



National Institute of
Diabetes and Digestive
and Kidney Diseases

Kidney Interagency Coordinating Committee Meeting

Virtual Meeting
March 13, 2020

Meeting Participants and Summary

Susan Mendley, M.D.

Executive Secretary, Kidney Interagency
Coordinating Committee
National Institute of Diabetes and Digestive
and Kidney Diseases
National Institutes of Health
Email: susan.mendley@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

Christine Chang, M.D., M.P.H.

Agency for Healthcare Research and Quality
Email: christine.chang@ahrq.hhs.gov

Preeta Chidambaran, M.D., M.P.H.

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

Paul Eggers, Ph.D.

National Institute of Diabetes and Digestive
and Kidney Diseases
National Institutes of Health
Email: paul.eggers@nih.gov

Paolo Fanti, M.D.

U.S. Food and Drug Administration
Email: paolo.fanti@fda.hhs.gov

Daniel Gossett, Ph.D.

National Institute of Diabetes and Digestive
and Kidney Diseases
National Institutes of Health
Email: daniel.gossett@nih.gov

Eleanor Hoff, Ph.D.

National Institute of Diabetes and Digestive
and Kidney Diseases
National Institutes of Health
Email: eleanor.hoff@nih.gov

Rekha Kambhampati, M.D., M.H.S.

U.S. Food and Drug Administration
Email: rekha.kambhampati@fda.hhs.gov

Meagan Khau

Centers for Medicare & Medicaid Services
Email: megan.khau@cms.hhs.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

Kevin McBryde, M.D.
National Institute of Diabetes and Digestive
and Kidney Diseases
National Institutes of Health
Email: kevin.mcbryde@nih.gov

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

Ryan Murray
American Society of Nephrology
Email: murray@asn-online.org

Andrew Narva, M.D., FACP
Indian Health Service
Email: andrew.narva@ihs.gov

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

Jenna Norton, M.P.H.
National Institute of Diabetes and Digestive
and Kidney Diseases
National Institutes of Health
Email: jenna.norton@nih.gov

James Oliver, III, M.D., Ph.D.
Uniformed Services University of the Health
Sciences
Email: james.d.oliver@us.army.mil

Afshin Parsa, M.D., M.P.H.
National Institute of Diabetes and Digestive
and Kidney Diseases
National Institutes of Health
Email: afshin.parsa@nih.gov

Leonard Pogach, M.D.
U.S. Department of Veterans Affairs
Email: len.pogach@verizon.net

Sharon Saydah, Ph.D.
Centers for Disease Control and Prevention
Email: zle0@cdc.gov

Murray Sheldon, M.D.
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

Loida Tamayo
Centers for Medicare & Medicaid Services
Email: loida.tamayo@cms.hhs.gov

Shamir Tuchman, M.D., M.P.H.
U.S. Food and Drug Administration
Email: shamir.tuchman@fda.hhs.gov

Anne Utech, Ph.D., R.D.N., L.D.
U.S. Department of Veterans Affairs
Email: anne.utech@va.gov

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

John Williams, Ph.D.

National Institute on Aging

National Institutes of Health

Email: williamsj6@mail.nih.gov

Susan Ziemann, M.D., Ph.D.

National Institute on Aging

National Institutes of Health

Email: susan.ziemann@nih.gov

Welcome and Introductions

Susan Mendley, M.D.

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

Dr. Susan Mendley welcomed members and attendees to the NIDDK Kidney Interagency Coordinating Committee (KICC) meeting. Dr. Mendley noted that this virtual KICC meeting is experimental and temporary because of the COVID-19 public health crisis and that the plans are to return to the in-person format when conditions are deemed safe. She reminded participants that the KICC was mandated by Congress in 1987 to meet yearly; however, because of the enthusiasm, the structure changed from a *pro forma* meeting to one that meets twice yearly and provides an active forum for communication among federal agencies working in kidney disease. The aim is to encourage cooperation, communication, and collaboration among all federal agencies engaged in kidney research and related activities. Dr. Mendley invited meeting attendees to introduce themselves.

