Kidney Interagency Coordinating Committee Meeting

Centers for Medicare & Medicaid Services Efforts in Chronic Kidney Disease and End-Stage Renal Disease

Natcher Conference Center, Rooms F1/F2
National Institutes of Health
Bethesda, MD
March 29, 2019

Meeting Participants and Summary

Andrew Narva, M.D., FACP
Executive Secretary, KICC
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Email: narvaa@niddk.nih.gov

Kevin Abbott, M.D., M.P.H.
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Email: kevin.abbott@nih.gov

Kathleen Blackwell, M.P.H.
Centers for Disease Control and Prevention
Email: kathleen.blackwell@cms.hhs.gov

Ann Bullock, M.D.
Indian Health Service
Email: ann.bullock@ihs.gov

Nilka Ríos Burrows, M.P.H.
Centers for Disease Control and Prevention
Email: nrios@cdc.gov

Andre Chappel, Ph.D.
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Email: andre.chappel@hhs.gov

Preeta Chidambaran, M.D., M.P.H. (via WebEx)
Centers for Medicare & Medicaid Services
Email: preeta.chidambaran@cms.hhs.gov

Sandeep Dayal, Ph.D.
National Institute of Diabetes and Digestive and Kidney Diseases
Email: sandeep.dayal@.nih.gov

Julia Jackson, M.A. (via WebEx)
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Email: julia.jackson@nih.gov

Meagan Khau
Centers for Medicare & Medicaid Services
Email: megan.khau@cdc.gov

Paul Kimmel, M.D., MACP
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Email: kimmelp@extra.niddk.nih.gov

Shari Ling, M.D.
Centers for Medicare & Medicaid Services
Email: shari.ling@cms.hhs.gov

Michael Lipp, M.D., M.B.A.
Centers for Disease Control and Prevention
Email: michael.lipp@cms.hhs.gov

Susan Mendley, M.D.
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Email: susan.mendley@nih.gov

Saadia Miran
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Email: saadia.miran@nih.gov

Robert Nee, M.D., FACP
Walter Reed National Military Medical Center
Email: robert.nee.civ@mail.mil

Lauren Oviatt, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Email: lauren.oviatt@cms.hhs.gov

Paul Palevsky, M.D.
VA Pittsburgh Healthcare System
Email: paul.palevsky@va.gov

Sarada Pyda, Ph.D., FACE
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Email: sarada.pyda@hhs.gov

Jesse Roach, M.D.
Centers for Medicare & Medicaid Services
Email: jesse.roach@cms.hhs.gov

Anand Shah (via WebEx)
Centers for Medicare & Medicaid Services
Email: and.shah@cms.hhs.gov

Murray Sheldon, M.D. (via WebEx)
U.S. Food and Drug Administration
Email: murray.sheldon@fda.hhs.gov

Robert Star, M.D.
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Email: robert.star@nih.gov

Kenneth Wilkins, Ph.D.
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Email: kenneth.wilkins@nih.gov

Welcome and Introductions

Andrew Narva, M.D., FACP
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)

Dr. Andrew Narva welcomed members and attendees to the NIDDK Kidney Interagency Coordinating Committee (KICC) meeting. The KICC was mandated by Congress in 1987 to meet yearly to encourage cooperation, communication, and collaboration among all federal agencies engaged in kidney research and other related activities. The KICC meets twice yearly and provides an active forum for communication among federal agencies working in kidney disease The NIDDK hosts the Federal Chronic Kidney Disease (CKD) Matrix, an online resource that summarizes CKD-related activities and conveys the multifaceted and interconnected federal response. Dr. Narva reminded participants that this KICC meeting is closed to non-federal employees. Today's meeting will focus on the Centers for Medicare & Medicaid Services (CMS) efforts to address CKD and end-stage renal disease (ESRD) and will include agency updates. Dr. Narva invited participants to introduce themselves.

