STTR) program (R44), the Minority Health and Health Disparities International Research Training (MHIRT) program (T37), and Scientific Conference Grants (R13).

The R01 program at NIMHD is just beginning and supports applications that are very broad based and can include any disease or condition that impacts disparity populations. The goal of the R01 program is to support all investigators whose current research focuses on disease/conditions that disproportionately affect ethnic racial minorities, underserved populations, and rural and low-income populations. There are two types of R01 programs: one for NIMHD Health Disparities Research and one for NIMHD Social Determinants of Health research. These R01s may be given to established investigators or young investigators. In addition, funding by NIMHD is available through the R21 mechanism for the NIMHD Innovative Faith-Based Approaches to Health Disparities Research program and through the R25 mechanism for the NIMHD Science Education Initiative.

NIMHD-awarded grants with a focus on diabetes, kidney and digestive diseases include the following:

- R01: Trans-generational Impact of Maternal Obesity and Diabetes on Health Disparities
- R01: Understanding Health Disparities in the Progression of Type 2 Diabetes
- R01: Evaluating Payment Reform and Provider Practices to Improve Health Outcomes in Chronically Ill Disparity Groups: An Application to Renal Dialysis
- P20: Oklahoma Center on American Indian Diabetes Health Disparities
- P20: San Diego Partnership to Reduce Diabetes and CVD in Latinos
- P56: Cross-talk between mesenchymal cells and beta-cells during islet regeneration

Dr. Hunter explained that the NIH has five Loan Repayment Programs (LRPs), of which NIMHD has two LRPs:

- Health Disparities Research (HDR-LRP)—Encourages health professionals to engage in basic, clinical, or social and behavioral research that is directly relevant to health disparities issues. The program seeks to recruit and retain highly qualified health professionals in research careers that focus on minority health disparities research related to the medically underserved.

- Extramural Clinical Research (ECR-LRP)—Encourages health professionals from disadvantaged backgrounds to conduct clinical research. The emphasis on “clinical research” and on individuals from “disadvantaged backgrounds” highlights the need for the involvement of a cadre of physician-scientists in clinical research to strengthen the 21st century biomedical and behavioral workforce.

For both grant types, the amount of loan repayment is \$35,000, plus taxes and interest per year for 2 years, and you can re-apply after the 2-year period. The application deadline is December 1 of each year for each of the LRPs. In most years, the NIMHD can support approximately 300 applications. Since the program began in 2000, NIMHD has supported more than 2,500 loan recipients, who are now conducting health disparities research, many with R01s. The LRP offers an opportunity to merge all educational student loans that are issued in the name of the applicant. Most student loans qualify. Basic eligibility requirements are a doctoral-level degree, student loan debt equal to at least 20 percent of annual salary, U.S. citizenship or permanent residency, and a non-federal government job. Additional information is available from the website [www.lrp.nih.gov](http://www.lrp.nih.gov).

The race and ethnicity distribution of NIMHD LRP recipients is 36 percent Caucasian, 34 percent African American, 14 percent Latino, 8 percent Asian, 3 percent American Indian and Native Alaskan, 1 percent Hawaiian and Pacific Islander, and 4 percent other/no response.

In conclusion, Dr. Hunter presented research topics of LRP recipients. She encouraged participants to think about minority health and health disparities and to submit grant applications to NIHMD.

### ***Discussion***

In applying for grants or other funding, the study sections are put together based on the science in the application. Because NIMHD applications may be broad and trans-NIH, every attempt is made to put panels together that can give an accurate review of these applications. It is vitally important that each application gets a review of peers, whether it is basic science, clinical science, or a surgical project. The application must have clarity so that reviewers who are not in a specific field can still understand what the applicant is trying to do, how they are going to do it, and what outcome is the focus of the project.

### **NIH/NIDDK FUNDING OPPORTUNITIES**

*Dr. Judith Podskalny, Program Director, Division of Digestive Diseases and Nutrition, NIDDK, Bethesda, MD*

Dr. Podskalny provided an overview of funding mechanisms available through NIDDK and update of changes in the peer review process at NIH. NIDDK offers a wide range of funding for training (T32 and T35) and fellowships (F30, F31, and F32) for graduate and post-graduate medical students, as well as various K-awards for junior faculty and those in transition to higher positions. For newly-independent investigators, NIDDK offers R-series grants (R01, R03, and R21), and for more independent and experienced investigators, the R-series grants and U-series grants, such as U01s, for independent projects. It is expected that those who move from medical

school to being an independent investigator will become mentors for the next generation of young investigators. Dr. Podskalny provided details of the grant types offered by the NIDDK and qualifications and specifications for applications. Highlights included the following:

- **T-series (Training).** These are institutional grants. The Principle Investigator (PI) of the grant appoints students/fellows. There is no peer review of individual projects/students/fellows.
- **F-series (Fellowship).** There are individual grants, wherein the student/fellow is the PI. Applications are peer reviewed.
- **K-awards.** These awards are for early faculty, or post-doc to faculty transitions, and are awarded to protect time for developing a research career. The K08 and K23 are for physician-scientists, K01 for Ph.D.s, and the K99/R00 are for post-doctoral students who anticipate a job offer within two years.
- **Research Project Grants (R01).** The R01 is NIH's most commonly used grant program and is used to support a discrete, specified, circumscribed research project. The R01 can be renewed. There are no specified dollar limits unless this is specified in the Funding Opportunity Announcements (FOAs). Advance permission is required for applications requesting \$500,000 or more (direct costs) in any year, and the R01 is generally awarded for 3–5 years. All NIH Institutes and Centers (ICs) utilize the R01. The parent FOA may be found at URL PA-10-067.
- **Small Grants (R03).** The R03 provides limited funding for a short period of time to support a variety of types of projects, including: pilot or feasibility studies; collection of preliminary data; secondary analysis of existing data; small, self-contained research projects; development of new research technology, etc. These are limited to two years of funding with direct costs generally up to \$50,000 per year, and are not renewable. Although NIDDK does not participate in the parent R03 program, more than one-half of NIH ICs do. The parent FOA is at URL PA-10-064.
- **Exploratory/Developmental Research Grants (R21).** The R21 program, in which NIDDK does participate, encourages new, exploratory and developmental research projects by providing support for the early stages of project development. These sometimes may be used for pilot and feasibility studies. The R21 is limited to up to two years of funding with a combined budget for direct costs usually no more than \$275,000. No preliminary data is generally required, and most ICs utilize this mechanism. The web link for the R21 is at PA-10-069.
- **High Priority, Short-Term Project Award (R56).** This mechanism funds, for one or two years, high-priority new or competing renewal R01 applications with priority scores or percentiles that fall just outside the funding limits of participating NIH ICs. It was noted that investigators are not allowed to apply for R56 grants.

- **Diversity supplement program.** Features of this program include 1-2 years of support via a supplement to an already-funded NIH grant. For NIDDK, the contact person is Dr. Kevin McBryde ([mcbrydekd@mail.nih.gov](mailto:mcbrydekd@mail.nih.gov)).

There is a new look to the FOAs, including a shorter, less administrative information not relevant to application, but it still is template-driven. There have been numerous policy changes in 2011, including restrictions on page limits throughout the sections of the application. Complete information may be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-021.html>.

For career development awards (K-awards), a new 12-page limits applies to portions of the candidates' information combined with the research plan, plus 1 page for a description of training in the responsible conduct of research, 6 pages for the mentoring plan, a 1-page description of institutional environment, and the 1-page Commitment to Candidate's Research Career Development attachment. Statements by mentors, co-mentors, and contributors are limited to 6 pages, but this may change. Complete information may be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-027.htm>.

One important administrative change is that there no longer will be an error correction window. This means that applicants will no longer have the option of making changes to their applications once the due date has passed. It also means that submitting early should be a high priority for applicants.

Post-submission materials have also changed. They include possible revisions of the budget page if changes occur; addition of biosketches for new key personnel; inclusion of letters of support or collaboration for changes to key personnel; and adjustments due to natural disasters. Post-submission materials not allowed include updated specific aims and research strategies, late-breaking research findings, supplemental pages, or new letters of support or collaboration not resulting from a change to key personnel.

NIH will eliminate the 5-day grace period for receipt of letters of reference. These will now be due on the application due date. This change is effective as of April 8, 2011, for Fellowships and June 12, 2011, for Individual Career Development awards (K-awards). Complete information may be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-036.html>. The complete late policy, including the late policy for resubmissions, may be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html>.

The new policy for resubmission applications requires that these be submitted within 37 months of the original submission. The policy on late submission of applications has not changed, but has been reiterated in a policy notice found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html>.

Single-project U01 applications will be required to transition to mandatory electronic submission as of May 25, 2011. Soon, only letters of recommendation will be required for Fellowship applications and the current form that referees use will be eliminated. Also, soon applicants will

be able to submit Change of Grantee Institution (Type 7 applications) and Administrative Supplements (Type 3 applications) electronically.

## **WELCOME REMARKS**

*Dr. Griffin Rodgers, Director, NIDDK, Bethesda, MD*

Dr. Rodgers welcomed participants and noted that except for a recent vote by the Congress, this meeting would not have been held because of a government shutdown.

He reviewed the mission of the NIDDK, the many chronic diseases that are the responsibility of the Institute, and the organizational structure that includes three extramural Divisions focused on diabetes, endocrinology, and metabolism; digestive diseases and nutrition; and the kidney, urology, and hematology. The diseases being researched at the NIDDK are among the most devastating to society, including types 1 and 2 diabetes, cystic fibrosis, obesity, chronic kidney diseases (CKD), urological diseases, and end-stage renal disease (ESRD). The hematological diseases, including anemias, sickle cell disease, and other blood diseases are some of the diseases on whose study the Institute was founded on more than 60 years ago.

NIDDK's intramural program has been a leader in research in many areas. There are more members of the National Academy of Sciences in the intramural program at NIDDK than almost any other NIH Institutes and Centers (ICs).