Should Medicare Entitlement Be Made Permanent for Transplant Recipients?

Paul Eggers, Ph.D.

NIDDK, NIH

Dr. Paul Eggers discussed the Medicare entitlement for transplant recipients, which provides coverage for (among other things) immunosuppression medications for 36 months post-transplantation. He explained that 1 year of coverage and entitlement for Medicare kidney transplant recipients was included in the original 1972 legislation. In 1982, this legislation was revised to a 3-year entitlement, where it remains today. With the 1984 release of an effective, relatively expensive immunosuppressant, cyclosporine, this 3-year entitlement and subsequent loss of coverage became an issue. A view that is well accepted and the source of several perspectives in the field is that limiting coverage to 3 years is insufficient and that extending it is likely to be cost effective.

In 2019, the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) supported a study—Assessing the Costs and Benefits of Extending Coverage of Immunosuppressive Drugs Under Medicare—that made such an evaluation. The study concluded that extending Medicare coverage of immunosuppressive drugs beyond 3 years post-transplant would result in 10-year accumulated savings of approximately \$73 million. Dr. Eggers, in collaboration with KICC members, is developing a manuscript based on analyses of Medicare data that suggest that extending coverage may not yield such savings.

Dr. Eggers detailed some assumptions and supporting data about extending Medicare coverage that the manuscript highlights.

- **Transplantation is cheaper than dialysis**—Per the 2019 USRDS Annual Data Report (ADR), the Medicare expenditures for ESRD therapy in 2016 were higher for hemodialysis (\$90,971) and peritoneal dialysis (\$75,177) than transplantations (\$34,780).
- **Immunosuppressive drugs are expensive**—In 2012, the average wholesale price of a 1-year supply of post-transplantation therapy, tacrolimus-mycophenolate mofetil-prednisolone, was \$22,300, which is considered an expensive drug therapy. The USRDS standard analysis files (SAFs) from 2006 to 2015 showed that the Medicare Part B expenditures for these immunosuppressive agents revealed a significant increase in 2009 that steadily decreased to a

plateau, a trend that coincides with the expiration of the brand name protections and the use of the generic brands. In fact, the Medicare Part D data showed an increase in generic tacrolimus and mycophenolate mofetil prescriptions compared to brand names Cellcept® and Prograf®, translating to an average cost of these drugs per Medicare patient to just under \$4,500 by 2015. On May 11, 2020, costs for both tacrolimus and mycophenolate mofetil, according to a well-known medical computer application that tracks drug prices, GoodRX, still show a large difference in brand name versus generic sold by major grocery store pharmacies, with yearly costs for generic immunosuppressants less than \$500 per year. Of the total Medicare expenditures for transplant patients, immunosuppressive agents account for only 17 percent in 2005 and 11 percent in 2015 compared to Medicare Part A and Part B coverage of 83 and 89 percent, respectively.

- **The loss of Medicare coverage (i.e., disenrollment or loss of entitlements) causes patients to lose their dialysis grafts**—Despite the numerous publications suggesting a loss of grafts after Medicare disenrollment, the authors rarely present adequate supporting data of the actual rate of the failure. The 2018 SAFs on the post-Medicare outcomes after terminations from 2006 to 2012 revealed that 83.6 percent of patients had a functioning graft, 9.2 percent returned to dialysis, and 6.2 percent had died at 5 years of follow up. A comparison of patients who had returned to dialysis between 2001 and 2010 showed similar graft survival at 3 years, regardless of their Medicare status. The mortality rate for Medicare-disenrolled patients was lower than for those retaining coverage.
- **Extension of Medicare entitlement would reduce a return-to-dialysis rates**—A multivariate analysis evaluated the effect of loss of Medicare coverage, controlling for such contributing factors as donor type (living or deceased), age, sex, race/ethnicity, ESRD status, and dual entitlement (e.g., eligible for Medicare and Medicaid coverage) among first-time transplant recipients from 2001 to 2010. The results showed that the loss of graft was (1) lower for living donors, (2) higher in African Americans compared with other races, and (3) higher in dual entitlement beneficiaries. The effect from Medicare disenrollment was insignificant.
- **The savings would offset the costs**—In a short calculation of benefit, Dr. Eggers estimates that if Medicare paid \$4,000 for every 1,000 disenrolled persons, it would amount to \$4 million in costs per year. His assumption is that Medicare pays \$100,000 for every return-to-dialysis patient; therefore, the additional expenditure would have to prevent 40 transplant failures every year, translating to 4 percent. Given that the total failure rate for patients leaving Medicare is 2 percent annually, even if post-Medicare coverage eliminated 100 percent of all graft failures, it still would not cover the additional costs.