Estimated Savings to Medicare from the Special Diabetes Program for Indians (SDPI)

Sarada Pyda, Ph.D.
Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services (HHS)
Andre Chappel, Ph.D.
ASPE, HHS

Dr. Sarada Pyda presented on the estimated Medicare savings in the SDPI. She thanked Drs. Kevin Abbott, Ann Bullock, and Narva for their input to project. The SDPI was established by Congress in 1997 in response to the growing diabetes mellitus (DM) epidemic in the American Indian and Alaska Native (AI/AN) population in the United States. The grant program funds $150 million annually to support diabetes-related care for 301 Indian Health Service (IHS) programs. Grantees address local priorities and are required to implement a minimum of one best practice. Dr. Pyda reported that since 2011, the diabetes prevalence in the AI/AN population has been stable compared with the U.S. population.

ESRD can be a complication that occurs from DM and qualifies most individuals for Medicare coverage, regardless of the age of onset. Diabetes-related ESRD (ESRD-DM) accounts for the highest proportion of overall ESRD in the AI/AN population compared with other races/ethnicities; therefore, a diabetes intervention program would benefit this population. From 2000 to 2015, there was a marked decline in the ESRD-DM prevalence that coincided with the establishment of the SDPI. The purpose of this project was to estimate the savings (1) to the Medicare fee-for-service (FFS) program attributable to the AI/AN ESRD-DM decreased incidence and (2) attributable to the SDPI based on varying assumptions to the proportion of incidence decrease that may be a result of the SDPI.

Dr. Pyda detailed the project methods. Using the trend analysis, the number of averted ESRD-DM cases in the AI/AN population from 2001 to 2015 was estimated in two separate scenarios:

- Scenario 1, if the incidence of ESRD-DM in the AI/AN population had grown at the same rate as in the white population.

- Scenario 2, if the incidence of ESRD-DM in the AI/AN population had remained the same as in 2000.

The amount of Medicare FFS spending on ESRD treatment that would have been spent on the averted cases was calculated under the assumption that the rates of dialysis, transplantation, maintenance, and death were the same as for all-cause ESRD in the AI/AN population. The estimated costs of Medicare FFS treatment for DM or CKD were then subtracted from the estimated cost of ESRD treatment for the averted cases to approximate the amount of Medicare FFS savings from averting cases of ESRD. This amount was multiplied by varying proportions of what could be attributed to the SDPI.

Data sources used included the United States Renal Data System's (USRDS) *2017 USRDS Annual Data Report* for incidence rates and per-person per-year costs of dialysis, transplant, and maintenance; IHS annual report for AI/AN populations; and Acumen analysis of Medicare claims data to calculate the number of years on dialysis and annual rates of survival while on dialysis and after transplantation. The key findings were that compared with whites, in Scenario 1, there would have been approximately 2,602 additional diagnosed cases of ESRD-DM among AI/ANs and an additional $520 million Medicare spending from 2006 to 2015 had diabetic care not improved. The estimated amount of reduced spending attributable to the SDPI ranges from $208 million to $520 million, depending on assumptions regarding the proportion of the decline in ESRD-DM attributable to the existence of SDPI. Compared with the 2000 trajectory, Scenario 2, there would have been approximately 2,256 additional diagnosed cases of ESRD-DM among AI/ANs and an additional $436 million in Medicare spending for the same time period. The estimated amount attributable to the SDPI ranges from $174 million to $436 million.

Dr. Pyda elaborated on the policy implications of the SDPI analysis. The SDPI outweighs other factors in positively impacting diabetes resources across IHS during the past 20 years. Improvements in outcomes for the AI/AN population far surpass those observed for other races, suggesting that this program has had an important influence on health outcomes. ASPE's analysis was limited to savings accruing from averted cases of ESRD-DM, but there are other important sources of savings from improvements in diabetic care—including reductions in other diabetes-related complications, such as retinopathy—so the complete return on investment (before even factoring in the benefits of reduced illness burden on patients) from the program should be substantively higher. Importantly, these estimates lend support to the Administration's request for continued funding of the SDPI. In addition, funding for non-billable or currently under-reimbursed services also may be an effective strategy to consider for other public health efforts to decrease rates of diabetes. Furthermore, the improvements observed in AI/AN communities speaks to the effectiveness of community-developed prioritization of quality improvements.

