Kidney Interagency Coordinating Committee Meeting

Thursday, June 14, 2007
10:00 a.m. – 12:00 p.m.
NIH Natcher Conference Center
Bethesda, Maryland

Meeting Summary

Participants

Winnie Barouch, PhD
National Heart, Lung, and Blood Institute

Jim Burdick, MD
Health Resources and Services Administration

Patrick Donohue, PhD
National Institute of Diabetes and Digestive and Kidney Diseases

Paul Eggers, PhD
National Institute of Diabetes and Digestive and Kidney Diseases

Eugene Freund, MD, MSPH
Centers for Medicare & Medicaid Services

Robinson (Rob) Fulwood, PhD, MSPH
National Heart, Lung, and Blood Institute

Dan Garver
National Kidney and Urologic Diseases Information Clearinghouse

Elisa Gladstone, MPH
National Institute of Diabetes and Digestive and Kidney Diseases

Mary Harris
National Institute of Diabetes and Digestive and Kidney Diseases

Shirley Hilden, PhD
Center for Scientific Review

Jeffrey Kopp, MD
National Institute of Diabetes and Digestive and Kidney Diseases

Jukka Korpela, MD, PhD
National Institute of Allergy and Infectious Diseases

Tom Marciniak, MD
Food and Drug Administration

Andrew Narva, MD
National Institute of Diabetes and Digestive and Kidney Diseases

Cynthia Palmer, MSc
Agency for Healthcare Research and Quality

Thakor G. Patel, MD, MACP
Department of Veterans Affairs

Max Robinowitz, MD
Food and Drug Administration

Ellen Sommer, MBA
National Heart, Lung, and Blood Institute

Robert Star, MD
National Institute of Diabetes and Digestive and Kidney Diseases

Leah Suter, MS, RD
Health Resources and Services Administration

Ying Tian, MD, PhD
National Institute on Aging

James Tricoli, PhD
National Cancer Institute

Desmond Williams, MD, PhD
Centers for Disease Control and Prevention

I. Welcome and Introductions – Dr. Andrew Narva

Dr. Andrew Narva opened the meeting by welcoming the participants. He explained that Dr. Griffin Rodgers, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), was unable to attend the meeting because NIDDK was revealing the results of a large clinical trial related to the prevention of the development of cirrhosis and liver cancer in people with chronic hepatitis. He then read a statement prepared by Dr. Rodgers in which he applauded the participants' efforts to come together to identify ways to influence the chronic kidney disease (CKD) Federal agenda. Dr. Rodgers' statement emphasized the importance of collaboration, especially in the face of tightening budgets.

Dr. Narva led the introduction of the meeting participants. He then explained that the Interagency Coordinating Committee was created in 1987 by Federal statute. The purpose of the Kidney Interagency Coordinating Committee (KICC) is to encourage cooperation, communication, and collaboration among all federal agencies involved in kidney research and other activities. The National Kidney Disease Education Program (NKDEP) has identified improving the coordination of Federal responses to CKD as one of its goals. As such, NIDDK decided to focus this year's KICC meeting on the issue of CKD.

Dr. Narva identified some potential opportunities for trans-agency collaboration, including responding to pressing issues, such as EPO; planning for the development of the kidney disease chapter of Healthy People 2020; developing health care performance measures; and creating models of care for improved care of CKD.

II. Agency Presentations

NIDDK/NKDEP – Dr. Andrew Narva

Dr. Narva outlined NKDEP's mission which is reduce the morbidity and mortality caused by CKD and its complications by improving early detection of CKD, facilitating identification of patients at greatest risk for progression to kidney failure, promoting evidence-based interventions to slow progression of CKD, and supporting the coordination of Federal responses to CKD. He identified the program's key objectives for 2007 and 2008 as: helping primary care providers better assess and treat CKD; helping health professionals better educate patients about CKD; improving diagnostic tools used to assess kidney function; and improving coordination of Federal agencies working on CKD. Dr. Narva explained that NKDEP's target audiences are patients and the at-risk public, health professionals, and the laboratory community. He presented NKDEP's main messages and current activities for each of the target audiences.

He noted that NKDEP's developmental milestones are to: provide information and resources to patients with CKD; work with community health centers to improve CKD detection and treatment; collaborate with the Department of Veteran Affairs (VA); promote routine reporting of eGFR; and evaluate existing guidelines. Dr. Narva closed his presentation by describing NKDEP's past and current collaborations with agencies such as the Centers for Disease Control and Prevention (CDC), Center for Medicare and Medicaid Services (CMS), VA, Indian Health Service (IHS), Health Resources and Service Administration (HRSA), and the Food and Drug Administration (FDA).

CDC – Dr. Desmond Williams

After presenting national data on CKD and end stage renal disease (ESRD), Dr. Williams explained that Congress provided funding to CDC to begin "to develop capacity and infrastructure for kidney disease surveillance, epidemiology, and health outcomes." The resulting CKD initiative is led by CDC's Kidney Interest Group, which is housed in the Division of Diabetes Translation, but whose participants expand beyond the Division.