The integrated science at the NIDDK is illustrated by the focus on obesity, which impacts type 2 diabetes and can lead to chronic kidney disease. Evidence from NIDDK studies among the Pima Indians has shown these connections, but there is a message for the general U.S. population. The economic impact of these diseases is significant, with approximately two-thirds of the U.S. population being overweight or obese resulting in a direct cost of \$147 billion each year related to obesity; for type 2 diabetes, the cost is approximately \$200 billion for the 26 million Americans who have the disease; 23 million Americans suffer from chronic kidney diseases, costing approximately \$27 billion per year. Because most people with CKD do not die from ESRD but heart disease, when the impact of type 2 diabetes, CKD, and ESRD on the U.S. cost of medical care is coupled, it approaches 25–30 percent of the Medicare budget.

As for the NIDDK budget, there is a continual decline in it over time. The 2010 budget of \$1.931 billion was mostly for investigator-initiated research, which is the driving force among medical breakthroughs in our country. The recent American Recovery and rehabilitation Act (ARRA) funding helped fund programs in 2009 and 2010, but it now has ended. In constant dollars, the NIDDK budget has declined since 2006, and R01 paylines have slowed in a time when there has been an increase in applications for funding.

A few of the resources available from the NIDDK for researchers include GUDMAP, the nuclear receptor-signaling atlas, and central repositories with numerous types of tissues and other samples available for use. The eleven NIDDK Centers also focus on specific diseases and conditions relevant to NIDDK research. To bring together everything and to manage it properly, the NIDDK has developed various strategic planning documents in the past few years, as well as

ongoing program review and staff activities to support the core principles of the NIDDK. These core principles are to:

- Maintain a vigorous investigator-initiated research portfolio.
- Support pivotal clinical trials and studies given the importance of the diseases and conditions within the NIDDK research mission.
- Maintain a stable pool of talent, including new investigators.
- To foster exceptional training program.
- To make sure the knowledge gained through NIDDK research is translated to the wider scientific and medical communities.

Dr. Rodgers concluded his presentation by showing the commitment of the NIDDK for supporting new investigators through K-awards and T-awards. He asked that members of the NMRI contribute to the goals and mission of the NIDDK and improve the health of the nation and the world through their research. He asked that they submit ideas that the NIDDK can use in a period of flattening budgets to improve the processes of research. Everything is under review at this point and it is important that NMRI members participate in strategic planning for the future. He said that one way to improve chances of success in the NIH grant process is to take part in NIDDK-specific study sections, because knowing what is important to members of the study sections can improve understanding of what is expected. Another method for involvement is to participate in clinical studies sponsored by the NIDDK. This is especially true in minority communities.

### *Discussion*

The efforts by the NIDDK in translation are significant, including the National Diabetes Education Program (NDEP), the National Kidney Diseases Education Program (NKDEP), the Weight-control Information Network (WIN), and others. These programs are budgeted each year to make sure NIDDK's research is reaching the right populations and the medical communities in the locales that are relevant to higher incidence and prevalence of these conditions. These programs and the NMRI are important for finding patients for NIDDK clinical trials and other studies.

On a question about the recruitment of American Indians in NIDDK clinical trials and the enviable position some trials have of too many people available and willing to participate, Dr. Rodgers said that exclusion criteria should determine recruitment members. Even for those recruits that are excluded still could be involved in other studies or at least kept on a list for future studies.

## **IMPACT OF HEALTH CARE REFORM ON ACADEMIC MEDICINE AND RESEARCH**

*Dr. Ricardo Azziz, President, Georgia Health Sciences University, Augusta, GA*

Dr. Aziz presented a different kind of lecture; rather than science, he discussed healthcare reform and how it will impact academic medicine. In 2010, Congress passed healthcare reform based on the recognition that the country needed to do something about healthcare expenditures. Healthcare spending in the United States rose 1 percent to 17.6 percent of Gross National Product (GDP) in 2009, the largest one-year increase in history, mainly attributable to a 1.7 percent decline in the GDP, the largest decline since 1938. Our 17.6 percent of the GDP spent for healthcare in the U.S. represents the highest rate of money spent on healthcare in the world among developed countries. However, it is not just cost that is driving the healthcare reform issue, but the need to have the country feel as if they are getting good healthcare for the large amounts of money being spent. In fact, this is not the case. Thirty-five other developed countries have higher life expectancies than the United States, which has higher infant mortality rates, HIV/AIDS prevalence, and health inequities than other developed countries; clearly we are not getting the care we need for the money we spend. One of the starkest comparisons among the U.S. and other developed countries is on where we spend our money. For example, we spend almost double the amount of healthcare dollars on acute/emergency care than other developed countries. This is brought about by our high number of uninsured citizens, who only seek care when their conditions reach acute or emergency levels. In fact, the United States also has one of the highest uninsured rates (16.9%) of the developed countries, with disparities varying by region within the country. The Northeast U.S. has the lowest rate of uninsured persons at 12.4 percent, and the South has the highest at 19.7 percent.

The negative impact of healthcare on our economy has many origins, including relatively poor health habits (e.g., obesity and sedentarism, smoking, atherogenic and diabetiogenic food types, etc.), a large number of uninsured who seek only acute care, the profusion of technology, lack of outcomes-based medicine, the significant firewall between consumers and health expenditures, and the need for the healthcare industry to recover research and development costs. The outlook for healthcare costs is worsened by the increasing age (higher costs) and lesser youth (lower tax revenue) going forward; and the recessive economic environment. Worst of all, the promise of better health has not even been kept because our costly healthcare system has not resulted in a healthier population.

Dr. Aziz provided an overview of reasons for the current economic recession and how the “recessive environment” is likely to become the “new normal” for the foreseeable decade or more. One must understand what is driving the economy to understand how healthcare reform will be implemented within the economy.

Healthcare reform became law in 2010 through the Patient Protection and Affordable Health Care Act and the Affordable Care Act, which was more than 1,000 pages long. The pillars of the Act are “cost, quality, and access.” It is hoped that there will be a reduction in the cost of care and improve the health of the population. Wellness and prevention services will be expanded and a series of proposals within the Act give incentives to state and local agencies, and private

employers, to provide preventive services. The new law will reduce the number of citizens covered by healthcare, but also will reduce the number of uninsured from approximately 17 percent to 6 percent. Dr. Aziz explained many of the intricacies in the new law. One of the basics of the new law is reducing waste in the system and the use of duplicate or unnecessary tests. Best practices in medical care will be expected; outcomes will determine reimbursement, which is a controversial aspect of the new law.

Much of the concern about the new law is how to pay for it, especially for the large number of participants in the healthcare system and the expansion of coverage. As written, the new law is cost neutral, although this will not be known until the entire law is enacted by 2014.

Dr. Aziz described academic health centers (AHCs), how they are funded, and the impact of the new healthcare law on academic medicine. The growth of AHCs has occurred since the passing of the laws establishing Medicaid and Medicare in the 1960's, which specified that there would be money for academic research. Studies in the 1990's showed that the number of medical schools increased from 86 to 125 and the number of full-time medical faculty grew from approximately 11,000 to 90,000 between 1960 and 1995. The impact of federal money on AHCs also has allowed more medical education to be offered, although some educational expenses are paid from the clinical enterprise margin.

Challenges in the future for AHCs include the following:

- A further erosion of already lean clinical margins by increased costs (IT infrastructure, primary care investments, etc.) and decreasing reimbursement.
- Disappearing cross-subsidy support for research and education.
- The decrease in the relative amount of federal and state support for education and training.
- The decrease in the relative amount of federal support for research.
- The expansion of multi-mission faculty.

Opportunities include the growth in the experience of identifying and implementing novel and innovative approaches to solving problems, in research inquiry, and in experience in the development of standardized care plans; the development of existing opportunities for interprofessional training; readiness of multispecialty faculty practice groups and AHCs to be aligned/integrated; and the ability to embed quality, efficiency, and performance improvement in the training and education of students and residents, and subsequently staff and faculty.

Dr. Aziz's comments on the importance of education included a focus on developing, to the extent possible, faculty as either clinician-teachers, clinician-researchers, or researcher-teachers, rather than emphasizing the goal that everyone be able to do everything. There must be an increase in leadership development of faculty and staff and the frequency of conversations around Health Care Reform. In addition, there is a need to develop greater training and systems emphasizing the role of interprofessional teams and methods for coordinating care throughout

the healthcare continuum. Another issue for education is where we are going to get more physicians to serve the increased numbers of patients, especially in the elderly population. It is projected that there will be a shortage of approximately 130,000 physicians by 2025.

For the future, there is a need to improve research by expanding the field of competitive effectiveness, outcome, and healthcare delivery investigation, and chronic disease prevention; focus on developing collaborations and partnerships to enhance the translation, efficiency and outcome of research; and improve fund-raising and technology transfer.

Major issues for the future include the following:

- Build a stronger research base to support the increased needs in the healthcare system.
- Spend resources on comparative effectiveness research to evaluate the approaches used in disease prevention, treatment, and outcomes.
- Create a system that emphasizes evidence-based medicine, possibly through a patient-outcomes research institute

On the clinical care side of the healthcare system, it will be critical to implement systems to monitor/report quality in real time; begin testing novel methods of healthcare delivery and maintenance as pilots; begin developing primary care affiliations; implement an effective broad-based IT platform; align and integrate clinical and academic enterprise; and change the culture and incentives of clinical faculties and Chairs. It also is important to embrace and measure quality as a primary goal and determine what the best care model would be to ensure the health of the population.

Dr. Aziz said that the impact on hospitals will change in the next decade as they move to more of an outpatient base than an inpatient base. They must adapt to changing paradigms or risk becoming obsolete.

One model that has gained attention in the past few years is the Accountable Care Organization (ACO). ACOs are non-integrated and discordant organizational structures that have limited experience in coordination of care across the entire healthcare spectrum. They lack a primary care culture and infrastructure (e.g., IT infrastructure), strategies to alleviate the burden of training, a decentralized Department structure, and a Chair/Clinical Leader and faculty incentives and culture.

In conclusion, the AHCs must lead changes in healthcare delivery to address the concerns of cost, quality, and efficiency; must ensure our educational programs generate the physicians and researchers required of tomorrow's health care systems; and understand that research is critical to the effective realization of health care reform.

