National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)
National Institute of Health (NIH)

Kidney Interagency Coordinating Committee (KICC) Meeting
January 24, 2011, Natcher Conference Center

Meeting Participants and Summary

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I. Welcome and Introductions

Andrew Narva, MD, FACP

Dr. Narva welcomed committee members and thanked them for their participation. The purpose of KICC is to facilitate communication and collaboration across Federal agencies that are involved in addressing kidney disease. The committee is mandated by Congress.

II. Update on Quality Improvement Organizations

Kimberly Smith, MD, MS

The mission of the Quality Improvement Organization (QIO) program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. The program is overseen by the Centers for Medicare and Medicaid Services (CMS).

The QIO program is directing a special effort in 10 states and the Virgin Islands focused on chronic kidney disease (CKD). Each QIO is charged with improving statewide performance on three measures:

- Timely testing for urine microalbumin to identify early kidney disease due to diabetes;
- Prescription of an angiotensin-converting enzyme (ACE) inhibitor and/or angiotensin receptor blocker (ARB) to slow the progression of kidney disease in patients with diabetes and hypertension; and
- AV fistula placement for individuals who elect hemodialysis as their treatment option for kidney failure.

Data from this pilot are now being evaluated and lessons learned will inform future efforts to improve the care of this population.

Discussion

- Dr. Narva stated that the scope of work requires states to identify partners. The QIOs may need some assistance in selecting the most appropriate partners and members of the KICC could assist the QIOs in developing action plans.
- Dr. Germino asked if the ACE/ARB measure could have been revised instead of eliminated. Dr. Smith stated that they are looking at identifying mechanisms for getting the necessary data. Dr. Narva suggested using blood pressure control as a way of assessing the measure.

III. Project Update on AHRQ Comparative Effectiveness Review, Screening, and Management of Chronic Kidney Disease, Stages 1-3

Christine Chang MD, MPH

The Agency for Healthcare Research and Quality's (AHRQ) Evidence-based Practice Center (EPC) carries out reviews of all relevant scientific literature on clinical, behavioral, organizational, and financial topics to produce evidence reports, technical reviews (covering nonclinical methodological topics), and technology assessments.

The process is initiated when two nominating organizations suggest a topic. The reports are based on rigorous, comprehensive syntheses and analyses of the scientific literature on topics relevant to clinical, social science/behavioral, economic, and other health care organization and delivery issues. EPC reports emphasize explicit and detailed documentation of methods, rationale, and assumptions. These scientific syntheses may include meta-analyses and cost analyses. The resulting evidence reports and technology assessments are used by Federal and state agencies, private sector professional societies, health delivery systems, providers, payers, and others to improve the quality of the care provided to patients.

Currently, the EPC is conducting a comparative effectiveness review on the screening and management of CKD (Stages 1-3). According to Dr. Chang, there is a very large body of evidence to sift through and the analysis has been quite complicated. For example, the definitions of CKD are not always consistent across studies, which makes comparison difficult.

Key Questions for Chronic Kidney Disease Review

- In asymptomatic adults with or without recognized risk factors for chronic kidney disease (CKD) incidence, progression or complications, what direct evidence is there that systematic CKD screening improves clinical outcomes?
- What harms result from systematic CKD screening in asymptomatic adults with or without recognized risk factors for CKD incidence, progression, or complications?
- Among adults with CKD stages 1-3, whether detected by systematic screening or as part of routine care, what direct evidence is there that monitoring for worsening kidney function and/or kidney damage improves clinical outcomes?
- Among adults with CKD stages 1-3, whether detected by systematic screening or as part of routine care, what harms result from monitoring for worsening kidney function/kidney damage?
- Among adults with CKD stages 1-3, whether detected by systematic screening or as part of routine care, what direct evidence is there that treatment improves clinical outcomes?
- Among adults with CKD stages 1-3, whether detected by systematic screening or as part of routine care, what harms result from treatment?

To date, various activities have taken place.

