**Kidney Interagency Coordinating Committee Meeting**

**Systems Models as Public Health Tools for Chronic Disease**

Natcher Conference Center, Building 45, Rooms F1/F2
National Institutes of Health
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**Meeting Participants and Summary**


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**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 involved in kidney research and other kidney-related activities. 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. The focus of today's meeting, systems models as public health tools for chronic disease, will highlight use of computer modeling of populations to test interventions to improve outcomes. Dr. Narva noted the following agenda changes: the presentation titled "Assessing the Potential Savings of the Special Diabetes Program for Indians" has been postponed to the March 9, 2018 KICC meeting; and Ms. Jenna Norton, NIDDK, will provide an overview of the CKD electronic Care Plan (e-Care Plan).

**Overview of the CKD e-Care Plan Working Group: Progress and Path Forward**
*Jenna Norton, M.P.H.*
*NIDDK*

Ms. Jenna Norton provided an overview of the CKD Care Plan Working Group (Working Group), its progress, and the path forward. The Working Group comprises informaticists, patients, patient advocates, primary care providers, and nephrologists. The goals are to identify the CKD-related elements that should be included in a comprehensive e-Care Plan template and enable patients and clinicians to access, create, record, change, and receive these data elements across health care settings. In addition, the Working Group will generate an e-Care Plan template that will be consistent with the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator (ONC) for Health Information Technology certification criteria. To date, the Working Group has completed identifying and prioritizing essential and recommended data elements, as well as identifying data standards. The group will soon finish developing standards for identified gaps and is in the process of designing user-friendly dashboards compatible with Consolidated Clinical Document Architecture (C-CDA) in collaboration with the Veterans Health Administration (VHA) Human Factors and Usability Testing Laboratories. Pilot testing of the data elements design platform is in progress at established sites.

The Working Group leveraged the methodology of software developers to generate hypothetical human personas and scenarios to inform the e-Care Plan. The personas and scenarios, which reflect common challenges, guided the decision-making process on data priorities and display options. The personas include clinicians (e.g., nephrologists, primary care providers [PCPs], dieticians) and patients with varying stages of disease, comorbidities, and social circumstances. The scenarios reflect real-world examples of care plan interactions. Ms. Norton presented example personas and scenarios developed by the Working Group. A comorbidity persona depicted a hypothetical patient who had been diagnosed with type 2 diabetes, congestive heart failure, and progressive CKD. Information on background and lifestyle, challenges and health goals, and e-Care Plan expectations were collected. A scenario example involved a clinician conducting a quality-improvement project, which evaluated how data would be used in the e-Care Plan. In addition to personas and scenarios, the Working Group conducted patient interviews in partnership with the American Association of Kidney Patients to further guide decisions on which elements to include and prioritize in the e-Care Plan. Data on primary health and life goals, primary CKD-related health concerns, barriers to managing health needs, and treatment options were collected.

The Working Group developed the CKD e-Care Plan data set based on the personas, scenarios, and personal interviews. Information on goals, health concerns, interventions, and health status evaluation and outcomes, per the Health Level Seven (HL7) guidelines, are included. The Working Group prioritized these data into a minimum data set, priority A elements, and priority B elements. The minimum data set includes data elements deemed necessary for most users, while priority A and B elements may be needed only in specific settings. The draft data set was made available for public comment in the spring of 2017 and can be accessed from the NIDDK website: https://www.niddk.nih.gov/health-information/health-communication-programs/nkdep/working-groups/health-information-technology-working-group/development-electronic-ckd-care-plan/Pages/default.aspx

The Working Group focused on developing new standards for the CKD e-Care Plan. A standard for renal replacement therapy (RRT) options has been completed (r.details.loinc.org/LOINC/85597-3.html?sections=Comprehensive) and Logical Observation Identifiers Names and Codes (LOINC) established. A minimum set of CKD education topics is being developed and will be submitted in December 2017 to the LOINC standards group to establish a code. Additional new standards being developed include challenges to maintaining the treatment plan to address issues related to adherence; patient goals related to health, functional areas, health events, symptom management, and mental health; and clinical measure goals with applicable target values.

