Monday, February 27, 2017

Welcome and Introduction

Opening Remarks
Robert A. Star, M.D., NIDDK, NIH

Dr. Robert A. Star welcomed participants to the meeting. He reflected on the October 2015 workshop titled "Using Health IT to Identify and Manage CKD Populations" and its goal of transforming this amorphous topic into actionable ideas by enabling the NKDEP Health IT Working Group (HITWG) to provide insight into the future of CKD care. The ideas that emerged from the October 2015 workshop are the focus of today's meeting and include developing a computable phenotype to identify CKD patients, an electronic care plan template for CKD, and a business case model. Dr. Star explained that the NIDDK recognizes that advancing CKD research through health IT will require using complementary approaches that include precision medicine, pragmatic clinical trials, and population health studies. The Kidney Precision Medicine Project has been established to address the first approach, and funding opportunities are available. Pragmatic clinical trials are being conducted at the University of Texas Southwestern Medical Center, and the NKDEP is engaged in population health initiatives. Dr. Star expressed appreciation to Ms. Jenna Norton, the NKDEP, and the planning committee for organizing today's meeting.

Meeting Objectives
Paul Drawz, M.D., University of Minnesota
Andrew S. Narva, M.D., NIDDK, NIH

Dr. Paul Drawz, Chair, HITWG, thanked the participants for attending the meeting, both in person and via WebEx. He discussed the origin of the NKDEP HITWG, which met for the first time at the American Society of Nephrology annual meeting held in San Diego, California, in October 2012. The goal of the HITWG is to enable and support the widespread interoperability of data related to kidney health among health care software applications to optimize CKD detection and management. He recognized Dr. Uptal Patel, Duke University School of Medicine, previous chair of the HITWG, for his early leadership of the HITWG, Dr. Andrew S. Narva, NIDDK, and Ms. Norton for their support in establishing the HITWG. From 2012 to 2015, the HITWG discussed ways in which electronic health records (EHRs) and other technologies could be designed and used to affect the health of people with CKD; the HITWG published the summation of their work in the August 2015 edition of the *Clinical Journal of the American Society of Nephrology*.

The HITWG met in October 2015 to (1) identify pragmatic solutions for using existing health IT systems to improve CKD population management and (2) develop a repository to aggregate shared strategies and resources to facilitate CKD population health management (PHM). Moderated panels discussed PHM in public systems, in vertically integrated systems, and in private and research sectors, as well as health IT tools and solutions for PHM. Six priority activities were identified at this meeting, three of which will be reported on today: computable phenotypes to identify CKD patients—especially high-risk patients, electronic care plan templates for CKD, and the business case for identifying investment in CKD population management infrastructure. Working groups assigned to these three priority areas have been working actively for the past 18 months.

Dr. Narva remarked on the challenges of using health IT for data sharing and the importance of understanding the audience when developing recommendations and tools for CKD that are usable to both health informatics experts and clinicians. The NIDDK's main objectives for this meeting are to (1) share the progress of the HIT Work Group with the kidney community and (2) to identify additional opportunities to support or improve the use of health IT in CKD research and care. He reiterated that today's agenda includes updates from three HITWG subgroups: the CKD Computable Phenotype Subgroup, the Electronic CKD Care Plan Subgroup, and the CKD Business Case Subgroup. The afternoon session will involve short presentations on applying health IT to future CKD research. Dr. Narva acknowledged the work of the HITWG and its expert members, who volunteer their time, and the vision of Dr. Patel, the first chair of the HIT Work Group.

Part I: Development of an Electronic Phenotype for CKD

Overview of the CKD Phenotyping Working Group and Progress to Date
Paul Drawz, M.D., University of Minnesota
Kensaku Kawamoto, Ph.D., The University of Utah

Dr. Drawz presented an overview and progress update of the CKD Phenotyping Working Group and acknowledged its members, including co-chair Dr. Kensaku Kawamoto. The purpose of the computable CKD phenotype is to help health care organizations identify a candidate group of patients who are likely to be diagnosed with CKD to facilitate PHM, surveillance, and research activities; this would be achieved by providing IT departments with necessary tools and instructions that will help bridge the chasm between clinicians who treat people with CKD, quality improvement experts in PHM who may have knowledge of CKD and high-risk populations, and IT professionals who may not be well-versed in CKD. The working group adhered to its guiding principles to keep approaches simple by focusing primarily on CKD and enabling health care providers to make informed decisions using real-world data from EHR systems. Health care organizations can expand their capabilities to include related conditions, medications, and interventions. The working group defined the CKD phenotype as follows: an eGFR of less than 60 mL/min/1.73 m2 in the most recent test, with at least one value less than 60 mL/min/1.73 m2 more than 90 days prior, and proteinuria presenting as a urine albumin-to-creatinine ratio (UACR) of more than 30 mg/g in the most recent test with at least one positive value more than 90 days prior. Patients having received a transplant or those on dialysis, will be flagged, and clinical sites will need to decide whether to include these data in the phenotype. Also, health care organizations will need to make assumptions on race and ethnicity when that information is missing from the EHRs. The CKD phenotype will be less sensitive and more specific if patients are assumed to be African American and more sensitive and less specific if patients are assumed to be Caucasian.

Dr. Drawz emphasized that proteinuria is under-recognized as a major risk factor for cardiovascular disease and CKD progression. The CKD Phenotype Working Group established a subgroup to provide insight into the issue of the concordance of dipstick or urine albumin (UA) and UACR data reported in EHRs. The subgroup found that the relationship between UA and UACR results is not well-described and that overlap exists between the descriptive categories (e.g., normal, A1; moderately increased, A2; severely increased, A3). In addition, clinical sites routinely reported UA results more often than UACR. Upon review of data from patients with concurrent UA and UACR results from three representative sites—University of Minnesota Medical Center, Cleveland Clinic, and Columbia University Medical Center—the Subgroup summarized that (1) negative UA results are likely to correlate to UACRs of less than 30 mg/g in 75 percent to 83 percent of patients; (2) trace UA results might correlate to an UACR of less than 30 mg/g in 50 percent of patients; and (3) UA results of 30 mg/g or greater would correlate to an UACR of less than 30 mg/g in 16 percent to 36 percent of patients. Dr. Drawz explained that sites will have the opportunity to make choices on including patients with trace proteinuria in their initiatives. In developing the CKD phenotype, the Working Group also discussed acute kidney injury (AKI) status. After assessing the pros and cons, the group decided to include creatinine values regardless of the AKI status, thus keeping the computable CKD phenotype model simple.