- Key informant input on scope and key questions.
- Public comment on key questions.
- Protocol development including clarification of definition of CKD, reorganization of outcomes, assessment of properties of screening tests (i.e., accuracy and reliability), and a refinement and expansion of harms.
- Evidence review exploring patient characteristics, interventions, and outcomes.

In reviewing the body of evidence, the quality of individual studies is assessed. Studies are rated as good, fair, or poor. Considerations include use of randomization methods, consideration of potential confounders, comparable groups, reliable and valid measurements, clear definition of interventions, and appropriate analyses. Study outcomes are rated as either high, moderate, low, or insufficient, based on four domains:

- Precision;
- Risk of bias;
- Consistency; and
- Directness.

To synthesize the data, a meta-analysis is conducted, if appropriate. The data are stratified both by baseline CKD stage and CKD risk factors if possible.

The EPC anticipates releasing a draft of the CKD report by January 31, 2011, which will be followed by both a public comment period and peer review. After comments are incorporated, a final report is released.

The John M. Eisenberg Center for Clinical Decisions and Communications Science translates comparative effectiveness reviews and research reports created by the EPC into short, easy-to-read guides and tools for consumers, clinicians, and policymakers. Work on these products begins during the public comment period and includes focus groups as well as other methods. Tools such as a physician guide and a consumer guide will be produced.

Information is available on the work for the EPC on the following websites:

- Prevention Updates: http://www.ahrq.gov/clinic/prevenix.htm
- Comparative Effectiveness Updates: http://www.effectivehealthcare.ahrq.gov

Discussion

- Dr. Narva stated that NIDDK is currently conducting research related to urine albumin screening. It could confuse clinicians and patients if the EPC report shows that current screening recommendations are not supported by evidence. This is an opportunity for collaboration between NIDDK and AHRQ. In particular, the work of the National Kidney Disease Education Program's Lab Working Group is relevant to the EPC report. Dr. Chang stated that an EPC report is not a recommendation or a guideline. The evidence is intended to inform decisions. Even if there are gaps in the evidence, clinicians can still act. It is necessary to work together to frame the evidence in the best way.

Progress Report on the USPSTF Screening Guidelines for CKD
Tracy Wolff, MD, MPH

AHRQ is mandated by Congress to support the U.S. Preventive Services Task Force (USPSTF). The USPSTF is an independent panel of 16 non-Federal experts in prevention and evidence-based medicine and is composed of primary care providers (e.g., internists, pediatricians, family physicians, gynecologists/obstetricians, nurses, and health behavior specialists). The USPSTF conducts scientific evidence reviews of a broad range of clinical preventive health care services (e.g., screening, counseling, and preventive medications) and develops recommendations for primary care clinicians and health systems. These recommendations are published in the form of "Recommendation Statements." In releasing reviews, the USPSTF receives feedback on draft

recommendations from Federal health agencies—all reviews go to six Federal partners as well as other stakeholders.

Based on the reviews, there are three levels of certainty.

Steps to Develop Recommendations

- Define questions, outcomes using analytic framework
- Define and retrieve relevant evidence
- Evaluate quality of individual studies
- Synthesize and judge strength of body of evidence and make conclusion about certainty
- Estimate balance of benefits and harms
- Link judgment about certainty of evidence and magnitude of net benefits to recommendation

- **High:** Consistent results from well-designed, well-conducted studies in representative primary care populations.
- **Moderate:** Available evidence is sufficient to determine effects of preventive service on health outcomes. As more information becomes available, the magnitude or direction of the observed effect could change, and change may be large enough to alter the conclusion.
- **Low:** The available evidence is insufficient to assess effects on health outcomes due to:
    - Limited number or size of studies;
    - Important flaws in study design or methods;
    - Inconsistency of findings across individual studies;
    - Gaps in the chain of evidence;
    - Findings are not generalized to routine primary care practice; and
    - Lack of information on important health outcomes.

