Kidney Interagency Coordinating Committee (KICC) Meeting

Programmatic Implications of the United States Renal Data System (USRDS) for Federal Agencies

Natcher Conference Center, Building 45, Rooms F1/F2
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Meeting Participants and Summary

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Welcome and Introductions
Andrew Narva, M.D., FACP
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Dr. Andrew Narva welcomed the participants and provided a brief overview of the KICC, which was mandated in 1987 by Congress to improve coordination of the Federal response to chronic kidney disease (CKD). The KICC was designed to encourage cooperation, communication, and collaboration among all Federal agencies involved in kidney research. Ten years ago, the KICC was revitalized as an active group that enabled Federal professionals who work on kidney disease to better communicate and collaborate.

Dr. Narva indicated that the focus of the day's meeting was to discuss programmatic implications of the USRDS for Federal agencies.

Update from the Population Health Meeting
Andrew Narva, M.D., FACP
NIDDK, NIH

Dr. Narva provided an update on the "Using Health Information Technology (HIT) to Identify and Manage CKD Populations" meeting, held October 22–23, 2015. The purpose of the meeting was to identify pragmatic solutions for using existing HIT systems to improve CKD population management and to share strategies and resources that would facilitate CKD population health management efforts. The knowledge and insight gained from the population health management meeting also provided a framework for establishing a model system for managing chronic diseases in general using HIT. The meeting participants identified six priority activities. The first three of these priorities will be further developed and investigated by working groups launched by the National Kidney Disease Education Program (NKDEP) in the upcoming 6 months. They include developing a business case to justify investment in CKD population management infrastructure; developing an electronic care plan template for CKD; and developing computable phenotypes to identify CKD patients, with an emphasis on high-risk patients. The working groups that will be established to address these priorities are the CKD Care Plan Working Group, CKD Business Case Working Group, and CKD Phenotypes Working Group, respectively. Dr. Theresa Cullen will lead the Care Plan Working Group, Dr. Blake Cameron will lead the Business Case Working Group, and Drs. Paul Drawz and Ken Kawamoto will lead the Computable Phenotypes Working Group. Updates on the progress of the working groups will be provided at the next KICC meeting.

A full summary of the health management meeting on the use of HIT in the CKD population can be accessed on the NIDDK website at www.niddk.nih.gov/news/events-calendar/Pages/ckd-populations-2015.aspx.

What's New with the USRDS
Kevin Abbott, M.D., M.P.H.
NIDDK, NIH

Dr. Kevin Abbott acknowledged the mentorship that he has received from Dr. Paul Eggers, who was instrumental in the development of the USRDS. He also expressed gratitude to Drs. Robert Star, Gregory Germino, and Griffin P. Rodgers at the NIDDK for their strong support of the USRDS.

Dr. Abbott indicated that he would demonstrate in his presentation some of the tools, in-house applications, and mapping functions of the USRDS through an interactive overview of the USRDS website (www.usrds.org). As background, the Medicare End-stage Renal Disease (ESRD) program has been shaped by Federal legislation since its inception in 1972, including through Social Security Amendments and the National Organ Transplantation Act. Through 1999, research undertaken by the Centers for Medicare & Medicaid Services (CMS) was directed at identifying the causes of ESRD. Dr. Abbott shared his hypothesis that diabetes had been overstated as being causative of ESRD rather than a contributing factor. A better understanding of the role of type 2 diabetes in the etiology of ESRD would allow investigation of whether ESRD caused by other diseases should be treated differently.

The USRDS website contains content that includes Annual Data Reports (ADRs), services, publications, and the Renal Data Extraction and Referencing (RenDER) system. The ADR is divided into two sections: *Volume 1: CKD in the United States* and *Volume 2: ESRD in the United States*. ESRD data are provided almost entirely by CMS, and CKD data are provided by the National Health and Nutrition Examination Survey (NHANES) and, starting in 2015, by the Behavioral Risk Factors Surveillance System. Additional data sources, such as civilian insurance data, also will be included in the database starting in 2016.