### ***Discussion***

As the population ages, there is the hazard of end-of-life care that must be addressed. It is estimated that one-third of an individuals' lifetime cost of medical care occurs at the end of life.

AHCs take care of many uninsured during this period; it is anticipated that with the new healthcare reform, AHCs will be better off because they will have greater coverage for these individuals.

ACOs are similar to Health Maintenance Organizations (HMOs), with very high costs for out-of-network services. It is important to remember that economics is a social science and medicine must rely on many other disciplines to solve some of the problems seen in both the current and future healthcare system after full implementation of the new law.

There was a discussion about the individual mandate for health insurance and the role of government in advocating for healthy lifestyles. The example given was a person saying they do not want the government becoming so involved in their lives (e.g., health care requirements or food recommendations), but when they get sick, they expect the government to pick up the tab. This is conflicting information that may sometimes border on irresponsibility, but is part of the unique American personality. It is important that the medical system be aware that these conflicts exist in society.

There is good reason to understand how the clinical enterprise and research enterprise interact in the healthcare system. The AHCs have many bright individuals who understand that the research side and business side need to work together. This involves measuring outcomes and resources to improve quality. This will take input from both the clinical and research side.

## **LUNCH AND NETWORKING (INFORMAL)**

During the lunch period, NMRI members choose to sit at tables labeled by topic. This offered an opportunity for attendees to meet and discuss areas of research interest. Topics included diabetes, digestive diseases, hematology, kidney/nephrology, liver/nutrition, and obesity.

## **MOCK STUDY SECTION**

During a breakout session, participants attended one of the Mock Study Sections. Leaders of the session were provided with sample grant applications (some from meeting participants) to review and provide critical feedback. The Scientific Review Officer (SRO) led a discussion of the feedback sessions. One of the most useful activities during the session was the grading of the sample applications by "study section" participants, with direct feedback on why they would have scored the application as they did. The three study sections were comprised of the following Chair and SRO. Each mock session had experienced researchers who had been successful in grant applications; they provided real-life experiences about their quest for funding, often after being unsuccessful in their first attempts.

### **Mock Study Section 1**

*SRO: Dr. James Hyde, Senior Advisor, Research Training and Career Development Programs, Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK, Bethesda, MD*

*Chair: Dr. Susanne Nicholas, Associate Professor of Medicine, University of California, Los Angeles, CA*

## **Mock Study Section 2**

*SRO: Dr. Lakshmanan Sankaran, Scientific Review Officer, NIDDK, Bethesda, MD*

*Chair: Dr. Eddie Greene, Associate Professor, Mayo Clinic, Rochester, MN*

## **Study Section 3**

*SRO: Dr. Barbara Woynarowska, Scientific Review Officer, NIDDK, Bethesda, MD*

*Chair: Dr. Bessie Young, Associate Professor, University of Washington, Seattle, WA*

## **ROLE OF SCIENTIFIC SOCIETIES AND PROFESSIONAL ORGANIZATIONS IN FUNDING RESEARCH AND THE ROLE OF PHARMACEUTICAL COMPANIES IN FUNDING MEDICAL EDUCATION THROUGH GRANTS**

### **Boehringer Ingelheim Pharmaceuticals, Inc.**

*Dr. Amy Shabazz, Associate Director, Cardiometabolic Medical Affairs, FBM*

*Dr. Jene Martins-Richards, Senior Medical Liaison, Cardiometabolic Medical Affairs, FBM*

Drs. Martins-Richards and Shabazz described their backgrounds and provided information on clinical trials and research being conducted by Boehringer Ingelheim (BI) Pharmaceutical, Inc. Therapeutic areas of BI drug development include cardiovascular and respiratory diseases, and virology; BI currently is moving into the areas of oncology and diabetes, although BI does not have any approved drugs in these areas as yet.

BI was the original developer of tissue plasminogen activator (tPA), one of the most commonly-used drugs post-stroke, which was relicensed to Genentech.

BI grants are issued for education to patients, physicians, providers, or the general public. The educational grants are meant to address unmet medical needs and to bridge the gap on what the pharmaceutical industry knows and what they do from a patient and physician perspective. Grants can be awarded for Continuing Medical Education or other programs for organizations, not for individuals.

Drs. Martins-Richards and Shabazz demonstrated the information available on the BI website regarding funding opportunities. The website URL is <http://www.bipigrants.com/index.html>. Links are present for each area of interest to BI grants available in that area. There also is a tutorial for the website that includes definitions relevant to the grant process. The area reviewed was related to educational grants and included requirements and timelines for applications. Under the website area called investigator-initiated studies, there were instructions for applying for grants in specific disease areas, such as diabetes and endocrinology. It was noted that grants for diabetes and endocrinology cannot be approved until the FDA approves the interventions, which should occur in the second or third quarter of 2011. Dr. Shabazz encouraged participants to consider applying for BI grants.

### ***Discussion***

BI will consider any grant application, for example for hepatitis, but it depends on the concept.

## **American Liver Foundation**

*Ms. Susan Robinson, Vice President, Programs, American Liver Foundation, New York, NY*

Ms. Robinson provided an overview of grant awards and values offered by the American Liver Foundation (ALF). Their 2011 Research Awards Program sponsors research integral to the work of the ALF and of the American Association for the Study of Liver diseases (AASLD). The goal of this program is to improve treatment and find a cure. Since 1979, the Program has provided more than \$23 million in research funding to over 750 qualified scientists and physicians.

In April 2010, twelve scientists representing twelve medical and research institutions were awarded nearly \$1,000,000 to support their research in the areas of acute liver failure, biliary fibrosis, hepatic inflammation, hepatitis C, liver cancer, non-alcoholic fatty liver disease, and non-viral hepatitis.

There are numerous volunteer opportunities through ALF that support mission delivery. They are:

- **Education.** The core program is *Love Your Liver*, an interactive liver wellness education program targeted to elementary, middle, and high school students. The program educates students about the liver and the actions they can take to maximize their liver health and prevent liver disease. It can be tailored to elementary, middle, and high school students in the school and after-school settings.
- **Hepatitis C Program.** This program is just beginning and will focus on patient information and treatment options.
- **Non-Alcoholic Fatty Liver Disease (NAFLD).** This is a program with educational resources for patients and families.
- **Congressional Outreach.**
- **Board of Directors.**

These programs represent some of the most relevant programs that are of high interest to liver disease researchers and organizations. Ms. Robinson encouraged attendees to consider applying to the ALF grant program.

## **American Society for Bone and Mineral Research (ASBMR)**

*Dr. Kristy Nicks, Research Fellow, ASBMR Minority Subcommittee, Mayo Clinic, Rochester, MN*

The mission of the ASBMR is to be the premier society in the field of bone and mineral metabolism through promoting excellence in bone and mineral research, fostering integration of clinical and basic science, and facilitating the translation of that science to health care and clinical practice. Key objectives of the ASBMR are the nurturing and development of future generations of basic and clinical scientists; dissemination of new knowledge in bone and mineral metabolism; and proactive shaping of research and health policies based on scientific advances in the field.

ASBMR was founded in 1977 and has approximately 3,800 members, almost equally divided between U.S. and international scientists and physicians. The predominant specialties of ASBMR members are endocrinology, cell biology, and molecular biology, with the largest subset in basic research. Approximately 20 percent of current ASBMR members self-identify themselves as a minority.

ASBMR support for young investigators includes awards for abstracts at the Annual and Topical meetings, travel grants and awards to co-sponsored events and other research meetings, Junior Faculty Osteoporosis Research Awards, and Career Enhancement Awards.

Dr. Nicks presented the ASBMR Minority Subcommittee Goals. The Subcommittee is charged with increasing membership, facilitating the participation and promoting the professional development of under-represented minorities in ASBMR. The subcommittee's objectives are:

- Increase the number of under-represented minorities engaged in the bone and mineral research field by providing access to resources and training through the development of a mentoring program.
- Promote the advancement of research and careers for under-represented minorities through job opportunities and leadership positions within the Society.
- Develop relationships with other organizations to foster collaboration and raise awareness of ASBMR.

Dr. Nicks described the accomplishments of the Subcommittee, which included compiling and disseminating an annual list of research funding opportunities for under-represented minorities and sponsorship of networking events at the ASBMR 2005, 2006, 2010, and 2011 Annual Meetings (i.e., Minority Breakfasts, Receptions, Focus Groups, etc.).

### ***Discussion***

If a NMRI member wants to submit an application for a grant or other award, they would first need to join the ASBMR. With the exception of ASBMR meeting Young Investigator and Travel Awards, all other Society grant and award programs are available only to current members. Membership is available to any individual with an interest in the field of bone and mineral metabolism. Individuals can apply for membership at [www.asbmr.org](http://www.asbmr.org).

## **SCIENTIFIC PRESENTATIONS**

### **Lead Exposure and Chronic Kidney Disease Among Hispanics**

*Dr. German Hernandez, Assistant Professor of Medicine, Texas Tech University Health Sciences Center at El Paso, TX*

Dr. Hernandez explained that his talk would focus on: (1) understanding the link between lead exposure and kidney function at the population level; (2) describe the association between low-

level lead exposure and the progression of chronic kidney disease (CKD), regardless of the primary etiology; and (3) describe the cross-sectional association between blood levels and kidney function among Hispanic patients with CKD in the El Paso, TX, region.

In providing background, Dr. Hernandez noted that racial and ethnic minorities have a higher burden of end-stage renal disease (ESRD). Blacks, for example, have been shown to have the highest rates of ESRD among racial groups, and Hispanics have higher rates of ESRD than do non-Hispanics. Despite attempts to modify known risk factors such as hypertension, proteinuria, and glycemic control, disease progression still occurs. This raises the possibility of the existence of other factors that have not yet been identified. These could include factors such as health literacy, which often is not measured in studies. Similarly, environmental exposures as risk factors for chronic kidney disease (CKD) progression have not been studied fully.