The next steps are to finalize the phenotype and input Logical Observation Identifiers Names and Codes (LOINC), Current Procedural Terminology (CPT), and International Classification of Diseases (ICD) codes. Following these steps, validations will be conducted at four clinical sites using the established protocol for index date, patient identification, and data (e.g., demographics, GFR, UACR, UPCR, and UA). Each laboratory value will be assessed for the number of patients with at least one measurement, number of measurements per patient, date of most recent measurement, and descriptive statistics. Patients will be staged based on their prior GFR and flagged based on their end-stage renal disease (ESRD) status (e.g., transplant or dialysis). In parallel, the computable CKD phenotype will be validated against manual chart reviews of seven to 10 patients at each stage of CKD, five to 10 patients who have received a transplant, five to 10 patients on dialysis, and 20 patients without CKD, all randomly selected. Reviewers will be blinded to the electronic phenotype and will record the most recent laboratory values from the charts.

Alternative Perspective: Portability and Implementation of Computable Phenotypes
Jyotishman Pathak, Ph.D., Cornell University

Dr. Jyotishman Pathak discussed the key features and objectives of the portability and implementation of computable phenotypes. He described the Electronic Medical Records and Genomics (eMERGE) Network, a national network

established in 2007 that is funded by NIH's National Human Genome Research Institute. The eMERGE network began with five academic and medical centers and has since expanded to include an additional seven clinical sites and two pediatric sites. Its initial focus was to leverage existing EHR and genomics data from institutional biorepositories for biomarker discovery. Many genome-wide association studies (GWAS) and other related genomic studies require high volumes of system controls to achieve statistical significance; a single institution would be challenged to provide an appropriate sample size—the eMERGE network provides a solution to this problem.

Dr. Pathak shared some of the work that the eMERGE Phenotyping Working Group is engaged in. The goals in developing any EHR-driven phenotype are to develop high-throughput semiautomatic techniques and algorithms that operate on normalized EHR data and identify cohorts of potentially eligible subjects based on disease, symptoms, or related findings. The goal of phenotyping in general is to maximize, with a high level of accuracy (e.g., positive predictive values [PPV]), the number of subjects who show common phenotypes (e.g., diabetes or congestive heart failure) and strive to achieve high sensitivity and reasonable PPV for those possessing rare phenotypes. Ideally, the objective would be to design an optimizable phenotype for increasing or decreasing PPV and sensitivities; however, biases may require selectivity for changes to PPV or sensitivity. Typical components of EHR-driven phenotyping algorithms should include billing, diagnosis, and procedure codes; laboratory values; medications; phenotype specific co-variates; and unstructured tests (e.g., pathology and radiology)—all organized into inclusion and exclusion criteria. In each algorithm development process, health care professionals who treat patients develop a draft phenotype algorithm based on these typical components. Data analysts or other IT professionals in parallel transform data through many iterations for the algorithm; this process is not scalable.

Participants were asked to consider ways eMERGE could facilitate and reduce the chasm of semantics to provide scalable phenotype algorithms—a phenotype algorithm existing as a Microsoft Word file is not scalable for informaticists. Dr. Pathak detailed an example of a scalable hypothyroidism algorithm developed in the eMERGE network using multicenter EHR data; the features of this algorithm could be adapted for a CKD model. Key lessons learned regarding algorithm design and transportability demonstrated that significant expert involvement is needed, the process is highly iterative and requires time-consuming manual chart reviews, and representation of phenotype logic is critical. In addition, unified vocabularies, data elements, and value sets; reliable ICD and CPT codes; and natural language processing (NLP) are important to achieving standardized data access and representations. The eMERGE Phenotyping Working Group modified the algorithm development process to minimize human input by using a semiautomatic execution model. The group identified four components of phenotype execution automation: (1) standards-based computable phenotype algorithms; (2) standards-based clinical data modeling and representation; (3) robust, scalable, and repeatable rules-driven phenotype execution; and (4) a publicly available library of phenotype definitions, both for human consumption and machine interpretation. The eMERGE Phenotyping Working Group has developed a phenotype execution and modeling architecture (PhEMA) tool that consists of authoring, clinical data repository, execution, and library modules, which leverage existing efforts in the computational community. Future challenges and opportunities include expanding computable representation of phenotypic criteria (e.g., NLP); incorporating all EHR and insurance claims data; incorporating advanced analytical methods for phenotyping; developing portability and scalability; and incorporating multicenter clinical studies and large-scale systems demonstrations.

Moderated Discussion and Feedback from Participants

Dr. Drawz asked about the information necessary to facilitate multisite validations of the CKD phenotype and address the scalability. Dr. Pathak suggested establishing common validation criteria that would be translatable across sites and identifying implementation challenges early.

In response to a question about the use of NLP or unstructured data, Dr. Pathak explained that the use of NLP in algorithm development depends upon the disease state and the phenotype. For rare diseases, structured data often are incomplete or have not been recorded. The eMERGE Phenotyping Working Group uses a stepwise approach; the benchmark is 95 percent specificity and sensitivity, and the group undoubtedly had to consider unstructured data for the algorithm in some cases.

Participants discussed the vision of a computable phenotype for CKD. In visualizing this process for CKD from a health

care provider's perspective, Dr. Drawz commented that most patients are not aware that they have CKD—it is an under-recognized condition. Although treatments are available, adherence to those treatments is low. The opportunity exists to systematically identify patients with CKD who are not receiving guideline-recommended therapies. On a research level, EHR data is complete, and establishing a standard phenotype would allow retrospective analysis across sites and studies to better identify CKD patients. Dr. Kawamoto added that the CKD phenotype would enable better diagnosis regardless of the type of medical practice.

