



National Institute of
Diabetes and Digestive
and Kidney Diseases

Kidney Interagency Coordinating Committee (KICC) Meeting
March 15, 2013, 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 committee was created by Congress in 1987 and is mandated to meet yearly. The goal of the committee is to encourage cooperation, communication, and collaboration among all federal agencies involved in kidney research and other kidney-related activities. At the request of participants, the frequency of meetings was increased to two per year.

II. Affordable Care Organizations: The Comprehensive ESRD Care Initiative

Melissa Cohen, JD, MPA

The Centers for Medicare and Medicaid (CMS), Center for Medicare and Medicaid Innovation (CMMI) announced the Comprehensive End-Stage Renal Disease (ESRD) Care Model on February 4. This new Medicare model of payment focuses on improving care for beneficiaries with ESRD while reducing costs to the Medicare program. It was developed under the authority of the Affordable Care Act. It is the first disease-specific accountable care organization (ACO) initiative supported by CMMI. Under the demonstration project, organizations will be funded for up to five years—three base years and two option years. Letters of Intent for this initiative are due May 15, 2013. Full applications are due July 1, 2013.

The ESRD population is one CMS believes could benefit from a shared savings model. These beneficiaries constituted 1.3 percent of the Medicare population and accounted for an estimated 7.5 percent of Medicare spending, totaling over \$20 billion, in 2010. Roughly two-thirds of these costs are for care other than dialysis.

Patients often have underlying disease complications and multiple co-morbidities, which can lead to high rates of hospital admission and readmissions, as well as a mortality rate that is much higher than the general Medicare population. Because of these complex health needs, beneficiaries often require visits to multiple providers and follow multiple care plans, which can be challenging for beneficiaries if care is not coordinated. Such coordination can be difficult in a fee-for-service environment.

Greater care coordination will hopefully result in more patient-centered care and improved health outcomes.

Services will be provided by groups of health care providers and suppliers, called ESRD Seamless Care Organizations (ESCOs), which are similar to other ACOs supported by CMS. Providers will engage in voluntary arrangements in which they are held accountable for the

Model Hypothesis

Comprehensive medical management of, and better care coordination for, ESRD beneficiaries will result in improved outcomes and expenditure savings.

Key Features

- Comprehensive and coordinated care delivery
- Enhanced patient-centered care and improved communication
- Improved access to services

quality, cost, and overall care of matched beneficiaries. ESCOs will be clinically and financially responsible for all care offered to a group of matched beneficiaries (i.e., not just dialysis care or care specifically related to a beneficiary's ESRD).

Beneficiary costs will be measured as total Part A and B expenditures. Matched beneficiaries will remain in full fee-for-service Medicare, meaning that they retain freedom of choice in the selection of their care options. Because the model focuses on the role dialysis centers can play in the coordination of care, ESCO beneficiaries will be matched based on where they receive their dialysis care.

ESCO Requirements

An ESCO must have a taxpayer identification number (TIN), be a separate and unique legal entity, and be recognized and authorized to conduct business. It must be capable of:

- Receiving and distributing shared savings payments;
- Repaying shared losses, if applicable; and
- Establishing reporting mechanisms and ensuring ESCO participant compliance with program requirements, including but not limited to quality performance standards.

An ESCO is formed by participant-owners, who must include at least one of each of the following providers:

- Dialysis facility (large dialysis organizations [LDOs], small dialysis organizations [SDOs], hospital-based facilities, and independently-owned dialysis facilities);
- Nephrologist/nephrology group practice not employed by the dialysis facility; and
- Other eligible Medicare-enrolled provider or supplier including physicians and non-physician practitioners, but excluding Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) suppliers, ambulance suppliers, and drug/device manufacturers.

All dialysis facilities and nephrologists/nephrologist group practices participating in the ESCO must be participant-owners. This requirement ensures that providers have a significant responsibility and incentive to support the cost and quality outcomes of the model.