Researchers can obtain access to the data contained by the USRDS by submitting a data request. Two hierarchies of data requests exist: simple questions and hypothesis-driven research questions. The standard analysis files (SAFs) can be provided in response to research-related data requests at no charge to the investigator after applying to the Project Officer. Investigators are required to submit an application for a data request containing the following: (1) a data use agreement, (2) a research proposal, and (3) institutional review board (IRB) approval for the project. Recent updates to the data request form include providing more clarity for required signatures and a checklist for the SAFs required. Dr. Abbott, the USRDS co-Project Officer, reviews the research protocols and approves data requests.

Dr. Abbott reviewed the chapters of the 2015 ADR. He highlighted Chapter 8 of Volume 1, which describes the results of the Special Study Center on Transition of Care in CKD. This study examined the transition of care in CKD to kidney replacement therapy (i.e., dialysis or transplantation) using Veterans Administration (VA) data and data from the Kaiser Permanente-Southern California database. Some of the key findings include the following: (1) The ESRD rates were lower in the veteran population compared to the U.S. population. (2) The mortality rates were higher during the first several months of transition to ESRD for all providers. (3) The peak mortality rate at 2 months was higher in non-VA hospitals compared to VA hospitals.

Dr. Abbott also provided an overview of the information contained in Volume 2 on ESRD in the United States. A key finding is that the adjusted incidence rate of ESRD plateaued in the early 2000s and has declined slightly since 2006 (Figure 1.2), with a more pronounced decline in non-white populations (Figure 1.5). Volume 2 also includes a chapter on Healthy People 2020 (Chapter 2). USRDS data can be used to evaluate progress toward meeting Healthy People 2020 targets for ESRD, such as increasing the proportion of patients who use arteriovenous fistulas as the primary mode of vascular access (Table 2.9). Dr. Abbott also discussed the Special Study Center on Palliative and End-of-life Care (Chapter 14). He observed that hospice use has increased steadily during the time period and that costs associated with the last 30 days of life were higher for patients not receiving hospice care.

New chapters in the 2015 ADR include Medicare Plan D Prescription Drug Coverage (Chapter 7 of Volume 1) and Vascular Access (Chapter 4 of Volume 2).

Dr. Abbott shared findings from the Walter Reed Nephrology Program study, an example of a project carried out using USRDS data. He recognized Dr. Christina Yuan for her contributions in obtaining IRB approvals and assembling the data. He stated that the data had been collected from the CMS-2728 forms and that this study was as an early step in the process to test the hypothesis that diabetes was overstated in

the cause of ESRD. The study assessed 56 patients that had a type 2 diabetes diagnosis as recorded on the patients' CMS-2728 forms. Of the 56 patients, 12 did not meet the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines for CKD attributable to diabetes. The CMS-2728 forms, however, collect limited information on diabetic retinopathy. Three of the 12 patients classified as not having CKD attributable to diabetes had other conditions. Patients usually present with ESRD without having seen a nephrologist prior to their diagnosis. Within this study, 95 percent did not have nephrology visits prior to their ESRD diagnosis. Dr. Abbott pointed out that biopsy results of patients with atypical cases of diabetes showed associations with glomerulonephritis and ESRD.

USRDS data on ESRD incidence rate by health service area (Volume 2, Figure 1.3) indicate that such environmental exposures (e.g., heavy metals) might be associated with ESRD. ESRD incidence is hypothesized to be higher among African Americans, but the geographic pattern of adjusted incidence of ESRD instead is high along the Ohio and Mississippi Rivers and in the San Joaquin Valley, which does not correlate with high percentages of African Americans. The geographic distribution of type 2 diabetes prevalence also shows differences from that of ESRD. Income and lifestyle are being considered as possible causes for the geographic distribution of ESRD. Dr. Abbott indicated the need for tools to determine exposure to heavy metals and environmental toxins from biopsies and recommended that the KICC make this a priority.