Ms. Norton discussed early design efforts and pilot testing opportunities. The Working Group collaborated with the VHA human design factors team to develop wireframes (i.e., screen blueprints) and conduct usability testing. A draft clinician-facing wireframe will be completed soon and tested. The draft patient-facing wireframe needs to be developed. Pilot testing opportunities being explored include a partnership with the NIH collaboratory on Improving Chronic Disease Management with Pieces™ (ICD-Pieces™) study team to investigate technical aspects of data exchange across the four study sites: Parkland Health & Hospital System, Texas Health Resources, VA North Texas Health Care System, and ProHealth Physicians. Support through the VHA Business Associate Agreement funding mechanism is pending. The National Kidney Disease Education Program (NKDEP) co-submitted an application with the Agency for Healthcare Research and Quality (AHRQ) for the Office of the Assistant Secretary for Planning and Evaluation Patient-Centered Outcomes Research funding opportunity announcement. The goal is to test a comprehensive e-Care Plan for persons with multiple chronic conditions. The NKDEP CKD e-Care Plan will be proposed as a use case. The pre-application has been selected among the top five concepts for peer review, and NKDEP is hoping for an invitation to submit a full application.

**Discussion**

- Dr. Narva commented that the CKD e-Care Plan is designed to provide the basic care information the patient carries as they transition between health care settings, PCPs, and care platforms. Patients often are not aware of their treatment options or their CKD status. Also, no defined education elements exist for patient treatment. This standard has implications for developing quality measures, engaging population management, and providing data for research.

- Dr. Kevin McBryde asked about addressing vascular preservation in the CKD e-Care Plan. Ms. Norton explained that vascular preservation was not included in this version of the e-Care Plan but would be something to consider in the future. Existing codes do exist for data elements on the preparation and status for vascular access. Dr. Kevin Abbott asked whether the e-Care Plan included a pharmacy review or guidance on acute kidney injury (AKI). Dr. Narva clarified that the Working Group developed new standards to establish new codes that were currently not available. For example, no standards exist for documenting CKD education or plans for dialysis. This e-Care Plan is filling this gap. Dr. Meda Pavkov suggested including elements specific to

vascular access preparation in CKD progression cases. She noted that the e-Care Plan is comprehensive and implementation will be challenging. Ms. Norton commented on the difficulty in designing a plan that will be easy to use in a clinical setting yet provide the level of detail needed. The plan will be individualized to the patient and will include only codes reflective of a patient's conditions. Dr. Narva explained that all fields will not apply to all patients, and a document will generate automatically. He also noted the challenge in designing a manageable care plan that is more than prescriptive guidelines. The aim is to develop a tool that is easy for clinicians to use without posing undue burden. Other enhancements can be addressed in the future.

- Dr. Joel Andress asked whether progression from CKD to end-stage renal disease (ESRD) would be included. Ms. Norton indicated that the long-term goal is to have one care plan to address all conditions of patients. This iteration is focusing on a streamlined CKD plan. Dr. Narva noted the efforts of large dialysis organizations and electronic health records (EHR) developers to devise approaches that work without the constraints. The overarching goal is to adopt a one-care-plan model.

- Dr. Andress asked about the criteria for generating the goals and challenges list and whether they were reflective of the EHR. Ms. Norton explained that e-Care Plan goals and challenges not listed in the EHR will have to be added and that the pilot testing will provide more insight. Having this information in the e-Care Plan will encourage discussions between clinicians and patients over time. Dr. Andress noted that the Centers for Medicare and Medicaid Services (CMS) has had success working with patient groups to develop patient-reported outcomes in similar measures, and he will be happy to share connections to those patient groups with the NKDEP. Ms. Norton added that the group has been reviewing data from the Electronic Long-Term Services and Supports project, which is developing a data set of patient-centered goals. Dr. Narva pointed out that suggested guidelines are being developed and could be used to accelerate the development of tools/standards in the future. Dr. Robert Star asked whether a set of common goals would be included or built for each patient. Ms. Norton explained that patients will have options to choose from, which can be updated as new information is collected.