Discussion

- Dr. Susan Mendley asked about the increase in other forms of ESRD present in the AI/AN population. Dr. Pyda explained that the decreased prevalence represents total ESRD, but that ESRD-DM was the most common and made up the largest proportion of all-cause ESRD.

- Dr. Robert Nee wondered about the mortality rates during the period of decreased prevalence. Dr. Narva noted that the mortality rates were lower during this period, in general. Reservation-based dialysis units in Arizona and New Mexico have the lowest age-adjusted mortality rate; the standardized mortality rate on average is 0.5. He called attention to the 2014 study by Rios

Burrows *et al*. assessing survival and dialysis in AI/AN populations using USRDS data from 1995 to 2010, which revealed a strong correlation of AI heritage with survival.

- Dr. Narva commented that the intervention in kidney disease started in 1990. This decrease being observed 10 years out, beginning in 2000, is consistent with the natural history of the disease. The SDPI expanded and sustained systematic efforts in kidney disease as a component of the broader diabetes care package.

- Dr. Shari Ling commented on an opportunity in the quality improvement area regarding other scenarios. The CMS Center for Clinical Standards and Quality has assembled a change packet, which is a kit containing the best practices and available services. She asked about the elements of a similar package in the SDPI, if such a kit existed. Care coordination and connectivity are key—as well as integrating or embedding tools, constructs, or concepts, which would be items that CMS could begin to share. Dr. Pyda explained that the SDPI offers communities information on methods that can be improved but does not require that these improvements be demonstrated or implemented. This provides communities with the knowledge and framework necessary to pursue whatever improvements are a local priority

- Dr. Narva remarked that the locus of control for managing kidney disease in IHS is within the primary care setting. The IHS has a well-established diabetes care delivery system, and the approach was to modify the existing diabetes care system to better address diabetic kidney disease. There were no routine screenings, angiotensin-converting enzyme inhibitors had just become available, and only serum creatinine levels greater than 2 mg/dL were identified as requiring attention. The kidney community generally has been unsuccessful in making an impact in the broader population primarily because it remains kidney-centric. The issue is not just about engaging primary care physicians and nephrologists. A program that addresses all aspects of diabetes and employs an interdisciplinary model is an approach that could work.

- Dr. Ann Bullock commented that data feedback is an area that has been an immense influence in diabetes care. She called attention to the IHS Diabetes Care and Outcomes Audit (the Audit), in which 40 different elements of diabetes care are assessed. The Audit data informs quality improvement measures at local sites and is a requirement for SDPI grantees.

- Dr. Nee speculated that the Medicare cost savings would be even greater if indirect health care costs had been included in the estimates.

- Because the SDPI results were calculated based on the U.S. majority population, Dr. Paul Kimmel asked about translating these data to other populations and into clinical practice. Dr. Narva made several key points. There is no "magic formula" in the IHS, only the application of deliberate, simple, and sustainable interventions. The IHS universal health care system, which is lacking in the United States, makes the difference. There are no disincentives to collaborate with nurses and community health care workers in the IHS. In the U.S. health care system, patient education and screening need not be provided solely by physicians, who already are taxed for time; other health care workers can perform these services.

- Dr. Andre Chappel noted that the Extension for Community Healthcare Outcomes (commonly called Project ECHO) would be one avenue for increasing access to health communication specialists and training.