Discussion

- Dr. Paul Kimmel asked whether there were data on the rates of transition from late-stage CKD to dialysis comparing veterans undergoing dialysis at VA facilities with those cared for by commercial providers. Dr. Abbott responded that the data shown represent patients treated in the VA system. Outcomes for patients who start dialysis in the VA system and move to other facilities warrant investigation.

- Dr. Susan Crowley commented on observations from the transition of care report. Stratifying by age, the rate of decline in CKD was slower in older cohorts compared to the younger cohorts within the VA population. A stratification by causes of ESRD showed that patients with type 2 diabetes had higher rates of progression compared to those who were nondiabetic. One study showed that patients within the VA system tend to start dialysis earlier than patients at non-VA facilities.

- Dr. Crowley asked for more information about what is contained in the core data sets. Dr. Abbott responded that the core data sets include basic demographic information, information from the CMS Medical Evidence form, and information on payer history. The Researcher's Guide describes in detail the data provided in the different data sets.

Missingness in the USRDS Diet Data
Maria Kofas, M.S.P.H.
NIDDK, NIH

Ms. Maria Kofas provided an overview of the missing data concept and stated that the main goal of her presentation was to highlight the importance of data missingness and its effects on statistical analysis. Ms. Maria Kofas stated that her study of nutritional indices of care in ESRD as an intern at the NIDDK revealed problems of missing data in the USRDS. Missing data, which is a common problem in statistical analyses, occurs when values have not been given for specific variables. The following criteria were suggested for handling missing data: (1) Missing data at rates above 20 percent *must* be accounted for in the statistical analysis. (2) Missing data at rates of 10 to 20 percent *should* be accounted for in the

statistical analysis. (3) Missing data at rates less than 10 percent are unlikely to reveal associations that are not depicted in the remaining 90 percent of the sample.

Data on missingness for information about care by a kidney dietitian were taken from responses on CMS-2728 ESRD medical evidence forms and covered a 6-year period from 2007 to 2013. Question 18c asks whether the patient was under the care of a kidney dietitian (possible responses: yes, no, and unknown). The percentage of missing responses varied from 4.84 to 13.91 percent, averaging 8.42 percent. Examples of missingness of other variables include HbA1c test results (85.2%), albumin levels (26.5%), and whether patients received exogenous erythropoietin (EPO) (78.45%). Having high percentages of missing values for a variable would make it difficult to assess the true effect of the variable on the outcome without making restrictive assumptions. Also, most types of statistical software require complete records, and missingness can increase in adjusted analyses (e.g., from 8.42% to 10.39% for the question on care by a kidney dietitian).

General guidelines for missing data are to minimize the amount and impact of missing data, choose the appropriate method for analysis, and use caution in replacing missing values. Strategies for handling missing data can be adopted from those used in clinical trials and include the following: document reasons for dropouts and proportions of missing data in each group; use study designs that minimize the chance of dropouts or intermittent missingness; collect post-dropout data on the primary endpoints; consider preponderant "dropout" as an endpoint; conduct pre-specified primary analysis; and run sensitivity analyses.

There are three categories of missing data—missing completely at random, missing at random, and missing not at random—and knowing the applicable category is important when determining which approach to take to account for missingness. Methods for handling missingness include list-wise deletion, imputation, and maximum likelihood. Continuous and categorical variables occasionally require different methods (e.g., imputing missing values as the mean or median vs. imputing missing values as the mode). For longitudinal data, missing values can be replaced either by carrying the last observation forward or carrying the baseline observation forward. Hot-deck imputation is the most widely used imputation method and involves replacing missing values individually with available values from similar respondents. The multiple imputation method is a simulation-based technique for handling missing data that can be used for many different types of data and minimizes the underestimation of the variance. It involves replacing missing values by plausibly simulated values. The multiple imputation method was used to examine the USRDS diet data.

In conclusion, Ms. Kofas emphasized the importance of considering missingness. The impact of missingness can be minimized by designing the study accordingly, collecting post-dropout data, and identifying types and patterns of missingness that will help choose the most appropriate method for handling the missing values.