Dr. Theresa Cullen asked about ways to expedite the work being done so that clinical sites and other health IT enterprises can benefit from the quality measures that have been developed and are in place. Dr. Pathak commented that the eMERGE Working Group believes the tools would bring added value; this message could be conveyed to health care organizations.

A participant asked about the exclusion criteria for single AKI events. Dr. Drawz stated that including AKI would increase the sensitivity, but excluding it entirely from the phenotype would be challenging.

In response to a question on the lessons learned in the development process, Dr. Drawz pointed out that the validation process will require participating sites to record information on IT communications so that other sites without the same resources could learn what was successful and what was not.

Dr. Cullen asked about best practices on data modeling. Dr. Pathak shared his experiences with Epic Systems Corporations' Epic modeling software and pointed out other groups, such as the Observational Health Data Sciences and Informatics (OHDSI) Consortium, the Clinical Information Model Initiative (CIMI), Health Level Seven (HL7), and Fast Healthcare Interoperability Resources (FHIR). Their concepts are overlapping, but they may not all follow a single approach. The key is to provide flexibility and support for more than one data modeling activity when developing the CKD phenotype. Dr. Kawamoto added that functional best practices would be better.

A participant asked about quality control and quality assurance measures that would guard against slow drifts and algorithm sustainability. Dr. Drawz noted that drift could be incurred with new measurements standards for the laboratory values, but probably not as much as what would be encountered from use of billing code data. The validations process would need to capture and correct drifts. Dr. Pathak pointed out that the role of phenotype metadata is critical. The Phenotype Knowledgebase (www.phekb.org) contains appropriately annotated metadata, and implementation results are provided for each version of the algorithm. Drift is captured and compensated for in each version of the algorithm. Dr. Kawamoto added that the process was labor intensive and accuracy levels should be kept to high standards. End users can help to identify problems early.

Part II: Development of an Electronic Care Plan for CKD

Overview of the CKD Care Plan Working Group and Progress to Date

Theresa Cullen, M.D., M.S., Regenstrief Institute

Dr. Cullen presented an overview of the CKD Care Plan Working Group, the progress, and the path forward. The working group focused on evaluating the current care plan standards and identifying the CKD-related elements that should be included in a comprehensive electronic care plan template. In addition, the group aims to (1) develop a plan that enables patients and clinicians to access, create, record, change, and receive key patient information and goals across settings and (2) establish a template that would be consistent with the U.S. Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology (ONC) certification criteria. To date, the working group has completed identifying and prioritizing essential and recommended data elements, as well as identifying standards. The group is filling gaps in existing standards and using the data elements as the foundation to design user-friendly Consolidated Clinical Document Architecture (C-CDA) compatible dashboards.

To improve planning for the CKD care plan and identification of the elements to be used, the working group developed personas and scenarios to support this work. Personas were developed depicting hypothetical people (personas) in situations (scenarios) that reflect common challenges regarding the transfer of key patient information to guide their decision-making process on data priorities and display options. The personas include clinicians (e.g., nephrologists,

primary care providers, and dieticians) and patients with varying stages of disease, comorbidities, and social circumstances. The scenarios reflect real-world examples. Patient interviews provided insight on their life and health goals, primary CKD-related concerns, barriers to managing health needs, and treatment options. This information further guided the working group's decisions on which elements to include and prioritize in the care plan. These examples are available to meeting participants upon request.

Subject-matter experts and patient representatives also were involved in making informed decisions for the CKD care plan data set. Information on goals, health concerns, interventions, and health status evaluation and outcomes, per the HL7 guidelines, was included. The working group prioritized these data into a minimum data set, priority A elements, or priority B elements. The minimum data set included data elements deemed necessary for most users, while priority A and B elements may only be needed in specific settings. The draft data set will be made publicly available within the next few weeks. In identifying data standards, the working group found that many areas were missing, including CKD education topics and renal replacement therapy (RRT) options. The group developed a minimum set of CKD education topics and RRT options and submitted these lists to the LOINC standards group for creation of LOINC codes. The early design efforts for the electronic care plan and C-CDA data still are under development.

The next steps will be to develop standards for identified gaps, conduct human factor and usability testing, and establish pilot sites for testing. The Veterans Health Administration (VHA), and Dr. Susan Crowley, VHA's National Program Director for Kidney Disease and Dialysis, and the VHA's Human Factors and Usability Testing Laboratories offered their support with the design aspects of the care plan. The next step is to propose a usable design that is consistent with current standards and test this design in the veteran population with input from health care providers and nutritionists. The VHA already is using the Virtual Lifetime Electronic Record Health Information Exchange program that shares C-CDA data throughout the U.S. Department of Veterans Affairs (VA) system. Several opportunities remain to be explored, and members of the kidney research community representing institutions that wish to serve as pilot sites are welcome to contact the NKDEP HITWG.

Alternative Perspective: Efforts to Promote Care Plans Standards Adoption and Implementation
Elizabeth Palena Hall, R.N., M.I.S., M.B.A., ONC (via WebEx)

Ms. Elizabeth Palena Hall discussed efforts of the Office of the National Coordinator for Health Information Technology (ONC) to promote adoption and implementation of care plan standards. The ONC is the principal federal entity that coordinates nationwide efforts to implement and use health IT and electronic exchange of health information. ONC has established the ONC Health IT Certification Program, which provides assurance to purchasers and other users that a system meets the technological capability, functionality, and security requirements adopted by HHS. Developing a care plan requires three components: inputs, which are the resources used to inform the care planning process; a process, consisting of the steps and actions taken to generate the care plan; and an output, the care plan, which is the direct evidence of having performed the process. A diverse range of health IT tools exists to support activities across the care plan model. In May 2016, HHS detailed its vision for a Comprehensive Shared Care Plan (CSCP) that was published in the February 2017 edition of the *New England Journal of Medicine Catalyst*. The CSCP is envisioned as a plan that uses IT to enable the clinical team to collaborate seamlessly to address the full spectrum of the patient's needs across all care settings and over time—a longitudinal person-centered care plan. Efforts to achieve this goal are ongoing.

