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New Models of CKD Care Including Pharmacists: Improving Medication Reconciliation and Medication Management

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Abstract

Purpose of review—Chronic kidney disease patients are complex, have many medication-related problems (MRPs) and high rates of medication nonadherence, and are less adherent to some medications than patients with higher levels of kidney function. Nonadherence in CKD patients increases the odds of uncontrolled hypertension, which can increase the risk of CKD progression. This review discusses reasons for gaps in medication-related care for CKD patients, pharmacy services to reduce these gaps, and successful models that incorporate pharmacist care.

Recent findings—Pharmacists are currently being trained to deliver patient-centered care, including identification and management of MRPs and helping patients overcome barriers to improve medication adherence. A growing body of evidence indicates that pharmacist services for CKD patients, including medication reconciliation and medication therapy management, positively affect clinical and cost outcomes including lower rates of decline in glomerular filtration rates, reduced mortality, and fewer hospitalizations and hospital days, but more robust research is needed. Team-based models including pharmacists exist today and are being studied in a wide range of innovative care and reimbursement models.

Summary—Opportunities are growing to include pharmacists as integral members of CKD and dialysis healthcare teams to reduce MRPs, increase medication adherence, and improve patient outcomes.

Keywords

Chronic kidney disease; healthcare models; medication therapy management; pharmacists

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Introduction

Patients with chronic kidney disease (CKD) are a complex population with significant medication-related problems (MRPs) and medication safety issues. MRPs can be classified into several categories [1], including adverse drug reactions, drug interactions, inappropriate doses, and suboptimal laboratory monitoring [2;3]. For example, the incidence of hypoglycemia in CKD patients increases as glomerular filtration rate (GFR) declines because of decreased insulin clearance [4;5]; however, many healthcare providers do not monitor glucose status closely. In addition, many hypoglycemic agents require dosage modifications or avoidance and few are used in CKD stage 5 patients. However, a wider range of agents could be safely used with appropriate monitoring by healthcare personnel with extensive knowledge of the pharmacokinetic and pharmacodynamic properties of these medications [6].

Poor medication adherence also presents a major challenge to achieving optimal CKD outcomes [7–12]. One study showed worse long-term adherence to key cardiovascular medications after myocardial infarction in elderly patients with lower levels of kidney function than in those with higher levels [7]. Higher rates of medication nonadherence have been associated with increased mortality risk in hemodialysis patients [13]. One large cross-sectional study observed associations between uncontrolled hypertension and CKD patients with greater medication nonadherence [14]. However, the greatest potential for reducing future morbidity and costs for end-stage renal disease (ESRD) care is to reduce the rate of kidney disease progression and incident ESRD cases [15]. Accordingly, this review discusses reasons for gaps in medication-related care for CKD patients, pharmacy services to reduce these gaps, and successful models that incorporate pharmacist care and reduce MPRs.

Causes of Medication-Related Problems and Suboptimal Adherence

MRPs for CKD patients must be considered in the broader context of our healthcare system. Effective medication management depends on optimal functioning of healthcare structures and processes. Over a decade ago, an Institutes of Medicine report highlighted the burden of medication errors in the US and brought the issue of patient safety to the forefront of healthcare policy debates [16]. In the US healthcare system, MRPs cause significant patient morbidity and mortality [17;18] and excess cost [19]. One in four ambulatory patients experiences at least one MRP [18], and MRPs cause up to one in six hospital admissions, most of which could be avoided [20]. MRPs may contribute to over 100,000 deaths annually and their economic burden on the healthcare system is estimated to be over $175 billion [19]. The IOM concluded that most medical errors resulted from a convergence of multiple contributing factors, and that preventing errors and improving patient safety requires a systems approach to address deficient healthcare structures and to modify conditions that contribute to errors [16].

Suboptimal medication adherence is one of the largest problems in healthcare today [21–23]. Survey data demonstrate that over half of the prescription medicines dispensed in the US are not taken as prescribed [24]. As many as 50% of prescriptions fail to produce the desired

results because of improper use, and 14% to 21% of patients never even fill their original prescriptions [21;25;26]. Numerous studies have demonstrated how nonadherence to medications accounts for worsening disease, death, and increased costs [21;27;28], particularly for patients with multiple chronic conditions and the elderly [29;30]. Cost estimates suggest that poor medication adherence accounts for one-third to two-thirds of all medication-related US hospital admissions annually, with resultant costs around $100 billion [21].

