Kidney Interagency Coordinating Committee Meeting

Tuesday, June 24, 2008
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. Narva welcomed everyone to the meeting of the Kidney Interagency Coordinating Committee (KICC) and led the introduction of the meeting participants. He explained that KICC was created in 1987 by Federal statute to encourage cooperation, communication, and collaboration among all federal agencies involved in kidney research and other activities. Over the years, KICC became mostly inactive except for the annual meetings. Because an effective Federal response to the increasing burden of chronic kidney disease (CKD) requires inter-agency collaboration, KICC has been revitalized to develop meaningful communication that fosters collaboration and coordination. He provided an overview of the ways that the agencies represented at the meeting are involved in the Federal response to CKD.

PRESENTATIONS

CKD CDC Surveillance Project
Desmond Williams, MD, PhD

Dr. Williams opened by noting that the KICC meeting is one of the most important annual meetings he attends because he gets an opportunity to network and always learns something new. He explained that the Centers for Disease Control and Prevention (CDC) Surveillance Project is truly a team effort with members from Johns Hopkins School of Public Health, the University of Michigan, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), in addition to CDC. The CKD surveillance advisory group consists of members from many of the agencies represented in the meeting.

The Surveillance Project is looking at the whole spectrum of CKD—not just stages four and five. CDC has a preventive agenda and therefore it aims to learn about earlier stages to reduce development of CKD and progression to end stage renal disease (ESRD). The overall goal of the project is to develop a national

surveillance system for CKD based on existing national and regional data sources. Because this is a resource intensive project, CDC is implementing it in phases. To that end, the aims are to identify and prioritize topics and measures relevant to CKD surveillance; evaluate each data source/topic-measure-indicator combination; plan for integration of all the data source to form a functional national surveillance system; assess the feasibility of integration of all the data sources, including the United States Renal Data System (USRDS) and the diabetes surveillance system; pilot test; and disseminate a final report and recommendations.

Dr. Williams described ten desirable characteristics of a CKD surveillance system, which include sensitivity, stability, and ability to represent the US population. He described the design of the Surveillance Project, highlighting its multidimensional aspect. The first step was to identify, investigate, and evaluate potential data sources through an extensive literature review to find the data sources. They then conducted interviews with key informant from each of the data source organizations to learn more about at the data.

Dr. Williams provided definitions for 'topics/domains," "measures," and "indicators." He used eGFR as a sample indicator because while GFR estimating equations are useful in clinical settings, there are problems with using them for public health purposes. Most of the equations are dependent of age, sex, and race and that information is not always available.

In the first pass, CDC will be focusing on the following six topics: burden of CKD, awareness of CKD, burden of risk factors for CKD, health consequences in CKD patients, CKD processes and quality of care, and health system capacity for CKD. He provided examples of domains, measures, and indicators for burden of CKD and CKD risk factors. CDC had to rank domains, measures, and indicators because they initially came up with over 150 measures and indicators. They went through a two-step process by systematically reviewing the rankings of the steering committee and the advisory committee. He then listed the first and second prioritized measures for each of the six topics.

The next phase was to evaluate each data source against the desirable characteristics to assess its utility. He presented a mock evidence data table for NHANES and USRDS. Because albuminuria in National Health and Nutrition Examination Surveys is based on a one-spot measure, CDC is exploring the idea of a "second measure" pilot test and is working with NIDDK on funding options.

CDC is now working on transferring the information they have collected to a website. The data will provide information on flexibility, data quality, and sensitivity and positive predictive value. Dr. Williams described a health care system approach to national CKD surveillance. He highlighted the health systems they have already engaged, including managed care plans, Veterans Administration hospital database, and health care networks. They will validate these data sources against national data sources to see how they can work together. They are looking next into engaging the Indian Health Service and Federally Quality Health Centers.

Dr. Williams outlined future directions of the Surveillance Project, which include conducting a pilot test of the integration of data and data sources, developing of a web-based report, and developing a brief CKD fact sheet for lay public with input from KICC participants. He closed by highlighting the three ways that KICC participants can help: continued support for data sharing and access, open communication channel for comments and suggestions, and other collaborative opportunities for data sharing, analyses, and reports.