Discussion

- Dr. Kimmel commented that the appropriate choice of theoretical framework for handling missing data could be perceived differently by different reviewers. He asked whether removing the missing data would result in the same conclusion for the association of survival with diet care. Ms. Kofas responded that the direction of the association was the same but the degree (strength) of the relationship between survival and diet care was different and that, in many cases, uncorrected missingness can affect conclusions. Col. James Oliver III commented that a potential problem with excluding data is not knowing whether they are representative.

- Dr. Joel Andress commented that the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) data had a certain degree of missingness and suggested investigations with CMS

to address the problem and make policy changes. Dr. Star asked whether there were differences in missingness in VA data compared to CMS data. Dr. Andress responded that differences in providers and the completeness in their records might account for some of the missingness in CROWNWeb. Also, the large dialysis organizations (LDOs) provide large batch files that include many different electronic medical record (EMR) systems, each of which may have different data requirements. Dr. Kimmel highlighted the problems of performing research using administrative data sets, which are created for reasons other than research. Dr. Andress agreed and noted that CMS (and others) depend on administrative data sets for performance assessments and surveillance monitoring.

- Dr. Abbott commented that the nephrology journals are in the early stages of addressing missing data and that uniform standards are needed.

Agencies' Usage of USRDS Data and Proposed Enhancements
Moderator: Kevin Abbott, M.D., M.P.H.
NIDDK, NIH

Dr. Abbott moderated the session on agencies' usage of USRDS data and proposed enhancements. Presenters from CMS, the VA, the Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare Research and Quality (AHRQ) were in attendance.

Centers for Medicare & Medicaid Services
Stephanie Frilling, M.B.A., M.P.H., Center for Clinical Standards and Quality, CMS
Joel Andress, Ph.D., Center for Clinical Standards and Quality, CMS

Dr. Andress discussed the role of USRDS data in developing CMS quality measures for dialysis facilities. CMS relies heavily on USRDS data to establish the relevance of specific quality measures for the ESRD Quality Measures program, which create incentives for providers to improve their quality of care.

The CMS Dialysis Facility Compare website, for most of its existence (2001 to 2012), had four measures that were reported annually. Improvements in the quality measures program have expanded the measure set from 4 to 16 parameters. In 2013, the measure set was significantly expanded to include the standardized hospitalization ratio (SHR), as well as measures for dialysis adequacy and vascular access. In 2014, measures for anemia management (standardized transfusion ratio [STrR]), as well as mineral and bone disorders, were added. In 2015, the standardized readmission ratio (SRR) was added. The measure set will be further expanded in October 2016 to include an in-center hemodialysis consumer assessment of health care providers and systems (ICH-CAHPS), a measure of bloodstream infection, and a pediatric peritoneal dialysis adequacy measure. These measures expand the definition of quality care to include patient engagement and safety. They also expand the responsibilities of facilities to include outcomes that occur outside of the dialysis facilities themselves (e.g., transfusions) but which occur as a result of care received at dialysis facilities.

Common areas of focus in the USRDS and CMS measures include adequacy, vascular access, hospital use, transplantation, and pediatric ESRD. New areas of quality measure development for CMS are access to transplantation, including patient education and referrals; function (i.e., if patients are receiving appropriate care, whether they are able to function well); and patient-reported outcomes. Other areas in which CMS could adapt measures from the USRDS include CKD, cardiovascular disease, Medicare expenditures, Part D prescription drug coverage, and international comparisons.

Ms. Stephanie Frilling discussed the role of USRDS annual report data in supporting CMS policy. CMS rulemaking is supported by USRDS data on non-Medicare payer information, the Part D prescription drug analysis, CKD costs versus ESRD costs, ESRD rates by race and ethnicity, and national trends.