Because of this enormous impact, many researchers have sought to understand the contributing factors related to MRPs and poor medication adherence. Using semi-structured interviews, Rifkin and colleagues showed that CKD patients held medication beliefs and priorities that were discordant with conventional medical opinion, but rarely discussed with their physicians [31]. This study identified several patient concerns about medication use, including polypharmacy, medication prioritization, side effects, and barriers to discussing medication adherence with their physicians. These factors are mitigated and outcomes are optimized by effective interactions between patients, providers, and the healthcare system. Several unintentional and intentional patient-related factors affect adherence. Unintentional nonadherence relates to limitations in abilities and resources (e.g., forgetfulness, lack of information, emotional factors, low health literacy, cost); intentional nonadherence relates to motivations and beliefs (e.g., other priorities, decisions to omit, concerns about efficacy or side effects, lack of involvement in treatment decision-making). Although these barriers may be highly modifiable with appropriate interventions [21], physicians and other providers may contribute to medication nonadherence through overly complex prescription regimens, poor communication regarding medication benefits and side effects, ineffective therapeutic relationships, and failure to address medication costs or formularies. Healthcare system factors often include limited access to medications through restricted or frequently changing formularies, office visit time limitations, care by multiple physicians, and lack of health information technology.

Factors that optimize communication are increasingly the focus of multifactorial strategies to improve adherence by addressing cultural beliefs or attitudes, exploring patient barriers to adherence, and employing strategies such as the teach-back method. Potent strategies require effective communication to empower patients, educate them, and maximize their participation in medical decision-making. Regarding healthcare systems, team-based approaches expand the roles of nonphysician staff to evaluate medication use and problems, assist with patient education, and facilitate medication reconciliation. Closing gaps in medication-related communication is critical to improving medication adherence. Pharmacists are highly effective in addressing these barriers, but are often underutilized members of the healthcare team.

Medication Reconciliation and Medication Therapy Management

Closing medication-related communication gaps between CKD patients and their healthcare providers, and among the multiple providers who care for these patients, requires reevaluation of current US care models and of the team members traditionally included in these models. Many CKD patients are followed within primary care and internal medicine

practices, but are evaluated and managed by a variety of healthcare practitioners—an average of 4.7 (range 2–9) in one small study [31]. Often, electronic medical record systems used by various health practitioners and health systems are incompatible, requiring patients or caregivers to serve as the central conduit through which information flows. However, many CKD patients lack the necessary health and medication-related literacy to allow satisfactory communication with their healthcare providers [32].

An essential aspect of medication-related communication is an accurate medication list. The process by which this list is constructed is known as medication reconciliation [33]. To reduce risk of medication-related safety problems, it is critical that the medication list be updated at regular intervals and after any transition in care. Medication reconciliation is mandatory for hospital accreditation in the US and is included in the safety goals for ambulatory care settings [34]. A recent review of this topic suggested that approaches that use a multidisciplinary team (including a pharmacist) at hospital discharge work best to provide consistent services to all patients, and that these services may reduce hospitalization utilization costs [33]. A recent critical review of the medication reconciliation literature showed that the most successful interventions relied heavily on pharmacists [35].

Medication reconciliation by multidisciplinary teams at hospital discharge cannot meet the need for ongoing, regularly scheduled medication reconciliation for CKD patients in the outpatient setting. Ideally, medication reconciliation should occur along with regular medication review in the outpatient setting. Comprehensive medication review is the process by which the patient’s entire medication regimen is evaluated for effectiveness, safety, and convenience. The longitudinal process of assessing patients to identify MRPs, developing a care plan to achieve patient-specific goals, and performing follow-up evaluation is known as medication therapy management (MTM) [36].

MTM requires an advanced knowledge and skill set to assess each patient’s regimen in the context of his or her medical history, health literacy, and sociodemographic factors. Pharmacy curricula have been changing to emphasize patient-centered care. Pharmacists graduating in the past 10 to 15 years in the US with the entry-level PharmD degree have received broad training in the biomedical and clinical sciences, MTM, and patient-focused care. Although not all pharmacists can assume responsibility for patient MRPs, many seasoned pharmacists are advancing their knowledge and patient care skills through MTM certificate programs. Many new pharmacists are pursuing advanced postgraduate training programs in ambulatory care, community practice, or other specialty areas, and are becoming board certified and developing collaborative drug therapy management agreements with physicians [37].