In closing, Dr. Eggers noted that in extending Medicare coverage, transplants are undoubtedly less expensive than ongoing dialysis. Immunosuppression costs contribute minimally and are decreasing; Medicare-covered hospital and physician costs are much larger. Graft failure rates are not significant after Medicare disenrollment and are similar to the failure rates within Medicare coverage. This effect is likely because of the expertise of transplant centers in securing payments for immunosuppressive agents. Last, it is doubtful that extension of Medicare coverage beyond 3 years will generate significant savings. He made careful note that from nephrologists' perspectives, the 3-year termination rule is of major concern because it creates barriers to transplant access for persons with fewer resources (e.g., no source of funding) who often are not placed on the transplant waiting list.

Discussion

- Dr. Paul Kimmel called attention to dual eligibility as the index of poverty for CKD and ESRD populations used in the medical literature to derive dual eligibility.
- Aside from the expenditure aspects, Dr. Afshin Parsa noted that transplant recipients live longer and asked whether factoring in the cost of brand name versus generic would change the calculation of benefit for extending Medicare coverage. Dr. Eggers responded that data presented at this meeting reflect the trend up to 2015; data collected through 2017 have not been reviewed. He could not speak about the Medicare payment rates for 2020, the current cost of other drugs, or the cost of new formulations of tacrolimus and mycophenolate mofetil. Updated calculated costs are expected to be much lower.
- Dr. Mendley noted the barriers to affordable health care created by the Medicare 3-year entitlement limit for dialysis patients. Although transplant recipients are healthier, they may not necessarily have returned to the workforce and may not be receiving employer-sponsored health insurance.
- In response to a comment by Dr. Kimmel on the best forum for publishing Dr. Eggers' data, which defies the conventional wisdom of the pioneers in the kidney clinical and research communities, participants conveyed trust in the peer-review process, regardless of the journal. Although the scientific reviewers may not agree with the findings, they are not likely to overlook these data. Dr. Robert Star asked the Centers for Medicare & Medicaid Services (CMS) representatives about any issues this publication would present. Ms. Loida Tamayo of the Office of Minority Health, CMS, expressed concern about the unintended consequences of such a publication on minority populations and people with low incomes. Dr. Mendley highlighted that the annual cost of immunosuppressives may not be affordable for all patients, even if costs have significantly decreased; this fact, combined with the existing disparities in access to transplantations, should be included in the publication's discussion.
- Dr. James Oliver asked about other strategies (e.g., stock piling medications or alternate sources) being used by Medicare patients facing coverage disenrollment. Dr. Eggers explained the challenge of using CMS claims data on the use of immunosuppressives and hospitalizations in Medicare beneficiaries; once a patient leaves the CMS system, these data are no longer accessible. Whether a former patient returns to Medicare or is no longer living is outcomes information that CMS can provide. A *de novo* study of Medicare patients after disenrollment via interviews and surveys of transplant centers is one option to consider. Payments will be captured in Medicaid expenditures for dual-eligible patients. Dr. Mendley added that Medicare disenrollees are likely tiered (upper, middle, and lower) income. Age, and in some cases, state requirements affect Medicaid eligibility. The middle tier between affluence and poverty is more of an unknown in the clinical community.
- Given that the graft failure rate and costs are similar between Medicare and non-Medicare enrollees, Dr. Kevin Abbott asked whether there are definitive data showing that these patients were receiving employer-based health insurance.
- Dr. Eggers noted that transplantation has increased among Medicare beneficiaries and that 25 percent of this population with a graft are over age 65, so they do not lose Medicare coverage. Approximately 30 percent of the under-65 population receiving Medicare because of ESRD lose this coverage after 3 years.