In regard to future policy development, CMS is interested in care transition and has considered the following key issues: (1) improving health outcomes for patients during the onset of dialysis, (2) determining the unintended consequences of the Medicare Waiting Period, (3) enhancing patient-physician engagement after referral to the dialysis facility, and (4) enhancing engagement with patients and caregivers to so that they can make informed decisions on care. In reference to improving health outcomes in the onset of dialysis, CMS has reviewed Medicare claims data from 2012 to 2014. Evidence showed that at the onset of dialysis, mortality was twice as high during the first 120 days of dialysis compared to the post-onset period. In addition, higher rates of low hemoglobin, transfusion, and inpatient hospitalization were observed during the onset period as compared to the post-onset period. Rates of stroke, acute myocardial infarction, heart failure, pneumonia, gastrointestinal bleeding, and pericarditis also are higher at the start of dialysis.

Ms. Frilling commented that investigating the rate of heart failure among patients with ESRD would be a possible area for collaboration between CMS and the USRDS. Other areas of interest for CMS include acute kidney injury (AKI), disparities in care (e.g., by race and gender), new modalities, home modalities, quality of life, palliative care, intravenous (IV) nutrition, living donor transplants, and access to care by geographic location.

Discussion

- Dr. Kimmel asked about the source for the heart failure data and asked for clarification on the tracking of dates. Ms. Frilling responded that the data were taken from Medicare claims and form CMS-2728.

- Dr. Narva asked whether CMS would be reviewing the transitions in care. Ms. Frilling responded that CMS is interested in improving health outcomes and implementing policy changes in this area. For instance, the primary care physicians have transition of care "G" codes that can be billed for comorbid conditions. Better coordination of care would improve patient outcomes.

- Dr. Michael Flessner raised the issue of behaviors that can compromise eligibility for transplants, such as noncompliance with medications or dialysis, alcohol abuse, and drug abuse. Dr. Andress responded that ESRD Seamless Care Organizations (ESCOs), participating in the CMS Innovation Center's Comprehensive ESRD Care Model, are testing new ways to improve care for patients with ESRD. Transplantation is a difficult issue because of a lack of uniform standards for placing patients on the wait list and for deciding which patients receive transplants. Quality measures are intended to incentivize dialysis facilities to increase transplant rates for their patients, but transplantation is only a part of care coordination for patients. Dr. Flessner noted that readmission rates might be affected by private facilities transferring care of problematic patients such as drug abusers to public facilities. Dr. Shari Ling added that patients and their families are at the center of efforts to reform the transplant delivery system. The issue of transplantation is very complicated, however, and more consideration of data availability and gaps that will drive the system toward better outcomes is needed.

Veterans Administration
Susan Crowley, M.D., FASN
VA Medical Center

Dr. Crowley discussed the USRDS from the VA perspective. She commented that the VA has been considering how to increase participation in the repository and improve data analysis. She cited problems with the rollout of CROWNWeb for the VA's reporting of dialysis data to CMS. The objectives of CROWNWeb were to increase the volume of data captured, expand analysis, and facilitate reporting. Unfortunately, there have been some unintended consequences of CROWNWeb for VA data reporting. Prior to CROWNWeb, the VA's data reporting to CMS had been by manual paper entry to the ESRD Network. The change to CROWNWeb actually has resulted in fewer VA centers reporting. It will be necessary to foster new ideas to change the culture to increase reporting.

Dr. Crowley described the reasons for submitting veteran dialysis patient data to CMS. Submission of veteran dialysis patient data to CMS allows the VA to adhere to the community standard of federal reporting of quality of care and aggregated its data into the national repository of data contained in the USRDS. Executive Order 13410, Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care, called for transparency in gauging the quality of federally administered health care. The future of VA dialysis data reporting involves procurement of a national dialysis EMR by the VA that will enable electronic reporting to CROWNWeb. The VA is investigating automated data transmission possibilities from the VA to CMS. Automated data transmission will require updated data transfer and information security agreements between the VA and CMS.

Dr. Crowley commented on the data currently in the USRDS that have implications for the VA and highlighted two examples: quality of care data and epidemiological trends data. The national quality of ESRD care delivered in the community provides benchmarks to the VA for goal setting and comparative purposes. Epidemiological trends data on mortality, prevalence, and incidence of ESRD informs the VA resource utilization projections and proposed congressional budget requests.