MTM has been shown to improve clinical outcomes and reduce costs in the general population [38–43]. Researchers compared Blue Cross Blue Shield of Minnesota beneficiaries who had received MTM services by a pharmacist and similar beneficiaries who had not received such services, and showed significantly improved blood pressure and cholesterol measures and significantly reduced total healthcare expenditures for patients who received MTM services. In addition, total healthcare expenditure reduction exceeded the cost of providing MTM by more than 12 to 1 [38]. More recently, researchers evaluated

the impact of MTM (at least three MTM outpatient visits with a pharmacist) in high-risk members of a large employer group compared with propensity-score matched patients who were similar at baseline but did not receive MTM (n = 2250 patients in each group). Results showed that MTM significantly improved medication adherence and reduced hospitalizations and healthcare costs compared with no MTM. The program's return was double the investment [39]. Salgado and colleagues conducted a systematic review of pharmacist interventions in management of CKD patients [44]. They showed that pharmacist interventions may have a positive impact for these patients, but the evidence was sparse and none of the studies evaluated outcomes from comprehensive MTM services. No published studies have evaluated the effects of MTM on clinical outcomes and costs in CKD patients not yet receiving dialysis; however, two studies of CKD stage 5 dialysis patients lend support for MTM. A small randomized controlled clinical study by Pai and colleagues showed that identification and resolution of medication-related problems through pharmacist MTM services was associated with lower hospitalization rates and decreased drug costs [45]. Recently, results from a large observational study showed that integrated pharmacy services, including telephonic MTM by pharmacists, was associated with reduced mortality and hospital days [46].

Models that Incorporate Pharmacist Care and Payment Mechanisms

Multidisciplinary team models that include pharmacists have demonstrated significantly slower declines in GFR in both adult and pediatric nondialysis CKD patients, and shorter hospital stays for pediatric patients [47;48]. Estimates indicate that the additional salary costs of the multidisciplinary team (pharmacist, nurse, social worker, dietitian, data manager) could be recovered in one year if dialysis were delayed by one year in only 2% of pediatric patients [15].

A systematic review evaluating pharmacist interventions in controlled studies (688 patients total; 47 kidney transplant, 294 nondialysis CKD, 347 hemodialysis), showed reductions in all-cause hospitalizations (1.8 vs. 3.1, P = 0.02) and lengths of hospital stays (9.7 vs. 15.3 days, P = 0.06); reductions in the incidence of stage 5 CKD or death in patients with diabetic nephropathy (14.8 vs. 28.2 per 100 patient-years, $P < 0.001$); and a positive impact on blood pressure (mean systolic blood pressure 145.3 vs. 175.8 mmHg, P = 0.029), anemia (goal hemoglobin 69.8% vs. 43.9%, $P < 0.0001$, and serum phosphorus (1.81 vs. 2.07 mmol/L, P = 0.03) [44]. The pharmacist role included optimizing drug therapy, adjusting drug doses related to kidney function, laboratory monitoring, patient education, and medication reconciliation. Consensus papers further defining the role of clinical pharmacists in kidney transplantation and in nephrology have been published [49;50]. Other models of CKD pharmacy care have incorporated pharmacy technicians to generate medication histories for hemodialysis patients, an important component in the medication reconciliation process [51], and employed community pharmacists to identify MRPs in CKD patients using a standard set of criteria [52].

The appropriate number of full-time equivalent (FTE) clinical pharmacists per CKD patients is yet to be defined [15]. A funding model for clinical pharmacy services used successfully in one Canadian renal program supports one pharmacist FTE per 100 in-center hemodialysis

patients, or 200 home dialysis patients (peritoneal dialysis and home hemodialysis), or 300 stage 4–5 nondialysis CKD patients [53]. These funding ratios were not based on patient outcome data, but on ensuring equitable and consistent pharmacy care and a reasonable workload. It has been suggested that administrative data might help determine a ratio of allied healthcare professionals to CKD patients that is associated with acceptable outcomes and can serve as a minimum standard for healthcare funding [15].

Pharmacists in several countries, including the US, Canada, United Kingdom, Australia, and New Zealand, are now being remunerated for providing medication reviews [54]. Remuneration is typically based on a fee-for-service model, although a pay-for-performance model has also been suggested [55]. A recent meta-analysis of pharmacist-provided fee-for-service medication reviews found significant improvements in achievement of blood pressure and low-density lipoprotein cholesterol goals; 58% of the studies demonstrated improved medication adherence [54]. Many of these studies targeted patients with hypertension, diabetes, or both, and many included a smoking cessation component; hence, these programs could substantially delay CKD progression. Reimbursement models for pharmacist-directed MTM have also been successfully employed in the ambulatory care clinic setting with significant cost savings to insurers [41;56].

Due to growing evidence of the benefits of including pharmacists in chronic disease management programs more broadly, the 2003 Medicare Prescription Drug Improvement and Modernization Act mandated MTM services [57]. Services are provided by insurers primarily through community-based pharmacists in efforts to improve medication use to optimize therapeutic outcomes and improve medication safety. Initial requirements in 2006 were few, but requirements were expanded in 2010 to increase consistency among programs to deliver a minimum level of MTM services to eligible Medicare Part D beneficiaries. Most CKD patients with Medicare Part D coverage qualify for MTM services due to multiple targeted chronic diseases including chronic heart failure, hypertension, diabetes, and dyslipidemia; use of multiple medications covered under Part D; and covered Part D drug costs that exceed corresponding thresholds [58]. In 2012, Section 10328 of the Affordable Care Act further specified changes to Part D MTM programs to further strengthen the programs offered to Part D beneficiaries, and added ESRD as one of nine core conditions [59]. However, in 2016 coverage of phosphate binders and calcimimetics will shift from Part D to the ESRD Prospective Payment System, thereby lowering gross Part D drug costs for dialysis patients to such an extent that most of these patients will no longer qualify for MTM offered by Part D plan sponsors [59]. Other clinical and payment models should be considered to encourage dialysis providers to offer MTM services in the future.