Dr. Hernandez noted that residents in the vicinity of El Paso were exposed to lead from a local smelter. During the period 1969 to 1971, the smelter released 1,116 tons of lead into the environment. Lead smelting operations in the area ceased in 1985. Lead acts similarly to calcium and is deposited in the bone, where it accumulates, making the El Paso population (81.4% Hispanic) an appropriate group in which to study the effects of lead exposure on CKD.

Dr. Hernandez described the use of lead throughout human history, including sources of exposure. Lead has no known biologic function, so there is no known “safe” level. In addition, lead can affect almost any organ system. Lead is a known nephrotoxicant at high levels of exposure (blood lead levels of 70-80 mcg/dL). Such high levels of exposure generally are not seen any more in the United States. Early changes seen at this high level include: proximal tubular dysfunction (mainly in children); aminoaciduria; glycosuria; phosphaturia; eosinophilic intranuclear inclusion bodies; swollen mitochondria in tubular lining cells, distorted cristae; and a decline in glomerular filtration rate (GFR). These changes are reversible with removal of exposure, treatment with chelation (Ca-EDTA or DMSA/succimer), or both. Continued exposure, however, leads to chronic lead nephropathy, also called overt lead nephropathy, which clinically may involve: inactive urinary sediment, some proteinuria (<1-2 grams), hypertensive vascular changes, “saturnine” gout, and chelatable lead (body lead burden) > 600mcg/72 hr urine following the administration of 1gm of IM/IV Ca-EDTA. Treatment of lead nephropathy involves identifying and removing the source of lead exposure and Ca-EDTA treatment. More common in the United States today, however, are lower levels of lead exposure, with racial and ethnic minorities showing a higher burden of lead exposure according to the National Health and Nutrition Examination Survey (NHANES). In discussing low-level lead exposure and CKD progression, Dr. Hernandez described studies in Taiwan that showed that low-level lead exposure may act as an additional risk factor for CKD and its rate of progression. However, all of these studies were conducted at a single center in Taiwan; other populations have not been studied.

Dr. Hernandez and colleagues’ El Paso study is called the Paso del Norte Kidney Disease Study (PNKDS). The immediate aim of the study is to determine the prevalence of lead exposure among mainly Mexican-American patients with CKD in El Paso as a first step in studying lead exposure as a risk factor for CKD progression in the El Paso region. Study findings thus far include: in the El Paso region, predominantly Hispanic patients with CKD of varying stages do

have measurable levels of lead exposure; the relationship between blood lead levels and estimated GFR (eGFR) appears to be modified by diabetes mellitus; and among nondiabetic patients, there is a strong and significant cross-sectional association between higher blood lead levels and lower eGFR. Further studies are planned, including an attempt to replicate the Taiwanese studies.

### ***Discussion***

Oral chelation via succimer has not been fully studied yet, so comparisons between oral and intravenous chelation therapy cannot be made at this time. With chelation, it is important to make certain that patients do not have a continued source of lead exposure. If they do, chelation may do more harm than good because it may recirculate the lead in their bodies. This is less of an issue in patients with low blood lead levels, but it should be investigated on an individual patient basis.

To ascertain lead exposure in PNKDS, researchers modified the Texas State Department of Health lead exposure questionnaire. Items addressed included age of housing and use of specific traditional Mexican remedies. In Dr. Hernandez's previous work at a public hospital in San Francisco, patients were asked about sources of lead exposure. If none was found, patients were chelated initially to determine if they would have met entry criteria for the Taiwanese trials. If they did meet the Taiwanese criteria, chelation continued. Again, it is important to question patients thoroughly to ascertain all possible sources of lead exposure (e.g., a supplement they may be taking, especially if it is obtained from another country).

All PNKDS patients had CKD (stages 2-4) prior to enrolling in the observational study. None were true "lead nephropathy" patients. Some remediation has occurred in the areas of exposure near the smelter. The potential impact of the planned removal of the smelter is unknown.

The Taiwanese investigators postulated that lead might increase oxidative stress and reduce nitric oxide availability; thus, removing the lead might create a better vascular environment that might result in an improved eGFR.

In the Atlanta region, a significant detrimental effect was observed in children whose lead levels measured < 10 mcg/dl. The PNKDS does not involve children, but they may be more susceptible to the effects of lead because their bodies still are developing. In addition, children are at greater risk because they are more efficient at absorbing lead from the gastrointestinal tract. The idea that chelation may be detrimental to patients who have a current source of lead exposure should be considered carefully in children, as well.

### **Neurobiology of Obesity**

*Dr. Tiffany Beckman, Assistant Professor of Medicine, University of Minnesota, Minneapolis, MN*

Obesity in American Indians (AIs) is a major public health problem. Some AI tribes, such as the Pima Indians, have the highest prevalence of obesity in the world, and obesity-related medical conditions are among the top causes of death in AIs. AI women are 1.4-times more likely than

Caucasian women to be obese, which contributes to childhood obesity. In addition, 75 percent of Pima women in the United States are obese, compared to only 20% of Mexican Pima women.

To account for this, it must be noted that a transition occurred in the 1950's from lower-calorie traditional foods to a mainstream American diet that includes fast food. To illustrate the impact of environmental factors rather than genetic factors, it has been shown that the Pima Indians who live in the Sierra Madre mountains of Mexico retain a traditional lifestyle of hunting and gathering where they haul their own water, grow their own food, and remain physically active, and they have far less obesity than their American counterparts. The Pima Indians who live in the U.S. desert reservation of Arizona eat a high-fat diet of government commodities and are sedentary. They cannot grow their own food in the desert climate.

Dr. Beckman provided an overview of the biologic pathways that influence eating behavior. Human eating behavior is driven by complex regulatory factors that are coordinated by the brain. For example, adiposity signals, such as leptin, insulin, and ghrelin, reflect the state of energy balance in the periphery act in the hypothalamus. Satiety signals that communicate about the presence of food in the gut act in the hindbrain, specifically in the nucleus of the solitary tract. However, food has rewarding or pleasurable properties such as smell, taste, and appearance, and the reward value of these inputs are processed in pathways that include the midbrain's ventral tegmental area and the striatum, including the nucleus accumbens. In addition, cognitive factors such as the social situation, the person's emotional state, or any attempts to volitionally control their eating also affect eventual food intake. Centers that regulate behavior can be found in the prefrontal and orbitofrontal cortex and other brain regions.

Dr. Beckman described a study to examine the impact of cognitive factors on the brain's response to food intake. The study used naltrexone, an FDA-approved drug for alcohol and opioid dependence, to determine its viability for the control of eating behavior. The study in rats indicated naltrexone was able to control eating behavior if injected into the amygdala.

Using Functional Magnetic Resonance Imaging (fMRI) to study brain activity during feeding or viewing foods was a strategy used to better understand brain response to food. One study in people has shown that brain activation to fattening food cues in reward pathways differs from that to non-fattening food. This response is enhanced in obese women compared to lean women, which suggests obese women have overactive reward circuitry in the brain when exposed to food.

An ongoing randomized placebo-controlled, double-blind, crossover pilot study of 30 obese and 30 lean AI women investigated naltrexone and visual stimuli, using fMRI to compare study groups. Preliminary data from the first group of participants from this pilot study was presented. The aims of the study were to use fMRI to compare brain activation associated with the response to visual food cues in obese versus lean AI women; to use fMRI to compare the effects of naltrexone versus a placebo on brain activation associated with response to palatable food cues; and to compare the effects of a single dose of naltrexone versus a placebo on caloric consumption. Results indicated the following:

- Food cues trigger robust responses in brain areas central to regulation of food intake.

- Responses to food cues, especially high energy, “fattening” foods appear to be a regulated aspect of feeding behavior.
- Opioidergic neurons in specific brain regions appear to be important.
- Functional neuroimaging studies can inform us about brain mechanisms underlying our perception of appetite and satiety.
- More work in this discipline is needed.

### ***Discussion***

There are other receptors, such as dopamine, and pathways in the brain other than the opioid receptors that are involved in food behavior. Naltrexone is specific for the opioid receptor and is used for other pleasure-seeking behaviors such as cocaine use and gambling.

One of the observations over the years is that AIs are becoming more Westernized in their diets. There is little data prior to the change to the Western diet, although it is known that fewer calories were consumed by AIs prior to Westernization.

### **MARCO CABRERA POSTER AND NETWORKING SESSION—OVERVIEW**

Participants were invited to see the posters submitted to the NMRI Annual Workshop. This year, 27 posters were submitted in three categories: Basic Science, Clinical Science, and Translation. During the poster review, judges observed the posters and chose winners for each category; the awards were given to recipients on the second day of the workshop.

### **DINNER ADDRESS**

#### **Genetic diversity, race and health: What are we learning?**

*Dr. Charles Rotimi, Director, Center for Research on Genomics and Global Health, National Human Genome Research Institute, NIH, Bethesda, MD*

Dr. Rotimi presented information on the emerging genomic era and the fact that scientists have been able to produce the complete DNA sequences of many organisms, including genomes of humans, microbes, insects, animals, and plants. The post-genome era presents scientists with unprecedented opportunities and challenges, with a major challenge in understanding how differences in DNA sequences inform our understanding of human history and health. An important teaching from the new information about the genome is what it can tell us about human history.

This history of human migration from Africa approximately 200,000 years ago resulted in genetic diversity in human alleles, although approximately 90 percent of human alleles are shared. The study of alleles has resulted in the identification of population-specific variations that allow an understanding of the human diaspora from Africa. One finding is that interbreeding occurred in the Middle East but not in Africa between early man (i.e., *Homo sapiens*) and what is known as Neanderthal man.

One of the techniques for looking at genetic differences among humans is to look for single nucleotide polymorphisms (SNPs), common points in the genome where there are different base pairs. Most genetic variation is evenly distributed around the world, but some—such as the genetic variation for light-colored skin found in Europeans and the reduced ability to sweat found in East Asian populations—are unique to geographic locations. The HAPMAP project has determined that 99 percent of human DNA is shared by all humans on earth. Genetic variation is not constant across animal species. Those species that have not had evolutionary bottlenecks, such as gorillas, chimpanzees, and *Drosophila pseudoobscura*, have a great amount of genomic diversity; those that have had evolutionary bottlenecks, such as humans and cheetahs, have far less genomic diversity.