Questions the United States Renal Data System Can Answer

Kevin Abbott, M.D., M.P.H.

NIDDK, NIH

Dr. Abbott described CMS data that are available in the USRDS and expressed appreciation to CMS and the NIDDK for continued support of the USRDS. Because registry data are limited in providing the necessary tools for adjusting for socioeconomic status in ESRD patients, related information is inferred from the U.S. Census Bureau data. For example, ecological-based data, such as ZIP codes, are merged with median household income data but are not indications of an individual's level of poverty. The CMS variable "dual-eligible," which is used to determine whether individual patients are eligible for both Medicare and Medicaid, is a metric that includes patients receiving care who are at less than 135 percent of the poverty level. The dual status and eligibility varies by state. In the general Medicare population, from 2015 to 2016, less than 9 percent of beneficiaries were dual-eligible—the percentages may vary when factoring in the use of other CMS programs such as Medicare Advantage. Of the less than 9 percent, the dual status tends to be higher in minority populations. Asians have the highest relative percentages of being dual-eligible as compared with Native Americans and Hispanics—blacks are more likely than whites and females more than males.

Dr. Abbott detailed some of the peer-reviewed publications that have used USRDS data on dual eligibility as a metric for individual-level poverty. Nee *et al.* in 2016 reported that median household income and dual-eligibility status correlate to the likelihood of receiving pre-ESRD nephrology care. In 2015, Kimmel *et al.* evaluated the association of racial disparities, poverty, and mortality in the general Medicare population. This model demonstrated that adding dual-eligibility status, which the authors describe as "buy-in", as an individual level covariate eliminated the racial disparity for blacks, which was once correlated with increased mortality.

To determine the frequency of dual eligibility in the Medicare population, the NIDDK, with support from its current service contractor, performed updates to existing USRDS data. In the incident dialysis patient population by modality and payor, from 1980 to 2017, the percentage of patients who start dialysis with Medicare as the primary payor decreased. The percentage of dual-eligible patients significantly increased during this same period but remained stable from 2010 to 2015. For the incident peritoneal dialysis and transplant patients, the percentage of dual-eligible was less than that of the incident hemodialysis patients. In the prevalent patient population for the same period, the trends are similar with the exception that an increasing number of hemodialysis patients become dual-eligible over time. In the percent incident ESRD dual-eligible patients, the relative demographics (e.g., age, race, and sex) are similar for patients 65 and older (general Medicare population) compared with those younger than 65 (Medicare disabled population), with the exceptions that the proportions (38 % versus 24 %) are significantly higher in patients younger than 65 years of age.

Dr. Abbott highlighted several trends in the U.S. ESRD population based on recent USRDS ADRs. From 2000 to 2016, the standardized incidence of ESRD decreased across all racial groups. The most notable decrease has been in the Native American population—a success the Indian Health Service (IHS) credits to establishing the Special Diabetes Program for Indians as well as other tailored interventions. Although the general theme in the policy community is that ESRD incidence remains unchanged, these data are compelling given the increasing age of patients starting on dialysis. From 2001 to 2017, the adjusted all-cause mortality for prevalent patients decreased by 25 percent in the first decade and by 40 percent over two decades and across all modalities (e.g., hemodialysis, peritoneal dialysis and transplant). The mortality rate in peritoneal dialysis patients was once higher than that in hemodialysis patients, but this trend has not been observed in recent years. For the next ADR, efforts will focus on completing

evaluations of the standardized incidence of ESRD in the U.S. population stratified by health service area (i.e., one or more counties of self-sustained routine hospital care) in the Hispanic population.

