

Kidney Interagency Coordinating Committee Meeting

Friday, June 12, 2009
9:00 a.m. - 12:00 p.m.
NIH Natcher Conference Center
Bethesda, Maryland

Meeting Summary

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Welcome and Introductions

Andrew Narva, MD

Dr. Andrew Narva welcomed everyone to the meeting of the Kidney Interagency Coordinating Committee (KICC), introduced himself, and led the introduction of the meeting participants. He explained that the mission of the congressionally mandated Kidney, Urologic, and Hematologic Diseases Interagency Coordinating Committee (KUHICC) is to encourage cooperation, communication, and collaboration among all Federal agencies involved in kidney research and programs.

PRESENTATIONS**Healthy People 2020 Objectives**

Paul Eggers, PhD

Dr. Paul Eggers presented the proposed Healthy People (HP) 2020 objectives as they compare to current HP 2010 objectives. Some objectives will remain the same; but others may be rephrased or appear in several versions due to variation in denominator populations or specific situations. For each objective, he stated one or more of the following: the goal (e.g., incidence, prevalence, or mortality rate), the nation's success in meeting previously-stated goals, the dataset that is or will be used for baseline and future comparison, and issues or controversies that are being addressed to finalize the list of 2020 objectives. The main data source for these objectives is United States Renal Disease Study (USRDS), however Dr. Eggers stated that National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is hoping to incorporate data from both the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA).

Participant Questions/Comments

- Dr. Leonard Pogach expressed concern about objectives not being supported by evidence-based research, particularly objectives related to A1C, ACEs and ARBs, pre-hypertension, and lipids. He recommended that evidence levels be reflected in the objectives and modified as evidence levels improve.
- Dr. Kevin Abbott suggested adding caveats regarding the use of A1C, which is dependent on the patient's hemoglobin level, and the use of fructosamine, which depends on the patient's albumin level.

NIDDK should not assume that all providers know how to use these tests. Dr. Pogach agreed and added that the A1C test is a complex issue, requiring an exercise in caution.

- Dr. Robert Star posed a question regarding the assessment of the level of glycemic control and the availability of data sets that NIDDK could be using for developmental goals. Dr. Desmond Williams said that National Health and Nutrition Examination Survey (NHANES) measures the level of awareness of CKD in the United States (US) population; results show that the level of awareness is less than 5% in stages 1 and 2, and about 41% in stage four. CDC continues to track these data.
- Dr. Narva mentioned that professionals use the term “microalbumin test” for various tests, which is part of the reason that NKDEP discourages use of this phrase. He added that most guidelines suggest a quantitative measure and asked Dr. Eggers if they can narrow the assessment to people who either have a urine albumin-to-creatinine ratio or a 24-hour collection.
- Dr. Bernard Kozlovsky commented that a recent conference presenter reported that 59% of end-stage renal disease (ESRD) patients on dialysis (in the presenter’s region) were not given information about transplantation as a treatment option. He asked the committee if they found this to be true through their research. Dr. Narva responded that USRDS data suggest that a high percentage of patients have received information about transplantation, but knows from experience that many patients do not hear about transplantation or do not hear about it in a positive way. Ms. Casey said that a new regulation (October 2008) for dialysis facilities requires patients to be informed of all treatment options including transplantation. In addition, the decision to refer a patient for transplant must come from a transplant center as opposed to the dialysis center; and the plan of care must outline whether or not the patient is a transplant candidate and has been waitlisted. Dr. Eggers clarified that the HP 2020 goals are suggestions and that they reflect ranges of outcomes. He feels that HRSA and USRDS have fair ascertainment of whether or not a person receives a transplant or is waitlisted; however, he recognizes that documentation on how the patient is informed about transplantation may be questionable.

CKD Surveillance Fact Sheet

Sharon Saydah, PhD, MHS

Dr. Sharon Saydah presented on CDC’s plan to create a CKD fact sheet. Its purpose is to provide definitive information about the burden and consequences of CKD in the US. CDC envisions this fact sheet will be used and customized by partners, as needed, so that it can address different needs and target audiences. It will be modeled after a similar CDC fact sheet on diabetes. The fact sheet will be updated on a regular basis (e.g., every 2 years) with as-needed mini-updates in the interim.

CDC foresees that the development of the two-page fact sheet will be an interagency activity, with participation from key partners, including KICC members and patient advocacy groups. CDC recognizes that certain issues will be raised, such as the definition of CKD, so it welcomes input from others. CDC also welcomes input about data sources that should be used to best represent the US population.