As an example of local diversity impacting human disease, the *LARGE* and *DMD* genes found in populations in Nigeria, Africa, protect against Lassa fever (sleeping sickness), an evolutionary variation that has relevance to that location but serves no advantage in other populations, such as those in Northern Europe. Similar variations are seen in the genetic influences that account for the 15-20 percent lower level of bilirubin observed in African Americans compared to their white counterparts in the United States and in the variation in the number of copies of the human amylase gene among populations. Amylase copy number is related to the intake of starchy foods, as seen in the lower numbers in African and Asian populations, but higher numbers in European populations. These variations illustrate how the environment has shaped our genome.

An interesting aspect of genetic variability is self-reported ethnic label and genetically-determined ancestry. Anecdotes indicate that it is difficult to know whether a person who self-reports that they belong to one racial or ethnic group without confirmation by genomics. One marker that has been described in the literature is lung-function determined by forced expiratory volume in 1 second (FEV<sub>1</sub>). Data from the Coronary Artery Risk Development In Young Adults (CARDIA) study indicated that African ancestry was inversely related to FEV<sub>1</sub>.

There also are human genetic variation implications for differential response to drugs. For example, SNP rs12979860 near the *IL28B* gene, encoding interferon-lambda-3, is associated with ~2-fold difference in response to treatment for Hepatitis C in patients of European ancestry and African-Americans. Because the genotype leading to better response is in substantially greater frequency in European than African populations, this genetic polymorphism also explains approximately half of the difference in response rates between African-Americans and patients of European ancestry.

This leads to the question of whether race or ancestry is the issue; for example, “black” is used for a wide range of individuals from different backgrounds and different genetic makeup. This can be illustrated by the genetic variant at the HLA-B\*5701 (rs2395029) allele, which significantly reduces the incidence of abacavir hypersensitivity in patients being treated for HIV. Because this allele only existed in one percent of Africans it was thought that there was no reason to genetically test African patients for this allele before beginning treatment [It was noted that the allele is present in 8 percent of Whites and therefore these patients were genetically-tested before beginning abacavir treatment.] HAPMAP studies, however, showed that although the prevalence of the allele was near 1 percent in all Africans, it was distributed differently among African subpopulations such as the Yoruba in Nigeria (0%), Luhya in Kenya (3.3%), and

the Masai in Lenya (14%). This indicates that ancestry should be considered for the individual, not just membership in a racial group.

The same situation has been seen in the use of beta-blockers for cardiovascular disease and hypertension. Approximately 40 percent of African Americans have a variant (G protein-coupled receptor kinases [GRKs]-Leu41) that provides a natural beta-blocker. If a physician treats the 60 percent who do not have GRKs-Leu41, these patients do very well on beta-blockers. However, the 40 percent who have the allele do not have any effect. Data that combines the two groups will give the result that beta-blockers are not effective in African Americans. The take home message from this example is the individuals cannot be treated as representative for all those who physically resemble them, or have some of the same ancestry.

Although studying human genetic variation is important for many reasons, it does not support the concept of “race.” The following comment on race was published recently and may be as accurate a definition as can be supported by science:

*“Race, in countries like the U.S. at least, is a fuzzy social construct by which people with one or two superficial similarities are often clumped together. It reflects simplistic cultural habits reinforced by the questionable practices of government statisticians and medical researchers, among others. Ethnic binning may simplify thought processes and, in some cases, negate them altogether. But using genetics to define race is like slicing soup. You can cut wherever you want, but the soup stays mixed.”*

A misperception of the genetics and drug issue is that we will someday have drugs for white people and drugs for black people (or other racial groups). This is not true. What we will have is drugs for people with certain genetic characteristics regardless of their race or ethnicity. It is likely in these groups there will be individuals from every human racial or ethnic group. As an example, Dr. Rotimi gave the example from his childhood in Nigeria. It was not unusual to get malaria a few times during the year, and he and his family would be treated with chloroquine. Dr. Rotimi would take the drug and have severe reactions and not sleep for days; his grandmother would take the chloroquine and have no reaction. Clearly there are genetic variants at work within the same family.

Dr. Rotimi provided a brief look back at his past, from a child in Nigeria through his undergraduate work at the University of Mississippi to his present position at the National Human Genome Research Institute at the NIH. As a child, he did not accept anything on faith, but wanted to find out for himself. He loved math and science as a child and high school student and later at the University of Mississippi he looked around and questioned why there was such a high incidence of disease in his State and community among African Americans. This led him into the field of biochemistry and genetics. He pursued his Ph.D. in epidemiology, statistics, and genetics, primarily due to his experiences as an administrator in a 268-bed hospital in Greenville, MS. These experiences spurred a lifetime search for the causes of health disparity.

He spoke of the importance of mentors in his career and the ability to recognize where you are in your career development. The following are good points to remember as one develops a scientific career:

- **Science is vast.** Don't be afraid to follow your interests as they develop.
- **Enjoy what you do.** Not everyone enjoys looking through a microscope.
- **“A to B” is not one road.** Don't be afraid to take the road less traveled.

Dr. Rotimi concluded his presentation by providing quotations from scientists that express the love of science and exploration that must be present for success in science but also advise those in pursuit of a scientific career to have patience because the scientific process often is long and slow. His final advice was to remember that science is, “what makes you get up in the morning and want to come in every day is curiosity.”

**FRIDAY, APRIL 22, 2011**

**BUSINESS MEETING AND COMMITTEE REPORTS**

**Oversight Committee Report**

*Dr. Shirley Blanchard, Associate Professor, Creighton University, Omaha, NE*

Dr. Blanchard, past Chair of the NMRI Oversight Committee, reviewed the membership and procedures of the Committee. She noted that the Committee consists of 10 members from various constituencies of the NMRI and members serve a 3-year term. Terms are staggered so that 50 percent of the members rotate off at the end of each year, and terms are congruent with Planning Committee terms. The Chair serves four years for reasons of continuity: one year as Chair elect, two years as Chair, and one year as past Chair. The Chair and Chair-elect are appointed by committee members. The Committee convenes by conference call every three months, with the fourth meeting coinciding with the NMRI Annual Workshop.

The committee's mandate is to facilitate the development of active mentoring between senior and junior members, facilitate outreach, establish groupings of network members based on interests and goals, and match mentors and mentees. The committee coordinates with professional societies that support NMRI regional and annual meetings, evaluates NMRI effectiveness, pursues the retention of NMRI members, and ensures that members fall within the specific programmatic areas of NIDDK.

Committee goals for the past year included monitoring the formalized mentoring program for member career development; identifying specific learning activities; scheduling a focus group to brainstorm how to recruit and retain members; and producing a DVD for recruiting new members. The DVD, which is now in production, will require NMRI members to sign a consent form to allow their pictures/video to be posted on the NIDDK website and to be included in the NMRI marketing video.

Results from the 2010 NMRI Questionnaire were presented and discussed, with comparison to the 2009 NMRI Questionnaire. Dr. Blanchard reported that the number of members completing the questionnaire rose from 28 in 2009 to 111 in 2010, which makes the value of the data more significant. The questionnaire had 24 questions in 2010. Highlights included the following:

- **Academic Status:** Of the 111 respondents, approximately 46 percent were Assistant Professors, 21 percent were Associate Professors, and 5 percent were Professors. Approximately one-third were tenured and two-thirds were not.
- **Meeting Attendance:** Ten percent of respondents reported that they have attended all NMRI meetings; approximately 74 percent have attended more than one meeting.
- **Reasons for Attending:** The five most common answers for why members attend the NMRI meetings include professional mentorship (73%); research opportunities (69%); to enhance grant-writing skills (65%); assistance in developing management skills (51%); and continuing education (37%).

- **Career Development:** Those responding to the question of how the NMRI has helped them in their career, multiple members answered that the NMRI allows them to interact with administrators and stay current in NIH policies; NMRI supports them in mentoring undergraduate researchers; teaches best practices to succeed as a minority investigator; and provides knowledge on how to submit a focused grant application. Above all, mentoring was the main choice as the benefit most valued by being a member of NMRI. On a scale of 1 to 10, NMRI members rated career development at the NMRI as 8.
- **Assisting the Tenure Process:** The NMRI has built a track record of scholarship and service for assisting in the progression of members toward tenure. This is accomplished through letters from the NMRI to faculty institutions, mentoring, making sure research remains the focus of NMRI members, and giving assistance in understanding the tenure process.
- **Mentorship:** More than 70 percent of NMRI members would like to be a mentor, and more than 60 percent would like to have a mentor.
- **Grants:** Of those responding regarding the number of grants they have submitted this year, 41 members have submitted 61 grants, with 16 grants having been funded. This is impressive given the difficult economic times that have made grant seeking more competitive.

Dr. Blanchard asked NMRI members to continue to report their publications, presentations, grants, and tenure and promotions, and to complete the NMRI Questionnaire during the coming year. She also asked that they complete the post-workshop evaluation for this workshop. As for the coming year, she asked that each member recruit one or more new members and to contact at least one organization or society to support the NMRI.

Dr. Virginia Sarapura presented data and information on the NMRI Mentoring Program. The Program provides learning activities on how to be an effective mentor and mentee, helps match mentors and mentees, and creates a framework for continued communication between mentor and mentee. Possible mentors and mentees can find information on the NMRI website at <http://nmri.niddk.nih.gov/>. There have been 23 pairs of mentor/mentees matches in the past three years and by all accounts, these have been very successful.

The Mentorship Program has a structure that encourages communications between mentors and mentees, but also includes the responsibility to have regular contact and documentation of interactions. Dr. Sarapura asked attendees to ask questions of any of the members of the Oversight Committee if they are interested in taking part in the Mentorship Program.

### **Planning Committee Report**

*Dr. Sylvia Rosas, Assistant Professor, University of Pennsylvania, Philadelphia, PA*

Dr. Rosas thanked the Planning Committee members and recognized them with a round of applause. She announced that Dr. Juan Sanabria has volunteered to be the Chair of the 2012

NMRI Annual Workshop. She asked for volunteers for the Planning Committee for next year's workshop and asked that people step forward soon so planning can begin.