In addition to participant-owners, ESCOs can include other providers and suppliers, which are an individual or entity that:

- Is a Medicare-enrolled provider or supplier other than a DMEPOS supplier, ambulance suppliers and drug or device manufacturers;
- Is identified by an National Provider Identifier (NPI) or CMS Certification Number (CCN); and,

Participant-Owners

A Medicare-enrolled entity that:

- Is comprised of one or more ESCO providers/suppliers, each of whom bills under the same Medicare-enrolled TIN assigned to the entity;
- Has an ownership stake in the ESCO;
- Is a signatory to the ESCO Model Participation Agreement; and
- Assumes a minimum portion of the liability for shared losses ("downside risk") as specified by CMS and agrees CMS may recover such shared losses.

- Bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to a TIN of an ESCO participant.

Providers and suppliers are allowed to receive a portion of the shared savings from the ESCO.

To be eligible to apply for the current initiative, an ESCO must have a minimum of 500 ESRD matched beneficiaries. All the facilities included in the ESCO must be within a single market (i.e., no more than two contiguous Medicare CBSAs with permissible inclusion of contiguous rural counties that are not included in a Medicare CBSA). For rural applicants not included in any Medicare CBSA, the market area of the ESCO will be defined based on a geographic unit no larger than a state. While the focus of the services is local, providers can submit multiple applications if they wish to provide services in a larger geographic area.

Once established, an ESCO must maintain an identifiable governing body. Requirements for the governing body include:

- ESCO participants (owners and non-owners) must have at least 75 percent control of the ESCO’s governing body;
- No one participant in the ESCO can represent more than 50 percent of the membership on the governing body;
- Members must place their fiduciary duty to the ESCO before the interests of any ESCO participant; and
- An independent ESRD Medicare beneficiary representative and a trained and/or experienced non-affiliated, independent consumer advocate on the governing body must be a member.

Beneficiary Matching

A “first touch” approach will be used for matching. This will be based on the beneficiary’s first visit to a dialysis facility during a prescribed look-back period. The beneficiary is matched to the ESCO for the duration of the demonstration, unless they lose eligibility. After initial enrollment, beneficiaries will be added to an ESCO on a quarterly basis with the look-back period being the previous quarter.

Beneficiary Matching Criteria

To be matched to an ESCO, a beneficiary must be:

- Enrolled in Medicare parts A and B
- Receiving dialysis services
- Reside in the United States and within the market area of the ESCO and receive at least 50% of his/her annual dialysis services (measured by expenditures) in the ESCO’s geographic area
- Age 18 or above Must NOT have already been assigned or aligned to a Medicare ACO or another Medicare program/demonstration/model involving shared savings at the date of initial matching for the ESCO Model

Beneficiaries must NOT:

- Be enrolled in a Medicare Advantage plan, cost plan, or other non-Medicare Advantage Medicare managed care plan
- Have a functioning transplant
- Have Medicare as a secondary payer

Pediatric beneficiaries (age 17 and under) are excluded from matching due to different needs of this small population (<1% of total ESRD beneficiaries).

Payment Arrangement

A shared savings/loss model will be used. For each performance year, the historical expenditure baseline will be risk-adjusted, trended, price-adjusted, and bundle-adjusted to form an updated benchmark reflecting the performance year to compare with the ESCO's actual performance year. There are different risk arrangements depending on the make up of the ESCO and whether an LDO is participating. Non-LDO ESCOs have the option of phasing in risk over time. This makes it more feasible for less experienced organizations to participate.

Quality Performance

To be eligible for shared savings, ESCOs will be required to meet a specified threshold based on five domains:

- Preventive health;
- Chronic disease management;
- Care coordination/patient safety;
- Patient/caregiver experience; and
- Patient quality of life.

The quality measures that will be used are currently under development. It is expected that the measures will be available prior to the time that applications are due.

Data Sharing

Matched beneficiary claims data will be shared with ESCOs to help care improvement efforts. Beneficiaries will be able to opt out of data sharing within the first 30 days of enrollment or at any time thereafter. CMS plans to share the following data files and reports with ESCOs on a regular basis.

- Detailed, standard (not customized), historical (one year) claims data on matched beneficiaries who have not opted out of data sharing (at the start of the first performance year).
- Historical claims data as additional beneficiaries are matched to the ESCO (during each performance year).
- Standard beneficiary-level claims feeds, which will include beneficiary identifiers, and services delivered by providers inside and outside of the ESCO (monthly).
- Total Medicare Part A and B expenditures and claims lag reports (monthly).
- Financial reconciliation reports, including the ESCO's performance on quality and patient experience metrics (annually).

