



National Institute of
Diabetes and Digestive
and Kidney Diseases

Kidney Interagency Coordinating Committee (KICC) Meeting

The Pharmacist's Role in Chronic Kidney Disease (CKD) Care

Natcher Conference Center, Building 45, Rooms F1/F2
National Institute of Health (NIH)
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Welcome and Introductions

Andrew Narva, M.D., FACP

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

Dr. Andrew Narva provided a brief introduction to the KICC. Thirty years ago, the KICC received its mandate from Congress to meet annually for the purpose of encouraging cooperation, communication, and collaboration among all of the federal agencies involved in kidney research and other activities. Ten years ago, the KICC was revitalized, and now representatives from most federal agencies involved in kidney disease meet twice a year and communicate regularly between meetings, with the KICC providing an opportunity to talk frankly about the issues that they confront. Federal activities in response to CKD are multifaceted, including surveillance, professional education and outreach, delivery of and payment for CKD care, scientific research, quality improvement of therapy, and public education and outreach.

Dr. Narva noted that the proceedings of this meeting would be summarized and published online.

Dr. Narva invited the participants to attend the upcoming meeting titled “Using Health Information Technology to Identify and Manage CKD Populations,” scheduled for October 22–23, 2015, on the NIH campus in Bethesda, Maryland. The meeting will explore ways to advance the management of CKD using the tools of health information technology.

One of the goals of the National Kidney Disease Education Program is to support the role of pharmacists in CKD care. Pharmacists are a valuable resource with much to offer, but many physicians have a limited perception of the role that pharmacists should play, as was apparent from the proceedings of a recent advisory panel, comprised mostly of physicians, on increasing the role of pharmacists in CKD care. This meeting is intended to provide pharmacists with an opportunity to inform the KICC about how they might help to advance CKD care and improve outcomes, a precedent for which is represented by pharmacists in the Indian Health Service (IHS).

Are We Reaching Our Full Potential in CKD Care? Medication-management Services in CKD

Amy Barton Pai, Pharm.D, B.C.P.S, F.A.S.N., F.C.C.P.

Albany College of Pharmacy and Health Sciences

Dr. Amy Barton Pai presented information about how pharmacists can provide patient care to improve outcomes in patients with CKD, introducing two models of an advanced scope of practice for pharmacists in kidney disease care: the Veterans Administration (VA) and Canada. The challenge is to extend this model to the United States, primarily to the private sector. The most common cause of CKD is diabetes and hypertension; therefore, CKD is preventable. Less than 10 percent of patients with Stage 1, 2, or 3 CKD are aware that they have kidney problems, pointing to the need for more awareness and education, particularly when early detection can help prevent the progression of kidney disease to kidney failure. The public health impacts of CKD are large, with 26 million American adults having CKD, millions of others at increased risk, and end-stage renal disease (ESRD) rates that are not declining steadily. Patients are more likely to see their pharmacists regularly than their primary care providers.

Pharmacists can help in chronic disease management. Self-management and medication adherence, which together are necessary for chronic disease management, both are problematic, but the communication skills of pharmacists that are part of their education can benefit patients in these areas. Patient knowledge about CKD and medications is poor, as a study that interviewed Stage 4 patients about the purpose of their medications and their diagnosis revealed. Reasons to engage the pharmacist in chronic disease management include that pharmacists are highly accessible, pharmacists likely are seeing patients more

frequently than their primary care provider, and self-management and medication management are linked. Where allowed by law, some pharmacies are creating counseling areas for pharmacists to step out from the pharmacies and interact with patients.

Pharmacists have created complicated names for what they do, which creates undue confusion because all of these paradigms at the core refer to providing patient care. These paradigms include comprehensive medication management services (CMMS), collaborative drug therapy management (CDTM), and medication therapy management (MTM). Dr. Pai shared a video that was created to support the extension of CDTM in New York State. Originally, CDTM in New York was implemented as a pilot program that was restricted to teaching hospitals, but a bill was passed recently that permits CDTM to be practiced in all hospitals, diagnostic and treatment centers, hospital-based outpatient centers, and some nursing homes. Some progress has been made, therefore, but the primary goal remains to have community pharmacists involved in the care of patients with kidney disease.

The data on the effects of advanced pharmacy practices on patient outcomes are conflicting. A report to the U.S. Surgeon General illuminated the positive role of pharmacists (under CDTM) in the VA and IHS, whereas a report to the Agency for Healthcare Research and Quality (AHRQ) evaluating MTM indicates that relatively little benefit to the patient outcomes. This confusion illustrates the need for pharmacists to demonstrate improved patient outcomes from their care. Dr. Pai noted that many pharmacists do MTM, but not all of them collect data.