New data in the USRDS with implications for the VA include the Special Study Center on Transition of Care in CKD, discussed earlier by Dr. Abbott. The study consisted of enrollees in integrated health care systems, and included data from the VA and Medicare files. The first cohort (2007–2011) consisted of veterans and examined the prelude period, which is 5 years prior to the onset of dialysis. The 2014 report contains a description of characteristics of the VA enrollee population with ESRD. The 2015 report includes incidence rates of ESRD in veteran enrollees, comorbidities at dialysis initiation, medication use before and after transition, laboratory test changes, and hospitalization data. Data currently not in the USRDS that would be useful to the VA include global veteran population data, VA user versus VA enrollee outcomes, and purchased veteran care outcomes.

The USRDS is a tool to achieve the goal of eradicating CKD. A goal for the future is to use the USRDS to understand the role of nonclinical care on outcomes. Important determinants of health outside clinical care data include community resources, patient self-management, and practices used by population health programs.

Dr. Crowley stated that the USRDS is a phenomenal public health surveillance system for the ESRD population, and the inclusion of veteran data would enable data-driven decision making on the best value health care systems for veterans with ESRD. To that end, facilitated CROWNWeb reporting is being pursued by the VA. She emphasized the value of the USRDS Special Study Center on Transition of Care in CKD and advocated for its continuation. Expanding analyses by the USRDS will enable progress toward the goal of CKD eradication.

Centers for Disease Control and Prevention
Nilka Rios Burrows, M.P.H.
Division of Diabetes Translation, CDC

Ms. Nilka Rios Burrows updated the KICC on the use of the USRDS at the CDC. Ms. Burrows discussed the use of the USRDS in the U.S. Diabetes Surveillance Program (www.cdc.gov/diabetes/data). The data sources for the U.S. Diabetes Surveillance System include the USRDS (which includes VA data), vital statistics, and national and state surveys. The age-adjusted rate for diabetes-related kidney failure has been decreasing since 1996 and attained the Healthy People 2020 target in 2004. Assessment of ESRD among Native Americans using the general population denominator (with and without diabetes) suggest a plateau in ESRD resulting from diabetes, whereas using a diabetic population-based denominator indicates that a decrease in incidence has been realized. Studies on racial and ethnic differences in trends in ESRD and declining ESRD incidence among people with diabetes initially were met with skepticism, but others subsequently have reported similar trends. The adjusted incidence of diabetes-related ESRD from 2000 to 2011 show a declining disease prevalence in Native Americans.

Another use of USRDS data at the CDC is the national CKD Surveillance Project (www.cdc.gov/ckd/surveillance), which is part of the CDC's CKD Initiative. The health consequences topic on the CKD Surveillance Project website uses USRDS data and provides indicators related to 10 of the 14 Healthy People 2020 objectives for CKD. In addition, the CKD Initiative's website (www.cdc.gov/ckd) contains a link to the USRDS website.

The USRDS also provides data on care and outcomes. These data, combined with data from the Indian Health Service, were used in a study of survival on dialysis among Native Americans and Alaska Natives with diabetes. When the data were analyzed by blood quantum, those with lower degrees of Native American ancestry were found to be less protected from death by any cause at initiation of dialysis.

Proposed enhancements to the USRDS that would be beneficial to the CDC include adding more environmental and health care features at the start of dialysis, providing more information on CKD care, and enhancing the ability to obtain parameters describing care during the course of ESRD treatment.

The CDC dialysis team has an upcoming funding opportunity announcement, the SHEPheRD (Safety and Healthcare Epidemiology Prevention Research Development) Program. The program will support prevention research and efforts to prevent health care-related infections in dialysis patients; is aimed at dialysis providers and large health care systems; and contains a focus on research partnerships, joint quality improvement projects, National Healthcare Safety Network-related collaborations, and surveillance implementation.

The CDC also maintains an interactive website that uses USRDS data for diabetes surveillance (www.cdc.gov/diabetes/data). The website highlights the decrease in diabetes-related incidence of ESRD and contains state- and national-level data.