In response to a previous request from the Ambulatory Patient Groups to describe the uptake on home therapies (e.g., hemodialysis, peritoneal dialysis, and transplant) in ESRD patients, Dr. Abbott pointed out that from 2000 to 2007, the number of patients starting home therapies increased. After a 3-year decrease from 2007 to 2010, a modest upward trend has continued. Among all ESRD patients, the percent on home therapies reaches the nadir at 6 months post-ESRD initiation and then increases through 36 months post-initiation. This effect, Dr. Abbott attributes to failure of the peritoneal dialysis and patients then switching over to in-center hemodialysis. Although not done at home, transplantation classifies as home therapy and contributes to much of the increase. Nine percent of patients age 65 and older started home therapy as compared with 17 percent in patients less than 65 years of age.

Discussion

- Dr. Mendley pointed out that the data on dual-eligibility frequency strongly demonstrate that incident hemodialysis patients are at a lower income level than the incident peritoneal dialysis patients and transplant recipients. Dr. Star added that these data also indicate that low-income patients have fewer treatment choices regarding modality.
- Dr. Mendley also clarified that the ESRD population has a threefold likelihood of being dual-eligible as compared with the general Medicare population, translating to ESRD as a disease of poverty. Dr. Kimmel added that the NIDDK made this observation previously, which reflects the race/ethnicity of the ESRD population.
- Although preliminary data indicate that lower estimated glomerular filtration rate (eGFR) at ESRD start is associated with improved survival, Dr. Abbott noted that adjusting the mortality to account for the starting eGFR could be considered in future analysis in the USRDS.
- Given that hemodialysis is a small percentage of home therapies as compared with peritoneal dialysis and the pathways are different, Dr. Star suggested presenting these data separately and not grouped.
- Dr. Andrew Narva asked about the interest of investigating the impact of Medicaid expansion on kidney disease care and outcomes in the USRDS. Dr. Eggers noted that his brief analysis on the comparison of the states that opted for the expansion versus those whose programs did not change showed no differences in the ESRD population that had Medicaid as a secondary coverage. Dr. Abbott added that NIDDK-supported investigator Dr. Amal N. Trivedi is investigating this exact topic and that Trivedi *et al.* reported some of their results in 2017. He also noted that efforts will likely expand to evaluating the effects of COVID-19 in this context.
- Dr. Ann Bullock highlighted the IHS' universal access to health care as the major factor contributing to the largest decrease in kidney failure in the Native American population in which the poverty rate is one of the highest. The IHS also targets triage its resources and perform primary care-based interventions.
- A participant commented on the strong correlation of ESRD with poverty observed in the data but emphasized not overlooking other components that may actually cause ESRD.

- Dr. Star suggested combining the two presentations—Questions the United States Renal Data System Can Answer and Transplant Failure and Medicare Disenrollment—into a single manuscript on unexpected findings in the ESRD program and poverty issues.

Electronic Care Plan for People with Multiple Chronic Conditions

Jenna Norton, M.P.H.

NIDDK, NIH

Ms. Jenna Norton described the basis for care plans and provided updates on the NIDDK CKD electronic (e)-Care Plan and the joint NIDDK–Agency for Healthcare Research and Quality (AHRQ) Multiple Chronic Conditions e-Care Plan projects. Generally, a comprehensive shared care plan gives a person direct access to his or her information; puts the person’s goals at the center of decision-making; is holistic and inclusive of clinical and nonclinical data; follows the person through high-need episodes and periods of health improvement and maintenance; and facilitates care coordination. The current health care system lacks the infrastructure to share patient data across care settings, placing undue burden on patients, family caregivers and clinicians to collect and transfer patient information. In the kidney disease populations, patients have multiple providers, are serviced in multiple care settings, and are particularly challenged to aggregate their information. The clinical team is left without the necessary information to properly care for the patient. The e-care plan aims to provide a central location for patient data that is easily accessible to patients, family caregivers, and clinicians. In addition, an e-care plan provides a central location for research access to comprehensive patient data.