Dr. Rosas also encouraged attendees to complete the Workshop Evaluation sheet so they can see what has been valuable at this year's workshop.

## **POSTER SESSION AWARDS**

*Dr. Rosas*

Dr. Rosas thanked poster judges for volunteering to review and score each poster during last evening's Poster Session. She then announced the poster award winners:

**Clinical Science Award:** Rasheed A. Bologun, Associate Professor of Medicine, Department of Medicine/Nephrology, University of Virginia, Charlottesville, VA

### **GDS-15 as a Predictor of Mortality in Elderly Hemodialysis Patients**

*Rasheed A. Balogun<sup>1</sup>, Seki A. Balogun<sup>2</sup>, Alyson L. Kepple<sup>3</sup>, Jennie Z. Ma<sup>4</sup>, Faruk Turgut<sup>5</sup>, Csaba P. Kovcsy<sup>1,6</sup>, and Emaad M. Abdel-Rahman<sup>1</sup>*

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**Translation Science Award:** Ayotunde Dokun, Assistant Professor, University of Virginia, Charlottesville, VA

### **Impaired Ischemia-Induced Expression of Dual-Specificity Phosphatase (Dusp) in Type II Diabetes**

*Ayotunde O. Dokun<sup>1</sup>, Rebecca Maddox<sup>1</sup>, Caitlin Azzarello<sup>1</sup>, and Brian Annex<sup>2</sup>*

*<sup>1</sup>Division of Endocrinology and <sup>2</sup>Cardiovascular Medicine, Department of Medicine, University of Virginia, Charlottesville, VA*

**Basic Science Award:** Jorge Artaza, Assistant Professor, Department of Internal Medicine, Charles Drew University/University of California, Los Angeles, CA

### **Vitamin D Promotes Myogenic Differentiation by Inhibiting Cell Proliferation and Modulating the Expression of Pro-Myogenic Growth Factors and Myostatin in Skeletal Muscle Progenitor Cells**

*Leah A. Garcia<sup>1</sup>, Keisha K. King<sup>1,2</sup>, Monica G. Ferrini<sup>1,2</sup>, Keith C. Norris<sup>1,2</sup>, and Jorge N. Artaza<sup>1,2</sup>*

*<sup>1</sup>Department of Internal Medicine, Charles R. Drew University of Medicine and Science, Los Angeles, CA; <sup>2</sup>Department of Medicine, David Geffen School of Medicine at the University of California at Los Angeles, Los Angeles, CA*

**Basic Science Award:** Michelle Foster, Research Assistant Professor, Department of Psychiatry, University of Cincinnati, Cincinnati, OH

**Visceral Adipose Tissue Removal or Transplantation-Induced Improvement in Glucose Tolerance in Mice: Prospective Role of Hepatic Triglyceride Storage**

*Michelle T. Foster<sup>1</sup>, Haifei Shi<sup>2</sup>, Randy J. Seeley<sup>3</sup>, and Stephen C. Woods<sup>1</sup>*

*<sup>1</sup>Department of Psychiatry, University of Cincinnati, Cincinnati, OH; <sup>2</sup>Department of Zoology, Miami University, Oxford, OH; <sup>3</sup>College of Medicine, University of Cincinnati, Cincinnati, OH*

**POSTER SESSION PRESENTATION**

**Social Determinants of Racial Disparities in Chronic Kidney Disease**

*Dr. Deidra Crews, Assistant Professor of Medicine, The Johns Hopkins University School of Medicine, Baltimore, MD*

Dr. Crews provided data showing that approximately 26 million Americans have kidney damage or decreased kidney function. Chronic kidney disease (CKD) is generally conceptualized along a continuum, with most people having normal kidney function, some being at increased risk of developing CKD, and some developing kidney damage, and some progressing to have end-stage renal disease (ESRD). Approximately 500,000 Americans have ESRD. After more than two decades of increasing incidence rates of ESRD in the American population, there appears to be a slight decline in the past few years.

ESRD incidence is up to 4 times greater in racial and ethnic minorities, with a higher prevalence and onset at a younger age. For example, the average age of ESRD onset is 65 years in American Whites, greater than that for African Americans (58.7 y), AIs (56.6 y), and Asian Americans (60.0 y). For Hispanics, the median age at onset is 58.5 years; for non-Hispanics it is 63.5 years.

To understand whether patients with CKD will progress to ESRD, there must be a definition that defines pre-ESRD based on the stages of CKD. In the Reasons for Geographic and Racial Differences in Stroke (REGARDS), patients were characterized by an estimated glomerular filtration rate (eGFR) less than 60 ml/min per 1.73 m<sup>2</sup> (i.e., the standard from the Modification of Diet in Renal Disease [MDRD] study). REGARDS results indicated that Blacks had a lesser degree of the defined eGFR than Whites, but a greater prevalence of stages 4 and 5 CKD, which is more advanced CKD and may lead to earlier mortality.

In the Multi-Ethnic Study of Atherosclerosis (MESA), Whites had greater or equal prevalence of pre-ESRD CKD (eGFR <60 by MDRD) and cystatin-C-based equations (a biomarker of kidney function) when compared to Blacks, Chinese, or Hispanic individuals. Differences were more striking among women in the study than among men. Data from the National Health and Nutrition Examination Survey III (NHANES III) indicate that racial/ethnic minorities with and without diabetes have greater odds of albuminuria compared with Whites.

The Atherosclerosis Risk in Communities (ARIC) Study showed that socioeconomic disparities also exist in CKD. Results from ARIC illustrated that individuals living in the most impoverished neighborhoods in the United States have more than a 3-fold increased risk of ESRD when compared to those in the wealthiest neighborhoods. It also showed that the differences among Blacks is not as great between those living in low socioeconomic status (SES) neighborhoods and those living in higher-SES neighborhoods. SES also has an impact on the prevalence of albuminuria, with lower SES individuals having a higher prevalence of macro-albuminuria than higher-SES individuals.

Dr. Crews said that her research question has been, after looking at data from the previous studies, whether there is an interaction between race and SES. She described the Healthy Aging in Neighborhoods of Diversity Across the Lifespan (HANDLS) Study, a prospective cohort study on differential influences of SES and race on a number of different health outcomes. Unique design properties of HANDLS are that there are approximately the same number of Blacks and Whites, and approximately the same number from each level of SES. The first wave of data collection has been completed on this 20-year study, which includes participants from 12 neighborhoods in Baltimore, Maryland. Baseline results show that lower SES Blacks have a higher prevalence of CKD. These differences did not exist among Whites. In addition, results from logistic regression models confirmed racial differences in the relationship between low SES and CKD, even after adjustment for diabetes and hypertension.

In the past decade, genetic polymorphisms have been found that are associated with CKD (specifically non-diabetic proteinuric kidney disease) and African ancestry. To determine if SES influences the relationship between ancestry and CKD among African Americans, Dr. Crews and colleagues examined albuminuria in the HANDLS Study. It was found that there were no statistically significant differences in albumin/creatinine ratio by ancestry, but there was a relationship between poverty and albuminuria. In looking at income categories among these participants, there was an inverse relationship between albuminuria and SES level. Further analyses of the REGARDS study found a similar relationship between income and albuminuria.

There are many factors that might be responsible for disparities in CKD, such as SES, biology, education, alcohol and drug abuse, and segregation. Poor nutrition was one factor that was investigated and it was found that lower SES individuals often do not have access to healthy food and do not have the resources to buy healthier foods. In the HANDLS study, participants are being asked questions about food security. Results will be known in a few months.

Dr. Crews said she does not know the answers to each of the questions posed during her presentation, but further studies will try to find logical answers to some. These further studies should be able to identify the most important factors that influence the higher rates of kidney diseases among different racial and ethnic groups, as well as groups separated by socioeconomic disparities.

### ***Discussion***

A research gap exists in Hispanic populations in this area, and this is an area that should be studied. Some of the same challenges seen in studying African Americans and SES/CKD is

likely seen in the Hispanic community. One of the most challenging things is finding enough high-SES Hispanics to be able to make appropriate comparisons to Whites.

The intervention for the high-risk population that Dr. Crews has identified in her work has not been determined. Dr. Crews is exploring possibilities for the intervention, and is focusing on a lifestyle interventions.

The issue of food insecurity is one that is going to be investigated in the Food Inventory assessment of the HANDLS study. Dr. Crews plans to do a separate geospatial study, which will look at the SES status of the county, which can influence a better living environment in a wealthy county regardless of the SES status of individuals. The CHEERS program in Memphis is looking at these issues and is working with grocery stores to improve access to healthy foods.

Psychosocial factors also are important and can be an influence that impacts poverty. Heart-rate variability is an indicator of stress, and a few studies have shown that African Americans have a low heart-rate variability, which can lead to higher rates of cardiovascular disease and possibly future risk of ESRD. Data on heart-rate variability has been collected in the HANDLS study.

### **SO YOU THINK YOU KNOW PUBMED®**

*Ms. Rose Foster, Group Manager, Health Promotion and Outreach, Oak Ridge Institute for Science and Education, Oak Ridge, TN*

Ms. Foster reviewed resources available through the National Library of Medicine (NLM), located on the NIH campus in Bethesda, Maryland. The NLM is the world's largest collection of biomedical information, but also includes toxicology and environmental health resources. PubMed is the most widely known resource available through NLM. It is one of several databases under NCBI's Entrez retrieval system, has links to full-text articles at participating publishers' Web sites, as well as biological data, sequence data, and more from other Entrez Databases and from third parties, and provides literature searches through MEDLINE.

In PubMed, it is possible to find a specific citation; embargoed articles; journals that comprise PubMed Central (PMC); citations to articles reporting research conducted with specific methodologies, including those that report applied clinical research; and systematic reviews. Other functions include the use of My NCBI Collections to save search results indefinitely; build a bibliography or collection; submit NIH-funded research directly into PMC; and access more than 700 texts in life sciences and health care.

