

National Kidney Disease Education Program (NKDEP)

**National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK),
National Institutes of Health**

Kidney Interagency Coordinating Committee Meeting
January 13, 2010 – Natcher Conference Center

Meeting Participants and Summary

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Sciences*

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Indian Health Service

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Shen Xiao, MD, PhD
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I. Welcome and Introductions
Andrew Narva, MD

Andrew Narva briefly introduced the Kidney Interagency Coordinating Committee (KICC) for the benefit of first-time participants. He explained that KICC was mandated by Congress in 1987 to encourage cooperation, communication, and collaboration between Federal agencies involved in kidney disease. While at the Indian Health Service in the late 1990s and early 2000s, Andy participated in several KICC meetings, but the brief annual gathering was not widely attended and did not live up to its stated objectives. Since NIDDK began serving as the coordinating agency of KICC a few years ago, however, participating Federal agencies have become more aware of other agencies' activities, and true collaborations have occurred. Dr. Narva displayed and briefly discussed the Federal CKD Matrix, available on the NKDEP website, which makes it easy to see what Federal agencies are doing across six different dimensions of chronic kidney disease (CKD)—from screening to paying for dialysis, and many activities in between.

Participants introduced themselves.

II. CDC's CKD Initiative
Desmond Williams, MD, PhD

Dr. Williams explained that he and his colleagues would provide an overview on CKD and economics, the national CKD fact sheet, and results from a CKD surveillance project and related dissemination strategies. He began by identifying individuals who have helped the Centers for Disease Control and Prevention (CDC) estimate the economics of CKD, including researchers from Research Triangle Institute and Paul Eggers from NIDDK. To estimate the direct medical costs of CKD, CDC used National Health and Nutrition Examination Survey data linked with Medicare claims data, and developed cost estimates based on Medicare reimbursements. Medicare expenditures were estimated to 2006 dollars using the Medicare component of the consumer price index.

The team used a baseline model and two alternate models to estimate the economic costs of CKD, with and without adjustments for certain variables, including diabetes and hypertension. In general, the annual costs of CKD increase by stage, although the difference in cost between stages one and two is not significant. Total estimated costs of CKD is \$66 billion per year for the over-65 population; Medicare bears the largest costs for both CKD and kidney failure. Dr. Williams reminded the group that Diabetes Complications and Control Trials data showed that intensive vs. conventional approaches to controlling

blood glucose reduce the incidence of complications for CKD (e.g., 60 percent reduction in complications, using intensive methods). Prevention can reduce expenses.

Another study focused on cost-effectiveness of screening and early treatment. CDC developed a lifetime model that followed disease progression through CKD stages in a cohort of simulated patients from age 30 until age 90 or death. The researchers used several studies and data sets to assign values to various factors in the statistical models. Several analyses were performed to determine the impact of various factors on the lifetime risk of developing CKD and ESRD for different screening scenarios.

During the discussion of cost-effectiveness of screening, Dr. Williams presented a slide showing the effect of screening frequency on the incremental cost-effectiveness ratio. The information on this slide led to several questions and comments:

- When asked about what appeared to be no difference in costs per year per person identified (with ESRD) across frequency-of-screening scenarios, Dr. Williams said that the longer the time period between screenings, the greater the cost-effectiveness of screening events (measuring costs and quality-adjusted life years (QALY) on a per-person screened basis).
- Dr. Narva and Dr. Eduardo Ortiz asked what was included in the costs and why costs remain essentially the same across screening scenarios. Dr. Williams said costs were for screening and treatment, and QALYs were measured on a per-person-screened basis. Dr. Williams added that costs remain similar across scenarios because the screening costs are so low compared to the treatment cost of one person with ESRD that they have relatively small impact on annual patient costs. This was also observed in the sensitivity analyses.
- Dr. Winnie Barouch asked why the ESRD incidence remains the same across frequency of screening. Dr. Williams said these were annual cumulative incidence values and that there were small differences in the cumulative incidence that were not apparent because of rounding.

Dr. Williams finished by summarizing CDC's analyses: screening and early treatment in high risk groups was most cost-effective when screening began at age 50, annual screening and early treatment was highly cost-effective for persons with diabetes in all age groups, but annual universal screening was not found to be cost-effective. He added that CDC also used data from a screening program (CHERISH) to determine who benefits most from screening. Results from logistic regression and classification tree analyses yielded findings in support of those listed above.