The issue of benefits and harm is often difficult to measure for the following reasons:

- Potential harms are real but hard to quantify;
- Includes psychological and physical consequences of false-positives, false-negatives, "labeling," overtreatment;
- Magnitude and duration of harm subjective, hard to compare to benefits; and
- No explicit criteria for magnitude.

The recommendations are also rated based on net benefits.

- A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial.
- B: The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.
- C: The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.
- D: The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
- I (for inconclusive): The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

A standard process is used to draft and finalize recommendations. A vote takes place at the regular USPSTF meetings, which are held three times each year, and feedback is sought from stakeholders. Stakeholders include Federal agencies, professional organizations, consumer groups, and policy organizations. In addition, recommendations are provided for public comment. Following the review process, final recommendations are released.

Discussion

- Ms. Ashe-Goins asked about how recommendations are communicated to the public. Dr. Wolff stated that recommendations are posted on the USPSTF website after release.
- Ms. Ashe-Goins asked if health insurers are included in the process as they are ultimately asked to pay for the recommended services. Dr. Wolff stated that the USPSTF and AHRQ are working to better communicate recommendations beyond just clinicians and patients. The USPSTF is also working to increase transparency so there is an understanding of the process. Dr. Chang added that in the EPC process, cost is not included in the effectiveness review.
- Dr. Williams added that not doing cost-effectiveness analysis is a lost opportunity. Dr. Chang replied that the EPC is not allowed to do cost analysis due to statutory restrictions. Dr. Williams added that the cost and complexity of doing longitudinal studies present challenges. In addition, sometimes analysis misses the intangible benefits of screening. For example, CKD screening can identify other conditions such as diabetes. Dr. Wolff stated that the work of the USPSTF is evolving and that they are looking at advanced methods of analysis. In particular, the USPSTF is looking into the issue of screening for co-morbidities.
- Dr. Narva raised the issue of breast cancer screening and how the reaction to the USPSTF findings demonstrated the lack of understanding of population-based screening. The media perpetuated the misunderstanding. Dr. Wolff acknowledged that communicating the information to the public is a challenge. Dr. Kozlovsky added that many primary care providers get their information from the media and never look at the actual recommendations. Dr. Wolfe stated that the Task Force is working with communication experts to improve how recommendations are communicated to providers and the public.
- Dr. Narva asked what the USPSTF does with unanswered research questions. NIDDK is interested in finding the most important questions that need to be addressed by research. This is an area for collaboration. Dr. Wolff stated that the USPSTF always identifies research gaps and prioritizes them across recommendations.

Health People 2020 Kidney Goals
Paul Eggers, PhD

Healthy People provides science-based, national objectives for promoting health and preventing disease. Every 10 years, the U.S. Department of Health and Human Services (HHS) leverages scientific insights and lessons learned from the past decade, along with new knowledge of current data, trends, and innovations. Since 1979, Healthy People has set and monitored national health objectives. Kidney disease was first included in Healthy People 2010 with the first goals

addressing end-stage renal disease (ESRD). In Healthy People 2020, the goals address the entire spectrum of kidney disease.

Health People 2020 Goals for Chronic Kidney Disease

CKD–1: Reduce the proportion of the U.S. population with CKD.
CKD–2: Increase the proportion of persons with CKD who know they have impaired renal function.
CKD–3: Increase the proportion of hospital patients who incurred acute kidney injury who have follow-up renal evaluation in six months post discharge.
CKD–4: Increase the proportion of persons with diabetes and CKD who receive recommended medical evaluation.

CKD–4.1: Increase the proportion of persons with CKD who receive medical evaluation with serum creatinine, lipids, and microalbuminuria.

CKD–4.2: Increase the proportion of persons with type 1 or type 2 diabetes and CKD who receive medical evaluation with serum creatinine, microalbuminuria, HbA1c, lipids, and eye examinations.

CKD–5: Increase the proportion of persons with diabetes and CKD who receive recommended medical treatment with angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers.
CKD–6: Improve cardiovascular care in persons with CKD.

CKD–6.1: Reduce the proportion of persons with CKD who have elevated blood pressure.