Ms. Foster provided a demonstration of PubMed and highlighted specific resources available and how to best use them. She described the use of the Limits function, Medical Subject Headings (MeSH) headings, and the MESH database. Using access to the Internet, Ms. Foster navigated through the various resources in PubMed and MEDLINE, giving examples of specific searches and limits imposed on the search.

Ms. Foster encouraged NMRI members to register for My NCBI. It is an easy way to store searches, update stored searches to see the latest entry, display links to Web resources (LinkOut), choose filters to group search results, and build My NCBI collections.

Tools in PubMed include the following:

- **Single Citation Matcher:** If you know the citation or parts of the citation, this function allows you to move directly to PubMed record for that citation.
- **Clinical Queries:** There are three search filters available in Clinical Queries. They are clinical study categories, systematic reviews, and medical genetics.
- **Topic-Specific Queries:** This function provides specialized PubMed searches on health care quality and costs.
- **PubMed Mobile/PubMed for Handhelds:** This is a new function of PUBMED that allows a simplified mobile-friendly Web interface to PubMed and uses the same basic search functionality and content as Standard PubMed. It displays the article title, first author's name, journal abbreviation, and year of publication and uses the link to Standard PubMed for MeSH vocabulary.

For comparative effectiveness research (CER), NLM resources have the ability to conduct specialized searches to inform discussions on or relating to CER. Search strategies can be designed to compare the benefits and harm of different interventions and strategies to prevent, diagnose, treat, and monitor health conditions in “real world” settings.

One of the potentially valuable resources at NLM are the websites to submit research. NIH Public Access provides a policy on public access to NIH-funded research results ([publicaccess.nih.gov](http://publicaccess.nih.gov)).

There also is a NIH Manuscript Submission System for submitting final manuscripts for inclusion in PubMed Central ([nihms.nih.gov/](http://nihms.nih.gov/)). Resources also include a section of My NCBI on Managing Compliance Policy Using My Bibliography, which helps facilitate management of publication compliance ([nlm.nih.gov/pubs/techbull/jf10/jf10\\_myncbi\\_redesign.html](http://nlm.nih.gov/pubs/techbull/jf10/jf10_myncbi_redesign.html)), and Research Reporting Guidelines and Initiatives for many organizations with charts that list major biomedical research reporting guidelines ([nlm.nih.gov/services/research\\_report\\_guide.html](http://nlm.nih.gov/services/research_report_guide.html)).

### *Discussion*

A benefit for using an institutional account for PubMed, rather than an individual account, is that the institution may be able to allow access to more journals than might be accessible to the individual.

NLM has a function for individuals to get e-alerts through the registration for My NCBI. It is possible to schedule regular updates to searches that you have conducted.

A comment was made regarding the statement that NIH has an “open access” policy. In fact, this is a “public access” system. The difference is that “open access” would mean that journal access would be immediately after publication. Although this is true for some journal articles, most are kept from placement on PubMed for a period of time, such as one year before the full

article is available. Another criticism is that PubMed Central only contains NIH-funded research, which only accounts for approximately 10 percent of all published work. MEDLINE/PubMed has all published journal articles, albeit sometimes only the abstract of the full article with a link to where you may purchase the full article.

## **PARALLEL INTERACTIVE WORKSHOPS**

### **How to Balance Personal/Professional Life**

*Dr. Joan Von Feldt, Professor of Medicine, University of Pennsylvania, Philadelphia, PA*

Dr. Von Feldt provided insights into challenges researchers have in balancing their personal and professional lives. The research environment often is not a 9-to-5 job because of the need to perform steps in investigations that are directed by protocols or needs of a study. Hearing from participants, many of the challenges include giving up parts of their social lives, demands of family life, and all the other stresses on personal lives that are part of any job.

Dr. Von Feldt asked participants to describe the current balance between their personal and professional lives, and to rank it on a scale from “not satisfied” to “very satisfied.” A second activity was to rank how a child, significant other, or other person involved in their lives would rank the balance. This activity was used to begin the discussion about differences in the way participants feel about the balance and how others around them feel about the balance. Generally, those around them feel the balance is better than the researcher does.

The next activity involved listing personal achievements and goals, personal challenges, professional achievements and goals, and professional challenges. After discussion of these topics, participants were asked to write a mission statement that they live by or that they want to live by.

During discussions following the activities, the following overview statements were collected.

- For those more experienced researchers, the pressure to achieve more in their professional life becomes greater, while at the same time, their personal life is often demanding more as children become older and home relationships mature.
- By and large, those involved in the researcher’s personal lives understand the demands of the professional position and work. They understand that there are times when they cannot have the time needed for every event in their lives.
- Things become easier as you age, although there still is a need to balance needs in both personal and professional lives.

Dr. Von Feldt asked that an addition to the mission statement that everyone “be kind to yourself.” Often, people do not spend enough time meeting their needs; this becomes more important the longer one is in a job.

The last activity was to draw two parallel lines on a map of the United States from Maine to the West Coast, and to write achievements on the two lines: two past achievements, two current achievements, and two future achievements. Obstacles were added to the map and colors were used to distinguish those at each step of the career ladder. Lines were drawn between achievements and obstacles that reflected those that had intersected during their career or their personal life. For example, a child's illness would affect both personal and professional spheres, but a denial of tenure would affect mainly the professional life. The point of this exercise is to show that everyone has obstacles they need to overcome, with both personal and professional impacts. Everyone has detours, which can enrich a person's life because they develop resilience and allow one to reassess one's strengths and weaknesses. The exercise also showed that most people have time to change their personal and professional lives as they progress in their careers.

### **How to Budget and Manage Your Funds (Basic and Clinical)**

*Dr. Keith Norris, Executive Vice President for Health Affairs and Research, Charles R. Drew University of Medicine and Science, Los Angeles, CA*

After introductions, Dr. Norris presented advice based on his experiences on how to build a laboratory and/or a research team, and how to budget and manage funds.

The laboratory depends on the personality of the leader, the drive, and the goals. Successful laboratories begin with an end in mind that focuses the research area and helps clarify who one needs on the team and what resources are needed. It is important to identify a senior mentor or mentors to get as good advice as is available. Identify the "go to" person for grants, contracts and/or finances, and the "go to" colleague who can help you. Next, understand the criteria for promotion within the organization.

Hiring decisions can influence the access you will have to funding and the types of projects developed. It is important to understand the type of individuals you will need to enhance your project goals. Other advice regarding personnel is to pick persons that will stay with you, because training takes money and time and quality is better than quantity. Above all, realize that time goes by quickly and it is better to hit the ground running because there is always more to do than you will have time to do it.

Regarding the budget, the following are important steps along the way to realizing your research agenda:

- **Detail your needs in your budget.** Salary/benefits, supplies, travel, equipment and maintenance, phone, postage, publication fees, dues for professional organizations, and IRB/IACUC preparation support should be included. Also, don't forget advertising for positions, temporary staff, cost-of-living expenses over the life of the project, participant stipends, animal costs, core lab charges, and IP filing costs.
- **NIH grant management.** Grants are awarded to grantee organizations on behalf of the PI. Expenditures need to address aims, and certain expenses are generally considered to be institutional costs and not covered by a grant. Carrying forward more than 25 percent of an unobligated balance requires NIH approval, and rebudgeting requires approval by the

sponsored programs and/or NIH. NIH encourages the PI to maintain contact with the NIH Program Official with respect to the scientific aspects of the project, and encourages the PI to maintain appropriate contact with the Grants Management Officer concerning the business and administrative aspects of the award.

- **OMB Circular A-21.** This establishes the principles for determining costs applicable to grants, contracts, and other funding mechanisms. The tests of allowability of costs are: (a) they must be **reasonable**; (b) they must be **allocable** to sponsored agreements under the principles and methods provided herein; (c) they must be given the **consistent** treatment of generally accepted accounting principles; and (d) they must conform to any limitations or exclusions set forth in these principles or in the sponsored agreement as to types or amounts of cost items.
- **Allocable cost:** A cost is allocable to a sponsored agreement if certain requirements are met. Work with the sponsored agency to identify those allocable costs before beginning spending funds.
- **Be wise how you spend the money from your startup package.** If you receive extramural funding, you need to know whether you can keep the money from your startup package. This is usually money that has fewer restrictions on how and when you spend it compared to a grant. Whatever the situation, you should get the details in writing.
- **Keep detailed records.** Keep accounts separate and align expenses with funding sources using an Excel or other spreadsheet. Get clarity on what are institutional resources and what is grant related (OMB circular/OSP), and complete quarterly progress reports with budgets for your area and grants. It also is wise to meet with grants/finance officials often to make sure your records match theirs.
- **Managing Time:** Managing time is one of the most important aspects of budgeting and implementing a project. Certain tasks must be completed before others are started, but you must be balanced and create mandatory fun and personal time.

### **How to Find a Successful Collaboration (Basic and Clinical)**

*Dr. Jackson T. Wright, Jr., Professor of Medicine, Program Director, William T Dahms Clinical Research Unit, Clinical and Translational Science Collaborative, Case Western Reserve University, Cleveland, OH*

Dr. Wright described his experiences in collaborating in the African-American Study of Kidney Disease (AASK), ALLHAT trial, CRIC trial, LIFE trial, ACCOMPLISH trial, and now the SPRINT trial. He indicated that he was able to work with an outstanding group of collaborators in all these trials. He posed two questions to participants: (1) Is it necessary to have collaborators? (2) What strategies are most effective in developing these collaborations?