Dr. Pai illustrated the lack of a holistic understanding of the capabilities of pharmacists. A proposal for a study set in a community pharmacy to show that pharmacists provide effective, proactive, community-based, patient-centered care that will improve outcomes in patients with or at risk for CKD was submitted to the NIH for a planning grant for better CKD outcomes. Some reviewers characterized the proposal as innovative and pharmacists as well trained and accessible, but others revealed discomfort with the pharmacist providing direct patient care, asking what pharmacists would do for patients if they experienced acute distress and how they would refer the patients to the clinic for immediate attention or followup. The study's protection for human subjects was judged unacceptable.

Dr. Pai described public health screenings that are conducted at community pharmacies and involve pharmacy and nursing students. The students screen for high blood pressure, blood glucose, and proteinuria, as well as educate patients. The program illustrates that pharmacists can help improve public health.

Dr. Pai stated that a bill has been introduced in the House and Senate, the Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592-204, S. 314-30), which would allow pharmacists to provide services and bill, similar to nurse practitioners and physician's assistants, in underserved areas.

Discussion

- Dr. Michael Flessner commented that it was unexpected and unfortunate that the proposal was challenged on the grounds of inadequate protection for human subjects. The National Kidney Foundation's Kidney Early Evaluation Program (KEEP[®]) has been an ongoing program for approximately 15 years without institutional review board (IRB) approval. Pharmacists, nurses, and even volunteers have been screening individuals as part of KEEP[®].
- Dr. Kevin Abbott asked about how a pharmacist would approach a physician if a patient was experiencing side effects that might lead to a change in medication. Dr. Pai replied that academic pharmacists already have that care paradigm integrated, but other pharmacists need to build engagement with other providers because they are not in the same location. In New York, for example, community pharmacists are being trained to work with shared health information

portals. The portals provide a mechanism to deliver information to physicians. The goal is to facilitate communication and interaction from both sides.

- Dr. Susan Zieman asked Dr. Pai to describe CDTM in more detail. Dr. Pai responded that CDTM is individualized by state as a result of differences in legislation. It allows for an expanded scope of practice, typically including advanced prescribing privileges. In New Mexico, for example, pharmacists have a very advanced scope of practice. Pharmacists can obtain a clinician designation and establish their own practice. Pharmacists have collaborative agreements with a physician. The goal of expanding the scope of pharmacists' practices in New Mexico was to address the shortage of providers. New York is more restrictive and requires obtaining individual consent for each patient to have a pharmacist involved in his or her care. CDTM in New York, unlike New Mexico, also is restricted to certain locations. Typically in CDTM, pharmacists manage specific disease states within the context of medication management.
- Dr. Joel Andress stated that CMS intends to evaluate the effectiveness of medication reconciliation in ESRD care. The current measure for medication reconciliation is whether or not it has occurred. One of the strategies that CMS is pursuing to increase quality of care is care coordination. A barrier to care coordination has been barriers to interactions between dialysis facilities and external providers. Given that chronic disease management is comprised of self-management and medication adherence, patient adherence has been considered a significant issue and a reason that medication adherence is not primarily a responsibility of dialysis providers. Dr. Andress suggested that Dr. Pai's presentation delegates some of the responsibility for medication adherence—as well as other measures such as function, quality of life, and readmissions—to dialysis providers. Dr. Andress asked Dr. Pai for more detail on how she conceptualizes a more generalized responsibility for patient care for dialysis providers. Dr. Pai stated that determining an accurate medication list is the goal of medication reconciliation. She indicated that she and her colleagues had submitted a proposal to CMS for a pharmacist and pharmacist technician team to do medication reconciliation for dialysis patients. The grant proposed moving the billing for that service under Part B and suggested that the reduction in the total cost of care would cover the cost of the salary of the pharmacist and pharmacist technician. The grant was unsuccessful, however, and received the response that pharmacists should not be prescribing drugs. MTM was not considered by the reviewers as advanced practice, which indicates that pharmacists have not been able to communicate effectively the extent of their role in patient care. Dr. Pai stated that Dr. Dan Martinusen would provide more detail about the multifaceted impacts of his model for the role of the pharmacist in CKD.
- Ms. Nilka Rios-Burrows commented that the Patient-Centered Outcomes Research Institute (PCORI) might be able to help advance the application of the study to show that patient-centered care by pharmacists might improve outcomes for CKD patients. Dr. Narva indicated that there have been multiple funding opportunity announcements for type two translational research, including the one to which Dr. Pai applied. He added that PCORI funds such studies. The lack of success of the proposal suggests that in addition to building a community of researchers to study the effectiveness of pharmacists in providing care, a community of reviewers who understand the issues needs to be created. Otherwise, such proposals with nurses and pharmacists as principal investigators will not be successful. Another example of the issue of a restricted view of the pharmacist's role is the response to including eGFR in electronic scripts, which are seen by pharmacists. The National Kidney Disease Education Program (NKDEP) has explored this idea because pharmacists often are not aware that the patients they are serving have CKD. The concept was presented to an oversight group, but the response was that physicians would not want to be contacted by pharmacists. NKDEP also works with nurse practitioners, who represent an additional missed opportunity to contribute more to patient care.