CKD–6.2: Reduce the proportion of persons with CKD who have elevated lipid levels.

CKD–7: Reduce the death rate among persons with CKD.
CKD–8: Reduce the rate of new cases of ESRD.
CKD–9: Reduce kidney failure due to diabetes.

CKD–9.1: Reduce kidney failure due to diabetes.

CKD–9.2: Reduce kidney failure due to diabetes among persons with diabetes.

CKD–10: Increase the proportion of CKD patients receiving care from a nephrologist at least 12 months before the start of renal replacement therapy.
CKD–11: Improve vascular access for hemodialysis patients.

CKD–11.1: Increase the proportion of adult hemodialysis patients who use arteriovenous fistulas as the primary mode of vascular access.

CKD–11.2: Decrease the proportion of adult hemodialysis patients who use catheters as the only mode of vascular access.

CKD–11.3: Increase the proportion of adult hemodialysis patients who use arteriovenous fistulas or have a maturing fistula as the primary mode of vascular access at the start of renal replacement therapy.

CKD–12: Increase the proportion of dialysis patients wait-listed and/or receiving a deceased donor kidney transplant within one year of ESRD start (among patients under 70 years of age).
CKD–13: Increase the proportion of patients with treated chronic kidney failure who receive a transplant.

CKD–13.1: Increase the proportion of patients receiving a kidney transplant within three years of ESRD.

CKD–13.2: Increase the proportion of patients who receive a preemptive transplant at the start of ESRD.

CKD–14: Reduce deaths in persons with ESRD.

CKD–14.1: Reduce the total death rate for persons on dialysis.
CKD–14.2: Reduce the death rate in dialysis patients within the first three months of initiation of renal replacement therapy.
CKD–14.3: Reduce the cardiovascular death rate for persons on dialysis.
CKD–14.4: Reduce the total death rate for persons with a functioning kidney transplant.
CKD–14.5: Reduce the cardiovascular death rate for persons with a functioning kidney transplant.

Discussion

- Dr. Flessner asked if there is a uniform cut-off age for kidney transplant and whether 70 years of age is appropriate. Dr. Eggers said that much of the increase in transplants has been in patients over age 65. There is still a great need for organs for people under 65 years of age.
- Dr. Kopp asked if the transplant goal was the same for 2010 (e.g., 10 percent increase). Dr. Eggers stated that improvement must be shown across all goals and progress will be assessed at the mid-course review.

NKDEP EHR Initiative
Andrew Narva, MD, FACP

CHC-CKD Goals and Objectives

To improve detection and management of chronic kidney disease (CKD) in community health centers by identifying:

- Performance measures health centers could adopt for CKD screening and management
- Materials/tools/training health centers need to support implementation of system-level changes
- Effective practices for dissemination

The National Kidney Disease Education Program (NKDEP) CHC-CKD Pilot project included six community health centers (CHCs) in the two-year project (2008-2010). As part of the study, the CHCs implemented activities based on the Chronic Care Model. These included: changes to electronic health records (EHRs)/registries, including CKD reports and templates; standing orders and lab slips for CKD; continuing medical education trainings for providers and center staff; CKD education; group visits for CKD; and community screening events. The participating CHCs provided monthly data reports, attended regular meetings related to the study, and received technical support from NKDEP.

Over the course of the study, five of the CHCs implemented EHRs—four different EHRs were used. The EHRs appear to be designed primarily for billing and proved hard to adapt for tracking patients. Therefore, the collection of data across the five sites presented some challenges. There was great variability in the quantity and quality of the data provided.

NIDDK is exploring developing a standardized CKD data set for EHRs to support quality improvement efforts. Various tools can be incorporated into EHRs:

- Clinical decision support;
- Reminders;
- Population health management;
- Process changes in addition to health information technology (HIT);
- Quality measures; and
- Health information exchange.