- Dr. Michael Lipp asked to what degree the SDPI is a diabetes intervention that addresses the DM sequelae. Dr. Bullock noted the IHS/Joslin Vision Network Teleophthalmology Program, established in 2000, in which diabetic retinopathy data are collected. A recent publication of the program showed similar reductions as the SDPI study, except the study has no longitudinal data. In another recent report, there was an 80 percent reduction in hospitalizations for uncontrolled DM in the AI/AN population in the IHS health care system from 2000 to 2015. Also, the CKD risk factors declined during this period.

- Dr. Ling wondered about the availability of this economic model (e.g., methods) used in the SDPI study to be shared.

- Dr. Robert Star commented that these findings address various CMS payments and that it would be interesting to understand how they would relate to the IHS health care system.
  Dr. Bullock reiterated that the IHS health care system is a universal system, and beneficiaries do not pay for services or care; different care packages are available depending on eligibility.

Novel Payment Models for Improving CKD and ESRD Care in Medicare Patients
Kathleen Blackwell, M.P.H.
CMS

Ms. Kathleen Blackwell explained that the CMS Center for Medicare & Medicaid Innovation (CMMI) is currently running one payment model—Comprehensive ESRD Care (CEC)—and is in the process of launching two new models—Comprehensive Kidney Care (CKC) and ESRD Treatment Choices (ETC). The CEC Model is a specialized accountable care organizations model that began in October 2015, runs through December 2020, and focuses on beneficiaries with ESRD. The model consists of two cohorts and 37 ESRD Seamless Care Organizations (ESCOs), and more than 50,000 beneficiaries are currently aligned (e.g., receive treatment) to the model. The first cohort began in 2015 and was composed of 13 ESCOs representing three large dialysis organizations (LDOs)—Fresenius, Dialysis Clinic, Inc. (DCI), and DaVita—and one non-LDO. Twenty-four additional ESCOs joined in 2018 comprising the second cohort, the majority of which were from Fresenius.

Per the October 2017 evaluation report for performance year 1 of the CEC Model, approximately a 2 percent reduction in Medicare Parts A and B expenditures was seen relative to a comparison group. This reduction was driven by a 6 percent decrease in hospitalizations and an 8 percent lessening in catheter utilization. Ms. Blackwell emphasized that the ESCOs were incentivized to align Medicare beneficiaries to dialysis, which the CMS thinks had the greatest impact. The number of dialysis treatments per beneficiary was increased and was statistically significant, and ESCOs developed relationships with hospital emergency room departments to coordinate care and avert unnecessary admissions. Both qualitative and quantitative feedback provide support for a coordinated care model, which focuses on the needs of beneficiaries with CKD, rather than on the needs of the general Medicare population. Although the CEC model has been effective, Ms. Blackwell noted that areas of improvement are needed. Efforts should—

- "Go upstream" (e.g., CKD stages 4 and 5 [CKD 4/5]) to include care for beneficiaries before they reach ESRD.
- Create financial incentives and care relationships to better support kidney transplants.
- Establish a stable and predictable benchmark and payment mechanism beyond shared savings.
- Increase direct nephrologist incentives with an alteration of their basic payment structure.

- Provide modality selection (e.g., home dialysis) beyond the total cost of care incentives.

Ms. Blackwell described the proposed payment models that the CMMI will run from 2020 to 2025, their features, and the impact to CKD and post-transplant beneficiaries. Further details will be presented at a future meeting.

Clinical Quality Measures: Access Transplantation, Anemia Management, and Future Development
Jesse Roach, M.D.
CMS

