Redefining Medication Management in Dialysis: A Kidney Pharmacy Quality Pyramid

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Patients with end-stage renal disease treated with dialysis are often prescribed complex medication regimens, placing them at risk for drug-drug interactions and other medication-related problems. Particularly in the context of a broader interest in more patient-centered value-based care, improving medication management is an increasingly important focus area. However, current medication management metrics, designed for the broader patient population, may not be well suited to the specific needs of patients with kidney disease, especially given the complexity of medication regimens used by dialysis patients. We propose a kidney pharmacy-focused quality pyramid that is intended to provide a framework to guide dialysis organizations, health care providers, and/or clinicians with respect to an optimal medication management approach for dialysis patients. Incorporation of core programs in medication management, including medication reconciliation, safety programs, and medication therapy management for patients at high risk for medication-related problems, may result in improved outcomes. Although a growing body of evidence supports the concept that active medication management can improve medication adherence and reduce medication-related problems, these strategies are viewed as costly and are not widely deployed. However, if done effectively, pharmacy-led medication management has the potential to be one of the more cost-effective disease management strategies and may greatly improve outcomes for these complex patients.

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A CHANGING LANDSCAPE AND THE MEDICATION MANAGEMENT OPPORTUNITY

In the context of a broader interest in more holistic value-based care, the potential for improvements in medication management is an important focus area. Within the drug and medical supply industries, pharmacy/prescription drugs (retail) represents the seventh largest medical sector spend in the United States. Despite this tremendous expenditure, there is significant room for cost savings and improvement in outcomes. Poor medication management is thought to be responsible for 125,000 deaths annually and contributes to an estimated 21% of hospitalizations, resulting in $100 to $289 billion per year of costs to the US health care system. Currently, the Centers for Medicare & Medicaid Services (CMS) requires Medicare Part D plans to have medication therapy management programs, but it remains unclear whether such programs have an effect on clinical outcomes.

As the dialysis industry begins to move from a fee-for-service platform toward integrated value-based care models such as End-Stage Renal Disease (ESRD) Seamless Care Organizations (ESCOs), nephrology professionals have an opportunity to simultaneously drive cost efficiencies and clinical outcomes. Medication management programs are one important mechanism by which to achieve these goals. Key components of a medication therapy management program are described in Table 1. A recent study found that among patients enrolled in ESCOs operated by a large dialysis organization and who were recently discharged from the hospital, participation in a multidisciplinary medication therapy management program was associated with a 50% lower hospital readmission rate compared to nonparticipation.

MEDICATION METRICS

Nephrology was one of the first medical specialties to use scientifically based clinical practice guidelines to inform population-based patient care. These are complimented by a set of performance measures that are intended to monitor the effect of guidelines on population-level outcomes. However, within the realm of medication management, quality oversight bodies such as CMS, the National Committee for Quality Assurance, the Pharmacy Quality Alliance, and the National Quality Forum have generally focused on non-nephrology disciplines to develop quality measures.

Quality measures developed by these organizations are currently used to create a “star rating” for Part D plans and/or Medicare Advantage plans. These quality measures emphasize elements such as customer service, patient experience, drug pricing accuracy, and safety (Table 2). Importantly, Medicare Advantage Plans, which are responsible for both medical and pharmacy benefits, have consistently higher scores than stand-alone Part D plans, which are responsible for the pharmacy benefit only. There is considerably more incentive for Medicare Advantage plans to deliver high-quality medication-related services because they can reap the benefit of reduced downstream health care costs.

At present, there are a handful of metrics that pertain specifically to medication management for dialysis patients. First, the CMS ESRD Conditions for Coverage require documentation of a quarterly medication reconciliation. Second, CMS requires that each dialysis
patient’s comprehensive plan of care include a medication history, developed within 30 days of admittance to a dialysis facility, and that the medication history be updated at least annually for stable patients or monthly for unstable patients. Although medication reconciliation is considered important and associated with improved outcomes, such reviews are often completed by dialysis facility nursing staff under the operational and financial constraints of dialysis providers. Furthermore, quarterly medication reconciliation may not be frequent enough. Some have suggested shorter intervals, although the optimal interval and post–transition of care episode for medication reconciliation have not been determined.

Beginning in 2022, CMS will require dialysis facilities to report on a new Quality Incentive Program measure with respect to medication reconciliation. This measure will describe the percentage of patient-months in a dialysis facility for which a medication reconciliation was performed and documented by an eligible professional. Within each facility, patients eligible for the reporting measure will be those who received a minimum of 7 hemodialysis treatments at the facility in the reporting month. Personnel who may perform medication reconciliation include physicians, registered nurses, nurse practitioners, physician assistants, pharmacists, or pharmacy technicians. Implementation of this new measure is consistent with the relatively high risk for medication-related problems among dialysis patients due to factors.