Integrating Clinical Pharmacy Services in CKD at the VA—A Collaborative Approach

Chai Low, Pharm.D.

VA San Diego Healthcare System

Dr. Chai Low described the process of integrating clinical pharmacy services in CKD at the VA. The objectives of his talk were to describe the scope of clinical pharmacy services for CKD/ESRD patients at the VA San Diego (VASD), illustrate the collaborative approach to integrating clinical pharmacy services in CKD, review evidence of clinical pharmacy services affecting patient care in CKD, and identify opportunities and challenges for incorporating clinical pharmacy services in CKD.

Dr. Low provided information about the nephrology and clinical pharmacy services at VASD. VASD has 10 to 12 nephrology attending physicians and four renal fellows per year, an inpatient consult service, outpatient CKD/ESRD/post-transplant clinics, an in-house dialysis unit, and a small peritoneal dialysis (PD) program. Two full-time equivalent pharmacists at VASD provide inpatient care as integral members of the nephrology consult team; outpatient care, including medicine reconciliation and review; and care for ESRD patients, including for hemodialysis and PD patients. Nephrology-trained pharmacists include a pharmacist with a fellowship in nephrology, as well as a pharmacist with a postgraduate year 2 (PGY2) residency in critical care and nephrology. With the hiring of a second renal pharmacist, a new type of inpatient renal consult team was formed at VASD with the pharmacist serving as an integral member, conducting daily rounds with the renal consult team, reviewing medication charts, serving as a drug information expert, and acting as a liaison for transition of care when the patient is discharged.

To show the impact of pharmacists on patient care, data was collected for inpatient pharmacy interventions. Interventions were categorized—including drug interactions, dose/frequency adjustments, untreated diagnoses, adverse reactions, and duplications of therapy—and cost avoidance was calculated. Between December 1, 2010, and November 1, 2011, more than 400 interventions were documented, and more than 90 percent of these were accepted. The projected cost avoidance for 1 year after deducting the pharmacist's salary was approximately \$500,000.

VASD offers outpatient erythropoiesis stimulating agents (ESA) clinics for CKD patients where pharmacists practice independently in collaboration with a nephrologist. Patients are referred by nephrologists to clinics for evaluation. The scope of practice defines prescriptive privileges, clinical responsibilities, and oversight. Dr. Low shared the protocols for anemia management by iron therapy and Epoetin Alfa (EPO) dosing for CKD and dialysis patients. Outpatient ESA clinics evaluate the appropriateness for initiation of ESA/iron therapy, educate and counsel patients on the risks and benefits of ESA/iron therapy, initiate ESA/iron therapy per an established collaborative protocol, order labs for monitoring, determine follow-up frequency, conduct a medication review and reconciliation, and triage patients with acute conditions requiring medical attention. Currently, 80 active CKD patients on ESA are being monitored by these outpatient clinics, six to eight new consults are received per month, and patients are seen within a month of consult. Between 2008 and 2014, renal pharmacist encounters per year ranged from approximately 200 to almost 500 and currently average about 250 per year.

The outpatient CKD clinic is an access clinic for patients with advanced CKD, post-transplant patients, and fee-basis ESRD patients. It offers anemia management, medication review and reconciliation, recommendations for resolution of medication-related problems, and formulary management and prescription processing.

The ESRD program includes an in-house hemodialysis unit and has biweekly hemodialysis rounds with attending physicians. Management of anemia; bone dystrophy; and hypertension, diabetes, and other comorbidities is offered. The program also includes a monthly medication review reconciliation. Approximately 10,000 chronic hemodialysis encounters occur per year.

The PD program is small, averaging 10 to 12 patients seen monthly by an interdisciplinary team and monitored for anemia, mineral bone disorders, hypertension/diabetes, peritonitis, and medication review and reconciliation. The average number of encounters in the past 3 years has risen to approximately 350.