CDC took an important first step toward developing public health strategies for CKD by convening an expert panel in March 2007. They are working to establish a national CKD surveillance system that will work seamlessly with United States Renal Data System (USRDS) and CDC's diabetes surveillance systems. So far, CDC has developed the surveillance protocol and is now in the process of identifying relevant data sources. CDC is also working on a screening and demonstration project to identify individuals at high-risk for CKD through a collaborative agreement with the National Kidney Foundation (NKF). The initial plan is to conduct the demonstration projects in four states, with the hope of expanding to more states if additional funding can be secured. CDC is funding a number of studies to examine the economic impact of CKD in the United States.

One study looks at the direct and indirect economic burden of CKD; the second uses a projection model to estimate the future burden of CKD and to test various interventions. Other activities include supplementing kidney measures in the National Health and Nutrition Examination Survey, conducting a study on kidney diseases in the elderly in collaboration with the National Institute on Aging, and conducting a natural history of CKD study in collaboration with VA.

CDC has developed external partner networks with many Federal agencies, including NIDDK/NKDEP, CMS and VA. In closing, Dr. Wiliams highlighted the release of kidney-related articles in the *Morbidity and Mortality Weekly Report* in commemoration of World Kidney Day 2007, the State Diabetes Prevention and Control Programs, and the new Kidney Disease Initiative website.

CMS – Dr. Eugene Freund

Dr. Freund explained that CMS is in the middle of a decision-making process related to CKD initiatives and therefore was unable to share many specifics at this time. He highlighted Fistula First as a great model for effective collaboration. Its goal was to increase the prevalence of AV fistulas in ESRD patients. This goal was achieved with the help of the VA and 27 coalition members. The next step will be to increase the rate of fistulas in incident ESRD patients undergoing hemodialysis. CMS is working to incorporate this goal in the upcoming Quality Improvement Organization (QIO) contract. Dr. Fruend discussed the QIO program. He highlighted a pilot study currently underway in Detroit which uses information technology approaches to improve CKD care with a focus on primary care physicians and nephrologists.

Dr. Freund closed his presentation by explaining the increased expectations of measurable outcomes for the QIO program. NKDEP and CDC have been key partners in helping CMS to develop some of these measures.

VA – Dr. Thakor G. Patel

Dr. Patel provided a brief overview and history of VA's health care system, highlighting some key improvements, including the adoption of evidence-based practice guidelines and quality measures and the implementation of electronic health records (EHR). Dr. Patel focused on the features and benefits of VA's EHR.
For care of patients with diabetes, VA offers evidence-based clinical reminders, personal diabetes profiles, automated decision support for complex patients, and web-based diabetes education and care management. Dr. Patel presented data on diabetes prevalence, process quality, and intermediate outcomes.

Dr. Patel provided an overview of VA's Pre-ESRD guidelines for Primary Care. Developed in 2002, these were the first guidelines for primary care on management of CKD. These guidelines are being revised to incorporate eGFR, stages of CKD, and slowing progression of CKD. Dr. Patel explained that the VA incorporated eGFR system-wide by releasing a patch to all centers. Any time serum creatinine is ordered, eGFR is also reported. Currently, VA reports numeric values for values over 60. He pointed out the many benefits of having eGFR in the database; for example, eGFR data can be linked with medications, laboratory results, co-morbid conditions, and blood pressure control. It also allows for tracking of progression of CKD over time.

IHS – Dr. Andrew Narva
(Dr. Narva presented on behalf of Dr. Vincent Berkley who was unable to attend the meeting due to an illness.)

Dr. Narva provided an overview of IHS, describing it as a primary care organization that delivers care to approximately 1.5 million American Indians. The rates of diabetes and CKD among American Indians are very high. Consequently, in some communities, 1-2% of the adults are on dialysis.

The improvement in CKD care at IHS has been made through the diabetes care delivery system. Dr. Narva presented ESRD data on race and prevalence, which showed a stabilizing trend in ESRD rates among American Indians. To confirm that this effect was not caused by an increase in the denominator (i.e., the number of Americans who self-identified as American Indians), IHS examined similar data among Southwestern American Indians – a community which tends to consist of 'full-blooded' Indians and therefore not likely to change. The same stabilizing trend was also apparent. Dr. Narva described the Pima study, an National Institutes for Health study that has been underway for nearly four decades, which provided further evidence that the decrease in ESRD may indeed be related to improvement in care to patients with diabetes.

Dr. Narva highlighted some of the lessons learned from improving CKD care at IHS: changes are usually implemented by non-physician health professionals, although physician support is necessary; it is critical that

existing health care professionals feel more comfortable with treating kidney patients and delivering necessary care; and changes have to be tailored to patient populations and health care delivery systems.