Discussion

- Dr. Crowley asked about CMS' expectations in terms of applications. Ms. Cohen stated that CMS expects to receive applications from both large and small dialysis organizations, which is why multiple tracks were created.
- Dr. Crowley asked why ESCOs are required to have 500 beneficiaries—this could exclude potential applicants such as university practices. Ms. Cohen stated that it is the expectation that each ESCO will include multiple dialysis sites. The number was set by

CMS actuaries to ensure that the savings calculations are accurate. CMS is exploring lowering the number of beneficiaries required.

- Dr. Williams asked how patients will benefit from the ESCO model and how will CMS assure the quality of care. Ms. Cohen stated that the ESRD population was selected because of the significant amount of care required by patients and the potential benefits from better care coordination. The model is designed to provide incentives for providers to work together and create a better care environment for beneficiaries. In addition, beneficiaries have input via the governing body. CMS will closely monitor the initiative to ensure there is no harm to participating beneficiaries.
- Ms. Hand asked how the quality measures will be put into operation and whether standard measures will be used. Ms. Cohen stated that CMS will be using existing quality instruments.
- Ms. Hand asked the origin of the term “seamless care organization.” Ms. Cohen stated that the term is commonly used at CMMI.
- Dr. Star asked how the issue of patient dumping and passing will be addressed. Ms. Cohen stated that CMS is aware of this concern and taking steps to address it. The specified historical look back period starts prior to the release of the funding announcement (January 1, 2013). The first touch approach specifies that ESCOs are responsible for a patient when the initial dialysis claim is filed. Since they are responsible for all Part A and B costs of the patient, the ESCO has an incentive to manage that patient’s care.
- Dr. Star asked why dialysis centers are the focus of the initiative when two-thirds of care costs are outside the dialysis center. Ms. Cohen stated that the hypothesis is that since patients are regularly receiving care at dialysis centers, the centers are in a good position to create a coordinated care environment that will result in better patient management.
- Dr. Kimmel asked what will happen if the ESCOs lose money. Ms. Cohen stated that CMMI does not expect everything to work. This is a small-scale demonstration to test a possible model of care.
- Dr. Germino asked if ESCOs will be required to pay hospitalization costs of beneficiaries. If so, will they be able to successfully negotiate with multiple hospitals. Ms. Cohen stated ESCOs are required to cover total Medicare Part A and B expenditures. All of the providers will be compensated through regular fee-for-service Medicare.
- Dr. Narva stated that Part D costs are not included in the model. Not capturing drug-related costs could compromise care. Ms. Cohen stated that the quality measures will provide sufficient protection for patients and prevent poor care. Since the ESCO is responsible for the patient for the life of the model, short-term/sub-par fixes could cost the ESCO money.
- Dr. Williams asked about the voluntary nature of patient participation. If there is only one provider in the area and that is the ESCO, how does the patient truly have choice? Ms. Cohen stated that the beneficiary has continued access to any provider they had access to prior to the ESCO and will be able to see that provider on a Medicare fee-for-service basis. Beneficiaries are not limited to providers that are participating in the ESCO. Dr. Williams added that limiting provider options exposes patients to significant risk. Ms. Cohen stated that the intent is to create a care environment where patients chose to participate because the care is better.

III. Pragmatic Trials and the Patient-Centered Outcomes Research Institute

Mike Flessner, MD, PhD

Patient-centered outcomes research (PCOR) and comparative effectiveness research (CER) are conducted for a variety of reasons. In particular, PCOR and CER address various, ongoing health care challenges:

- Need to address important clinical questions;
- Patient and provider dissatisfaction;
- Declining health care statistics;
- Limited access to care/lack of health coverage;
- Increasing cost of care.

In this type of research, there are various outcomes that can be used to measure the effectiveness of a treatment protocol or intervention.

Patient-Reported Outcomes: most useful for measuring a concept best known by the patient or best measured from the patient perspective. The instrument must be specific to the disease/treatment and to the setting.