The total renal pharmacist encounters annually—including inpatient, outpatient, and dialysis clinic services—is approximately 1,500. A nephrology pharmacist at the VA spends the majority of his or her time as a clinician, but he or she also serves as an educator, counseling patients and teaching pharmacy residents; collaborates with research projects; and acts as an administrator. As a clinician, the renal pharmacist collaborates with a team of nephrologists, nurses, dietitians, social workers, and other pharmacists. Patients have expressed preferences for being served by the team rather than on a fee basis. The VA's nephrology pharmacist was recognized by an award from the Allied Health Professional award program, and Dr. Low was the recipient of the Under Secretary of Health's Excellence in Pharmacy Practice award in 2010. As an administrator/manager, the renal pharmacist participates as an integral member of the monthly dialysis continuous quality improvement (CQI) meetings, reviews and updates clinical protocols and guidelines, manages formulary processes, coordinates and designs order sets, and is involved in service expansion and improvement projects. Regarding the role of the renal pharmacist as an educator, the VA has offered an American Society of Health-System Pharmacists (ASHP)-accredited PGY2 Nephrology Pharmacy Practice Residency program since 2009. As an educator, the renal pharmacist also serves as preceptor for pharmacy students and PGY1 residents; is invited for renal grand rounds; presents seminars to renal fellows, nurses, and other pharmacists; and presents on medication management at national conferences. The renal pharmacist also is a researcher and scholar, contributing to new literature in nephrology, conducting collaborative research, serving as a research mentor for PGY1 and PGY2 residents, presenting research abstracts at professional conferences, and publishing research studies in peer-reviewed journals in collaboration with other medical professionals.

A review was conducted of 21 studies, only 4 of which were controlled trials and 7 of which were quantitative, of clinical pharmacy services in CKD and ESRD. The review found that the most common comorbidity managed by clinical pharmacists was anemia, the physician acceptance rate of interventions was 79 percent, and the most common drug-related problem was incorrect dosing. Almost all of the studies reported positive impacts as a result of clinical pharmacist involvement, but the authors of the review commented that more randomized controlled trials are needed to further determine the benefits of clinical pharmacy services.

A recent paper on clinical excellence in nephrology identified six domains to master. These qualities were communication and interpersonal skills, professionalism and humanism, knowledge, skillful negotiation of the health care system, scholarly approach to clinical practice, and exhibiting a passion for clinical medicine. Dr. Low focused on two of those domains: knowledge and skillfully negotiating the health care system. Regarding addressing gaps in knowledge, currently only two PGY2 pharmacy practice residency programs exist. A more broad-based training program is needed. A curriculum in renal pharmacotherapy for pharmacists is being developed, and a nephrology Practice and Research Network offers educational programs at American College of Clinical Pharmacy (ACCP) annual meetings. Regarding skillful negotiation of the health care system, pharmacists are poised to become actively involved in the care of the growing CKD patient population, but the Centers for Medicare & Medicaid Services (CMS) does not recognize the necessity of including pharmacists as members of interdisciplinary teams, so more advocacy is need for clinical pharmacy services to improve patient outcomes. Dr. Low estimated that a suitable ratio might be one renal pharmacist for every 150 to 180 active clinical patients. The justification for hiring a full-time pharmacist can be made by mapping all of the duties and responsibilities of the pharmacist during a 40-hour week.

Dr. Low concluded by pointing out the novel clinical pharmacy practice model in CKD, accomplished through collaboration, offered by the VA; citing current literature that supports positive patient outcomes

from clinical pharmacy services; and noting the need to address the opportunities and challenges of clinical pharmacy services.