- Dr. Kenneth Wilkins asked whether a qualitative evaluation survey or A/B testing would be performed in the pilot studies. Ms. Norton explained that randomizations to compare the e-Care Plan to usual care will more than likely be conducted at the sites and A/B testing would be a desired method.

**Cost-Effectiveness of CKD Risk Scores for Screening: The CKD Health Policy Monitor**
*Meda Pavkov, M.D., Ph.D.*
*Centers for Disease Control and Prevention (CDC)*

Dr. Pavkov presented an overview of the CDC CKD Health Policy Model, the applications, and ongoing projects. She acknowledged the role of RTI International and the CDC's CDK Initiative in developing the model. There was a 15-percent prevalence of CKD in the general U.S. adult population from 2011 to 2014, affecting 30 million people. Risk factors for CKD are diabetes mellitus (DM), hypertension (HTN), and obesity. Health care costs are high and increasing. The onset of CKD and disease progression can be delayed or prevented with the currently available treatment. The aim of the CKD Health Policy Model is to accurately microsimulate the incidence, progression, and treatment of CKD using parameters derived from an in-depth epidemiological literature review, clinical trials, and a prior cost-effectiveness study. The model has been extensively validated and is updated as new data are introduced. Evaluations of CKD

stages, complications, and mortality, as well as cost-effectiveness of CKD interventions, are the clinical and economic outcomes, respectively. Five cost and effectiveness measures are used in the model: (1) annual expected medical costs for each CKD stage and complication, (2) annual expected stage 5 and ESRD costs, (3) intervention costs from CKD screening and treatment, (4) effectiveness as measured in quality-adjusted life year (QALY), and (5) an incremental cost-effectiveness ratio (ICER). The model structure incudes seven states: normal or no CKD, CKD stages 1 through 5, and death.

Dr. Pavkov discussed applications of the CKD Health Policy Model. Simulating the future burden of CKD in the United States, the estimated residual lifetime incidence of CKD in three U.S. adult cohorts—ages 30–49, 50–64, and 65 years and older—and estimated prevalence of CKD among U.S. adults ages 30 years and older and 65 years and older in 2020 and 2030 were used as measures for future burden of CKD. Data showed that the lifetime incidence of CKD in adults ages 30 to 49 is 54 percent, 52 percent for ages 50 to 64, and 42 percent for persons age 65 and older. The projected prevalence of CKD in 2030 in the 30-years-and-older population is 16.7 percent and 37.8 percent in the 65-years-and-older population.

Determining which population benefits most from screening and identifying optimal screening frequency are two questions that remain unclear. The model was used to simulate cost-effectiveness of CKD screening. Simulated cost-effectiveness of screening for albuminuria showed that screening was cost-effective in the adult diabetic population, but not in the total adult population. The cost-effectiveness of using risk scores (Bang *et. al.,* 2007) to screen for Stage 3 CKD revealed that a CKD risk score with a threshold of 0.02 and a 2-year follow-up was most effective for CKD screening. Differences in the recommended hemoglobin (Hb) treatment (i.e., erythropoietin-stimulating agent [ESA]) target for CKD have been reported. Yet, no existing guidelines have considered the costs or cost-effectiveness of ESA treatment. The model incorporated the potential tradeoff between the benefits of higher Hb targets and the side effects of higher ESA doses needed to achieve them. Simulations of the cost-effectiveness of anemia treatment in CKD suggest that achieving a target Hb of 10.5 g/dL is most cost-effective in persons with CKD stages 3–4. Also, treatment guidelines on the treatment of anemia in persons with CKD should include costs and QALYs.

