PARTNERS IN RESEARCH: Developing a Patient-Centered Research Agenda for Chronic Kidney Disease

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Chronic Kidney Disease (CKD) was the 9th leading cause of death in the United States in 2014.¹ In the U.S., more than 20 million people over the age of 20 have CKD. The highest rates of CKD are seen in individuals over 60 years of age,² and diabetes and hypertension are the most frequent causes of CKD in the U.S.² CKD and end-stage renal disease are very costly to treat. Medicare spending for beneficiaries ages 65 and older who have CKD, prior to reaching end-stage renal disease, exceeded $50 billion in 2014, representing 20% of all Medicare spending in this age group.² In addition, even though the end-stage renal disease population represents less than 1% of the total Medicare population, it has accounted for about 7% of Medicare fee-for-service spending in recent years (over $30 billion).²

Inequities in CKD and end-stage renal disease incidence, risk factors and disease treatment have been consistently reported in diverse socioeconomic racial and ethnic groups within the U.S. population.³⁻⁵ A recent study showed that rates of kidney function decline were higher in Blacks compared to Whites and that kidney disease incidence was higher in Blacks and Hispanics.⁶ Compared with White patients, Black patients are less likely to have pre-end-stage renal disease nephrology care,⁷ receive adequate dialysis treatment,⁸ have an arterio-venous fistula placed for dialysis access⁹ and have access to kidney transplantation.¹⁰ Moreover, non-English speaking patients with end-stage renal disease are less likely to be placed on a transplant list than English speaking patients.¹¹

Low socio-economic status is a well-known risk factor for CKD,¹² and has been linked to increase in albuminuria and low kidney function in multiple studies.¹³⁻¹⁷ Among patients at high risk of kidney disease, those without health insurance are more likely to die or to progress towards end-stage renal disease than insured patients.¹⁸ Likewise, increased neighborhood poverty is strongly associated with higher end-stage renal disease incidence and a lower chance of being placed on a transplant list.¹⁹,²⁰

Because CKD patients have multiple comorbid conditions, they see diverse healthcare providers in various settings, which can lead to adverse consequences such as conflicting medications and redundant testing.²¹ Poor communication between primary care physicians and specialists is an issue for patients with multiple comorbidities and may threaten quality of care.²²

Health care providers have different electronic health records systems that do not “talk to each other,” leading physicians to spend countless hours “chasing data” in order to provide appropriate care for their patients.

Additionally, the care of CKD patients – before and after starting renal replacement therapy (dialysis or transplantation) – remains highly fragmented, creating a high burden of disease on patients and the healthcare system as a whole.²³ For instance, most patients with CKD report having a primary care physician, but only a small percentage is likely to have seen a nephrologist. This lack of specialist care is most likely due to barriers such as insufficient insurance coverage or low awareness.²,²⁴ As illustrated in Figure 1, awareness of kidney disease is very low among individuals with low kidney function. Less than 50% of individuals with severe loss of kidney function (stage 4) are aware of their kidney disease.
Figure 1. Awareness of Kidney Disease Among NHANES Participants with CKD

Data Source: National Health and Nutrition Examination Survey (NHANES), 2001-2012 participants aged 20 & older. From USRDS 2016 Annual Data Report. NHANES is a representative survey of the United States population.

CKD stages represent levels of kidney function according to glomerular filtration rate (GFR) and presence of kidney damage such as albuminuria. Stages are numerated from 1 to 5, with 5 representing the lowest kidney function.

Stage 1: Kidney damage with normal kidney function: GFR ≥ 90 mL/min/1.73m²
Stage 2: Kidney damage with mild loss of kidney function: GFR 60-89 mL/min/1.73m²
Stage 3: Mild to moderate loss of kidney function: GFR 30-59 mL/min/1.73m²
Stage 4: Severe loss of kidney function: GFR 15-29 mL/min/1.73m²
Stage 5: Kidney failure: GFR <15 mL/min/1.73m²

Hospitalizations are frequent in patients with CKD. The rate of all cause hospitalizations increases with worsening of kidney function and with the number of comorbidities. The rate of hospitalizations for patients with CKD is as high as 430 per 1,000 patient-years. Cardiovascular events and infections are the most frequent causes of hospitalizations and death in CKD patients, and patients with CKD are more likely to die of a cardiovascular event prior to reaching end-stage renal disease than to reach end-stage renal disease.