At the Federal level, various efforts are underway to integrate the EHR and health information exchange into health care delivery. The Office of the National Coordinator for Health Information Technology (ONC) is leading the effort to standardize EHRs and has set standards for "meaningful use" of EHRs. HHS has set standards in terms of how providers should utilize EHRs. There are six measures (three core and three alternate) for eligible providers, as well as additional non-core measures. ONC is also setting up processes to support the development of infrastructure and to provide technical assistance to providers. CMS has launched an incentive program for providers in support of meaningful use.

NIDDK is considering establishing a working group to identify what CKD-related data and measures should be included in the EHR and which of these data elements should be included in data warehouse. NIDDK is interested in working with other Federal agencies on this project. If similar efforts are underway, this presents an opportunity for collaboration.

Discussion

- Ms. Ashe-Goins suggested that Kaiser Health System could serve as a model for integrating EHRs. Dr. Narva stated that the National Heart, Lung and Blood Institute is engaged in a similar process and, Indian Health Service (IHS) has implemented an EHR across their system. The challenge is finding people who understand the entire process and can provide high-level input.
- Dr. Crowley stated that the U.S. Department of Veterans Affairs in Cleveland has developed a CKD registry and has a successful system in place to monitor and manage CKD.
- Dr. Williams stated that CDC is working with various groups to develop the National CKD Surveillance System. There are various challenges related to the collection of data. Dr. Narva added that it is hard to identify these patients. If EHRs can serve to identify these patients, they can help to improve surveillance. Data warehouses, which store some of the data from EHRs, also must add CKD measures. Dr. Star added that EHRs can support research efforts in terms of identifying health outcomes.
- Dr. Wolff stated that AHRQ has conducted research related to the EHR but not specific to CKD. Jonathan White is the director of the HIT team at AHRQ.

HRSA Quality Improvement Initiative
Matthew Burke, MD

While introducing Dr. Burke, Dr. Narva commented that CHCs see the population at highest risk for CKD.

The goal of HRSA's Bureau of Primary Health Care (BPHC) is to improve the health of underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services. Each year, CHCs see almost 19 million patients. Of these, 92 percent are at or below the 200 percent poverty level, 38 percent are uninsured, and 63 percent are racial/ethnic minorities. As Dr. Narva mentioned, this is a population at risk—63 percent of patients have hypertension and 71 percent have diabetes.

CHCs have a very high rate of patient satisfaction. More than 80 percent of patients reported the overall quality of services received was "excellent" or "very good," and more than 80 percent reported that they were "very likely" to refer friends and relatives.

Under the Affordable Care Act, CHCs are receiving $11 billion in funding over the next five years for operation, expansion, and construction. This increased funding will enable CHCs to nearly double the number of patients seen over the next five years, making primary health care available for a total of 40 million people.

BPHC is supporting the implementation of the patient-centered medical home (PCMH) model by CHCs. The model emphasizes evidence-based, coordinated care integrated throughout the primary care platform. To fully realize this model requires the meaningful use of HIT. The model supports improved patient care, including improved care for patients with CKD through enhanced tracking and prevention compliance; a patient-centric, primary care lead team approach; and more readily accessible data for use in continuous quality improvement efforts.

Patient-Centered Medical Home Joint Principles

- Physician-directed practice team
- Whole person orientation
- Care is coordinated and/or integrated
- Quality and safety
- Enhanced access
- Payment recognized and aligned
- HIT supports all domains

BPHC's PCMH initiative is designed to encourage and support CHC efforts to attain the distinction as a Patient-Centered Medical/Health Home. The goals of this initiative are to: 1) support a culture of quality throughout the CHC programs; 2) support CHCs to be recognized as PCMH; 3) leverage incentive payments associated with PCMH designation; 4) promote meaningful use of HIT; and support quality improvement. As of the beginning of March 2011, over 350 sites have expressed interest in enrolling in the recognition process.

Discussion

- Dr. Narva reported that it is important to move CKD care to the primary care setting, as this is where most interventions can be managed.

- Dr. Williams asked about the evaluation of PCMH. It is important to make sure that other agencies can track outcomes. Dr. Burke stated that they will be tracking the outcomes over time. CHCs track both patient outcomes and provider satisfaction.