Participant Questions/Comments

- In response to a question by Dr. Ann Bullock, Dr. Williams confirmed that CDC is currently conducting an analysis based on race and ethnicity.
- Dr. Narva suggested CDC use Chronic Renal Insufficiency Cohort (CRIC) data to obtain good information on transition rates.
- Dr. Gregory Germino asked if the team's modeling assumed different cost-effectiveness rates for treating early diabetic nephropathy versus the impact of treating hypertension. Dr. Williams responded by stating that the majority of patients with CKD have both diabetes and hypertension. Dr. Germino pointed out that the approach does not separate out the effect of early treatment on diabetics vs. non-diabetics. Sensitivity analyses for several factors, according to Dr. Williams, did not show a difference in impact.

- Dr. Ortiz asked Dr. Williams to provide more detail on the graph showing the sensitivity analyses and effect of 25 percent increases and decreases in lifetime model factors. A 25 percent increase in screening costs, for example, would result in a reduction of cost-effectiveness.

III. Development of National CKD Fact Sheet

Sharon Saydah, PhD, MHS

Dr. Saydah reminded KICC representatives that the CKD fact sheet is being developed for the purpose of providing numerous audiences with definitive information about the burden and consequences of CKD in the United States. Partners will be able to customize the fact sheet to address their organizations' needs and those of their audiences. The fact sheet will be updated on a regular basis, with the possibility of mini-updates as new data become available. CDC's goal is to release the fact sheet on March 11—World Kidney Day.

Individuals from all KICC agencies have been invited to contribute to the fact sheet's development and/or offer feedback on the document. CDC is now collating feedback collected since the summer of 2009 and is preparing to solicit feedback from the larger public, including non-governmental organizations. Dr. Saydah outlined the topics that will be covered in the fact sheet, including a brief description of CKD, its causes, and how it is treated. The resource includes prevalence estimates, based on current NHANES data, by age, sex, race, ethnicity, and diabetes and hypertension status. It also includes risk factors for the development and progression of CKD, as well as the health consequences of CKD, including cardiovascular disease, ESRD, and other consequences. The final section addresses what can be done about CKD.

Participant Questions/Comments

- Dr. Kevin Abbott mentioned that the incidence of wounded warriors needs to be determined, as this group is more vulnerable to CKD due to nephrotoxicity issues caused by use of antibiotics and contrast dye procedures. Dr. Abbott asked that CDC consider this for the future.
- Dr. Williams confirmed that the fact sheet is written for both lay and professional audiences. CDC is not planning to develop two versions; the agency wants one fact sheet that can be understood and adapted by various users. Dr. Saydah added that different agencies and partners can add more specific information for their audiences.
- Dr. Williams confirmed that the fact sheet and the website from which the fact sheet will be downloaded will include a list of all agencies that have been involved in the development process. This is how the Diabetes Fact Sheet has been handled by CDC.
- Dr. Williams asked that participants inform Dr. Saydah of other organizations that should be invited to review the fact sheet.

IV. CKD Surveillance and Website

Dr. Williams

The national CKD surveillance system is being developed in collaboration with the University of Michigan, University of San Francisco, and Johns Hopkins University, as well as with assistance from Dr. Eggers of NIDDK's Division of Kidney, Urologic, and Hematologic Diseases (KUH) and the with the CDC

contractor, Northrop Grumman. Dr. Williams explained that CDC determined that a web-based tool (vs. a printed report) is more practical for making CKD surveillance data available to a broad range of users. CDC and their partners have been working on a website design, which was previewed at last year's American Society of Nephrology (ASN) meeting. Feedback has been used to improve upon the tool. Dr. Williams showed the group the website by showing the prototype as a PDF image of the site's pages. The site will be designed for casual users as well as researchers who may be looking for data by certain variables.

Dr. Williams showed meeting participants that data will be accessible by various categories, including prevalence, incidence, awareness, burden of risk factors, health consequences, process and quality of care, and health care system capacity. Within these categories, data will be available by various clinical conditions (e.g., albuminuria, anemia, cardiovascular disease), demographic groups, outcomes, and data sources. In some cases, users will be able to view and stratify data by multiple variables. The site will use left-side navigation bars as well as drop-down features to help users select various options for viewing data. Users will often be able to download tables and graphs, and sophisticated users will even be able to download raw data for their own analyses. Footnotes will be included with tables, when necessary, as well as references and sources for data.

Participant Questions/Comments

- Dr. Seiji Hayashi said it would be useful if CDC could show others how data can be used for community health planning.
- Dr. Williams finished by stating the site, when actually constructed, will need to be tested. Those who would like to help test the site should email Dr. Williams.