Ongoing projects include simulating the cost-effectiveness of blood pressure targets in persons with CKD, modeling the impact of obesity on the burden of CKD in the United States, continuing to update the model, and designing a tool—CKD SreeenScore—that evaluates for each patient the need for CKD screening and the appropriate screening frequency.

**Discussion**

- Dr. Andress asked whether the CKD Health Policy Model could be used for modeling the outcome and consequences of Hb and ESA dosing in ESRD cases. Dr. Pavkov explained that the model is available upon request, but is complex to use without assistance. Updates and refinements to the model have been ongoing, and development of a streamlined version that will be available to the public is planned.

- Dr. Abbott speculated that a cost-effectiveness model incorporating age rather than DM or HTN would result in cost savings, given the data in the study by Bang *et. al*., which showed an odds ratio greater than 20 for ages 60–69, which was independent of CKD risk factors. Dr. Pavkov observed a higher weighting with age than any other parameters modeled.

- Dr. Star asked whether the Tangeri model (Tangeri *et. al.,* 2011) had been considered. Dr. Narva explained that the Tangeri model assessed CKD progression, whereas the models currently used in the cost-effectiveness studies evaluate persons meeting the criteria for CKD. Dr. Star also asked about the effects of efficacy and treatment in relation to age of the patient. Dr. Pavkov explained that epidemiological data are used in the modeling algorithms, which is a limitation of

the model. The estimated glomerular filtration rate alone is not the predictor; the associated risk factors play a role. Dr. Pavkov referred participants to the 2010 Hoerger *et. al.* publication, which details the model's construction and assumptions.

- Dr. Abbott commented that excluding AKI from the model reduces its predictive power. Dr. Pavkov acknowledged that the model does not include AKI and called attention to a soon-to-be-released CDC *Mortality and Morbidity Weekly Report* that will have details on AKI and hospitalization.

**Methodological Approaches for Care Management of Patients with Multiple Chronic Conditions**
*Jayasree Basu, Ph.D.*
*AHRQ*

Dr. Jayasree Basu reported on the issues of modeling health outcomes in patients with multiple chronic conditions (MCC) and AHRQ's MCC investments. Chronic conditions are physical and behavioral health conditions that last for 1 year or longer. Patients with MCC have two or more chronic illnesses at the same time. Treatment for MMC patients accounts for 70 percent of the Nation's health care costs, underscoring a need for effective health care. The different components influencing health care outcome in patients in a model for chronic disease include community, health systems, and multi-level patient factors—the care is complex, but could be manageable. A conceptual model for MCC has the same components as a single disease model, but a gap (i.e., complexity) exists between patients' needs for care and the ability of the health care system to support those needs. Several issues are associated with modeling MCC. Most health care research and methods focus on single conditions and healthier populations. Health outcomes are either disease-specific or general and do not address the complexity of MCC. Furthermore, the MCC population is highly heterogeneous and difficult to identify, presenting measurement issues related to appropriate clustering of chronic conditions and incorporation of stages of disease progression.

Dr. Basu discussed the AHRQ's MCC investments and noted the urgent need to improve the health and health care of MCC patients that parallels the need to develop new methods for studying this population. Established risk prediction modeling approaches for the identification and management of high-risk individuals are not specific for MCC. It is unclear which approaches are more effective for specific MCC subgroups. Questions on accounting for heterogeneity, capturing population characteristics not included in claims data, measuring chronic illness burden/chronic condition cluster, and measuring meaningful outcomes remain. To address the methodological challenges in research for MCC patients, AHRQ funded seven exploratory and development (R21) grants in 2014. A total of 59 research grants have been funded within the AHRQ MCC Research Network over a 6-year period. Dr. Basu detailed two of the seven modeling MCC grants. The population health initiative "Innovative Research Methods to Study Children with MCC" was led by Dr. Jay G. Berry, Boston Children's Hospital. The goals were to adapt for children the adult-based AHRQ Clinical Classification System to identify MCC in children, assess conditions that most affected health outcomes and the use of resources, and target those conditions for clinical intervention. The approach was to assess the effect of comorbid conditions on health care spending for children with cerebral palsy using the Pareto principle ranking, multivariable linear regression, and classification and regression tree analysis methods. A key finding was that pediatric adaptation of the AHRQ Clinical Classification System used with methods informed by the Pareto principle distinguished, with clinical fidelity, the co-occurring conditions responsible for the most health care spending in children with cerebral palsy.