Discussion

- In response to a question from Dr. Crowley, Ms. Burrows affirmed that VA data were used in the CKD Surveillance Project.

Agency for Healthcare Research and Quality
Ernest Moy, M.D., M.P.H.
Center for Quality Improvement and Patient Safety, AHRQ

Dr. Ernest Moy discussed the use of USRDS data at AHRQ. The Center for Quality Improvement and Patient Safety, AHRQ, publishes the National Healthcare Quality and Disparities Reports, which are annual reports on health care quality and disparities that are presented to Congress. AHRQ uses USRDS data to track health care for patients with CKD. The data collected included transplantation rates, access to a nephrologist, and development of ESRD. This collaboration was very productive initially, but as a result of improvements in CKD quality measurement and access issues, the USRDS feed has been reduced.

The AHRQ is aware of the advantages of having specific measures to report to Congress. Re-establishing the USRDS feed would be useful for health disparities reporting. In the changing health care environment, however, the data that best measure accomplishments in providing quality care to people with CKD and opportunities for improving care should be emphasized. Dr. Moy suggested that this would be a good topic for future KICC agendas. The National Healthcare Quality and Disparities Reports can be accessed from the AHRQ website (http://nhqrnet.ahrq.gov).

Improving Transplantation Access
Shari Ling, M.D., Center for Clinical Standards and Quality, CMS
Renee Dupee, J.D., Center for Clinical Standards and Quality, CMS

Dr. Shari Ling discussed the need to improve access to transplantation, noting that the health care system is changing and a redefining of roles is needed. The objectives of efforts to improve transplantation access have been improving outcomes for people with CKD and enabling more well-informed decisions. Where variations in outcomes from current practices are found, room for improvement exists. By considering a range of treatment options, including novel therapeutics and devices, outcomes may be improved. Dr. Ling suggested that the KICC dedicate a session to discussing improving transplantation access.

Ms. Renee Dupee, who is leading efforts at CMS to understand quality improvement options for kidney transplants, discussed plans for an interagency initiative. Ms. Dupee asked participants to consider three numbers: three, five, and zero. The typical hemodialysis patient spends 3 days per week at the dialysis center and, on average, 5 hours per dialysis session. Improving transplantation access would reduce the time spent in dialysis to zero, thereby improving quality of life. Opportunities exist to reduce the kidney discard rate and increase donation following circulatory death. Based on Organ Procurement and Transplantation Network data from 2012 to 2014, kidney discard rates vary considerably by organ procurement organization (OPO). The highest performing OPOs, transplant centers and hospitals, are using 87 percent of kidneys recovered, and the lower performing OPOs are using 80 percent, indicating an opportunity for reducing the kidney discard rate. Also, high performers are using 30 percent of kidneys following cardiac death, whereas the U.S. average is 15 percent, another indication of an opportunity for increased donations.

The CMS Center for Quality Measures and Standards, in collaboration with the Health Resources and Services Administration (HRSA) Division of Transplantation, is considering an interagency initiative to conduct care delivery model tests to increase the number of annual kidney transplants by reducing the kidney discard rate and increasing donations following circulatory death. The projected benefits include increased quality of life for people with ESRD. Additional benefits were discussed using sample numbers, including the yield of an additional 2,000 transplants, savings of $250,000 per year to Medicare in ESRD care, and an estimated aggregated savings to the U.S. system of $750 million. These sample numbers are preliminary and pending further analysis.

Discussion (Agency Needs)

Dr. Star asked whether CMS is able to perform pragmatic, large-scale trials on reimbursement policies. Dr. Ling responded that CMS is an implementation agency and does not focus on human subjects research. Different care and payment models are evaluated under CMS' demonstration authority by the CMS Innovation Center, however, including how to better coordinate care for ESRD. Dr. Star asked whether CMS would have the authority to investigate differential payment for dialysis sessions of different lengths. Mr. Tom Duvall stated that the Innovation Center has broad authority. Part of the implementation of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA), addresses new methods of payment for eligible physicians, including nephrology-specific models.