Ms. Hall described examples of pilot care plans and implementations. In its care plan proof-of-concept project, which started in 2015, the Blue Cross Blue Shield Association developed a prototype to demonstrate how standards can be used to enable providers and payers in accountable care organizations and patient-centered medical care homes to identify and track which patients are in care management programs. The outcome of this project proved that sharing a digital care plan in a C-CDA care plan document template is feasible and that this type of exchange document aligns with existing health information technologies. The City of New York's Delivery System Reform Incentive Payment (DSRIP) Program is designed to improve care coordination and care management of Medicaid beneficiaries across 12 performing provider systems. This care plan implementation process is divided into two phases: Phase 1 pilots were conducted from January 2016 to December 2016, and Phase 2 pilots will extend from 2017 to 2020. Other care plan pilots that might be of interest to the CKD Care Plan Working Group include the HL7 Personal Advanced Care Plan; the National Council for Prescription Drug Programs' HL7 Pharmacy Electronic Care Plan, piloted by Community Care of North Carolina; and the Comprehensive Primary Care Plus model from the Centers for Medicare and Medicaid

Services (CMS).

Ms. Hall detailed the challenges and barriers to adopting a care plan. Although standards are available, there are too many to choose from, and additional testing, validation, and real-world implementation are needed for current standards. Health care organizations often implement robust care planning capabilities that do not use nationally recognized standards and most are not certified to the ONC 2015 Edition Care Plan certification criteria at this time. Building consensus on the use of these standards is critical. Policies to support electronic care planning between providers and individuals and acceptance of patient-generated information supplementing the care plan are lacking. Care plan adoption is hindered by governance barriers, such as limited consensus on the processes, procedures, and workflow to support longitudinal care plans and the need for consolidation and reconciliation of multiple plans. Operational and cultural barriers include variability in vendor adoption and implementation of care planning capabilities, lack of consensus on care plan component data sets, limited awareness of longitudinal care plans and consensus on their value, and lack of clarity on the role of care team members and outcomes. Financially, significant resources are necessary to build, maintain, and share care plans, and a business case model is needed.

ONC's call to action asks the kidney research community for continued validation and verification of the HL7 C-CDA care plan standard. In addition, more evidence is needed to determine whether C-CDA is scalable across various clinical settings and provider groups. Ms. Hall conveyed ONC's appreciation for the efforts of the NKDEP HITWG and its subgroups to advance and test a care plan in CKD populations.

Implementing HL7 FHIR® for Care Plan Interoperability
Viet Nguyen, M.D., Leidos, Inc.

Dr. Viet Nguyen presented on implementing HL7 FHIR® for care plan interoperability. The FHIR® standard builds on prior HL7 and American National Standards Institute (ANSI) data format standards and is designed for rapid implementation. Key differences from other tools are the focus on implementers, the targeted support for common scenarios, and leveraging of cross-industry web-based technologies, such as application programming interfaces (APIs). Content is freely available in FHIR® and is supported in multiple paradigms and architectures; FHIR® demonstrates best practice governance.

The FHIR® care plan resource, or common data model, describes how practitioners intend to deliver care to an individual patient, group, or community for a certain period. The resource has a computable structure, varying degrees of potential uses, dynamic care teams, and a care plan template; it also is multidisciplinary, references other care plans, and links patient conditions, goals, and activities. Additional details can be accessed from the FHIR® Foundation's website at build.fhir.org/careplan.html. Dr. Nguyen described the elements and referenced resources available in the care plan model to date and guided participants through a demonstration video (www.youtube.com/watch?v=mLsu8B37c20&feature=youtu.be) of a proof-of-concept FHIR® computable care plan developed for the VA.

As in the demonstration, a CKD care plan and care coordination model would be a computable, dynamic care plan created by patients and care providers and sharable across all care settings. The model would be able to link to quality measures and would be either specific to CKD or comprehensive to include other conditions, with the ability to link those conditions to goals, objectives, and activities of care. Future directions for the CKD FHIR® care plan and the kidney research community will be elaborating and diversifying the CKD use cases, defining data processes and data elements, performing gap analysis of care plan resources, testing and modeling the CKD care plan, creating the CKD care plan profile, conducting a FHIR® pilot demonstration with stakeholders, expanding stakeholders to include payers and researchers, and engaging with the FHIR community to improve the standard.

Moderated Discussion and Feedback from Participants

A participant asked about the value proposition and the best use of a care plan that would benefit the patient. Panelists emphasized that patient engagement is critical and noted that the NIDDK and the HITWG have embodied this philosophy throughout their activities in developing a CKD care plan. Furthermore, the CKD care plan would empower patients to be a part of their own care, and other groups are already working to develop an implementation guide for use

of common clinical data sets that patients can access, which will be made public by the end of 2017. They noted the challenge in engaging patients in the early implementation phase of pilot projects. The goal is to bring patients into the care planning process at a later stage of development.

In response to a query about ways that FHIR® could address problems relating to collecting relevant clinical data and delays in processing those data to drive existing quality improvement programs, Dr. Nguyen commented on efforts in place to support the clinical decision-making community within HL7. The FHIR® standard could build, teach, and train quality measures developers to capture relevant data elements on the front end. The leaders of the health services platform community will convene a meeting with registry providers in July 2017 to help them better understand FHIR®; these issues could begin to be addressed at this meeting.

Participants asked about the comprehensive approach, patient-centered aspects, and prioritization support for clinicians and about how the patient interview information would be linked within the CKD care plan. Dr. Cullen explain that the Care Plan Working Group focused on determining a minimum data set that would be transmitted into a C-CDA care plan; FHIR® also presents an opportunity to accelerate these efforts and supports prioritization. The initial patient interviews were limited and may not be representative of the CKD or ESRD population; additional assessments will be needed. Ms. Hall added that collection of patient-generated information (e.g.; patient goals and preferences) and social determinants information should be part of the care plan process and many of the care plan standards implementations have this data on their roadmap, albeit some implementations are focusing on patient-generated data in later pilot phases.