Chronic Diseases and End-Stage Renal Disease in Delaware

Chronic diseases are prevalent in the state. In 2015, 25.2% of White, 27.1% of Black, and 16.9% of Hispanic/Latino adults were diagnosed with diabetes, cardiovascular disease or asthma, compared to 21.4%, 24.5% and 17.1% respectively in the United States. The prevalence of diagnosed diabetes among Delaware adults doubled from 4.9% in 1991 to 11.5% in 2015. Adults diagnosed with diabetes are more likely to be overweight or obese.
Delaware adults has more than doubled from 13.0% in 1992 to 29.7% in 2015.\textsuperscript{29} About 34.5% of adults in the state have high blood pressure, well above the national average of 30.9% and the Healthy People 2020 Target of 26.9%\textsuperscript{30} In addition, 17.6% of adults in Delaware self-report fair or poor health compared to only 12.6% nationally.\textsuperscript{28}

In 2013, there were 2,287 patients in chronic renal replacement therapy in Delaware. Of those, 46.1% were Black and 51.5% were White, 59.1% were male, 40.9% were female. The majority of the patients were in hemodialysis (63.9%), some in peritoneal dialysis (8.0%) and 27.9% had a kidney transplant. Diabetes and hypertension were the primary causes for ESRD in these patients and both were more prevalent among Blacks (38.1% and 28.5%, respectively) than among Whites (33.5% and 14.9%).\textsuperscript{2}

### Linking Data for Kidney Care

The project “Linking Data for Kidney Care,” led by Dr. Claudine Jurkovitz, MD, MPH, a senior Investigator in the Value Institute at Christiana Care, was awarded a two-year pilot grant from the Delaware Center for Translational Research (CTR) ACCEL Big Data Pilot program at the end of 2014. The objectives of this project are: (1) To build a CKD registry by joining the electronic health records (EHRs) of multiple sources to build longitudinal records of care for patients with CKD; (2) To reduce hospitalization rates of patients with CKD by predicting their risk of hospitalization within a defined time-frame after an office visit; (3) To examine transitions of care of children with CKD to adult care.

Care coordination is especially important for young adults with CKD who transition from the nurturing environment of pediatric care to the independent environment of adult care. Continuity of complex multidisciplinary care is therefore of concern for these patients.\textsuperscript{30} Many of these children, as they become young adults, may have impaired cognitive function leading to difficulty in keeping physician appointments and adhering to their medication prescriptions.\textsuperscript{31,32} Medication adherence is a major issue when considering the long term outcomes of young adults with CKD transitioning to adult care.\textsuperscript{33,34}

The ultimate long term goal of “Linking Data for Kidney Care” is to improve care coordination of patients with CKD by providing real-time access to patients’ information across providers. By linking data from the Nephrology Associates P.A., practice, the Christiana Care transplant practice and the records of the Nephrology practice at Nemours/Alfred I. duPont Hospital for Children, Dr. Jurkovitz and colleagues have illustrated a proof of concept for the patients with CKD in the State of Delaware by transforming these EHR systems into a common model and then merging disparate systems into a unified database. They hope to ultimately use this framework and the methods applied to build a statewide CKD registry. All of the partners involved in the pilot project use comprehensive EHR systems containing demographic, clinical, laboratory and treatment information. These records were linked to the records of the Medical Group of Christiana Care (MGCC) to explore follow-up of these patients, Christiana Care acute care to assess hospitalizations, the United States Renal Data System, for renal replacement therapy patient history, Medicaid claims data, for assessing resource utilization, and the Social Security Death Index (SSDI), to ascertain death. Analysis of the database is ongoing.
Eugene Washington Engagement Award

While the ACCEL Big Data Pilot Grant Program provided funds to develop the research infrastructure and preliminary data necessary to solicit independent external support to expand the CKD database to other sources of data and include real-time transactions, this funding did not support stakeholder outreach and engagement. The research team recognized that in order for a statewide CKD registry project to be successful and useful to patients and health care providers, they needed to solicit the input and buy-in of all stakeholders including patients, health care providers, payers, and administrators.

Aside from a few notable examples such as the Patient Centered Outcomes Research Institute (PCORI)-funded Patient Powered Research Networks, Big Data and registry projects are often undertaken without patient and key stakeholder input and buy-in despite the recent push for patient engagement and concerns regarding data security, privacy and stewardship. Developing patient and stakeholder trust and soliciting their input and direction are invaluable to understanding how to design and evaluate registries. For example, patients may have specific concerns about data security and sharing that they could not otherwise express. Other stakeholders, such as physicians and payers, may have an interest in patient perspectives, but not have the resources or knowledge of how to cultivate a group of actively engaged patients. Because of this, registries are often designed to address gaps in the evidence without significant input from patients, stakeholders, or knowledgeable partners.