The population study for the elderly "Combination of Chronic Conditions Determining Clinical Relevance and Resource Use" was led by Dr. Siran M. Koroukian, Case Western Reserve University. The aim was to identify and rank specific combinations of chronic conditions, functional limitations, and

geriatric syndrome that are most predictive of health care outcome and resource use among the elderly. The study used a 2008–2010 Health and Retirement Study cohort and classification and regression tree model or CART. Key findings showed that the most important drivers of health outcomes are functional limitations and geriatric syndromes, not chronic conditions—functional limitations are important drivers of health care costs. The study concluded that the CART model identifies empirically emerging combinations of conditions that are relevant to the outcome of interest.

Dr. Basu summarized new contributions from AHRQ grants, key data challenges in MCC modeling, and new special emphasis notices. Future directions for MCC methods include developing a tailored approach to target specific subpopulations, as well as validation of additional outcomes, linking of non-claims data, and advancing collection and use of patient-reported outcomes and patient contextual data. In addition, efforts will focus on (1) including MCC patients in shared decision-making, (2) new AHRQ initiatives that are supporting learning health systems, and (3) value-based reimbursement models, such as CMS Medicare Access and Children's Health Insurance Program Reauthorization Act and Quality Payment Program.

**Discussion**

- In response to a query from Dr. Narva on distinguishing chronic condition complications, Dr. Basu noted the challenge of identifying the stage of the chronic disease in MCC patients.
- Dr. Star wondered about the worst outcomes in a multimorbidity model for the elderly in which chronic conditions, functional limitations, and geriatric syndromes intersect regarding attributable risk. Dr. Basu explained that the study suggested that when combined with geriatric syndrome and functional limitations, chronic conditions increased the risk of worse outcomes and higher health care costs.
- Dr. Andress asked whether major organ failures (e.g., heart, kidney, or respiratory) clustered in MCC cases in these studies. Dr. Basu explained that the study findings and conclusions did identify clusters, empirically, using the new data mining approach, CART.
- In response to a query from Dr. Abbott on whether a chronic condition correlated with impaired functional status, Dr. Basu stated she was not aware of such a correlation, but will consult with study investigators.

**CKD Population Health Cost Model**
*Nathan Brajer*
*Duke University, NDKEP Health Information Technology Working Group*

Mr. Nathan Brajer described the CKD Population Health Cost Model. He acknowledged other members of the Business Case Working Group subgroup who have guided this effort. In 2014, the annual costs for CKD were 25 percent of the total Medicare costs and averaged $21,857 per patient compared to $10,803 for non-CKD patients. ESRD patients accounted for 2.5 percent of the total Medicare population, and annual costs were 13 percent of the total Medicare costs. The goal of the Business Case Working Group is to develop a business case framework that will assist health care organizations in evaluating investments in new infrastructure and programs to support CKD population health management. The design is a population-level cost model that assists health advocates in answering important questions. The use case options include estimating current costs, future costs with no changes, future costs with interventions, and providing insight into population-level levers of control. Model development was completed in March 2017, and the tool now is accessible to the public. The model is built on the Microsoft Excel platform and is easy to use, dynamic, and flexible. The Working Group explored partners for alpha testing and received interest from DaVita Inc., the National Kidney Foundation, Geisinger Health System, and Cleveland

Clinic. In addition, the group will partner with Cleveland Clinic's Accountable Care Organization Analytics Team to test and validate the model using the Cleveland Clinic's data.