V. Progress on the Healthy People 2020 Kidney Goals

Paul Eggers, PhD

To assess the country's progress toward meeting kidney-related Healthy People (HP) 2010 objectives, Dr. Eggers began his presentation by comparing the baseline, goal, and current rates for established objectives. He then presented the proposed HP 2020 objectives and discussed how each is being retained, retained but elaborated on, or added. 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.

NIDDK is finalizing these goals but continues to accept feedback. The National Kidney Foundation (NKF), for example, recently requested that one objective measure the cardiovascular death rate in those diagnosed with CKD. Much of this revision process is under the control of the United States Renal Disease Study (USRDS) because it is the main data collector, but in the future, reporting activities will be shared with CDC.

Participant Questions/Comments

- Dr. Susan Crowley asked if NIDDK is planning to include patient education goals.
 - Dr. Eggers said that NKF had also asked this question and that it is up for consideration.
- Dr. Crowley also asked if there is a way to measure a reduction in dietary sodium intake by patients with CKD as a result of patient education.

- Dr. Eggers said that this measure would not be included in HP 2020 because there is not an easy way to measure it.

VI. Quality Improvement Organizations and the Fistula First Initiative

Teresa Casey, RD, LD

Ms. Casey explained that her presentation would provide an update on the CKD Initiative of the Quality Improvement Organizations (QIO) and the Fistula First Breakthrough Initiative (FFBI). She is the Centers for Medicare & Medicaid (CMS) team leader for both projects.

The QIO-CKD Project aims to improve the quality of life for patients with CKD by partnering with local and national organizations and by working with providers to promote evidence-based care. The program aims to: improve CKD detection in diabetic patients, prevent or slow progression of CKD through drug treatment, and increase counseling regarding renal replacement therapy as evidenced by arteriovenous fistula (AVF) placement in new hemodialysis patients. Contracts for this program were presented to ten states and the US Virgin Islands. The QIOs have recruited more than 2,000 providers from more than 944 practices. All have performed assessments and identified barriers for opportunities for improvement. Ms. Casey shared some of those barriers and provided examples of approaches or innovations used by providers to promote sustainable quality improvement.

Ms. Casey described some of the milestones for the QIO-CKD Project. For example, CMS measurement data will be available on a quarterly basis, and evaluation periods are scheduled for February and November 2010. In addition, CMS is planning a partner and provider survey, which will assess the extent of systems change facilitated by the QIOs to improve CKD care.

CMS has preliminary quarter four and quarter five data for each of the three focus areas of the QIO-CKD Project. The results are:

- CKD detection (measurement: urine microalbumin testing): 10 QIO centers are passing the 18-month target in quarter five.
- Prevention of the progression of CKD (measurement: ACE/ARB treatment): 5 QIO centers are passing.
- Renal replacement therapy counseling (measurement: AVF placement for incident patients): 8 QIO centers are passing.
- In total, 6 QIOs are passing the 18-month target for all three measures by quarter five.

CMS hopes for continued improvement and progress throughout the three-year period. At the end of this project, CMS will release its 10th statement of work, which will likely expand the project beyond the 10 QIO centers. Funding will affect how the project is expanded in the future.

Ms. Casey presented highlights and advancements made by the FFBI, which continues to optimize vascular access. Since March 2009, the program:

- Conducted a root cause analysis.
- Convened its Technical Expert Panel in June.
- Developed a strategic plan for improving AVF rates to 66 percent nationally.
- Redesigned and updated its website to include:

- A chart containing data related to vascular access each year. Currently the chart shows 2008; CMS hopes to post 2009 data shortly.
- The FFBI strategic plan, which lists seven strategies to reach its goal.
- Fistula First's 13 change concepts. Fistula First added two new change concepts to the original 11. CMS' work groups are working to produce tools to support these two new change concepts (and bolster the other change concepts), which will be added to the site when complete.
- Activated five working committees for strategic plan implementation.
 - Progress on the implementation of the strategic plan will be posted on the Fistula First website on a regular basis.

Ms. Casey presented data slides compiled by Network 5 (a contractor for FFBI), which included: a chart of national AVF rates, prevalent AVF rates by state, and prevalent AVF-use rates. She added that CMS is looking to incorporate catheter-reduction messages into their projects.

Participant Questions/Comments

- Dr. Narva commented that the need for increasing AVF placement and for reducing catheter use is a perfect example of why collaboration is needed. Both issues are dependent on better CKD care, and working with other agencies that can address patients in earlier stages will be advantageous. He added that NKDEP is developing provider education videos for use by Fistula First.