Health-Related Quality of Life: represents patient's general perception of effect of illness and treatment on physical, psychological, and social aspects of life.

Biomarker: a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or biological responses to a therapeutic intervention.

Surrogate Endpoint: a biomarker that is used in therapeutic trials as a substitute for a clinically meaningful endpoint. Treatment effects on a surrogate endpoint are expected to predict treatment effects on the outcomes of clinical interest. When surrogate endpoints are used, there is always some residual uncertainty about the nature of a treatment's benefit

Pragmatic Trials

Pragmatic trials are used to measure effectiveness under real world conditions. Some key characteristics of pragmatic trials include:

- Open to all individuals with condition of interest, regardless of risk, co-morbidities, adherence;
- Flexible implementation;
- No specific research-related expertise needed;

Definitions

Comparative Effectiveness

Research: research designed to inform health care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.

Pragmatic Trials: trials designed to measure effectiveness—the benefits the treatment produces in routine clinical practice.

Patient-Centered Outcomes

Research (PCOR): Designed to help people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options.

- Can be conducted in various clinical settings; and
- Limited follow-up of subjects.

There are various common features of pragmatic trials that support flexibility and ease of implementation:

- Simple consent process;
- Simple interventions;
- Systems interventions;
- Cluster randomization; and
- Large sample size.

An important aspect of a pragmatic trial is the learning that takes place within the health system. Research and care delivery are conducted simultaneously. Data collection is facilitated by the use of technology such as electronic health records (EHRs). Ideally, these efforts result in improved care.

Pragmatic Trials: Examples

NIH Health Care Systems Collaboratory
 Research network of multiple providers (HMOs/AHCs) with suitable health information technology systems. The network serves approximately 14 million patients.

- Creates an efficient clinical research platform with common governance/policies, virtual data warehouse, and tools/processes to streamline clinical research.
- Efficiently conducts PCOR/CER studies.
- Efficiently conducts large genetic-epidemiology studies.

Time to Reduce Mortality in ESRD (TiME) Trial
 The study is a collaboration between the University of Pennsylvania, NIDDK, other academic institutions, and two large dialysis organizations (LDOs). This intervention explores the benefits of lengthening the dialysis session duration to 4.25 hours for patients new to dialysis. The study proposes to include 402 facilities (over 6,400 patients).

Dialysis care is well suited for pragmatic trials. It is a single payer system, data are available (United States Renal Data System, dialysis provider organization data), and there are existing quality improvement initiatives. Other aspects of dialysis care that facilitate pragmatic research include:

- Study population is highly accessible with uniform and frequent clinical encounter schedules;
- Highly granular and uniform data collection is part of clinical care; and
- Dialysis provider organization infrastructure allows for centralization of activities and ability to conduct trial in large number of facilities across a large geographic area.

While dialysis centers present a research opportunity, there are challenges to conducting research in these settings. These include.

- Multiple layers of buy in are required;
- Possible disruption in dialysis center activities; and

Dialysis: Possible Research Questions

- Duration of hemodialysis sessions?
- Dialysis solution potassium concentration?
- Blood pressure target?
- Phosphorus target?
- Hemoglobin target?
- Preventive health care?
- Anticoagulation for atrial fibrillation?

- Organizational and administrative structure increases the risk of contamination across the cluster.

Patient-Centered Outcomes Research Institute (PCORI)

The Patient-Centered Outcomes Research Institute (PCORI) is authorized by Congress to conduct research to provide information about the best available evidence to help patients and their health care providers make more informed decisions. PCORI's research is intended to give patients a better understanding of the prevention, treatment, and care options available, and the science that supports those options.

PCORI will commission research that is responsive to the values and interests of patients and will provide patients and their caregivers with reliable, evidence-based information for health care choices. It is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. The research explores patient-focused questions about what should happen, options, and how the healthcare system can improve care.

Based on the PCORI model, research questions should address the following criteria:

- Assess the benefits and harms of preventive, diagnostic, therapeutic, or health care delivery system interventions to inform decision making, highlighting outcomes and comparisons that matter to people;
- Is inclusive of an individual's preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life;
- Incorporate a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination;
- Investigate optimizing outcomes while addressing burden to individuals, resources, and other stakeholder perspectives.