Ms. Norton reminded participants of the six priority areas identified in the October 2015 NIDDK-sponsored workshop on using health information technology to identify and manage CKD populations, one of which was to develop an e-care plan for CKD. In January 2016, the NIDDK established a CKD Care Plan Working Group to create this plan with input from patients, caregivers, and a variety of clinicians involved in CKD care. This plan would enable patients and clinicians to record, change, access, create, and receive key data, including health information and goals and preferences across settings. The major activity was to identify key data elements (clinical and social) and associated standards critical to comprehensive care for people with CKD. To inform CKD data element identification and prioritization, the Working Group captured the patient voice thorough interviews, developed personas and scenarios, and solicited input from stakeholders on all levels. To date, the Working Group has developed 11 hypothetical but realistic personas, identified more than 300 data elements for CKD and associated standards from common clinical terminologies, and designed a clinician-facing dashboard to display the data elements.

One of the 11 personas representing the patient experience is Betsy Johnson, a person with multiple chronic conditions, including type 2 diabetes, CKD, and congestive heart failure. Betsy is a retired schoolteacher and widow who lives with her daughter. Her physician encourages her to consider her preferences for treatment if her kidneys fail, but Betsy finds thinking about this scenario stressful. After receiving conflicting advice from many different physicians, Betsy is challenged in wanting her doctors to know what is important to her. Betsy wants the e-care plan to (1) help keep her many providers on the same page, (2) contain a unified summary of goals and plans that is reviewed by her entire care team and works for all her conditions, (3) provide educational resources, and (4) offer an easier way to schedule appointments. Ms. Norton highlighted features of the draft design and pointed out the lessons learned in the project. The e-care plan must be a dynamic data set to enable user-centered displays and must be a balance between brevity and comprehensiveness. A single-disease approach to e-care planning is unsustainable for people with multiple chronic conditions and their healthcare providers.

Ms. Norton explained that the AHRQ–NIDDK Multiple Chronic Conditions e-Care Plan Project is building capacity for pragmatic patient-centered research by developing an interoperable e-care plan to facilitate aggregation and sharing of critical patient-centered data across home-, community-, clinic-, and research-based settings for people with multiple chronic conditions. The Project deliverables include standardized data elements for diabetes, cardiovascular disease, and chronic pain; clinical information models and Fast Healthcare Interoperability Resources® (FHIR) profiles; and a pilot tested e-care plan application and implementation guide. All deliverables will be open-source and publicly available. Ms. Norton acknowledged both the Project’s Federal Team and Technical Expert Panel.

Ms. Norton emphasized that the NIDDK CKD e-Care Plan was the starting point for providing a framework for the NIDDK–AHRQ Project that will leverage other ongoing efforts, such as the CMS/ONC Electronic Long-Term Services and Supports Pilot, the Social Interventions Research and Evaluation Network Gravity Project, and the HHS Substance Abuse and Mental Health Services Agency Omnibus Care Plan. Future work will need to expand to include many other diseases and conditions as well as continued advancement of standards-based work, use of FHIR for research for robust health information exchanges, and widespread use of common clinical terminology.