New Models of Care: Including Pharmacists

Several implementations of team-based approaches that include pharmacists are practiced in clinical care, and more are being studied in a wide range of innovative care delivery models. Pharmacists have long been involved in the care of transplant recipients; however, their role in multidisciplinary transplant teams was mandated relatively recently [50] through changes in the United Network of Organ Sharing bylaws and Centers for Medicare & Medicaid Services accreditation standards. Several studies have demonstrated favorable effects of

transplant pharmacist involvement in addressing factors associated with allograft loss by improving education and medication adherence. Despite lack of such mandates for CKD and ESRD patients, similar observations in several studies indicate favorable effects of pharmacist involvement [60].

Recently, integrated pharmacy services to Medicare-covered dual-eligible dialysis patients (including medication delivery to dialysis units or home, refill management, prior authorization assistance, medication review with pharmacists on program entry, opt-in telephonic MTM with pharmacists) were shown to be associated with reduced hospitalizations and mortality [48]. If further research shows cost reductions or neutrality, this type of model could be scaled up and provided to all dialysis patients using a shared cost-savings financial model.

With early successes in establishing mechanisms to finance MTM programs, they will likely expand and flourish with corresponding changes that include adding structural mechanisms to achieve scale. The Affordable Care Act and Health Information Technology for Economic and Clinical Health Act also help expand use of health information technology, which will provide tools to process an explosive volume of available clinical data. MTM is a natural application of this data, allowing patients, providers, and insurers to better understand and use health information to its fullest potential. National efforts to increase implementation of electronic medical records and electronic prescribing may further increase adherence by identifying patients at risk or with suboptimal adherence, and targeting them for intervention [61]. Finally, several new models of pharmacy care are being evaluated within patient-centered care models, across care transitions through care coordination, and as part of accountable care organizations [62]. Together, these efforts to improve medication use through alignment of financing, regulatory incentives, and evaluation of new care models have tremendous potential to improve the quality of care delivery with a focus on improving medication adherence and safety.

In summary, pharmacists are ideal members of the healthcare team to address education and communication gaps between patients, providers, and healthcare systems that contribute to MRPs and suboptimal medication adherence. Because CKD patients have numerous comorbid conditions requiring many medications, their risk for such problems is particularly high. Across the spectrum of care delivery settings in the US, opportunities to include pharmacists as integral members of clinical care teams are growing. Newer models of care and reimbursement currently being evaluated in several studies and trials will help inform additional ways to incorporate these critical members of the healthcare team, who are especially well suited to designing effective, safe, and convenient medication regimens for CKD patients. Many opportunities exist for pharmacists who practice in primary care and community pharmacy to affect care of patients with early CKD. Nephrology clinical pharmacists can assist in educating their primary care and community pharmacy colleagues to include CKD assessment and management as an integral part of community-based MTM programs to aid in preventing and halting progression of CKD [49].

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62**. Tuttle KR, Tuot DS, Corbett CL, et al. Type 2 Translational Research for CKD. Clin J Am Soc Nephrol. 2013 Optimizing clinical outcomes for CKD will require that clinical evidence is effectively translated into clinical practice, yet few type 2 translational studies have been conducted. This review summarizes the critical elements of translational research, focusing on its phases, facilitators, and contexts. Examples from a portfolio of studies funded by the NIDDK illustrate the enormous potential of type 2 translational research for improving CKD care.

Key points

- Chronic kidney disease (CKD) patients are at high risk for medication-related problems (MRPs) and have demonstrated poor adherence to key cardiovascular medications.
- Current pharmacist training is focused on providing patient-centered care, identifying and resolving MRPs, and improving adherence.
- Medication therapy management (MTM) provided by pharmacists has been shown to reduce MRPs and improve medication adherence in CKD patients.
- Growing evidence indicates that pharmacy services and including pharmacists in clinical care models may result in a slower decline in glomerular filtration rate, reduced hospitalizations and mortality, and decreased lengths of hospital stays in CKD patients, but more robust translational research is needed.
- Scalable clinical care and reimbursement models are needed to fully address the complex medication-related needs of CKD patients.