NKDEP Kidney Disease Education and CKD Diet Training Curricula
Eileen Newman, MS, RD

NKDEP has developed new materials, which will be available in 2011.

- ***Kidney Disease Education Kit***. This six-lesson kit for patient educators is a joint project by NKDEP and IHS. It features materials from NKDEP, NIDDK, NIH, and CMS and was prompted by the Medicare Improvement for Patients and Providers Act (MIPPA). Content includes the basics of kidney disease, disease management, disease progression, how to treat kidney failure, preparing for treatment, and living with kidney failure. Each lesson includes objectives, a suggested outline, "take away" resources for patients, additional clinical information for educators, and sample outcomes assessment questions. The education kit will be an online tool, which will allow users to customize the information for various populations. The kit will be available in early 2011.
- ***Dietitian Outreach***. The goal of the project is to involve general practice dietitians in CKD education. Since May 2007, NKDEP has been working with the American Dietetic Association (ADA) to do so. As part of the project, nutrition materials have been developed. These materials focus on the role of medical nutrition therapy (MNT) in CKD management. Both provider and patient materials are available online, and NKDEP is also currently printing hardcopy versions. A certificate program in CKD nutrition management is under development. The program will address key topics including burden of disease, identification and monitoring of CKD, how to slow progression, complications, key nutrients, and renal replacement therapy. The program is scheduled for release in May 2011, and ADA will promote the program to its members.

Discussion

- Ms. Ashe-Goins asked if other professionals like diabetes educators can be certified. Ms. Newman said that CMS regulations do not currently support CDEs as providers of CKD education. However, NKDEP has collaborated with AADE to help diabetes educators address CKD.
- Ms. Ashe-Goins added that the National Kidney Foundation has developed many materials related to the involvement of patients' families.

Agency Updates

- CDC: Dr. Williams reported that CDC will be producing an *MMWR* for kidney disease month in March. In addition, CDC will be launching the CKD surveillance website this year.
- NIDDK: Dr. Flessner reported that a CKD scientific meeting and CKD trials will take place July 19-20.

- AHRQ: Dr. Wolff reported that the USPSTF will consider the evidence this year for Screening for CKD in asymptomatic adults. Draft and final recommendations will be released on the USPSTF website at: http://www.uspreventiveservicestaskforce.org/. Dr. Chang added that AHRQ is taking a more active approach in engaging stakeholders in topic identification. It is currently putting together a stakeholder panel and identifying topics appropriate for systematic review.
    - Dr. Narva asked if AHRQ conducts reviews of patient education materials. Dr. Chang responded that AHRQ is moving toward this but that systematic review methods are not appropriate to assess these activities.
    - Dr. Wolff reported that AHRQ has funded some work in patient education and how to communicate recommendations. Most of this work has focused on shared decision making.
- HRSA: Dr. Kozlovsky reported that HRSA is focusing on living donor safety. Data must be collected on the risk over time, especially since many living donors are young. This needs to be considered in terms of CKD.
- NIDDK: Dr. Star introduced the Kidney Research National Dialog (KRND). The KRND is an interactive Web-based dialogue to address the significant problem of kidney disease through the identification of critically important questions or objectives and the research strategies to address them. The results will be used to prepare a "Blueprint for Kidney Research" that clearly articulates future opportunities to be implemented by the entire research community. KRND will be used beyond the development of the Blueprint. NIDDK envisions it as a forum for cross-disciplinary discussions and collaborations. KRND can be found at http://krnd.ideascale.com.
- NIDDK: Dr. Narva announced that NIDDK is working to promote the adoption, maintenance, and sustainability of evidence-based interventions through Type 2 (T2) translational research. A workshop was held in October 2010 to identify possible T2 research questions for CKD, and a Request for Applications (RFA)(http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-10-011.html) has been released that emphasizes innovative approaches for settings serving high-risk individuals. Applications are due in February 2011.

Adjournment

Dr. Narva closed the meeting, thanking participants for their participation.