Discussion

- Dr. Gregory Germino observed that the estimation of the cost savings from pharmacist interventions assumes that another medical professional would not have discovered the same error. Dr. Low agreed, but stated in the cases considered, the pharmacist was responsible for discovery.
- Dr. Flessner indicated that at the University of Mississippi, a pharmacist was integrated into the teams for dialysis, the transplant service, and occasionally the CKD clinic. An initiative at the NIDDK has been proposed to gather data on the use of drugs in continuous renal replacement therapy (CRRT) for intensive care unit (ICU) patients. It is difficult to predict the dosing of drugs in these patients because they are volume expanded and have poor perfusion of their liver and other organs. The goal is to produce an open-source model that doctors of pharmacy can use in ICU patients under CRRT. Dr. Low agreed that ICU patients are unpredictable in their response to drugs and noted that the literature provides very limited guidance on dosing. A need exists for more pharmacokinetic studies in this patient population. Dr. Susan Crowley, who also is at the VA, agreed that the model of having pharmacists participate in rounds in the ICU, as well as the ESA clinic, has proven very beneficial. She pointed to the need for more pharmacists to participate in ICU care. Pharmacists also would be an asset in rounds of dialysis patients and CKD clinics. They would be a strong asset for transition of care and medication reconciliation.
- The participants discussed the training needed for pharmacists to assist with CKD patients. Dr. Pai suggested that a more abbreviated training program than a full year of PGY2 training might be sufficient. Six weeks might be sufficient for pharmacists to become proficient in basic nephrology. Dr. Narva stated that at the IHS, a few months sufficed to train interested pharmacists. Dr. Pai noted that a pharmacist training program that is focused on dialysis exists, but a CKD management training program is needed. She added that the pharmacy workgroup had advised that to engage pharmacists to use more CKD knowledge, a training program should be structured around diabetes and hypertension care. The participants agreed that the key activities are locating pharmacists who are interested in learning about nephrology and creating demand from the nephrology community. Dr. Narva stated that NKDEP has focused on training generalists to provide care to patients with CKD. Training community pharmacists could enable them to address many patient issues (e.g., nonsteroidal anti-inflammatory drug [NSAID] avoidance).
- Dr. Narva observed that dialysis patients often receive care from a variety of providers. He asked Dr. Low how medication reconciliation is managed for patients who receive dialysis care outside of the VA and come to the VA for the rest of their care. Dr. Low responded that such patients, who might be seen no more than once per year at the VA, often provide a list of medications that is different from what is in their medical record. Patients are asked to bring in all of their medications. Medication reconciliation requires significant effort, but it provides value because it is safer to know what the patient is taking.
- Dr. Zieman asked how pharmacists interact with other providers when medication reconciliation is handled for patients with other chronic conditions such as diabetes. Dr. Low replied that the culture at the VA is such that other cosigners can be notified quickly. The pharmacist can communicate with the patient's primary care provider and identify them as a cosigner. Medication adherence is promoted by simplifying drug regimens. Dr. Robert Nee added that at

Walter Reed National Military Medical Center, the dialysis and transplant patient care teams include an embedded pharmacist with a doctorate of pharmacy who conducts rounds with the teams and shares the same electronic medical records. This model might be difficult to translate into private practice, however, where having an in-house pharmacist is unlikely and differences exist between medical record systems. Dr. Low responded that although hiring a pharmacist might be expensive, it might be more expensive over the long term not to employ a pharmacist, who can increase the quality of care while reducing costs.

- Dr. Address asked whether pharmacists are included in any of CMS' ESRD Seamless Care Organization (ESCO) projects. Mr. Tom Duvall replied that none of the ESCOs have a pharmacist. For the ESCO project and accountable care organization (ACO) programs in general, Medicare Part D is incorporated; therefore, the organizations are not at risk for financial costs of Part D. The general philosophy of CMS has been to provide financial incentives and allow care organizations to develop their own models. Addressing care models is something CMS will consider at a later date. Dr. Address countered that care organizations are at risk for the consequences of drug-related problems and are held accountable for them.
- Dr. Address also inquired whether there are data on the impact of medication reconciliations performed by a pharmacist versus a nephrologist. Dr. Narva observed that in his experience, nephrologists have too many patients who are taking too many drugs for nephrologists to perform medication reconciliations in dialysis units. Dr. Flessner stated that he performed medication reconciliations when he was part of a team in the dialysis unit that included pharmacists, nurses, and other medical professionals. He did not perform medication reconciliation for every patient but did do it for some. Dr. Narva responded that medication reconciliations can be done with different degrees of thoroughness. At the IHS, a pharmacist performed medication reconciliations at the dialysis unit. Dr. Pai agreed that a true medication reconciliation is time consuming, especially in private practice. She is writing a journal article on the relationships of pharmacists and pharmacist technicians that addresses the quality of medication reconciliations performed by pharmacists versus nephrologists.
- In response to a question from Dr. Abbott about whether there is a standardized approach to identifying medication interactions, Dr. Low stated that there is not a standard of care for CKD pharmacists. Measurable tools to assess the services rendered by clinical pharmacists in CKD care are needed. A participant stated that the two major electronic health systems have alerts for medication interactions, but these have not proven to be very effective and are ignored by many providers. Dr. Narva responded that the literature suggests that physicians ignore these alerts but pharmacists respond to the alerts.

Role of the Pharmacist in CKD Care—A Canadian Perspective

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Dr. Martinusen provided a perspective on the role of the pharmacist in CKD in Canada. His objectives were to illustrate the interprofessional collaborative relationship between the pharmacist and the rest of the renal care team in Canada, demonstrate successes and opportunities resulting from pharmacist involvement in CKD at the patient and population level, and help define the funding model for inclusion of pharmacists in CKD care. Dr. Martinusen serves as a clinical pharmacy specialist in nephrology; the chair of the Pharmacy and Formulary Committee of the British Columbia Provincial Renal Agency (BCPRA), the jurisdiction of which includes the evaluation of drug use, assessment of new drug use,

developing symptom guidelines, and restricting drugs; and an educator as a professor at the University of British Columbia and mentor to pharmacy residents.