CDC’s proposed approach is to develop a small methods group to address these issues, send a draft of the fact sheet to a larger group of reviewers for feedback, and seek consensus by all agencies and parties. The target release date is March 11, 2010, which is World Kidney Day.

Participant Questions/Comments

- Dr. Narva commented that several issues may challenge the development of the fact sheet, such as defining and staging of CKD. He recommends that CDC focus on those with progressive CKD. Dr. Williams agreed that controversy exists in regards to the definition and classification of CKD, noting that he recently heard related discussions at the World Congress of Nephrology conference. Specifically, many do not accept the current definition of CKD. A follow-up meeting to discuss the issues is scheduled for October. Dr. Narva added that NKDEP does not promote the current approach to staging.

- Dr. Star asked that CDC consider using data from the Chronic Renal Insufficiency Cohort Study (CRIC)—a long-term progression study of about 6,000 people with CKD—which will be available soon. Dr. Star mentioned that the CRIC study will review nine or 10 different definitions of kidney and cardiovascular progression, and will include death and risk factor equations. He added that NIDDK is planning to develop a scoring system or progression/risk factor calculation. Dr. Williams mentioned that CDC will be reviewing the significance of other kidney measures, but on a smaller-scale, and should gain clarity over the next year or two regarding which patients need the most attention.
- Dr. Eggers mentioned that the number of people diagnosed with CKD remains controversial and agreed with others about the importance on focusing on those at risk for progression.
- Dr. Abbott asked Dr. Williams if the fact sheet will account for patients with acute kidney injury (AKI) because it may be an independent or overlapping factor. Dr. Williams said that most data sets make it difficult to distinguish the difference between AKI and CKD; therefore, CDC will treat AKI cases as CKD cases. Dr. Star added that NIH will address this in two ways: 1) The CRIC study will research cases of AKI, and 2) The ASSESS AKI study, which is a long term study of patients diagnosed with AKI in a hospital setting to monitor any progression of kidney and cardiovascular disease over a three or more year period of time. This study should begin in September.
- Ms. Teresa Casey added that she is pleased that CDC is developing this fact sheet and asked if Dr. Saydah could elaborate on CDC's timeline. Dr. Saydah said that CDC envisions its methods group meeting this summer, and hopes to send a proposal to a larger group in September. Once the methods have been agreed upon, CDC anticipates sending a draft fact sheet to others for review in November. Dr. Williams added that the methods group will primarily consist of people with CKD data and/or analytic experience and that the fact sheet's development will be a very organic process.
- Dr. Eggers introduced a new online product from USRDS, which is a series of tables that makes data available much earlier than the Annual Data Report (ADR) series. Data is now available through the second quarter of 2008, whereas the 2009 ADR, which will be released in fall, will publish data through 2007.

Quality Improvement Organizations and Medicare Improvements for Patients and Providers Act (MIPPA) Updates

M. Teresa Casey, RD, LD

Ms. Casey explained that her presentation will provide an update on the CKD initiative of the Quality Improvement Organizations (QIO) and on MIPPA Section 152(b). Fifty-three QIOs, with goals to improve health care among Medicare beneficiaries, currently contract with Centers for Medicare & Medicaid Services (CMS). The current theme-based three-year statement of work (SOW) began in August 2008 (posted online for those interested in learning more) to address CKD amongst Medicare patients. Limited to 10 states in the current SOW, the goal is to increase the frequency of early detection of CKD in beneficiaries with diabetes, the use of medication (e.g., ACEs and ARBs) to slow the progression of kidney failure, and renal replacement therapy counseling prior to the initiation of dialysis. Additionally, QIOs must monitor their interventions and data to ensure that their work does not unintentionally cause a disparity to worsen. They are responsible for evaluating state-level data to identify disparities, choosing a disparity to focus on, choosing an improvement target, and reporting quarterly on their progress to reduce that disparity. QIOs are also expected to enter into collaborative relationships within their states and conduct activities that support achievement of at least one of the CKD clinical focus areas—all with the goal of achieving sustainable CKD system-level changes.

Limited to claims data, the QIOs measure the annual urine microalbumin testing in the diabetic patient population, measure the frequency of ACE and ARB use in patients with hypertension, diabetes, and CKD, and monitor the incident hemodialysis arteriovenous fistula (AVF) rate. The goals are 4% improvement at 18 months and 10% improvement in 28 months using either relative improvement (first measure) or reduction in failure rate calculations (second two measures). If QIOs meet the goals for all three measures, they will have improved the care of 7,300 beneficiaries.