Participants lauded the efforts of the Care Plan Working Group and suggested developing a diagnostic tool for patients to capture information on lifestyle choices that would be used to inform their care. They also recommended that the CKD care plan model provide a core list of tasks for making informed decisions on transplants. Dr. Narva stated that the objective in developing a computable CKD care plan is to provide a product that is compact and usable, communicates the necessary patient information, and is not too prescriptive. Dr. Cullen added that the working group engaged nephrologists in various phases of development of the CKD care plan.

In response to a query about the role of the EHR following adoption of the CKD care plan, panelists commented that the EHR will remain the primary tool for managing patient information. The care plan and FHIR® are complementary to assist with transitioning patients from one care setting to the next and in decision making. The ONC is in the process of harmonizing the C-CDA and FHIR® standards.

A participant asked whether focus groups and usability testing will be conducted with providers to assess the care plan before implementation. Dr. Cullen explained that the VHA's Human Factors and Usability Testing Laboratories will conduct those tests and meeting participants interested in knowing more as the process progresses are welcomed to contact the NKDEP for more details.

The working group acknowledges the difficulties that persist in care plan reconciliations, including medications, diagnoses, and lab values. In addition, the working group is aware of the problem of clinical information overload and is still trying to define the best balance between providing adequate clinical data and usability for the busy clinician.

Part III: Development of a Business Case for CKD Population Health Management

Overview of the CKD Business Case Working Group and Progress to Date
Blake Cameron, M.D., M.B.I., Duke University
Nathan Brajer, M.D., M.B.A. candidate, Duke University

Dr. Blake Cameron provided an overview and update of the Business Case Working Group activities. He expressed appreciation to a subgroup of the Business Case Working Group, which has guided this effort. The goal of the Business Case Working Group is to develop a generalizable business case framework that will assist health care organizations in evaluating investments in new infrastructure and programs to support CKD PHM. The outcome will be a universal business case model and customizable tools for health care organizations. Dr. Cameron was joined by subgroup member

Mr. Nathan Brajer, who presented progress in developing an Excel-based CKD cost projection tools.

Mr. Brajer summarized that the Model, a population-level cost model, helps health advocates answer important questions by estimating current costs, future costs with no changes, and future costs with interventions. The Model software is ready for alpha testing, and organizations wishing to take advantage of this tool are encouraged to participate. The working group needs data and user feedback to refine the Model. Interested parties can contact the NKDEP HITWG; details about the Model can be found on the Duke Institute for Health Innovation website: dihi.org/projects/ckd-population-health-cost-model.

Mr. Brajer demonstrated the Model's software with an example, "CKD Population Health Cost Model." He emphasized that the software is simple and easy to use, accessible to anyone who utilizes the Microsoft Excel platform, and dynamic and flexible. The Model 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 and include the total CKD and ESRD cost breakdown, total cost projections, cost estimates per member per year, and drivers that affect changes in cost.

The next steps for the working group will be to conduct rigorous validations of the Model—opportunities are being explored with Duke Health, Geisinger, and the National Kidney Foundation. Efforts will continue to recruit alpha testers to further develop and validate the Model. Mr. Brajer noted that health care organizations systematically underinvest in CKD programs. Thus, the NKDEP HITWG and the Business Case Working Group have developed a cost model to help health advocates and decision makers realize the positive financial implications of investing in CKD population health programs.

Identifying High-Risk Patients—The Optum Experience
Paul Drawz, M.D., University of Minnesota

Dr. Drawz described the Optum–University of Minnesota (UMN) collaboration to identify high-risk patients. The CKD to ESRD transition may be the overarching challenge for the nephrology community. Per the United States Renal Data System's (USRDS) 2010 Annual Data Report (ADR), 43 percent of patients never received care from a nephrologist prior to starting dialysis, and 25 percent had not seen a nephrologist earlier than 1 year prior to starting dialysis. More than 75 percent of dialysis patients in the United States start the process with a venous catheter. According to the USRDS 2007 ADR, a large percentage of patients start dialysis in the hospital (i.e., crash into dialysis). The costs associated with the CKD to ESRD transition are very high. In the first month of transition, the patient's costs are $30,000 for commercial insurance plans (e.g., Optum) and $22,000 for Medicare Advantage. In addition, patients who transition as inpatients cost $36,000 more over the first 6 months than those who transition from CKD to ESRD as outpatients. These data clearly demonstrate that an opportunity exists to identify CKD patients, schedule nephrology visits, provide referrals for vascular access or transplants, and, at a minimum, provide referrals for home dialysis, peritoneal dialysis, or arteriovenous (AV) fistula vascular access.

Optum, a subsidiary of United Healthcare, proposes to identify high-risk patients with diabetes and hypertension and no prior nephrology care. They reported estimated costs for these high-risk patients as $1,500 to $2,000 per member per month. The Optum-UMN collaboration will merge two health information systems. Optum will identify high-risk patients, UMN will provide the clinical analyses and propose the necessary interventions, and Optum will provide the care coordination. The benefits to Optum will be slowing the disease progression and reducing inpatient transitions, which will, in turn, reduce costs. UMN will benefit from identification of a high-risk population, improved quality of care and care management, and increased referral for transplants.

Moderated Discussion and Feedback from Participants

Participants asked about including emergency room data to capture rapid kidney decline or AKI patients and whether clinical interventions will be performed without the aid of primary care providers or nephrologists in the Optum–UMN study. Dr. Drawz pointed out that rapid kidney decline could be modeled from EHR data, but the Optum–UMN collaboration will not collect those data. Initially, Optum proposed to identify all high-risk patients living in the state of Minnesota who fit the criteria and planned to contact patients through mailings to suggest renal assessments. UMN recommended obtaining consensus from the primary care organizations before contacting patients; these issues still are being resolved.