Patients and community are at the core of the services that the BCPRA provides. The BCPRA operates under the auspices of the Ministry of Health and the Provincial Health Services Authority and prescribes how renal programs in the province are operated. The BCPRA funds and coordinates service delivery across six health authorities, 11 home hemodialysis training sites, 12 PD clinics, 13 hospital dialysis units, 14 CKD clinics, and 27 community dialysis units. The BCPRA's successes include delaying the progression of disease, as shown by the recent significant drop in the growth of dialysis; having one of the lowest ratios in Canada of dialysis stations per capita as a result of early intervention and the growing use of home-based therapies; achieving the highest rate of independent dialysis in Canada, including PD and home hemodialysis; operating the only province-wide registry in Canada for kidney and transplant patients; providing the most extensive financial support for renal medications in Canada in the interest of removing as many barriers to adherence as possible; and offering the first provincial medication reconciliation program for chronic outpatients, a vital service for kidney disease patients. Pharmacists are directly involved in many of these achievements.

The BCPRA hosts a website (www.bcrenalagency.ca) that provides resources, a significant number of which have to do with medications. The agency has developed "Best Practices: Kidney Care Clinics," which is a blueprint for what a kidney care clinic should look like and is available online. The best practices guidelines describes the role of the pharmacist in kidney care and the funding model and is one of BCPRA's most downloaded documents. The BCPRA also has developed a guideline for medication reconciliation in kidney care clinics.

A variety of partnerships and research linkages exist in which pharmacists are part of collaborative research teams. Organizations included among these partnerships and linkages are the Canadian Institutes of Health Research, Canadian Society of Hospital Pharmacists, Canadian Association of Nephrology Nurses and Technologists, Canadian Society of Nephrology, and Kidney Foundation of Canada.

Evidence exists supporting the beneficial effects of clinical pharmacists on patient care. A systematic review revealed that clinical pharmacists improved inpatient medical care with no evidence of harm. Clinical pharmacists interacted with the health care team on patient rounds, interviewed patients, reconciled medications, performed discharge counselling, and conducted followup. Although improved patient outcomes are most important, a study on cost avoidance showed the cost of drug-related problems to be \$1.33 for every \$1 spent on medications and that a pharmacist's care saved \$4 for every \$1 spent on medication. An investigation of the effectiveness of a pharmacist-managed diabetes clinic showed a significant decrease in microalbuminuria at followup. A position statement by the ACCP suggested the conditions that clinical pharmacists can manage in CKD, supported by improvements that have been seen in outcomes. A randomized, controlled study of patients undergoing hemodialysis who received pharmaceutical care demonstrated a decrease in the number of drugs used, cost of drugs, number of hospitalizations, and length of stay. A case example of anemia management showed reduced time to achieve anemia treatment targets and increased patient time within the hemoglobin target range, reduced within-patient variability in ESA dosing, a decrease in time spent by nephrologists reviewing and prescribing anemia therapy, increased career satisfaction for registered nurses and pharmacists involved in the delivery of protocolized anemia management, and substantial cost savings in drug costs alone. The benefits of protocolization to patients include a slowing of the rate of growth of dialysis; a decrease in the cost of treating anemia despite an increase in patient population; and a decrease in strokes, cancer-related deaths, deaths from all causes, congestive heart failure hospitalizations, and dialysis starts.

Renal patients benefit the most from the involvement of specialized pharmacists because renal patients suffer multiple comorbidities, are hospitalized often, and are prescribed many medications that change

frequently; therefore, they are at the highest risk of adverse drug events and medication errors. Renal pharmacists help to minimize the risk of falls, optimize anemia care, minimize drug errors, minimize drug-related adverse events, optimize medications, coordinate medication management, and educate patients and the health care team. The growth of the number of renal pharmacists has led to involvement in activities such as research. Current renal pharmacist-led research includes biosimilar use in nephrology; de-prescribing in chronic kidney disease; anemia management protocols; evaluation of cinacalcet use; design, implementation, and evaluation of a glomerulonephritis formulary, which has involved the development of the glomerulonephritis (GN) Network and Registry; and creating a framework for funding very expensive medications for rare diseases. Pharmacists' work in medication reconciliation and patient management has been recognized by Accreditation Canada, numerous journal publications, provincial patient safety and quality awards, and awards from the Canadian Society of Hospital Pharmacists.