VII. New Medicare Coverage for CKD Education

Jamie Hermansen, MPP

Ms. Hermansen provided a brief overview of Section 152(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), kidney disease patient education (KDE) services. This new Medicare Part B benefit became effective on January 1, 2010 and is designed to provide Medicare beneficiaries who have been diagnosed with stage four chronic kidney disease with comprehensive information regarding the management of comorbidities, prevention of uremic complications, and options for renal replacement therapy. These KDE services must be provided by "qualified persons," which include physicians, physician assistants, nurse practitioners, and clinical nurse specialists. In addition, providers of services that are located in rural areas can provide KDE.

CMS and the Agency for Healthcare Research and Quality held two feedback sessions in 2008 to solicit feedback from stakeholders. These meetings were held in accordance with the statute, which required the Secretary to set standards for the content after consulting with relevant stakeholders. The final rule was published in the Federal Register on November 25, 2009, and specifies beneficiary eligibility, session specifications, standards for content, and the development of outcomes assessments.

Participant Questions/Comments

- Dr. Crowley asked if social workers or dietitians could be involved in the KDE process.
 - Ms. Hermansen said that a social worker or dietitian are not considered a "qualified person" under the final rule, but she encouraged Dr. Crowley to review the final rule provisions regarding the definition of a qualified person or contact CMS with any additional questions.
- Dr. Narva asked about payment rates.

- She referred him to the physician fee schedule which contains information about two new G-codes established for the KDE benefit.
- Dr. Narva offered the services of KICC to Ms. Hermansen in the event that CMS needs public/constituent comments in a public setting.

VIII. NHLBI CVD Risk Factor Guidelines Status Report

Eduardo Ortiz, MD, MPH

Dr. Ortiz provided a status update on National Heart, Lung, and Blood Institute's (NHLBI) cardiovascular disease (CVD) risk factor guidelines. NHLBI's vision is to provide global leadership through research and education to enhance the health of all individuals so that they can live longer and more fulfilling lives. Dr. Ortiz shared NHLBI's major goals as outlined in its strategic plan and explained that a subcategory of its third goal is to promote the development and implementation of evidence-based guidelines in partnership with individuals, professional and patient communities, and health care systems and to communicate research advances effectively to the public.

NHLBI's past CVD guidelines include the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC); Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP - Adult Treatment Panel); and Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. NHLBI is now coordinating efforts to update each of these individual guidelines and is also working to create an integrated CVD risk-reduction guideline. The Institute is using an evidence-based approach for developing critical questions, searching and retrieving the literature, reviewing the literature, grading the evidence, summarizing the evidence, and making recommendations. The approach will use innovative informatics tools and techniques, address user needs, take a lifespan approach, and consider implementation issues throughout the process. NHLBI is currently working to finalize a pediatric integrated CVD risk-reduction guideline, for which the Institute did not use the new approach. NHLBI hopes to complete the evidence reviews by fall 2010, with the guidelines released in 2011.

In addition to creating and updating the guidelines, Dr. Ortiz explained that NHLBI has developed a virtual collaborative workspace to facilitate communication between NHLBI and its expert panels. They have also been working with a contractor and the National Library of Medicine (NLM) to develop and test newer and more effective approaches to searching and retrieving the literature.

Participant Questions/Comments

- Dr. Narva commented that NIDDK has a policy against developing clinical guidelines and he appreciates NHLBI's efforts because of the controversial issues surrounding the kidney guidelines.
- Dr. Williams stated that this guideline process is important and impressive, and that there is a need for this rigorous evidence-based review process in the kidney community. He asked if NHLBI has tested the automated approach to searching and retrieving the literature and if it would be made public if found successful.
 - Dr. Ortiz said that NHLBI is interested in further evaluation of this approach. They have been working with the NLM to compare NHLBI's results with that achieved using a more traditional search process.

- Citing a study conducted by Dr. Cindy Boyd, Dr. Basil Eldadah noted that the idea of integrating guidelines is welcome. He asked Dr. Ortiz about any considerations that the committee will make regarding integration of guidelines.
 - Dr. Ortiz stated that developing an adult integrated cardiovascular risk reduction guideline is quite a complex and challenging undertaking. At this point, the goal is to integrate blood pressure, cholesterol, and obesity with the other major cardiovascular risk factors. It will also include a unified approach to lifestyle and risk assessment.
- Dr. Crowley said that she looks forward to reading the integrated guidelines and assumes that her colleagues at other Federal agencies, such as the VA and DoD, will as well.
 - Dr. Ortiz added that NHLBI has also established an Implementation Work Group and is thinking about implementation issues throughout the guideline development and dissemination process, rather than waiting until after the guidelines are developed.