Participant Questions/Comments

- Dr. Narva asked how CDC plans on using systems modeling to provide projections that might be helpful for Centers for Medicare and Medicaid Services (CMS) and other health care delivery organizations. Dr. Williams responded that for the economic study they are developing a model that would predict the number of people that who develop CKD in US. The last pass was very productive; they found that they could almost accurately predict the prevalence of CKD over the lifespan. They have difficulty with predicting stages four and five because of the small number of people in those stages. There are a lot of gaps and they had to make assumptions about eGFR and stage transition points. They are, however, building the system with enough flexibility to allow them to input more information and to refine the model in the future.

United States Preventive Services Task Force Processes
Mary Barton, MD, MPP

Dr. Barton thanked KICC for inviting her to present and noted that we are poised on the edge of developing a CKD evidence base that will help the community understand clearly what role screening might play in diminishing the morbidity due to this disease.

The Agency for Healthcare Research and Quality (AHRQ) is congressionally mandated to support and convene the United States Preventive Services Task Force (USPSTF), which is an independent group of 16 non-governmental volunteers who are experts in primary care, prevention, and research methods. The USPSTF recommendations are independent of the government. Much of the scientific support and literature reviews are done by the Evidence-Based Practice Centers (EPC), which is a separate AHRQ program. These 16 centers use consistent and best-practice methods and approaches to review the literature and they are maximally transparent in presenting the evidence. The EPCs are among the vanguard in the world at extracting decision-relevant synthesis from published evidence. Another component of USPSTF is the participants who observe USPSTF meetings, which convene three times a year. The participants consist of representatives from primary care professional societies and Federal agencies. Dr. Barton described the structure of the USPSTF as follows. The EPCs, USPSTF, and AHRQ work together to determine the analytic framework. The EPCs then synthesize the literature and present the evidence to USPSTF. With support from AHRQ, USPSTF makes the recommendations, which are then disseminated through various fora.

The activities of USPSTF are to provide evidence-based scientific recommendations of preventive health services for use in primary health care delivery settings. The recommendations are applicable to the general population—or to large segments of it—without recognized symptoms. They focus on primary or secondary prevention issues; the task force defines secondary prevention as screening to find early appearance of disease that is not yet symptomatic. The recommendations cover screening tests, counseling, and preventive medications.

Dr. Barton delineated the steps for developing the recommendations, as follows:

1. Define questions and outcomes of interest—USPSTF makes distinction between intermediate and final health outcomes and is more interested in examining the final health outcomes;
2. Systematically review each question;
3. Estimate net benefit;
4. Determine certainty of evidence on net benefits; and
5. Link recommendation to judgment about net benefits.

She presented a generic analytic framework for screening for a disease. The key question of the framework is: does screening for the disease reduce morbidity and/or mortality. Chain of evidence questions include: Is the screening test accurate? Is the treatment effective with mild forms of the disease and among screen-detected people? Is there is a strong epidemiologic set of information about the link between intermediary outcomes and final health outcomes? They consider the adverse effects of screening and treatment. Dr. Barton presented the six critical appraisal questions that the task force uses to examine the assembled evidence provided by the EPC. These include generalizability, number and size of studies, and consistency of results with other studies.

The task force approaches the evidence by assessing the certainty of the overall impact. The certainty is graded across a continuum. If it is unlikely that the effects of the preventive service on health outcomes can be strongly affected by the results of future studies, then the certainty is high. On the other hand, if the evidence is insufficient to assess effects on the health outcomes, then the certainty is low. USPSTF then assesses the certainty of the net benefit—high, moderate or low—against the magnitude of the net benefit—substantial, moderate, small, or zero/negative. The combination leads the task force to grade the recommendations.

USPSTF makes 110 recommendations on 59 topics, and it updates the topics every five years. The Topic Prioritization Workgroup meets monthly to review and prioritize the internal queue of topics. Every other year, the Federal Register puts out a notice in January inviting organizations and individuals to nominate new topics. The workgroup reviews the nominations based on the selection criteria and chooses one or two topics to put into the queue for recommendations. The criteria include the public health importance of the condition, potential

for USPSTF to have an impact on clinical practice, and a balanced portfolio of topics to address diverse populations. In 2008, two CKD-related topics were nominated: screening for CKD in at-risk populations and screening using eGFR to prevent ESRD.