Dr. Martinusen discussed the need to develop a standard of care before determining key performance metrics. In its standards of practice, the United Kingdom Renal Pharmacy Group stipulates that renal pharmacists assess the suitability of each drug given the patient's level of renal function, timing of each drug administration, potential for drug interactions, volume of preparations if the patient is fluid restricted, ability of the patient to comply with the prescription regime, and monitoring required. The authors of a 2013 *Canadian Journal of Hospital Pharmacy* article, titled "Standards of Clinical Practice for Renal Pharmacists," presented what activities a renal pharmacist must do and what constitutes a patient review. They outlined the steps involved in a renal pharmacist patient review, which they distinguished from a community pharmacist review. They stated that developing standards of clinical practice for renal pharmacists helps to standardize patient care, set program priorities, develop competency assessment criteria, and develop funding models to include pharmacists. A case example from British Columbia funded renal pharmacists and illustrated the savings that can be realized from different sources, including an anemia management protocol and a medication reconciliation initiative. Other CKD projects that resulted from achieving a critical mass of renal pharmacists include the GN Network; a standardized approach to identifying and funding treatment based on best evidence; a targeted approach to using new drugs for rare diseases (e.g., tolvapatan for autosomal dominant polycystic kidney disease [ADPKD]); and a project developing key performance indicators for renal pharmacists.

Funding models can be complicated. The number of pharmacists needed is based on the size of the clinic in terms of the number of patients served and the glomerular filtration rate (GFR) of patients, given that a patient with a lower GFR is likely to have a more involved interaction with the pharmacist. Time motion analyses were used to estimate the minutes per visit for different acuities of patients, from which the number of full-time equivalents of pharmacists for different sized clinics was estimated, ranging from 0.5 (for a small clinic) to 3 (for a large clinic).

Dr. Martinusen reviewed the pharmacy services prescribed in the BCPRA's "Best Practices: Kidney Care Clinics." The pharmacist and/or registered pharmacy technician should assist in assessment and care planning, patient education, and medication reconciliation and external linkages (i.e., liaise with community pharmacies and facilitate medication coverage).

Discussion

- Dr. Address asked about the development of key performance indicators for renal pharmacists. Dr. Martinusen replied that he would provide the contact information of the person developing these indicators to Dr. Address.
- Dr. Narva asked Dr. Martinusen to recommend approaches that the United States might take to emulate Canada in its use of pharmacists in kidney care. Dr. Martinusen responded that he

believes that pharmacists are interested, willing, and able to be involved in kidney care. Even pharmacists who do not work in a kidney clinic are trained in pharmacokinetics and expert in determining appropriate doses. Determining dose often pertains to understanding kidney function. Therefore, being involved in kidney care is not a large step for pharmacists. In Dr. Martinusen's own career, his work included endocrinology and cardiology, and patient care always involved nephrology. He acknowledged that patients with kidney disease are complicated, but providing basic good care is not too large a transition for pharmacists. Dr. Pai added that the primary cost savings for dialysis patients are as a result of avoiding hospitalizations. Pilot programs can be performed, validated, and disseminated. The main challenge has been the greater community seeing pharmacists as direct kidney care providers.

- There was recognition that patients need to be educated about the services that pharmacists can provide to them. That the doctor of pharmacy degree is the terminal degree for pharmacists is not widely known. Dr. Martinusen stated that traditionally, pharmacists are thought of as working in isolation, compounding and dispensing drugs. That no longer is an acceptable model, and pharmacists have become clinically focused. Dr. Narva added that NKDEP has developed material to enhance the role of generalist pharmacists in managing CKD.
- Dr. Nee noted that the need for pharmacists is greatest in disadvantaged, minority, and low-income populations. In these vulnerable populations, barriers exist for patients to have access to care. Medication adherence is an important issue to address in disadvantaged populations. Dr. Nee asked whether initiatives exist to address disadvantaged populations. Dr. Pai responded that Congress is considering a proposal to allow pharmacists to bill like nurse practitioners and physician's assistants in low-service areas. Such a proposal would provide a reimbursement mechanism for pharmacists' services as they evolve from being product-oriented to being clinical. Community pharmacists will be key in providing clinical care because of their large numbers as compared to academic pharmacists. Community pharmacists finish their education with a doctorate of pharmacology degree, but many become disenchanted because of limitations on their ability to practice. These limitations make students less interested in entering the profession. Dr. Martinusen stated that in Canada, pharmacists strive to ensure that cost is not a barrier for good kidney care. The BCPRA patient population includes First Nations members, who have high rates of diabetes and hypertension. In this population, traditional beliefs about medicine can become a barrier to care. Dr. Narva observed that IHS patients with diabetes now have a decreased risk of ESRD, in contrast to First Nations patients with diabetes, who are served by the Canadian Ministry of Health. Dr. Narva noted that many of the sites where high-risk populations seek care (e.g., the VA, IHS, community health centers) are more likely than a private setting to have a pharmacist or a dietitian on site. Therefore, targeting education at the generalist pharmacist or dietitian is likely to have an impact.
- Dr. Martinusen has previously advocated for pharmacists to have access to laboratory results, but physicians were reluctant for pharmacists to have such access because they did not want to be contacted by another health professional about a laboratory result that they already knew about. Now when a patient enters a kidney care clinic, a request is sent to the patient's community pharmacist to enter a note stating "Chronic Kidney Disease—consider renal dosing" into PharmaNet, the British Columbia provincial database of prescriptions. In this way, community pharmacists are triggered to have a conversation with the patient about dose and perhaps contact the prescriber if the patient is not aware of their level of renal function or if a dose change is required.
- Ms. Tonya Saffer asked whether pharmacists have enough information about a patient's kidney function to make basic interventions such as dose adjustment recommendations or whether