CMS is working with a number of national organizations (including the Renal Physicians Association and NKDEP) to promote the goals of this initiative. QIOs provide on-site technical assistance, provide tools and resources, perform academic detailing on the CKD standards of care at the physician-office level, provide staff education on CKD screening and treatment, and provide patient education materials. Ms. Casey provided examples of the types of activities that are being implemented in pilot states per clinical focus area, such as provider recruitment, interventions, collection/utilization of tools/resources, and data collection and analysis.

Ms. Casey provided an update on the MIPPA Section 152(b) legislation, which provides Medicare coverage for Kidney Disease Patient Education Services for individuals with Stage 4 CKD. Up to six comprehensive educational sessions will cover: the management of comorbidities, including for purposes of delaying the need for dialysis; prevention of uremic complications; each option for renal replacement therapy (including at home and in-center hemodialysis and peritoneal dialysis); vascular access options; and transplantation. MIPPA also mandates that services be designed to ensure that the individual has the opportunity to actively participate in his/her choice of therapy, and be tailored to meet the needs of the individual involved. CMS held two events to solicit stakeholder feedback; transcripts are available online. CMS cannot comment on pending proposals to implement this section of the MIPPA legislation; however, CMS encourages people to look for the Medicare physician fee schedule notice of the proposed rule making, scheduled for release this summer. The proposed rule should include language on how CMS intends to implement the section.

Participant Questions/Comments

- Dr. Star asked if the CKD QIOs effort is being approached as an integrated program to improve the full scope of care, targeting the entire health professional team. Ms. Casey said that QIOs have adopted the Chronic Care Model as their logic model but that each QIO uses a different approach—most targeting the team. In general, CMS provides QIOs with guidelines but leaves interpretation and implementation to QIOs, so that CMS can evaluate effectiveness for the program's future expansion. CMS's support contractor will review the QIO interventions to see which are the most effective, but the method for this review has yet to be determined.
- Dr. Narva explained that many past health care improvement efforts have originated from the renal community, which has led to limited success because this community has little experience implementing change. He observed that QIOs have been successful, despite limited expertise in CKD, because they are specialists in improving care.
- Dr. Pogach reiterated his concerns about projects being supported by evidence-based research, particularly related to the recommended use of A1C, ACEs and ARBs, and assessment for microalbuminuria. Ms. Casey explained that CMS develops projects based on clinical practice guidelines and NQF endorsed measures, which do not change as quickly as the evidence does. She clarified that CMS does not dictate to QIOs the interventions they must implement. Instead, each QIO works with their partners to see what works best for them. Dr. Narva mentioned that NKDEP has been involved with several QIOs and understands Dr. Pogach's concerns. Because the program is decentralized, there is a gap between the agencies that set the standards of care and the programs that implement them.
- Dr. Narva observed that the MIPPA process has not been as transparent as the QIO initiative. Ms. Casey explained that CMS can solicit feedback, but this must be an open public process.. She said that agencies will have the opportunity to comment once language is placed in a proposed rule because CMS must respond to DHHS comments submitted during the clearance process and to public comment after the rule is published. Ms. Casey said that NKDEP may be able to help shape the content during the clearance process. Dr. Williams shares Dr. Narva's concern because he receives questions from Congressional staff and must continue telling them that he does not have updates.
- Dr. Pogach commented that members of the Federally-mandated KICC should be able to comment on the legislation and still be in compliance with Federal law. Ms. Casey encouraged others to share their concerns with CMS' Chief Medical Officer and Director of the Office of Clinical Standards and Quality and the MIPPA 152(b) contacts Jamie Hermanson and Marcel Salive.

Dr. Narva thanked Ms. Casey, conveyed that the QIO project is a model of collaboration, and encouraged others to implement the same model.

Educational Advisory on Estimating Kidney Function for Drug Dosing

Andrew Narva, MD

Dr. Narva explained that NKDEP has been addressing an important laboratory issue over the past few years — that creatinine determinations have not been standardized the way that other bio-clinical determinations have been. According to the College of American Pathologists' survey, about half of clinical labs are performing standardized creatinine determinations with methods that are traceable to the isotope dilution mass spectrometry reference system. Standardized creatinine gives lower creatinine values, which is a problem because creatinine is traditionally used in the Cockcroft-Gault equation to estimate creatinine clearance for drug dosing purposes. If the creatinine is lower, it will produce estimates of kidney function that are higher, which can result in higher doses of drugs.