Participant Questions/Comments

- Dr. Freund asked when does a characteristic that makes one a part of an at-risk population cross over to being a condition that could be treated by a further diagnostic test. Dr. Barton acknowledged that this is an important question for the task force to consider over the next five years.
- Dr. Narva asked about the status of the two CKD-related nominated topics. Dr. Barton noted that they are in the top group in this cycle, but we will not know until after the July meeting.
- Dr. Narva asked if there are any topics related to routine urinalysis in children. Dr. Barton said that screening urinalysis used to be covered, but it was dropped as the task force is less interested in tests per se, and more in actual health outcomes related to a specific condition or disease.
- In response to Dr. Xioa's comment about pediatric recommendations, Dr. Barton agreed that there are many challenges in compiling evidence about preventive services for children. Several developments should increase the availability of the data, including improvements in international communication, more publications in English, and other countries conducting studies with their national health systems.

Quality Improvement Organizations 9th SoW: Charting the Course for Quality
Mary Teresa Casey, RD, LD

Ms. Casey explained that she has been at CMS for quite a number of years but is new to the Quality Improvement Organization (QIO) program. She is the team lead for the 9th Scope of Work (SoW) CKD task, which was previously managed by Gina Clemens. Dr. Eugene Freund is the theme lead for the prevention part of the contract.

Dr. Freund thanked Dr. Barton for her presentation, pointing out while Medicare covers reasonable and necessary treatments for conditions, they cannot cover preventive services, except for cases of specific allowances and exceptions by law. He provided an overview of the development of the 9th SoW, which included input and oversight from both internal and external customers, including Office of Management and Budget, Department of Health and Human Services, and Congress. In this new three-year cycle, CMS is integrating more program evaluation for attribution and focusing on value-driven healthcare, health information technology, and reducing disparities. The current contract has four themes: beneficiary safety, beneficiary protection, prevention (core prevention, disparities—primarily in diabetes care, and CKD), and care transitions. They are still in the process of negotiating awards with both the subset of competitive contracts and the subnational component contracts.

CKD is a subnational theme and up to 13 state QIOs may be awarded these contracts. This is a brand new task for the QIOs; CMS wants to see what interventions the QIOs implement and how effective they are. This task may be a potential nationwide topic in the future 10th SoW. CKD task selection is based on QIOs' demonstration of need for CKD improvement in their states, a solid design for meeting the CKD goals, a solid description of planned community collaborative activities, a good understanding of implementing system changes, demonstrated capacity and competency, and a strong past performance record. There has been a great deal of interest in the CKD task among the QIO community and a majority of QIOs have submitted proposals. The announcements of the awards will take in place in late July.

The CKD task is composed of two tasks: Task 1 is Clinical Quality Improvement, which is the main focus, and Task 2, Community Collaboration, supports Task 1. Task 1 is divided into three clinical focus areas: detection (urine microalbumin testing), treatment (ACEI/ARB use), and counseling for renal replacement therapy. QIOs must assess the baseline for the three focus areas and identify any disparities, which could be ethnic, racial, socio-economic, or geographic. They must then identify interventions and specify improvement targets to reduce disparities. QIOs must monitor their interventions, ensuring that they do not have negative impacts on disparities; if they find a negative impact, they must take actions immediately to reverse it. Under Task 2, QIOs

will assemble and/or sustain active coalitions at the state or local level that conduct activities that support achievement of one or more of the clinical focus areas. The partners must include the ESRD network; state and local health department diabetes grantees; community health centers; local chapters of kidney organizations; state and county government representatives; provider groups such as nephrologists, vascular surgeons, dialysis centers; and community and patient representatives. The goal of Task 2 is to affect sustainable improvements at the system level. As part of Task 2, QIOs will participate actively in the National Fistula First Breakthrough Initiative (NFFBI). Ms. Casey briefly explained the benefits of arteriovenous (AV) fistulas. Activities will include targeting participating providers to implement clinical practices, targeting beneficiaries with education and intervention, disseminating tools and resources, and affecting system change. QIOs are required to use existing materials and resources; CMS will work with Dr. Narva and NIDDK, as well as others agencies and organizations, to provide QIOs with existing materials and resources.