Mr. Brajer demonstrated use cases and examples. He pointed out how the model could be used to estimate future costs with interventions for a care management program and could estimate future costs for a nephrology referral program to better understand its health system margin. As a CKD Population Health Cost Model, the software has the capability to simulate population-level disease progression from Stage 3 CKD to ESRD, track population-level costs, and project cost savings. The clinical and cost estimations generated were informed by literature reviews. The user has the option of choosing between two simulation conditions: base case and enhanced intervention. Clinical interventions include early nephrology control, hypertension control, and glycemic control. In the starting year, the model calculates the distribution of patients across the various CKD stages using national estimates. In subsequent years, patients are tracked as they remain stable, change status, or die. Annual costs are calculated at each stage. The key model parameters are progression and mortality rates, and inputs to the model were prepopulated with national estimate data. Minimum amounts of data are required from the end user, such as selecting the modeling outputs and choosing which clinical interventions to simulate. The model outputs are metrics that are a priority to health system leaders, such as the total CKD and ESRD cost breakdown, total cost projections, cost estimates per member per year, and drivers that affect changes in cost. Details about the model can be found on the Duke Institute for Health Innovation website: dihi.org/projects/ckd-population-health-cost-model.

The next steps will be performing testing and validation with Cleveland Clinic, publishing an overview of the model, publishing validation results, and exploring further development opportunities. Mr. Brajer remarked that health care organizations systematically underinvest in CKD programs. Thus, the Business Case Working Group has developed a cost model to help health advocates and decision makers realize the positive financial implications of investing in CKD population health programs.

**Discussion**

- Mr. Tom Duvall asked whether optimal transitions, vascular access, and transplant options would be included in the CKD model. Mr. Brajer replied that the model examines interventions related to CKD progression and transition to ESRD. Cost changes resulting from optimized transition to dialysis, defined in the model by the percentage of patients receiving early nephrologist referrals, are estimated through the combined effect of changing RRT modality (transplant versus peritoneal dialysis versus hemodialysis), changing mortality rates, and changing cardiovascular event rates.

- Dr. Abbott asked how over- or under-dosing medications and toxicity were being addressed. Mr. Brajer replied that those indications were not being captured. It is likely that toxicity already would have been addressed at this stage.

- In response to a query from Dr. Wilkins on the open-source software and customizations for other applications, Mr. Brajer explained that an open version of the model software has been shared with Cleveland Clinic for testing its data. Understanding how the model works is a prerequisite for sharing the interface. Dr. Narva added that the model is in the public domain, but is labeled accordingly to prevent others from adopting the concepts.

- Dr. Narva asked whether sensitivity analysis had been performed on the early nephrology referral data. Mr. Brajer indicated that those analyses had not be done, but would be considered in the immediate future.

**General Discussion**

- Dr. Abbott commented on the differences in reimbursement rates between atrioventricular (AV) fistula and AV graft vascular access and asked if there were updates. Dr. Jesse Roach pointed out that the Center for Medicare group at CMS who are responsible for rule making would be the best qualified to address those issues. Dr. Abbott wondered whether a GORE-TEX® stretched vascular graft, rather than a catheter, should be the preferred procedure in AKI cases. Dr. Pavkov suggested leveraging the work being done with Dr. Priti R. Patel at the CDC. Dr. Roach pointed that it would be necessary to determine whether the observation that infections increased in ESRD patients within 3 months after a catheter insertion was causative or correlative in AKI cases versus use of an AV graft.

**Adjournment**

Dr. Narva thanked the attendees for their participation and noted that the next meeting of the KICC is scheduled for March 9, 2018.