He shared several observations:

- In general strategies for developing collaboration in basic and clinical research areas are nearly identical. It is important to note that most research is conducted by research teams rather than individual investigators, and increasingly collaborative research in the future will involve multidisciplinary teams of researchers, particularly given the national focus on Clinical and Translational Science Awards (CTSAs).
- No one listed as author of 100 publications is first author on every paper. Each member of the team has to contribute; each assists each other in his/her research projects, and participates in the publication productivity. A successful research career depends on successful collaborations.
- Potential collaborators can be identified and contact with them initiated by multiple methods in this age of international communications.
- Collaborations can be in one's own institution, within departments, multi-institutional, and even international (e.g., ACCOMPLISH trial). Mentors and the individual's academic base serve as the initial base of one's research team. The eventual transition to develop one's own network of collaborators often corresponds with the transition from mentee to mentor. Associations with past mentors should be maintained, and all collaborators should be respected; the scientific community is small, and reputations (both positive and negative) can travel quickly.
- Those seeking collaboration or assistance on a project should consider the search as similar to going on a job interview: be prepared with relevant questions to ask; and ability to show that assistance provided would have a good chance of producing a measurable result or benefit. Mentoring and collaborative activities are investments, and all parties involved should be committed. A good approach prior to scientific meetings is to identify individuals to interact with and meet at the conference and contact them via email as a pre-introduction.
- A follow-up plan after meetings with possible collaborators should be developed. This could simply be a letter thanking the person for taking the time to meet or it may involve a specific proposal with the ideas or roles. One should be cautious however, that one remains in control their ideas; subtlety is involved in expressing ideas and proposals. When possible, researchers should identify a niche that is complementary to those that they intend to work with to show one's value.
- Clear roles should be delineated in the collaboration. Although collaborations can produce life-long friends, the primary function of collaboration is not to make friends. One does not have to like one's collaborators personally but always should be able to respect their expertise and ability to produce.
- All collaborators should be cognizant of what he/she hope to get out of the collaboration. In many collaborations, a researcher will bring a perspective from his/her community; it is that researcher's responsibility to make sure that data are appropriate and results are not misinterpreted.

### *Discussion in answer to questions*

The order of authorship and roles assigned to a publication should be and usually are developed early in the collaboration. The first and last authorship generally are not controversial; whoever received the grant and wrote the first draft is assumed to be first author (even if trainee or junior investigator). Discussions of first and last author usually only arise with large clinical trials and involves a contract and a steering committee. Most senior investigators generally do not feel the need to be first author on publications. Medical students would have to be exceptional to be first author; if the article centers on a trainee/mentoree's thesis, they should be first author. The senior or first author usually decides on the order of names in the publication; this is most often based on the amount of work done in the study and on the manuscript. Mentors can play a role in the placement of the authors in the middle of author list.

Some publications provide opportunities for spin-off articles for which a mid author might serve as the lead author.

A good approach when meeting with potential collaborators is to have already identified what one's role on a project and the specific niche in a collaboration.

In some cases, journal reviewers will raise questions about areas not discussed. In team research, however, everyone should have his/her part of the project, thus allowing all to have the opportunity to contribute to the manuscript.

To best resolve collaborations that are not working, one approach often is to complete that project and invite others for the next project. Collaborations are project specific.

When conflicts exist among the project team, stay focused on producing the data and the manuscript. Every team member was included on the team because of what he/she can add to the project; each member should be meet their commitment to the project regardless of personality issues. If face to face contact becomes too challenging, it may be reasonable conduct interactions via electronic media (email).

How to solicit letters of recommendation or support (e.g. for promotion/tenure) when involved with a large number of collaborators? A challenge in considering potential collaborations is that researchers may not write letters of recommendation for fellow collaborators. This can result in limiting participation in collaborations. One option is to identify and screen the people who might write the letter. In some instances, this may include seeking people who may not know one personally but can examine one's CV. In such instances, one strategy is to prepare an initial draft letter for them.

### **How to Develop a Research Idea and Establish a Research Program (Basic and Clinical)**

*Dr. Carlos Isales, Professor of Orthopedic Surgery, Georgia Health Sciences University, Augusta, GA*

Ideas can occur any time and from any place. The best ideas often come from informal discussions. There are two kinds of ideas: 1) incremental knowledge—extension of current knowledge; 2) paradigm shifts—idea that will change processes in a significant way. One

approach to working with both types of ideas is to obtain funding for incremental ideas while working on the side on any paradigm-shifting ideas. It is often easier to obtain funding for incremental ideas. Dr. Isales encouraged attendees to persist with their ideas, particularly the paradigm-shifting ideas.

The next step is to conduct due diligence about the subject matter of interest—that is, to determine the level of knowledge about the subject. The literature, both past and current, should be reviewed widely to identify what has been published about the idea or the general subject.

It is important to work with people who are trained in using specific laboratory or other tools, or to obtain the necessary training. Unproven ideas will be viewed with skepticism. Newer researchers should identify people who are experts in the area, and one can be respected and should solicit feedback from them regarding the idea.

Funding can be obtained from various sources, including: small intramural grants from one's institution; pilot grants supported by large grants (e.g., P30s) from NIDDK and NIH; and grants from small foundations (e.g., the Lions Club offers grants to help Veterans). Obtaining grant funding from NIH is easier if one has a track record of funding. The NIH "K" (training) awards grants specifically can help provide training in weak areas and strengthen R01 applications. The NIH is a proponent of training and funding rates for its K awards currently are much higher than for the R01.

A successful approach to selling one's idea(s) is to get the idea published in the literature and also presented at national meetings where thought leaders are present. People's perceptions change once an idea has been published. Although the goal is to publish in the most renowned journals, publishing in lesser known journals is a way to build a foundation and name recognition for the investigator. A strategy would be: identifying specialty journals read by study session reviewers, building up a number of publications in a given area so that people associate a researcher with that area, and then moving on to publish in more renowned journals. If the proposed idea is novel but the author has no publications in that area, the ideas will likely be dismissed.

Feedback is important and should be attended to seriously. A mentor can help introduce the mentee to people who can provide feedback regarding ideas, both within the institution and elsewhere, e.g., poster sessions. The idea is for other people to see the work. Comments from grant and journal reviewers should be read carefully and addressed but not taken personally. The reviewers try to make comments that are helpful, and professional attitudes should be maintained. In the grant application, there is no specific number of aims required, but researchers should have data for all the aims provided.

Investigators now work in teams, especially on NIH grants. Researchers should identify people who might be interested in collaborative efforts. Following the team identification, researchers should follow their applications through the review process, including through review of the reviewer rosters on the NIH Center for Scientific Review (CSR) webpage. Personal interactions with reviewers can make a difference with the application review. Researchers should make sure that reviewers are cognizant of the study area being described in their applications. A cover

letter could request a specific study session or Institute or even list several preferred study sessions; this can be particularly helpful for grants that address very specific niches.

### ***Discussion***

Ideas can be shared without being “stolen”. Initially, one should discuss the idea(s) with someone who can be trusted and is respected. Another strategy is to share the idea more widely, as it can be harder for one person to steal an idea if multiple people are aware that it originated from another researcher. A good mentor is important; the mentor should truly support the mentee’s career and not use the mentee to advance his/her own career.

Participants echoed the need for a great mentor, and encouraged focus on and elaboration of specific research over time. One attendee shared her experience in being open to a different approach to her area; she was able to partner successfully with bariatric surgery experts and study data that bariatric surgeons had collected.

Multiple sources of funding provide greater assurance that an individual’s research career will continue.

### **WRAPUP, NEXT STEPS, ADJOURNMENT**

*Dr. Rosas and Dr. Agodoa*

Dr. Rosas asked NMRI members to stand and tell everyone if they have received a promotion in the past year. The following members reported.

Deidre Crews—Assistant Professor

Sophia Hassan—first K-award

Lewis Roberts—to Professor

Rasheed Balogun—Assistant Dean at the University of Virginia

Michelle Foster—Assistant Professor, University of Cincinnati

Dr. Agodoa repeated that NMRI is devoted to its members academic and research success. He wanted new members of NMRI to know that the Network belongs to the members and NIDDK supports them in many ways. He commented that he received an email this morning sent to Dr. Rodgers and himself from Dr. Leon McDougale from Ohio State University. In the email, Dr. McDougale said the following:

See the good news below [referring to the body of the email].

*This week we received good news from Dr. Bob Burstein, Vice-Dean of Academic Affairs, that the Provost is recommending four of our faculty for promotion and/or tenure effective October 1, 2011. All that remains is for members of the Board of Trustees to approve the recommendations at their June meeting. Leon McDougale, M.D., M.P.H. is one of the four and has been recommended for Assistant Professor of family medicine and for tenure. Although I was unable to attend the NMRI conference this year, I want to extend my heart-felt thanks to this great career development program, and would not have reached this milestone in career advancement without attending the NMRI*

*conferences. The conferences were especially helpful in me learning how to write an exciting and fundable grant application. Please extend my sincere thanks to all involved with supporting this very important career development program. Now I can continue to assist others who are, or should be, in the academic medicine pipeline as we seek healthy equity.*

Dr. Agodoa said that this is what NMRI is all about and he congratulated the senior members who helped those like Dr. McDougle.

The success of the Network is dependent on senior members, who have supported NMRI through the years. He stressed that once a person is a member of NMRI, they remain a member until they let the Network know that they no longer want to belong. Dr. Agodoa thanked the senior members who were present.

Dr. Agodoa said that the NIDDK is the only NIH IC with a Network such as the NMRI, but he suspects they all will want to follow the lead because of its success. He talked about the success of the NIDDK summer internship program for minority high school and undergraduate students that began many years ago. At the time, no other IC was interested in taking part; this year, almost all ICs have put out a Program Announcement for a student internship program. This leads him to believe that other ICs will begin looking at the success of the NMRI and try to develop their own networks.

Dr. Agodoa presented certificates to Dr. Rosas for chairing the 9th NMRI Annual Workshop, to Dr. Blanchard for chairing the NMRI Oversight Committee, and to Dr. Omaima Sabek for chairing the November 2010, NMRI South Regional Workshop in Houston, TX. He thanked Dr. Juan Sanabria for accepting the Chair-elect position for the 10th Annual NMRI Workshop to be held in the spring of 2012.

NIDDK also is planning to hold another regional workshop somewhere in the Midwest Region and asked for volunteers to host the workshop. Dr. Agodoa asked that volunteers email Ms. Winnie Martinez if they have ideas for the regional workshop.

Dr. Agodoa thanked all those who helped plan this meeting, including NIDDK staff. Ms. Martinez asked that everyone complete an evaluation for the meeting, and let them know that she would be emailing a request for information for the NMRI Directory.

The meeting was adjourned at 12:40 p.m.