Dr. Jesse Roach reviewed the ESRD Quality Incentive Program (QIP) measures for access to transplantation and anemia management, and he highlighted future developments. The QIP reduces payments by up to 2 percent to ESRD facilities not meeting or exceeding the minimum total performance score set by CMS. Dr. Roach noted that the QIP measures have changed to include additional outcome measures that are more meaningful to patients clinically in terms of outcomes. For payment year 2020 and calendar year 2018, the ESRD QIP Measure Set included 8 clinical measures: in-center hemodialysis consumer assessment of healthcare providers and systems (ICH-CAHPS), standardized readmission ratio, Kt/V dialysis adequacy (comprehensive), standardized transfusion ratio, vascular access type measure topic (fistula, catheter), hypercalcemia, and standardized hospitalization ratio; 2 safety measures: National Healthcare Safety Network (NHSN) blood stream infection (BSI) measure topic and NHSN BSI clinical (dialysis event reporting); and 6 reporting measures: serum phosphorus, anemia management, pain assessment and followup, clinical depression and followup, NHSN health care personnel influenza vaccination, and ultrafiltration rate.

For payment year 2021 and calendar year 2019, the QIP Measure Set was revised to include 6 clinical measures, 2 safety measures, and 2 reporting measures. The vascular access measures were revised and many of the reporting measures have been removed, including serum phosphorus, anemia management, pain assessment and followup, and the NHSN health care personnel influenza vaccination. For payment year 2022 and calendar years 2019 to 2020, the clinical measures are continuing from payment year 2021 and include a new measure—the percentage of prevalent patients waitlisted (PPPW)—which is an access-to-transplant measure, one of two proposed in the ESRD Prospective Payment System rulemaking process. The 6 reporting measures have been removed.

Dr. Roach further described the QIP clinical measures that will continue in payment year 2022, some aspects of the dialysis facility performance criteria, and dialysis facility issues. The ICH-CAHPS is a measure of the percentage of patient responses to multiple testing tools. The composite includes nephrologists' communication and caring, quality of dialysis center care and operations, and provision of information to patients; the composite score is the proportion of respondents answering each response option by item, summed across all items within a composite. The overall facility rating is a summation of responses to the rating items grouped into three levels. The standardized readmission ratio is the ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day hospital readmissions. The Kt/V dialysis adequacy, which is a comprehensive value, is the percentage of all patient-months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period. Dr. Roach remarked that most facilities perform well on dialysis adequacy.

The standardized transfusion ratio (STrR) is a risk-adjusted facility-level transfusion ratio for all adult Medicare dialysis patients. For the vascular access type measure topics, facilities are credited for efficient and higher rates of arteriovenous fistula utilization and lose credit for catheter utilizations greater than

90 days. Dr. Roach emphasized that the hypercalcemia measure is not favored in the dialysis community but is mandated by law. Facilities report plasma calcium greater than 10.2 mg/dL or when a calcium value is missing. Dr. Roach pointed out that since the STrR measure was established, the International Statistical Classification of Diseases, 10th revision (commonly known as the ICD-10) was released. The facility coding practices have changed regarding transfusions and many may be missed. CMS has been discussing a less restrictive STrR approach or a new measure without a hemoglobin target. Patient-reported outcomes could be one option but may be too broad. CMS is soliciting advice from the KICC on this issue.

Dr. Roach highlighted the continuing safety and reporting measures and noted remaining issues. The NHSN BSI Measure Topic consists of two parts: the NHSN BSI clinical and dialysis event reporting. Facilities have reported problems with incomplete information coming from hospitals. Patients have strongly voiced their opinion on continuing this measure. The 6 reporting measures will be continued. The clinical depression screening and followup currently involves asking the patient to respond to a question on depression, which the CMS is reevaluating. A measure on depression that is more actionable is being considered. The ultrafiltration rate is not a measure of the number of patients achieving or not achieving the required data elements; rather, it is the percentage of patient-months for which a facility reports required data elements for ultrafiltration rate for each eligible patient.

Dr. Roach next summarized the dialysis facility community concerns and the CMS position on the addition of PPPW measure to the QIP. The dialysis facility community proposed several arguments in opposition to the PPPW; The transplant centers, not the dialysis facilities, should be responsible for wait listing patients; a patient's choice of treatment modality is negated; the number of preemptive transplants would be decreased; and the number of referrals to transplant centers will be increased.