Dr. Cameron asked the participants whether the business case model was adequate to address the questions of decision makers regarding costs and return on investment (ROI) and, if not, what improvements could be made. Dr. Kawamoto commented that more payment incentives are available in inpatient settings, whereas outpatient centers try to be more cost efficient but lack incentives for these efforts. The ROI would be a challenge for some payers. Dr. Kawamoto also asked whether revenue enhancements for identifying patients who should be receiving treatment for CKD were included in the Model and suggested focusing on process measurements and not just outcome data. Mr. Brajer explained that this type of estimation had not been done, but the Model has the capacity to make those cost estimates with the necessary data inputs. In response to a query on how cost savings with a business case compared to savings from other interventions, panelists pointed out that small changes in the cost associated with patients with stage 3 CKD would compute to noticeable annual savings for the health care organizations, given the large number of patients who have Stage 3 CKD.

In response to a question about lessons learned from health care organizations' partnering with academic institutions, as in the Optum–UMN collaboration, Dr. Drawz explained that Optum first approached UMN with its proposal. Projects of this nature can be accelerated faster than in academic or governmental settings, but priorities may change and abruptly bring a stop to the work. Nevertheless, the resources that the health care organizations could offer are nearly unlimited, and opportunities are available to conduct interesting studies with common goals between the two parties.

A participant wondered whether the business case model would be able to assess data from a nephrology clinic where CKD patients had received nephrology care. Mr. Brajer explained that the current CKD Population Health Cost Model does not have the ability to make cost assessments for that scenario; he reiterated, however, that the platform is dynamic and flexible. Customization for individual projects can be performed if outcomes data are provided.

Part IV: Applying Health IT to Future CKD Research and Care

National Institutes of Health Common Data Elements: Communication and Coordination
Liz Amos, M.L.I.S., National Library of Medicine, NIH

Ms. Liz Amos described ongoing efforts at the National Library of Medicine (NLM), NIH, to support common data elements (CDEs) and the NIH CDE repository. Any clinical trial data lifecycle begins with metadata—data that provide information about other data; biomedical research data and metadata are governed by many rules. Use of CDEs frequently applies in the early stages of the clinical trial data lifecycle and in the design and documentation of the trial. Primarily, clinical trials data are stored at NIH's clinicaltrials.gov registry. Resulting data sets may be deposited in data repositories, and analyses and publications are housed in NLM's PubMed. Researchers may be required to submit to regulatory agencies a package consisting of data analyses and protocols. Future researchers wanting to reproduce, replicate, and reuse data from prior clinical studies would be challenged to do so if the documentation from the start of the study is not readily available. In this age of data sharing and data reproducibility, leveraging the power of organizations with health information is one way to begin to address these challenges. To circumvent data reproducibility issues, researchers should determine whether a standard metadata framework exists for their field of study, identify external policies that might govern data collection and reporting, and identify the metadata framework of the data repositories they are using.

Ms. Amos described an example of a research collaboration of an NIH-funded study in which five different nursing research sites in the state of Nebraska used CDEs to address the issue of data coordination and reproducibility. Health

status was compared across sites, and all sites used the same standardized measure of health outcome, Euro-Qol 5D. She briefly explained that the NIH CDE initiatives include collections that span across disciplines, domains, and diseases. Ms. Amos emphasized that these initiatives were developed with input from the scientific community and were vetted publicly. A complete list can be accessed on the NLM website: www.nlm.nih.gov/cde/summary_table_1.html.

To improve coordination of and communication about the use of CDEs across the NIH Institutes and Centers and the internal and external research communities, the trans-NIH Biomedical Informatics Coordinating Committee established the CDE Working Group in 2012. The CDE Working Group, which developed funding opportunity announcements for providing a platform to encourage the use of CDEs, has since been incorporated into the NIH Clinical CDE Task Force, a subcommittee of the Scientific Data Council. In addition, the NIH CDE Repository—a tool that allows users to search across CDE initiatives, harmonize differences, and create new CDEs—is available to the research community and can be accessed from the NLM website: cde.nlm.nih.gov/home.

Putting Patients at the Center of Kidney Care Transitions: A Patient-Centered Outcomes Research Institute Project
Jamie Green, M.D., M.S., Geisinger Medical Center

Dr. Jamie Green reported on a Patient-Centered Outcomes Research Institute (PCORI) sponsored project, PREPARE NOW, a study being conducted at the Geisinger Medical Center kidney clinics in collaboration with Duke University School of Medicine. She co-leads the study along with Dr. Ebony Boulware of Duke University School of Medicine. PREPARE NOW—which stands for Providing Resources to Enhance Patients' And Families' Readiness to Engage in Kidney Care: Break the News, Review Your Options, Weigh the Pros and Cons—is about putting patients at the center of kidney care. Geisinger, a physician-led integrated health system in Pennsylvania, is located in an area with a stable regional population and is nationally recognized for its innovative use of EHR. Dr. Green explained that many patients transition from CKD to ESRD every year, but treatment options differ, each offering advantages and disadvantages to the patient; the best choice depends on a variety of individual factors, such as personal goals and values. Most patients report being unprepared to make decisions about their treatment even after being under nephrology care for years. The difficulty in predicting which patients will progress to ESRD is a challenge for decision-making experts and health care providers, but the fact that nephrology providers often have not been trained on how to have these conversations with their patients is an additional challenge. The PREPARE NOW study is an initiative that proposes to put patients at the center of kidney care transitions.

The specific aims of this study are to (1) establish a Patient-Centered Kidney Transitions Care infrastructure that prioritizes kidney patients' informed self-care and treatment decisions and supports patients through their transitions across kidney disease stages by providing education, psychosocial support, and biomedical preparation; and (2) study the effectiveness of the new Patient-Centered Kidney Transitions Care infrastructure in improving patients' values-aligned kidney care, empowerment, and well-being. The study, which began in January 2016, is a cluster randomized controlled clinical trial of a health system intervention across eight nephrology clinics at Geisinger. Recruitment is being conducted through the kidney transitions registry, and the study is expected to have a total enrollment of approximately 1,000 patients. Data are being collected through questionnaires via telephone surveys and from EHRs. Patient-reported outcomes, biomedical outcomes, and measures of health system culture all will be collected during the study.