Routine reporting of GFR using estimated GFR (eGFR), as calculated using the Modification of Diet in Renal Disease equation, has been another key effort of NKDEP's Laboratory Working Group. Dr. Narva explained that promoting the use of eGFR in drug dosing has become an issue because clinicians and pharmacists are very comfortable with the Cockcroft-Gault equation and, in some cases, the two equations give different estimates of GFR. In fact, some health care facilities are not proceeding with creatinine standardization because clinicians and pharmacists are very concerned that they will no longer be able to use the lab result to estimate kidney function for drug dosing purposes. It is universally agreed that standardization of creatinine is appropriate and necessary, so NKDEP has been working to develop an educational document that will provide guidance on assessing kidney function for drug dosing.

Dr. Narva stated that one of the benefits of having an interagency coordinating committee is that it has facilitated collaboration on this project with FDA, which has been very responsive.

CKD-RELATED AGENCY UPDATES

- **NKDEP**—NKDEP created a summary report for the new administration and other stakeholders that explains NKDEP's mission and activities, through the lens of the Chronic Care Model. The Federal CKD Matrix, a tool that outlines the many different Federal agency activities in place to respond to CKD, is now live on NKDEP's website. The program also continues its work with the Community Health Center (CHC)-CKD Pilot by facilitating collaborative meetings for the centers and providing other opportunities to share ideas on how to implement intervention activities. NKDEP is currently working to address the challenges of managing communication between primary care providers and the nephrologist, and discussing how to expand the Pilot over the next year. Materials in development include a urine albumin tear pad based on the *Explaining GFR* tear pad, a patient education brochure on the basics of CKD, pediatric materials, and diet materials to help general practice dietitians and primary care providers counsel patients on the CKD diet. NKDEP is in the process of expanding the Family Reunion Initiative to include a faith-based component. The Program also hosted two continuing education webinars for health professionals, which have been archived online.
- **CDC**—Dr. Williams distributed copies of an *American Journal of Kidney Disease (AJKD)* supplement, which contains an article on the proceedings of an expert panel meeting that CDC convened two years ago. The meeting focused on preventing the development, progression, and complications of CKD. *AJKD* also published a companion document in its March 2009 issue, which features public health recommendations for CKD. CDC's cost-effectiveness study of screening and early intervention is now complete; researchers are preparing manuscripts for submission to *AJKD*. CDC also completed a study of the economic burden on CKD, which looked at both direct and indirect costs; as well as a state screening demonstration program, which may be extended to additional states if funding allows. Abstracts on the program will be available at the next American Society of Nephrology conference. Additionally, CDC plans to add a second measurement of urine albumin to NHANES in collaboration with NIDDK's Division of Kidney, Urologic, and Hematologic Diseases.

- **NIA**—The National Institute on Aging (NIA) co-sponsored a workshop on CKD in older adults early last year to summarize the state of knowledge and to identify research opportunities. A summary of the workshop was published in the most recent issue of *Journal of the Association Society of Nephrology*. Additionally, NIA has been working with NIDDK to release a program announcement entitled Renal Function and Chronic Kidney Disease in Aging.
 - **NHLBI**—The National Heart, Lung, and Blood Institute (NHLBI) is taking a rigorous, evidence-based approach to developing guidelines that are user-friendly and practical. They are also working to develop an integrated cardiovascular guideline that spans across all cardiovascular risk factors in response to a need expressed by stakeholders. NHLBI is working on improving implementation of guidelines and collaboration with the performance measurement groups to collect their input on the recommendations early in the development of the guidelines. NHLBI will then work with these groups to ensure that the guidelines are consistent with the evidence and with the intent of the guidelines when they are turned into performance measures. Dr. Ortiz also briefly introduced the Clinical Decision Support Collaboratory.
 - **Department of Defense**—The Army has unique resources and tools, as well as records that complement the US Department of Veterans Affairs' (VA), and a data repository.
 - **FDA**— The US Food and Drug Administration (FDA) is working to determine how to best dose drugs with a narrow therapeutic index in the new standardized creatinine age. FDA will be comparing equations used to estimate renal function to determine which equation best predicts pharmacokinetic parameters and patient-safety and efficacy outcomes. FDA also recently initiated a discussion on the framework for creating a kidney bio-marker database for AKI and welcomes collaboration with KICC members. The Administration is also working with industry academia to look at kidney volume as a potential marker of polycystic kidney disease progression.
- VA**—VA has operational databases and access to data on patients with diabetes and ESRD, and welcomes ideas on how to utilize these resources.

Dr. Williams, Dr. Ortiz, and Dr. Pogach all suggested that KICC either expand the length of the annual meetings or the frequency of the meetings.

Dr. Narva thanked the participants for their presentations and discussion, as well as for their continued Federal service. He reminded the group that KICC has a quarterly newsletter, which is an opportunity to share information. NKDEP welcomes the interest in more frequent meetings and will schedule a meeting to take place in the next four to six months.