In February 2016, a team of stakeholders led by Dr. Jurkowitz applied to PCORI for a Eugene Washington Engagement Award. The goals of the Eugene Washington Engagement Awards are to facilitate expansion of patient-centered outcomes research/clinical comparative effectiveness research (PCOR/CER) and to encourage active integration of patients, caregivers, clinicians, and other healthcare stakeholders as members of the research process (www.pcori.org). The project “Engaging Stakeholders for a Patient-Centered Research Agenda for Chronic Kidney Disease in Delaware” received two years of funding in the Spring of 2016. The overall goal of this project is to cultivate a network of stakeholders, patients, health care providers, payers, and hospital administrators, who are invested in using the Statewide CKD registry framework to design and implement PCOR projects for patients with CKD. More specifically, the objectives of this project are:

- To inform all stakeholders of the CKD registry project;
- To better understand which outcomes patients, payers, and physicians are most interested in, how a registry could be useful to them, and what additional data are important for PCOR in this community;
- To teach Academic and Community Investigators to conduct research and write grants together;
- To solicit feedback on research designs that could be used to compare outcomes; data security, sharing and privacy issues in the context of research projects; and registry sustainability for research.

Partnering with the Community

The project kicked off with a conference on September 16, 2016 titled “Partners in Research: Developing a Patient-Centered Research Agenda for Chronic Kidney Disease.” The purpose of
this conference was two-fold: first to inform stakeholders on the CKD registry project, on the state of CKD in Delaware and nationally, on the issue of disparity in CKD, on PCOR and CER in CKD, and second and most importantly to begin a conversation with patients, their caregivers, healthcare providers and all other stakeholders about research questions and outcomes that are most important to them. Morning speakers were followed by moderated afternoon workshops where stakeholders proposed research questions and outcomes of interest.

There were five separate workshops centered on CKD, one on transplantation, and one on dialysis. There were 10-14 participants per workshop and workshops were assigned based on preference.

Moderators encouraged all group participants to propose questions. During later analysis, keywords were assigned to each question then categorized into themes and the frequency of themes was analyzed. From a total of 122 proposed questions, 19 themes were identified: CKD education, communication/ care coordination, medication/treatment concerns, transplantation, CKD progression, CKD screening, Care systems issues, social determinant of health, physical activity, access to care, comorbidities, quality of life, mental health, caregiver/family concerns, acute kidney injury diagnosis, dialysis related issues, nutrition issues, CKD prevention, and CKD awareness. Questions related to CKD education and communication/coordination of care were the most frequently raised and were shared across 6 and 5 workshops, respectively. Despite being in geographically distinct groups, stakeholders raised common concerns: how to educate patients, physicians, and the community about CKD, how to improve communication between patients and providers and how to improve communication and coordination of care between providers (Figure 2).

Figure 2. Theme Importance According to Number of Questions
Coordination of care between primary care physicians and specialists was further discussed at the first Partners in Research Town Hall meeting on January 24, 2017. Patients pointed out that most of the time, they were in charge of keeping all their providers in the loop, and regretted that there was no direct and better communication between physicians. In many cases, faxing information from one practice to another is still used but is not a reliable method as paper can be lost and the information may not be entered into the electronic health record. Everyone agreed that improving electronic health records systems connectivity would be key, but other methods such as texting or emails could be used as long as the information was transmitted in a secure, confidential and reliable way.

Additional Town Hall meetings will be held on March 21, April 19 and May 24 and will cover topics such as comparative effectiveness research, end of life issues in patients with end-stage renal disease, and confidentiality and security of data. The goal of these town hall meetings is to engage all interested stakeholders in discussing these issues together. Too often, people tend to debate issues within their own professional group or network and are not afforded the opportunity to share their perspectives with others from different backgrounds.

The Partners in Research team is also preparing to begin the Community–Academic Partnered research training on March 2, 2017. The first session will include a discussion about the IRB and ethics in research followed by a review of community-based participatory research principles.
Subsequent sessions on March 16, March 21 and April 19 will focus on how to design a research question and specific aims, comparative effectiveness research, qualitative and quantitative methods, program evaluation, study design, and a dissemination of results panel discussion. The goal of this training is for the community and academic investigators to learn to design research projects and write grants together.

Finally, the Partners in Research leadership team is organizing a second conference, which will be held on September 15th, 2017, at the Christiana Care John H. Ammon Education Center. The second conference will focus primarily on information sharing and dissemination. The participants of the Community–Academic Partnered research training will report back about their experience in the training and the Town Hall meeting discussion points will be summarized.

These conferences and meetings bring together multiple stakeholder groups to better ensure that the CKD registry is designed to improve the health and healthcare of individuals living with CKD and that future research involving the CKD registry is generated from the common voice of all stakeholders. We anticipate that this will lead to patient-centered and comparative-effectiveness research that generates knowledge that is useful and pertinent to patients’ lives and directly impacts their health and quality of life.

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