education is needed first. Dr. Pai responded that providing education, particularly to the community pharmacist, is something that is in development. Currently, community pharmacists must communicate with the prescriber to adjust dosages. Pharmacists in states with CDTM protocols have some autonomy. Dr. Pai stated that CDTM protocols vary from state to state, but pharmacists generally have the authority to call the provider to inform them that a dose is not correct for a patient. The challenge is to build a relationship of respect between pharmacists and providers. Most CDTM protocols require that a pharmacist check in periodically with collaborating physicians but the frequency varies by state (e.g., at the discretion of the team in New York, annually in New Mexico). Pharmacists act collaboratively as part of a health care team. Dr. Martinusen added that as clinicians, pharmacists tend to be conservative and believe in establishing dialogs with prescribers. Pharmacists usually are very conscientious about contacting prescribers about changes in dose even when they have the autonomy to do so. Ms. Rios-Burrows recounted an anecdote of an instance when a pharmacist was more knowledgeable than the physician and a better outcome would have resulted had the advice of the pharmacist been heeded.

- Dr. Andress stated that more efforts are being made within dialysis facilities to investigate how to prevent hospitalizations and readmissions of patients. A pilot program in West Virginia found a significant decrease in hospitalizations from care coordination and a nonsignificant but substantial decrease in readmissions. This study shows an interest in reducing hospitalizations and readmissions. If a connection can be made between involving pharmacists in kidney care and decreased hospitalizations and readmissions, it will create interest in this intervention in such settings as large dialysis organizations (LDOs). Dr. Martinusen responded that just focusing on medication reconciliation decreasing falls risk and hospitalization will reveal measurable differences.
- Dr. Narva stated that one of the grants funded by the NIDDK in its translational portfolio enabled a pharmacist to make a home visit to a CKD patient making the transition from the hospital to the home. The outcome of the study was successful, and the investigators received a grant from the state of Washington to extend the program to dialysis patients, which resulted in decreased hospitalizations.

Agency Updates

Mr. Duvall stated that the Comprehensive ESRD Care initiative is scheduled to begin the week following this meeting. The proposals of 13 ESCOs have been accepted by CMS, although some organizations have not completed their paperwork. Among these, there is good representation from LDOs, but there also are two non-LDO applicants. The program will be announced on October 4, 2015. Quality measures and financial methodology will be posted on the CMS website. CMS will be interested to determine whether the care model will provide better outcomes for dialysis patients. The ESCOs will have extensive data systems for sharing patient information, and CMS has provided them with historical claims information for their beneficiaries.

Dr. Crowley looked forward to the upcoming health information technology conference because health information technology will change the delivery of CKD care. For example, the VA already has an agreement with Walgreens to share health information; hopefully data sharing will be extended to other community pharmacies and providers. Dr. Narva noted that CKD patients obtain care from many sources; for them in particular, therefore, a need exists for integrated patient information systems.

Dr. Zieman indicated that the National Institute of Aging hosted a 1-day workshop in July 2015 on renal pathophysiology. It was dedicated in memory of Dr. Mahadev Murthy, who passed away suddenly in

May. Leaders from the field explored why the aging kidney becomes vulnerable to disease and what causes mineral and bone disorder in CKD. It is anticipated that the conference will lead to funding announcements.

Adjournment

Dr. Narva thanked the attendees for their participation. He noted that the next meeting of the KICC is scheduled for March 11, 2015. Tentatively, colleagues from CMS will discuss some issues facing the agency.