In PCORI's first round of funding, which was announced in December 2012, Francesca Tentori, MD of Arbor Research was funded for a kidney-related project.

Discussion

- Dr. Crowley asked about pragmatic trials with the network of LDOs and how the researchers will adjust for the Hawthorne effect (i.e., subjects modifying their behavior because they know they are being studied). Dr. Flessner stated that this is the nature of pragmatic trials—while there is always the possibility of contamination, the large number of patients (approximately 6,000) will help to address issues of power.
- Dr. Kimmel stated that the Collaboratory has developed relationships with LDOs. As a result of this collaboration, units were identified where the mean time was less than 3.5 hours—in these units increasing the time to 4.5 hrs would be a significant difference.
- Dr. Thompson asked what defines the end of a trial. Dr. Flessner stated that there is a specific time period, driven by available funding.

- Dr. Thompson asked whether the assumptions behind the power calculations will be revisited during the course of the trial. Dr. Flessner stated that there will likely be interim analyses and potential adjustments during the course of the trial.
- Dr. Thompson asked if it will be recommended to patients that they have longer dialysis sessions. Dr. Flessner stated that all patients will be prescribed a 4.25 hour session but patients will always be allowed to end sessions early. There is a possibility that patients will object to longer sessions, and their adherence will be determined on an ongoing basis.
- Dr. Abbott asked if increasing the session to 4.25 hours will be disruptive to the workflow in the dialysis centers. Do they have the capacity to increase sessions? Dr. Flessner stated that the providers have agreed to extend the sessions. At this stage it is impossible to predict outcomes.
- Dr. Star stated that this is a very innovative and challenging study. It remains to be seen whether it will work. Many of the challenges relate to logistics, not clinical questions. The study challenges many of the regulations within the system. If the study is successful, there are many more pragmatic studies that could be conducted in partnership with dialysis organizations. KICC members have been very helpful in providing feedback on how to structure the trial.
- Dr. Kim Smith stated that she is very excited about the trial and patients and providers need the answers that will be generated by the study.
- Dr. McBryde stated that it will be hard to directly tie outcomes mechanistically to the intervention. Dr. Flessner stated that this is the difference between a pragmatic and an explanatory trial. Pragmatic trials are not designed to answer questions of mechanisms; rather they answer the question: which clinical procedure or treatment is better.

IV. Kidney Health Initiative

Patrick Archdeacon, MD

The Kidney Health Initiative (KHI) grew out of discussions between the Food and Drug Administration (FDA) and the American Society of Nephrology (ASN). There was concern on the part of the ASN that the review of drugs that are used to treat kidney-related disease or that have off-target impact on kidney health did not always include the perspective of a nephrologist. FDA saw this interaction as an opportunity to promote clinical research in nephrology—a therapeutic area that lags behind many other disciplines in conducting randomized clinical trials. In addition to its interest in improving the safety of products that impact kidney health, fostering the development of new therapies is another primary focus of KHI. There have been few new therapies for kidney-related diseases and too few nephrology drugs, devices, and biologics have been approved in recent years.

As a result of this interaction, FDA and ASN signed a memorandum of agreement in August 2012 creating KHI, which is a public/private partnership. The Initiative was publicly announced and began accepting applications from Pioneer Members in September 2012. As of March 2013, there are 34 members including

KHI Mission

Advance scientific understanding of the kidney health and patient safety implications of new and existing medical products and to foster development of therapies for diseases that affect the kidney by creating a collaborative environment in which FDA and the greater nephrology community can interact to optimize the evaluation of drugs, devices, biologics, and food products.

professional organizations, providers, patients, researchers, government representatives, and representatives from industry (e.g., pharma/biotech/devices). The deadline for Pioneer Members is December 31, 2013.

Members pay fees based on a sliding scale. Fees will be used to support KHI projects. In addition, KHI will explore other sources of revenue such as grants and support from PCORI.