Dr. Star commented that vascular access differences observed in individuals recently have been linked to the standard of care rather than biological differences, as previously thought. Better outcomes were reported for individuals receiving care in a multidisciplinary setting. Dr. Star asked whether a method exists for testing this relationship within CMS. Dr. Ling commented that within the Innovation Center portfolio, different practice constructs exist, such as the Comprehensive Primary Care Initiative, but they are not disease-specific. Identifying individuals with CKD within those models could provide useful data. Testing care models that would be paid differently would fall under CMS authority. If known best practices for care processes exist, the Transforming Clinical Practice Initiative, a large quality improvement model test, would apply. Part of implementing the MACRA legislation will involve transitioning into alternative payment models. Evidence supporting which care processes result in better outcomes can be translated into quality improvement mechanisms.

Dr. Narva stated that an underlying cause must exist for the improvement of the prevalent fistula rate to the 74 percent level that Dr. Abbott showed. The change precedes pay for performance and might be attributable to publishing quality ratings for nephrology practices. It is an indication that CMS and other payers can be agents of change. Data collection in and of itself can change performance. The payers are in a unique position to improve the quality of care for complicated patients who receive care in a wide variety of settings. Regarding drivers for increasing the fistula access rate, Dr. Kimmel stated that a study by the NIDDK of reimbursement rates in 1998 to 2001 showed that reimbursement levels were higher for arteriovenous grafts compared to arteriovenous fistula access.

Dr. Abbott noted that Figure 8.5 of the 2015 USRDS Annual Report, which depicts the timing of hospitalization events relative to ESRD transition for veterans, indicates that almost one-half of individuals being treated for ESRD at military facilities were hospitalized to initiate dialysis. In the cohort of 46,625 participants, 22,000 were hospitalized during ESRD transition. This might reflect physicians not being confident about surveillance in satellite units, preferring hospitalization. High hospitalization rates for dialysis patients might be skewed by this practice. Dr. Kimmel cited the practice at George Washington University Hospital of initiating dialysis during the course of hospitalization because outpatient dialysis units would not initiate dialysis. This practice also conferred significant payment advantages.

Dr. Andress commented that a lack of communication between hospitals and dialysis facilities has created a gap in care that needs to be addressed as a quality issue. Facilities are rejecting individuals for hemodialysis because the use of venous catheters is viewed as an indication of inadequate surveillance. This is an example when quality improvement measures can have unintended consequences.

Dr. Kimmel commented that in addition to administrative barriers and maladaptive incentives, a large health shift occurs when individuals begin dialysis. As a result, AKI is not easily diagnosed. Dr. Andress referred to the previous data for the onset of dialysis, which showed large spikes in mortality during the

first 120 days of dialysis. The transition of patients from CKD to ESRD could be referenced back to the different tracks of care prior to the onset of kidney disease. CMS has missed an opportunity to address costs and patient care in ESRD by not treating CKD care as critical, and this was caused by the payment system. A transition from CKD to ESRD represents a failure to manage the disease. Gaps in care need to be addressed. The exclusion criteria of 90 days for evaluating the quality of care given by dialysis facility is reasonable for establishing a meaningful measure but is not a reasonable model for improving patient care.

New U.S. Government Accountability Office Study on Kidney Disease Research
William Black
U.S. Government Accountability Office (GAO)

Mr. William Black commented on the utilization of the USRDS at the GAO. He discussed the details of a study focused on Federal funding of kidney disease research. One main research objective will be to describe research funding across a range of conditions and categories. The main focus will be the NIH, but other federal agencies will be included. A second focus will be to understand the priorities that the NIDDK uses to allocate research funding. Emphasis will be placed on the knowledge gaps in CKD and how they are used to set priorities for funding.

Discussion

- Dr. Star suggested cost of care as another research objective. Mr. Black replied that although cost is not a primary research objective, it will be covered under spending on treatment. USRDS data will be used to provide the baseline data.

Adjournment

Dr. Narva thanked the attendees for their participation. He noted that the next meeting of the KICC is scheduled for September 19, 2016. It is possible that an interim meeting will be scheduled.