AHRQ – Ms. Cynthia Palmer

Dr. Palmer presented the mission of AHRQ—to improve the quality, safety, efficiency, and effectiveness of health care for all Americans—and listed its many customers, including health care providers, consumer and patients, policymakers, purchasers and payors, and other health officials. She then highlighted the following large databases that AHRQ maintains that may be of use to the kidney community: the National Healthcare Quality Report (NHQR), National Healthcare Disparities Report (NHDR), the Medical Expenditure Panel Survey (MEPS), and the Healthcare Cost and Utilization Project (HCUP).

Ms. Palmer provided some examples of recent AHRQ grants that are focusing on CKD and dialysis. She also shared information about the Evidence-Based Practice Centers and provided examples of two reports related to CKD. She dedicated the remainder of the presentation on the Accelerating Change and Transformation in Organizations and Networks (ACTION) program, which she directs. ACTION-funded contracts promote demand-driven innovation in health care delivery and focus on generalizability to promote spread to other settings. She outlined the contract process and explained that AHRQ anticipates awarding over a dozen contracts in FY07, totaling $11.6 million, with approximately 75% of funding from AHRQ and 25% from external sources.

HRSA – Dr. Jim Burdick

Dr. Burdick described the mission of HRSA's Division of Transplantation (DOT) as establishing donation as a public value and routine health practice; providing structure and oversight for a transplant system; and ensuring the safety, efficacy, and continual advancement of donation and transplantation. He noted that transplantation is more cost effective than dialysis and has better outcomes. Dr. Burdick outlined the social and behavioral grant programs, which focus on model interventions to increase donation rates, education of primary care doctors, and registry grants. He then provided an overview of the Transplantation Breakthrough Collaboratives. Since the Collaboratives started in 2003, organ donation has increased significantly every month.

He described an allocation study that is analyzing age-distribution of kidney recipients; he also presented prevalence graphs on "lost to follow up" for kidney transplant patients. He then reviewed the Clinical Interventions Grant Program, whose focus is on increasing the number of donors and transplantable organs and the studying the physiology of donor management and preservation. He explained that through a new initiative, DOT provides reimbursement of travel and subsistence expenses to living organ donors.

Dr. Burdick closed his presentation by highlighting a few inter-agency collaborations, including a living kidney donor follow study with the National Heart, Lung, and Blood Institute and the National Institute on Allergies and Infectious Diseases, as well as the Transplant Transmission Sentinel Network with CDC and FDA. The DOT also has frequent interactions with CMS.

FDA – Dr. Max Robinowitz

Dr. Robinowitz's presentation focused on regulatory issues and processes associated with the review and approval of medical devices. The FDA's Center for Devices and Radiologic Health (CDRH) regulates diagnostic, therapeutic, and general purpose devices; as well as in vitro diagnostic tests. All devices have common principles for regulation; the CDRH applies the Total Product Life Cycle concept and has components that interact with all stages of the cycle. Dr. Robinowitz discussed the value of FDA device regulation for the public as well some limitations. He then outlined FDA's role in technology transfer within the six-tiered model of efficacy for diagnostic devices. He presented on safety issues for therapeutic and medical devices and in vitro diagnostics tests.

FDA – Dr. Tom Marciniak

Dr. Marciniak presented on the work of FDA's Center for Drug Evaluation and Research (CDER), whose focus is to approve drugs. He explained that over the past five years, CDER has only approved three new products for CKD. CDER frequently deals with proprietary information, however, the reviews for approval are posted on FDA's website. Although most of CDER's activities are reactive, the Center does engage in proactive activities, including formal advisory committee meetings, informal meetings, working groups, and the issuance of

guidances. For each type of activity, Dr. Marciniak provided CKD-related examples, including an upcoming formal advisory committee meeting on predialysis use of phosphate binders and an upcoming meeting with NKF on proteinuria as a surrogate endpoint. Dr. Marciniak also referenced the CDER working group on renal studies, which might be an opportunity for collaboration with NIDDK.

III. Discussion and closing

Dr. Narva opened the discussion to all participants. The following topics were raised and/or briefly discussed:

- Use of Scribner Shunts as an alternative way to provide acute dialysis
- Response to EPO inquires
- Opportunities to collaborate with VA and identifying appropriate contacts
- Ways that the agencies can work together to increase the number of drugs available to slow CKD progression
- Importance of increasing the use of available interventions to slow CKD progression
- Developing models for improving care through HRSA Collaboratives and community health centers
- Current and planned studies looking at cardiovascular risk for CKD
- Possibility of working in small groups on issues of common interest

Dr. Robert Star invited participants to identify new areas of research for consideration by NIDDK. Participants listed the following: early stages of CKD, precursors, factors that predict progression, and transition between CKD and dialysis.

Dr. Narva thanked the participants for their thoughtful and relevant presentations and discussion, and said he looks forward to next year's KICC meeting and the interim conversations.