Dr. Green described the core health system intervention components. The intervention is composed of two parts: new health information tools, and new team members and programs—the patient remains at the center of the intervention. New team members and program interventions include a kidney transitions specialist or renal case manager, self-management and empowerment training for patients enrolled in the study, and shared decision making and psychosocial support that connects patients with peer mentors. Geisinger custom-built new health information tools to support patients and help personnel do their jobs better, which include a disease registry and risk prediction tool, tracking tool, a patient values survey tool, and a treatment preferences broadcast. The disease registry and risk prediction tool is located outside of the Epic EHR system but pulls data from the EHR to identify nephrology patients with a risk for progressing in their kidney disease. This allows renal case managers to find the highest risk patients and reach out to them. The tracking tool was designed to help case managers track individual patients and their desired treatment options. Treatment options are influenced by a patient-facing values survey tool, which allows patients to rate factors they may find important; this information is captured and fed directly into the EHR. The treatment preferences broadcast sends an

alert when the patient makes a treatment decision, posting ICD codes into the patient's "problem list," which caregivers and patients can view in the health portal.

Dr. Green explained that the PREPARE NOW project is a 5-year study and shared lessons learned from the study's first year. She emphasized the importance of getting leadership support to override roadblocks when implementing health information tools into clinical practice. In addition, researchers should engage stakeholders at all phases of the project, be flexible to change because IT development is an iterative process, and keep track of the established timeline. Dr. Green acknowledged the PREPARE NOW team and PCORI and thanked them for supporting the project.

Deploying Care Recommendations in the Electronic Health Record Using the HL7 FHIR® Clinical Reasoning Module
Kensaku Kawamoto, Ph.D., The University of Utah

Dr. Kawamoto discussed deploying care recommendations in EHR that are facilitated by the HL7 FIHR® clinical reasoning module. Two approaches currently exist for integrating CKD management guidelines into EHR: (1) a CKD management module that is integrated into the EHR but hosted centrally and accessed via the internet; (2) patient-specific care recommendations from the provider, with alerts and reminders posted to the EHR, which uses a centrally supported software service accessed via the internet. Not only are standards available for this type of interoperability across EHRs, but vendors also are beginning to coalesce in support of these standards. He used an example of an Epic EHR to demonstrate how a custom-designed CKD application containing information of interest to a nephrologist could be integrated into that specific EHR. The HL7 FHIR® Clinical Reasoning Module project team has encapsulated the logic for the demonstrated application into open-source software called Open Clinical Decision Support (OpenCDS). Dr. Kawamoto also demonstrated ways to integrate patient alerts and reminders into EHRs. Using OpenCDS, the team encapsulated the Centers for Disease Control and Prevention's Zika virus management guidelines for assessing risk into an application compatible with Epic and other vendor-supported EHRs.

Potential uses for OpenCDS applications for CKD include visualization of relevant data, development of patient-specific care recommendations, or creating EHR-integrated alerts and reminders related to gaps in care and self-management. Next steps include evaluating whether one or both approaches could help meet CKD needs, developing and disseminating capabilities, evaluating and improving existing methods, and advocating for more EHR vendor support in other areas of interoperability lacking full utilization.

Using Health IT to Engage Patients in Clinical Trials
Thomas Krohn, R.Ph., M.B.A., Antidote Technologies (via WebEx)

Mr. Thomas Krohn discussed ways to use health IT to engage patients in clinical trials. Much of the publicly available information about a clinical trial can be accessed from the study sponsor's website or clinicaltrials.gov and is primarily focused on compliance, the science, and the study objectives. A major challenge for patients today is that many of these informational resources are written from the points of view of the scientific and pharmaceutical communities, making it difficult for them to find accurate, complete, and personalized information. Patients often search for information using an internet search engine, which leads them to advocacy groups and then back to clinicaltrials.gov. Antidote Technologies, Ltd., a patient engagement IT company, begins to address this issue by developing ways to make the available content or medical research data usable.

Antidote's team of clinicians works collectively to bring semantic and syntactical order to the free text of the eligibility rules of clinicaltrials.gov by mapping this text to standard ontologies. This text then can be converted, using NLP and human curation, into patient-friendly questions. Antidote's ultimate goals are to help patients find studies relevant to them—Antidote Match™—and bring these trials to the patients—Antidote Connect™. This information also is provided to online health care organizations and patient advocacy groups, to help them serve patients. Currently, more than 100 partner organizations participate in Antidote Connect™. Mr. Krohn noted that Antidote has structured and made available to patients more than 50 percent of the studies currently recruiting in the United States, with plans to complete the match process by the end of 2017.

Mr. Krohn described another tool, Antidote Bridge™, that is used to provide patients with key practical information

(e.g., preset answers to questions) about the study that may not otherwise be available to them in plain language or may not be in the public domain. This tool also is provided free to study sponsors. Antidote aims to make as much information as possible available to those who need it—empowering medical research by helping patients. Understanding the role of health IT in engaging patients in clinical trials, Antidote is in the process of integrating its tools platforms at the point of care and has begun converting these platforms into APIs that will be made available to the health IT community. Additional information is available at www.antidote.me, or by contacting Mr. Krohn at tak@antidote.me.

Using Natural Language Processing to Understand the Epidemiology of CKD
Karandeep Singh, M.D., M.M.Sc., University of Michigan Medical School (via WebEx)

Dr. Karandeep Singh presented on ways for using NLP to better understand the epidemiology of CKD. He disclosed his relationships with Merck and noted that some of the findings in this presentation are unpublished work, which are subject to change after peer review. Dr. Singh explained that in determining the risk factors for ESRD, epidemiologists traditionally will generate risk factor data by following patients over time, noticing when some patients decline and others do not, and returning to patient questionnaires to determine which answers differed. Because prospective cohort studies are an ideal way to study risk factors and disease and they enable researchers to translate knowledge from the bench to the bedside, it is difficult to know whether researchers are asking the right questions or whether patients can be followed long enough to determine the answers. He also emphasized that epidemiologists may generalize findings to patients who were excluded from the prospective cohort studies. It is challenging for the kidney research community to apply findings from non-kidney-disease-related clinical trials because CKD patients often are excluded from large clinical trials for other conditions, such as cardiovascular disease.