The CMS position is to improve access to transplantation and identify the responsible party for the patients. Placing patients on a waitlist will not increase kidney transplants, but will begin to address the disparity in who receives a transplant, because the first patients in line to receive a transplant have been predominately white. The dialysis facilities can play a role in addressing transplant disparity. Regarding responsibility, the transplant centers shepherd patients in the process, but the initial contact—such as patient education, options, and health maintenance—are within the purview (onus) of the dialysis centers.

Discussion

In response to a query by Dr. Mendley on the performance of peritoneal dialysis, Dr. Roach replied that 80 to 90 percent of facilities met the specified Kt/V threshold for peritoneal dialysis, compared with 90 to 95 percent for hemodialysis. CMS is evaluating these data, and until a decision is made, underperforming facilitates are encouraged to reach the performance goals.

- Dr. Palevsky asked about the effects of non-dialysis-related infections that may occur in dialysis patients on the NHSN BSI quality measure. Dr. Roach explained that this topic remains a subject of debate of which the facilities are aware. Most have noted that not all non-dialysis-related infections are capable of being distinguished from dialysis-related, which remains a challenge.

- Dr. Star noted that two questions are not being considered in the PPPW conversation: What is the kidney community is looking to accomplish? How does the waitlist counter the health of the patient? Dr. Narva commented that the most compelling case for a PPPW QIP measure is that it addresses the issue of health equity.

- Participants made several points on quality measures and ESRD patients being waitlisted for transplants. The transplants should be reflective of the population being served. Care coordination between transplant and dialysis centers should be encouraged. There is a need to balance transplant centers' risk and quality measures. The role of dialysis centers in waitlisting is clear, but controls will be necessary to make sure that no geographical or population preferences are given. CMS could consider refining its risk adjustments for transplant centers.

Transplantation of Hepatitis C Virus-Positive (HCV+) Kidneys
Kevin Abbott, M.D.
NIDDK

Dr. Abbott reported on the status of HCV+ kidneys for transplantation. In a 2003 study, Dr. Abbott and colleagues revealed that 32 percent of HCV+ donor kidneys were transplanted into HCV-negative (HCV−) recipients from 1996 to 2001. The patient survivor outcomes were similar when donor/recipient were both HCV+ but was worse if the donor/recipient were mismatched in HCV status. Similar results were reported by others and recently by Gupta *et al.* in a larger study conducted in 2017. Despite these odds, a 2004 study by Abbott *et al.* suggest that HCV+ kidneys may affect the survival of waitlisted long-term dialysis patients. Policy changes only allow HCV+ donor-recipient transplantations.

In 2018, Bowring *et al.* reported that the kidney donor discard rates for HCV+ kidneys was 53.6 percent compared with those which were HCV−, although the quality of the HCV+ donor kidneys was superior based on the Kidney Donor Profile Index and even with the advent of improved treatments for active HCV, such as direct-acting antiviral (DAA) therapy. Currently, only 12.9 percent of kidney transplant recipients with active HCV infections are treated with DAA, and only 1.5 percent of dialysis patients are treated. Economic decision analysis indicates that receiving HCV treatment post-transplantation is preferable if HCV+ kidneys are readily available. In addition, the Kidney Disease: Improving Global Outcomes *2018 Clinical Practice Guideline for the Prevention, Diagnosis, Evaluation, and Treatment of Hepatitis C in Chronic Kidney Disease* suggests the use of an HCV+ donor if it improves the chances for transplantation and if treatments for HCV infection are administered post-transplantation.

In the Transplanting Hepatitis C Kidneys into Negative Kidney Recipients (commonly known as THINKER) study, the investigators reported in 2018 that 20 HCV− recipients transplanted with HCV+ kidneys and treated with standard treatment for active HCV (e.g., Zepatier) post-transplantation experienced an HCV cure. These data strongly suggest that HCV+ kidneys may be a valuable transplant resource. Dr. Abbott emphasized that the use of HCV+ kidneys could be one approach to treating patients waitlisted for transplantation and would be one way to expand the pool of available organs for transplants. The NIH has a multiprong approach to addressing kidney transplantations, which include issuing grants to support developing improved algorithms on kidney pair donations and supporting efforts focused on improving organ allocation and the decision cycle for deceased organ donations.