The three measures are: at least annual urine microalbumin testing among diabetic beneficiaries; one part D claim for ACEI/ARBs among patients with diabetes, hypertension and CKD (stages 1-4); and presence of AV fistula among new hemodialysis patients who have been diagnosed with CKD for at least 6 months and have had Medicare coverage for at least 6 months. Data sources include Part A, Part B, Part D, and a Medical Evidence Form, which is filled out when a patient starts dialysis. The CKD improvement targets are statewide targets. Ms. Casey presented the improvement targets that will be evaluated at the 18th and 28th month time period for each of the measures. Ms. Casey closed the presentation by inviting participants to discuss how to ensure that QIO CKD efforts complement existing CKD activities and how to best achieve synergy.

Participant Questions/Comments

- Dr. Narva said that the QIO project may advance the CKD cause more than other Federal activity because it is a national program with data collection. It is likely to stimulate change and bring attention to CKD.
- Dr. Xioa complemented the focus on AV fistulas. The United States has a much lower rate of AV fistulas than Europe because of companies promoting grafts. He asked if Medicare/Medicaid have any plans to change billing to encourage AV fistulas. Ms. Casey commented that this is an area of much focus for the NFFBI. One recent issue is that referring nephrologists are not marking "for AV fistula only" on the script to the vascular surgeons, which allow extra discretion on the part of the surgeon. Dr. Freund agreed that this is a complicated issue but pointed out that CMS has a great incentive to improve this because half of incident ESRD patients are already on Medicare.
- Dr. Ortiz commented on the 10% improvement targets, which can be impressive if the baseline is high, but less so if QIOs start with a low baseline. Ms. Casey responded by saying that once they have the baseline data, they will look at it to evaluate the targets, however, since the targets are approved by OMB, their ability to make changes may be limited. Dr. Ortiz also commented about encouraging intelligent—rather than indiscriminate—screening. Ms. Casey answered that they have tried to get at this point by, for example in the first measure, giving the QIOs credit in the numerator for patients with evidence of nephropathy or nephropathy treatment, or who receive ACEI/ARBs or visit a nephrologist, regardless of whether they have had urine microalbumin screening. Because they are using claims data, they are limited by what they can mine from the data. Dr. Eggers added that early nephrologist referrals are not always necessary, especially with older patients.
- Dr. Freund commented that the Kidney Disease Outcomes Quality Initiative guidelines provide a good roadmap for referrals. QIOs activities will focus on CKD stages one and two and then on four and five, but less so on stage three.
- Ms. Casey added that because this is a subnational task, they will be able to run comparisons against states that are not awarded the contracts to see what they can learn from the data.
- Dr. Narva pointed out that recommended annual monitoring of albumin excretion in diabetics is not just for detection of CKD, but to monitor reduction in albumin excretion—a therapeutic goal.

The CHC-CKD Pilot: Helping Community Health Centers Improve CKD Diagnosis and Management
Dr. Narva

NKDEP has been increasingly focusing on facilitating better care in the primary care setting for people with CKD. Community health centers (CHC) care for patients at high risk and have the demonstrated ability to improve care. NKDEP is working with five CHCs that participate in the Diabetes Disparities Collaborative to adopt system changes in the context of the chronic care model and to inform the development of tools for wider dissemination. The completed milestones include a kickoff meeting, a needs assessment, and the pilot launch. The needs assessment identified needs for reminders and useful guidelines for providers, better coordination with nephrologists, and patient education materials—especially for patients with low-literacy levels and limited English language capacity. NKDEP also learned that there is considerable room for improvement in screening practices, especially as they relate to urine albumin-to-creatinine ratio (UACR).

Through a collaborative model, the CHCs design, implement, and monitor performance improvements, and NKDEP provides technical assistance to enable them to use their process to improve care, specifically to modify their diabetes care delivery system process and to add several performance measures. These include screening all patients with diabetes through eGFR and UACR annually, improving blood pressure control, screening patients with eGFRs of less than 50 for complications, and providing basic CKD education.

Dr. Narva described a new NKDEP self-management support tool that the pilot CHCs are using, which helps providers explain GFR results and gives the patients take-home information. NKDEP also developed an algorithm that identifies how to screen patients and when and how to intervene. It is also providing a fact sheet for providers on GFR and UACR. In addition, NKDEP is sponsoring the development of software which helps to enable the collection of the performance measures from the electronic health records of CHCs. Using these elements, each CHC will design its own delivery system. Dr. Narva will visit each CHC and provide presentations on CKD detection and treatment to their clinical staff.