Discussion

- In response to a query from Dr. Eggers on whether an e-care plan works best in optimal managed care organizations and about examples of success, Ms. Norton noted that in integrated health systems (e.g., Kaiser Permanente) a single type of electronic health record (EHR) already is in place and this the e-care plan is not needed. The problem arises when patient receive care in multiple care settings where each setting is using different data standards to convey patient information, resulting in barriers to interoperability.
- Dr. Star called attention to the novel aspect of these e-care plan projects—stakeholder input—that drives the design. Dr. Mendley added that the patients interact with the e-care plan in a more meaningful way than previous models.
- Dr. Susan Ziemann emphasized maintaining a dynamic platform in which the patient goals and needs are continuously updated.
- Dr. Kenneth Wilkins asked about plans to provide a platform for downstream users to evaluate pragmatic trials once the NIDDK–AHRQ e-Care Plan is released in the open-source setting. Ms. Norton explained that plans are to implement and evaluate the e-care plan in a clinical setting that would be the model for others to use in their respective care setting. The NIDDK–AHRQ team could consider an additional deliverable that explicitly addresses implementation for downstream users. Dr. Kimmel remarked on evaluating the e-care plan at all levels, especially in patients, early and often. Ms. Norton explained that the first phase of the project is focusing on proof of concept; if the first phase is successful, future phases may address piloting and feasibility testing for improving patient outcomes.

Agency Updates

U.S. Department of Veterans Affairs Numeracy Campaign Updates

Leonard Pogach, M.D.

U.S. Department of Veterans Affairs (VA)

Dr. Leonard Pogach explained that the VA has been supporting hypoglycemic safety for a number of years. In 2012, the Choosing Wisely—Hypoglycemic Safety Initiative (CW-HSI) (www.qualityandsafety.va.gov/ChoosingWiselyHealthSafetyInitiative/Choosing_Wisely_at_the_VA.asp) was established (within the broader Choosing Wisely®) as a voluntary safety initiative to (1) increase awareness of hypoglycemic safety and (2) screen patients at high risk for hypoglycemia. The CW-HSI involves easy patient identification and standardized screening methods. To date, the CW-HSI has been adopted by approximately 75 VA facilities. A key component of this program is shared decision-making, which is critical to managing patients with diabetes and CKD. Among the 1.6 million veterans enrolled in the VA health system, about 1 out of 4 have diabetes, and about 400,000 veterans with diabetes have CKD.

Health literacy—one of the strongest predictors of health status—is often thought of as being able to read, write, and understand the written word. The 2017 Institute of Medicine (IOM, now the National Academy of Medicine) report indicates that many individuals do not recognize that numeracy is a key component of health literacy. Well-known individuals in the federal government have emphasized the importance of health literacy. In the context of diabetes and kidney health, such concepts as administration of insulin and individualized blood glucose/blood pressure control targets are important to avoid potential harm.

The VA Secretary announced in December 2019 the launch of the Understand Your Diabetes Numbers Campaign in the VA, which was followed by a formal press release in January 2020. The key messages include hypoglycemic safety, nutrition, and shared decision-making. A series of blogs and veteran-facing stories are planned, but the VA recognizes that awareness and knowledge alone are not sufficient. The goal of the campaign is to implement understanding of the diabetes numbers through interactions with clinicians, especially with diabetes educators. Although both telehealth and face-to-face interactions are suitable options, the VA has developed a Virtual Medical Center (VMC) as a tool to engage patients. In this avatar-based environment, certified diabetes educators will be able to meet with patients individually or in shared appointments regardless of geographic location. This approach is consistent with new regulations on Medicare reimbursement of telehealth.

Dr. Pogach concluded by presenting a case study of a patient with type 2 diabetes who had a toe amputated, cardiac disease, and frequent hypoglycemic reactions. The patient desired to be fitted with an insulin pump, but could not find the service needed in the private sector. The patient transferred his care to the Cleveland VA, a large tertiary care medical center with an established multidisciplinary diabetes team and recognized Diabetic Self-Management Training Accreditation Program. The VA met the patient's needs and established short-term goals involving nutrition and stringent medication controls. The patient needed to understand such numerical concepts as calorie counting, insulin correction doses, and pump management. Many of the clinical interactions were completed by professional teams communicating via telephone/telehealth without the patient's coming into the clinic. The patient was able to demonstrate his use of the insulin pump and was referred back to a VA community-based outpatient center for close monitoring. The patient is no longer hypoglycemic and has an improved quality of life. In closing, Dr. Pogach noted that the VA campaign on shared decision-making and hypoglycemic safety has included collaborations with AHRQ, HHS, and the U.S. Food and Drug Administration.