KHI has multiple objectives. These include:

- Create a platform to facilitate dialogue and research that informs regulatory processes;
- Identify areas in need of greater innovation or better defined regulatory pathways;
- Develop trial designs and approaches to data collection;
- Optimize post-market surveillance of products that affect kidney health; and
- Publish white papers regarding key issues and promoting execution of solutions.

In addition to two co-chairs, KHI's Board of Directors includes the following members.

- **Community Members**
 - Four health professionals with expertise in kidney disease
 - Two patient advocates interested in kidney diseases and related conditions
 - Four representatives from commercial interests that encompass the breadth of FDA's mission
 - Two at-large members, representing health professionals, patient advocates, or commercial interests as well as other stakeholders (such as ethicists and policymakers)
- **FDA Liaisons**
 - Center for Biologics Evaluation and Research (CBER)
 - Center for Drug Evaluation and Research (CDER)
 - Center for Devices and Radiological Health (CDRH)
 - Center for Food Safety and Applied Nutrition (CFSAN)
- **Other Governmental Liaisons**
 - Centers for Medicare and Medicaid Services (CMS)
 - National Institutes of Health (NIH)
 - National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
 - National Center for Advancing Translational Sciences (NCATS)
 - Centers for Disease Control and Prevention (CDC) (to be identified)
 - Agency for Healthcare Quality and Research (AHRQ) (to be identified)
- **Ex Officio Members**
 - As needed to ensure that the KHI Board of Directors is as inclusive, representative, and effective as possible

KHI will rely on members to identify areas of concern and submit possible projects. The Board of Directors will review and prioritize projects with regards to mission alignment, feasibility, and available resources. Member organizations will be asked to participate in work groups to execute projects. Work group participants will be selected based on expertise.

To identify pilot projects that could serve as models for subsequent project submissions by its membership, KHI asked the ASN Advisory Boards to submit possible topics. Of 34 candidates submitted, KHI selected three pilot projects.

Pharmacokinetic Data for Acute Kidney Injury (AKI) Patients Receiving Continuous Renal-Replacement Therapy (CRRT)

There is a lack data to guide the management of critically ill patients receiving CRRT. This project will develop a white paper that defines categories of drugs for which generating such data represent high, moderate, and low priority. The white paper will also provide recommendations regarding appropriate study design and context for study.

Lupus Nephritis Trial Design

The lack of established study designs represents a barrier to the development of safe and effective therapies for lupus nephritis. This project will aggregate and analyze data from trials exploring lupus nephritis treatment that were completed since 1987 to define complete and partial response criteria. Criteria will be tested against validation datasets from recent lupus nephritis.

Dietary Phosphorus

Management of calcium-phosphorus in patients with ESRD represents a major challenge. High levels of dietary phosphorus may contribute significantly to morbidity and mortality in such patients. Inorganic phosphates used in food processing may have a particularly high bioavailability and are increasingly ubiquitous in American diet. KHI identified this topic as deserving of attention, but has not yet identified a final project plan.

Future activities for KHI include an annual meeting (September 2013) and activities related to Kidney Week (November 5-10, 2013).

Discussion

- Dr. Star asked how KHI will solicit ideas for research projects. Dr. Archdeacon stated that submissions will be accepted through the KHI website. The KHI Board of Directors will meet in May to develop a process for selecting projects. Dr. Star added that it is important to focus on actual projects, not just concepts—there are many important questions that do not have obvious answers. The KICC could play a role in the identification of potential research projects. Dr. Archdeacon stated that the projects related to the FDA have been more successful because the agency is effective in reaching out to other partners that can make an idea viable.
- Dr. Narva stated that the phosphorus project is important and that the issue of food labeling needs to be addressed. The lack of labeling is a real barrier since patients do not

have the information they need to limit their intake. The project could be designed to engage the food industry.

V. Agency Updates

AHRQ Systematic Reviews

Elisabeth Kato, MD, MRP

AHRQ is conducting three kidney-related systematic reviews.