CKD-RELATED AGENCY UPDATES

- **NKDEP—**NKDEP is promoting CKD care as part of primary care, with special outreach efforts to diabetes educators and registered dietitians. Its Lab Working Group is focusing on urine albumin determination and reporting, which is currently not standardized. It is also working to develop recommendations on estimating kidney function in people with CKD when drug dosing; this is an important issue because creatinine values will decrease following creatinine standardization, and the Cockcroft-Gault equation—traditionally used to adjust drug dosage in patients with decreased kidney function—will no longer be usable. In addition, NKDEP is beginning to develop a pediatric initiative. The American Academy of Pediatrics no longer recommends routine urinalysis in children, which may be reasonable in the general population, but may not be appropriate for children with increased risk. NKDEP is also collecting content to populate the online Federal CKD matrix which includes summary of agency activities and contact information. Lastly, NKDEP is working actively with several key organizations including the American Association of Diabetes Educators, the American Diabetes Association, the American Dietetic Association, Diabetes Prevention and Control Programs (DPCPs), the American Medical Association, as well as some large managed care organizations.
- **NIDDK—**NIDDK is developing an initiative for translational research in CKD. The Frequent Hemodialysis Network is collecting data on cost effectiveness of daily dialysis. The Chronic Renal Insufficiency Cohort (CRIC) and the Chronic Kidney Disease in Children (CKiD) studies have been fully recruited and they will provide data to justify more attention to CKD, especially by USPSTF.
- **CDC—**The screening project will be going into the field sometime this summer. CDC will be doing a pilot screening test in four states and eight sites. Once they screen individuals, they will follow up with them up to monitor patient and provider behavior. They will also be giving partial funding to the National Association of the Chronic Disease Directors to set up a task force for CKD, which is likely to affect the DPCPs. They have also funded the CDC lab to study stability of CKD measures and how they relate to changing laboratory conditions and the National Center for Infectious Diseases to conduct a survey of dialysis centers and infectious disease rates. Results from the two economic studies will be available in the fall.

- **FDA—**FDA has actively participated in research and treatment of CKD, including discussion around using proteinuria as a surrogate endpoint for drug approval. They reviewed existing evidence and found that while proteinuria is an excellent biomarker for kidney injury, there is insufficient evidence for using it as a surrogate endpoint for drug approval. FDA is actively participating in identifying biomarkers for acute kidney injury. A consortium of biomarker companies put forth their study in animals for review. At this point, they are still in the process of data collection. They have identified some biomarkers of interest and are asking companies to voluntarily test these biomarkers in their clinical trials. FDA is also developing three CKD-relevant guidances: an update on approaching pharmacokinetic studies to yield better data on dosing patients with kidney impairment or kidney failure; the concept paper should be finalized by the end of the year; guidance treatment of lupus nephritis, which may be published in the next three or four months; and new guidance for two newly-approved solutions for acute kidney failure: hemofiltration and hemodiafiltration, which may be finished by early next year.
- **CMS—**In April, CMS published new regulations for dialysis facilities that are certified and paid by Medicare. This is the first time in 32 years that the conditions have been rewritten. Facilities have six to 12 months to become aligned with the various requirements of the new regulations. The facilities are required to submit electronic clinical performance measurements to CMS. This means that CMS will have timely data on all dialysis patients, which will be collected as of February 2009 and publicly available starting in late 2009. CMS has posted the updated list of the clinical performance measures for dialysis centers on its website. CMS is redesigning its ESRD Network Program to make it more valuable and effective. During the summer, CMS will hold public meetings to provide input on the redesign.
- **NHLBI—**The Division for the Application of Research Discoveries (DARD) is launching four new guideline efforts in cardiovascular disease (CVD): a new pediatric CVD integrated risk reduction guideline, an updated hypertension guideline (Joint National Committee 8), an updated cholesterol guideline (ATP4), and a new adult integrated CVD risk reduction guideline. DARD is developing these four guidelines in a coordinated manner.

Dr. Narva thanked the participants for their presentations and discussion, as well as for their continued Federal service.