Dr. Singh presented a case study of two patients with different clinical outcomes and explained that although clinical notes can illuminate why one patient had a worse outcome than the other, one bottleneck that results from unstructured notes is determining how to extract the data. MetaMap, a tool developed by the NLM for recognizing unified medical language system concepts in text, uses a knowledge-intensive approach based on symbolic NLP. This tool can be expanded to extract unstructured data from clinical notes and map the data to concepts related to CKD and to such risk factors as hypertension. Searching for predictors of health outcomes by considering multiple hypotheses is an idea borrowed from GWAS. To extend the idea to epidemiological studies, researchers can perform regression tests to test multiple hypotheses while adjusting for known risk factors that may confound the discovery of new relationships. He discussed results from a study he authored titled “Concept-Wide Association Study of Clinical Notes to Discover New Predictors of Kidney Failure,” published in the December 2016 edition of the Clinical Journal of the American Society of Nephrology.

In closing, Dr. Singh pointed out that this analysis also can be used to identify risk factors that predict medication non-adherence or understand other predictors of disease, especially now that 20 to 30 years’ worth of retrospective EHR data are available in my clinical settings.

Active Group Discussion

Dr. Drawz asked what drove the decision to situate the care coordination module outside of the Epic EHR system and whether attempts were made to house it internally in Epic. Dr. Green explained that this decision was prompted by the limited timeframe to develop this module and the challenge to make changes and organize the Epic systems in a timely manner. The potential to adapt a tool previously developed at Geisinger, called Supernote, to both pull data from Epic and support the entry of new fields that can be sent back into Epic was a viable option.

Participants lauded the efforts of the PREPARE NOW team in making successful strides in the first year of the study and thanked them for their efforts. They wondered whether the care coordination module was intended to serve as the foundation of a broader platform for disease management in general. Dr. Green responded that although her focus is nephrology, she expected that the functions that identify high-risk populations and treatment procedures and the care management module could be applied to other fields. In response to a question about publication and policy change possibilities, she affirmed that these data were intended for publication; the study is in the second of 5 planned years, so the study design will be published soon and other results will follow. Regarding policy, the study has partnerships with

numerous organizations that can help explore policy implications in the future.

Dr. Drawz commented on the insensitivity of billing codes to accurately identify AKI and CKD and wondered whether NLP could be used to identify these disease states in such cases. Dr. Singh responded that billing and procedure codes were used to initially identify outcomes in their concept-wide association study. Manual outcome validation showed that codes for ESRD frequently were recorded prior to patients' being started on dialysis, often in primary care visits or by a vascular surgeon performing an AV fistula. He noted work that Dr. Adam Wright at Brigham and Women's Hospital has done to identify CKD using the problem list. Dr. Singh and colleagues at the University of Michigan are planning to conduct similar studies with EHR data to determine precisely when patients are designated as having CKD.

A participant asked the NIDDK to comment on the existing dichotomy between granular and large-scale views of CKD when medicine is advancing quickly. Dr. Narva explained that the Institute's initial view was that the CKD Care Plan Working Group would be able to identify, in a short period, the elements related to CKD that would be part of a comprehensive care plan, but functional care plans for chronic disease are limited to nonexistent—those that do exist are disease-specific. Many patients with CKD have multiple diseases. He emphasized the need for a both single care plan that is not disease-specific and interoperability between the variety of settings where a patient may receive care. Participants emphasized the need for both detailed and broad views, because clinicians need standards that are both widely applicable and very detailed for individual patients. If researchers search for gaps and improve the system at these points, improvement will be incremental, but continual. Ms. Amos called attention to a resource, the Value Set Authority Center, which is provided by the NLM in collaboration with ONC and CMS and supports electronic clinical quality measures.

In response to Dr. Drawz's comments about ways to condense the outcomes from this meeting into a clear value proposition with one clear message and ways to use the ideas in this meeting to prompt real change in kidney care, participants emphasized the NIH's power to fund promising initiatives and utilize its strengths, such as the ability of the NLM to study population health. The opportunity is ripe for change in kidney care.

Dr. Narva asked about the relationship between CDEs and computable phenotypes and whether NLM would be the CDE clearinghouse. Ms. Amos explained that this initiative is very new and many CDEs are not yet in machine-readable formats. In an ideal situation, a clinical code would be attached to each element. Dr. Pathak called attention to such programs as NIH's All of Us and Big Data to Knowledge in regards to establishing a CDE clearinghouse, which would allow researchers to fulfill their responsibility of making computable phenotypes and other data publicly available.

Participants discussed the difficulty of utilizing the current level of technology to focus on the larger perspectives of patient-centered outcomes and patient engagement, and attendees commented on the need to push for more patient-centered ways of quantification and reimbursement.

Next Steps for Health IT in CKD Research and Care
Robert A. Star, M.D., NIDDK, NIH
Paul Drawz, M.D., University of Minnesota
Andrew S. Narva, M.D., NIDDK, NIH

Dr. Star remarked that one next step for the group is to decide on the appropriate patient-centered computer application to support CKD patient self-management. An integrated program that would provide details on preference, as well as prioritization of care, could be conceived as the ideal patient-centered app for CKD patients. Dr. Star thanked Ms. Norton, Dr. Narva, the organizers, the presenters, and other participants for supporting the meeting.

Dr. Drawz thanked the NIH for the opportunity to serve on the HITWG and Dr. Patel for his vision to explore health IT in the management of CKD. The objective is to keep the tools simple and available to the public. From a clinical research perspective, the data itself is the most powerful patient-centered tool, he added. NIDDK studies involving large cohorts should be linked to EHR data, and future randomized clinical trials should capture EHR data regardless of the experimental design. Dr. Drawz expressed appreciation to the organizers and participants for supporting the meeting.

Dr. Narva remarked on the work that has been completed within the past 2 years, which was reflected in today's

meeting. He thanked the participants for their efforts and Dr. Star for his continued support. Much remains to be done, and anyone is welcome to contribute to this open process to advance CKD care. The NIH appreciates the opportunity to facilitate this process.

Adjournment

The meeting was adjourned at approximately 2:45 p.m.