Discussion

- Ms. Norton commented on how the VA campaign aligns with the previously described e-care plans in integrating patient preferences into health care systems. Dr. Pogach explained how the VA's Understand Your Diabetes Numbers Campaign, and the CW-HSI messages are relevant to non-Veterans as well. Collaboration with other agencies can inform other initiatives including those discussed in this meeting.

Around the Room

U.S. Department of Veterans Affairs

Dr. Anne Utech explained that for COVID-19 preparations for dialysis, the VA is following the Centers for Disease Control and Prevention's (CDC) guidelines to prepare its hospitals, providing dialysis-specific information, and preparing staff for telework. For the EHRs, Dr. Utech noted the Congressional testimony the previous week regarding the update on the delayed deployment of the Cerner Corporation (Cerner) EHRs in the northwest region of the United States. Clinicians have expressed concern about the challenges and work remaining to ensure a smooth transition to Cerner. The VA is fortunate in having care coordination embedded in the existing EHRs, integrating cardiology, nephrology, and other specialties and communicating that to patients. The aim is to not to lose this model of success in the transition.

National Institute on Aging

Dr. Zieman reported that the National Institute on Aging (NIA) launched the Clinician-Scientists Transdisciplinary Aging Research (Clin-STAR) initiative for early-career investigators and specialists, which builds on the NIA's Grants for Early Medical/Surgical Specialists' Transition to Aging Research program. Clin-STAR is designed to transition clinical junior and senior or non-physician scientists to aging research and encourage them to join a national collaboration and mentoring network. Dr. Zieman reminded participants of NIA's Alzheimer's disease-related research funding opportunities to support investigations into the relationship between CKD, acute kidney injury, and cognitive impairment.

Centers for Medicare & Medicaid Services

Ms. Melissa Dorsey provided a brief update on the ESRD Networks. CMS has been in daily discussions with the CDC and the Office of the Assistant Secretary for Preparedness and Response regarding COVID-19 and the dialysis facilities. The Kidney Community Emergency Response (commonly known as KCER) Program is tracking, nationally, dialysis patients being tested for the disease. The CDC guidelines have been shared with the facilities. The lack of personal protective equipment also is being tracked.

Centers for Disease Control and Prevention

Ms. Nilka Ríos Burrows noted that the NIDDK publication on the CKD electronic phenotype for adults has been posted on the CDC website and that she looks forward to collaboration on the CKD and multiple chronic conditions e-care plans. Regarding COVID-19, the CDC is continuously posting resources on its website. The Center's communications team is working on generating frequently asked questions, and participants are welcome to contact Ms. Burrows if they have input. She announced that the Healthy People 2030 will launch at the end of March 2020. In addition, the Center director has a strong interest in interrogating social determinants of health (SDH) and welcomes collaborations as they relate to the ESRD population.

Discussion

- When asked whether a pediatric CKD phenotype was planned, Ms. Norton explained that the NIDDK is having discussions with CDC counterparts about this topic and that further details will be forthcoming.
- Dr. Mendley remarked on the discussions on SDH and ESRD that should continue across agencies; Drs. Abbott and Eggers are the most knowledgeable about these data. Although relevant publications are becoming more frequent, the issue is not broadly recognized.

Agency for Healthcare Research and Quality

Dr. Christine Chang explained that AHRQ currently is soliciting applications for a systematic review project focusing on transitions of care for children with renal disease. It anticipates funding the project in mid-May 2020.

Discussion

- Dr. Mendley called attention to the July 21–22, 2020, health care transitions workshop, which aligns with the AHRQ transitions of care project and is being co-sponsored by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the NIH Pediatric Research Committee.

Adjournment

Dr. Mendley thanked the presenters and attendees for their participation and adjourned the open session of the meeting.