- Triponin testing for the diagnosis, risk stratification and prognosis for patients with CKD (draft available for comment in August or September)
- Prevention of contrast induced nephropathy (key questions available for comment in April)
- Calcineurin inhibitors in kidney transplantation (to be initiated in summer 2013)

Dr. Kato asked if the group could inform her of any related research that is taking place at the same time or in the future. There are many opportunities for other federal agencies to participate in these reviews. AHRQ is interested in suggested topics for studies and individuals to participate in the development of key questions. Technical experts are needed to participate in designing the protocols for systematic reviews. Information is available at:

<http://www.effectivehealthcare.ahrq.gov>.

Discussion

- Dr. Crowley stated that the Department of Veterans Affairs is conducting a study titled *Prevention of Serious Adverse Events Following Angiography*. Dr. Steven Weisbord is the principal investigator. The Australian sites are enrolling subjects and the U.S. sites should begin enrollment soon. The estimated study completion date is December 2016.

CDC CKD Fact Sheet Update

Sharon Saydah, PhD

The National CKD fact sheet is designed to provide definitive information about the burden and consequences of CKD in the United States. CDC hopes to partner with other federal agencies in the development of this factsheet. The fact sheets can be customized by partners to address their needs and targeted audiences.

The 2010 fact sheet addresses the following topics.

- Summary of CKD
 - What is CKD?
 - How is it detected?
 - How is it treated?
- CKD is common among adults

- Risk factors for development of CKD
- Risk factors for progression of CKD
- Health consequences
- What can be done to reduce the burden or prevent or delay kidney failure

For the 2013 update, CDC proposes the following changes.

- Include reference document on website in order to reduce the length of the factsheet but at the same time provide reference material for medical and public health partners (e.g., methods for estimates, references for statements)
- Update CKD prevalence estimates
- Add lupus as a risk factor for CKD
- Update End Stage Renal Disease (ESRD) numbers

CDC will send the final draft of the fact sheet to participants for review and further input.

Following review, it will be submitted for clearance. Once finalized, it will be released on the CDC website.

Discussion

- Dr. Crowley asked about the target audience for the fact sheet. In the current version it is too technical for patients. Is it possible to develop separate fact sheets for professionals and patients? Dr. Saydah stated that the fact sheet is designed for the public health community. Dr. Williams added that NKDEP has various resources targeting patients and that these documents could be reviewed and revised as necessary.
- Dr. Narva stated that NKDEP is careful to convey that CKD prevalence is an estimate. In particular, NKDEP always uses the term “may” (i.e., X people **may** have CKD). Dr. Williams added that CDC uses ranges in their fact sheets due to the uncertainty related to the estimation of the prevalence of CKD. Dr. Star added that Dr. Eggers has an estimating equation that is used for the statistics presented on the NIDDK website.

Other Updates

- Dr. Zieman announced that the National Institute on Aging has released three program announcements on acute kidney injury in older adults. Earlier this year, program announcements were released on solid organ transplants in older adults. The announcements are co-sponsored by NIDDK.

National CKD Fact Sheet: Current Participants

- Agency for Healthcare Research and Quality
- Centers for Disease Control and Prevention
- Centers for Medicare and Medicaid Services
- U.S. Department of Veterans Affairs
- Health Resources and Services Administration
- Kidney Interagency Coordinating Committee
- National Institute of Diabetes and Digestive and Kidney Diseases
- National Kidney Disease Education Program
- National Heart Lung and Blood Institute
- American Society of Nephrology
- National Kidney Foundation
- United States Renal Data System
- University of Michigan Kidney Epidemiology and Cost-Center
- University of California, San Francisco/University of California, San Francisco Center for Vulnerable Populations

- Dr. Abbott stated that given the Kidney Disease Improving Global Outcomes (KDIGO) guidelines, pathologists at Bethesda Naval Hospital will be using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation for reporting estimated GFR. Dr. Narva added that the NIH clinical center also uses the CKD-EPI equation for reporting but there are questions in terms of the ranges used in reporting. This might be a topic for future meetings.

Adjournment

Dr. Narva stated that the topics presented at this meeting were suggested by members, and encouraged members to submit topics for future meetings.

Potential topics for a future meeting include:

- Harmonizing the various performance measures used by federal agencies;
- A presentation by CMS on their ESRD quality measure development projects.

Dr. Narva announced that the next KICC meeting is scheduled for September 27, 2013.