Discussion

- Dr. Ling commented on the facts that would be necessary to begin to address policy changes, including details on organ availability, the evidence, and cost savings. Dr. Abbott called attention to a recent cost analysis study on use of HCV+ kidneys for transplant, which he could forward to the KICC. Dr. Mendley added that including the number of potential donor kidneys never harvested would be one statistic to capture.

Agency Updates

NIDDK: The HiLo Trial: A Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Hemodialysis Patients
Paul Kimmel, M.D.
NIDDK

Dr. Narva explained that HiLo, a pragmatic, multicenter, observational trial, compares the effects of two phosphate management strategies: liberal phosphate control of 6–7 mg/dL (Hi) and strict phosphate control of less than 5.5 mg/dL (Lo). Approximately 4,400 patients will be enrolled in more than 100 dialysis facilities, and partners include DaVita, DCI, and the Dialysis Program at University of Utah Health. The primary outcomes are all-cause hospitalizations and mortality The principal investigators are questioning whether a CMS consultation is needed to advise on quality measures and the effect of the Prospective Payment System Bundle on the use of binders.

NIDDK: Apolipoprotein (APOL1) Long-term Kidney Transplantation Outcomes Network (APOLLO) non-CLIA Genotype Results

Paul Kimmel, M.D.
NIDDK

Dr. Kimmel described APOLLO, a nationwide study to evaluate the association of genotype of African-American kidney donors, living or deceased, with recipient outcomes in all racial/ethnic groups. The study builds on preliminary data, which suggest that two variants of the *APOL1* gene are associated with worse outcomes. Subsequently, several transplant centers have restricted the use of donor organs with two *APOL1* mutations. An APOLLO patient engagement group representing 26 African-American CKD, ESRD, and transplant patients has recommended to the research group that the *APOL1* data be made available on request to study participants. The options are to perform genotyping tests in a non-Clinical Laboratory Improvement Amendments (CLIA) laboratory, which will be less expensive than a CLIA-approved laboratory, where the cost would average approximately $250 per test. Dr. Kimmel noted that the controversy is about whether the genotype data are research results that can be returned to patients or whether they are clinical results meant to be discussed only in the context of patient care.

From the investigator's perspective, the APOLLO data are results that can be returned to research participants. Several entities have deemed these data as clinical results. The state of New York will prevent the return of research results for research participants if the tests are performed in a non-CLIA laboratory. The state of California is evaluating the issue on a case-by-case basis, but California's ruling is similar to New York's. The APOLLO protocol institutional review board encountered a CMS regulation that states that no non-CLIA results are to be returned to patients who are covered by CMS insurance. Dr. Kimmel conveyed that this is an important topic for the NIDDK and will affect all study participants who have CMS coverage. The NIDDK is seeking assistance from the CMS to provide insight into resolving this issue.

Discussion

- Dr. Ling appreciates the NIDDK's sharing this issue with the CMS. The expectations for CLIA are written in law. The purpose is to ensure that laboratories meet a certain standard on rigor and conduct of assays, which includes proficiency testing in the absence of a gold standard. There are two points to consider, ensuring high quality data in fields that are emerging and returning

information to patients, which have been discussed within the federal agencies. The next steps will be to review the CLIA law in the context of emerging science and capabilities. A National Academy of Medicine report offered alternative solutions for the CMS and NIH and would be a good place to resume discussions. A meeting is scheduled for April 1, 2019.

Adjournment

Dr. Narva thanked the presenters and attendees for their participation. He noted that the next meeting of the KICC is scheduled for October 11, 2019.