### Table 1. Medication Therapy Management Program

| Component                  | Description                                                                 | Timing          |
|----------------------------|-----------------------------------------------------------------------------|-----------------|
| Medication therapy management | Pharmacists or advanced practitioners address potential medication-related problems with patients and physicians in 3 steps: medication reconciliation, medication review, and issue resolution | Monthly         |
| Medication reconciliation  | Generate accurate and complete list of what medications a patient is taking, including prescription medications, over-the-counter medications, herals, and supplements | Monthly         |
| Medication review          | Review of medication list by advanced practitioners to identify medication-related problems such as gaps or duplications in therapy, kidney dosing/frequency issues, and contraindications | As needed, based on identified issues |
| Issue resolution           | Issues identified during the medication review are escalated to prescribers to resolve medication-related problems | Ongoing based on identified issues |
| Deprescribing              | The process of tapering, stopping, discontinuing, or withdrawing drugs, with the goal of managing polypharmacy and improving outcomes | Ongoing based on identified issues |
| Kidney-specific drug utilization review | Automated kidney clinical protocol performed runs on the patient’s medication list that flags potential medication-related problems that require resolution | Each time an updated medication list is produced |

### Table 2. Quality Measures Contributing to 2016 Star Rating for Medicare Part D Plans

| Measure                                                                 | Weight | 2016 PDP Average Score | 2016 MA/ PDP Plan Average Score |
|-------------------------------------------------------------------------|--------|------------------------|---------------------------------|
| **Drug Plan Customer Service**                                          |        |                        |                                 |
| Call center; foreign language interpreter and TTY available             | 1.5    | 4.0                    | 4.2                             |
| Appeals autofoward                                                     | 1.5    | 4.1                    | 4.5                             |
| Appeals upheld                                                         | 1.5    | 3.1                    | 3.3                             |
| **Member Complaints, Problems Getting Services, and Choosing to Leave the Plan** |        |                        |                                 |
| Complaints about the drug plan                                         | 1.5    | 3.5                    | 3.9                             |
| Members choosing to leave the plan                                     | 1.5    | 3.6                    | 4.2                             |
| Beneficiary access and performance problems                             | 1.0    | 3.9                    | 4.2                             |
| Drug plan quality improvement                                          | 5.0    | 3.8                    | 3.8                             |
| **Member Experience With Drug Plan**                                   |        |                        |                                 |
| Rating of drug plan                                                    | 1.5    | 3.2                    | 3.3                             |
| Getting needed prescription drugs                                      | 1.5    | 3.6                    | 3.4                             |
| **Drug Pricing and Patient Safety**                                    |        |                        |                                 |
| MPF price accuracy                                                     | 1.0    | 3.7                    | 4.5                             |
| High-risk medication for diabetes medications                           | 3.0    | 3.1                    | 4.1                             |
| Medication adherence for hypertension (RAS antagonists)                 | 3.0    | 2.7                    | 3.9                             |
| Medication adherence for cholesterol (statins)                          | 3.0    | 3.6                    | 4.1                             |
| Medication adherence for cholesterol (statins)                          | 3.0    | 3.5                    | 4.0                             |
| MTM program completion rate for CMR                                    | 1.0    | 2.3                    | 2.3                             |

Abbreviations: CMR, comprehensive medication review; MA, Medicare Advantage; MPF, Medicare Plan Finder; MTM, medication therapy management; PDP, Part D Plan; RAS, renin-angiotensin system; TTY, teletype writer.

Data source: 70. Measure added in 2016 with a default weight of 1.0; weight may increase for 2017 star ratings.
including polypharmacy, multiple comorbid conditions, and lower health literacy.

Although dialysis-specific measures are being developed, some of the Medicare Part D quality measures developed for the general patient population may be inappropriate for dialysis patients. For example, some pharmacy benefit management companies impose direct and indirect remuneration fees based on nonadherence to renin-angiotensin-aldosterone system inhibitors, statin medications, and diabetes medications, and although dialysis patients may qualify for these measures based on their comorbid conditions, data are lacking regarding the efficacy of these agents in the dialysis population, resulting in challenges in designing metrics that are clinically appropriate for dialysis patients. For example, although a direct and indirect remuneration fee may be tied to nonadherence to statin therapy, current evidence suggests that despite lowering low-density lipoprotein cholesterol levels, statins have little or no effect on cardiovascular outcomes among dialysis patients. Clinical guidelines in dialysis were recently updated to reflect these findings.24-30 It is clear that a more kidney-specific approach to medication management, accompanied by more thoughtfully designed metrics, is required.

**MEDICATION-RELATED ISSUES IN DIALYSIS**

The clinical complexity of dialysis patients places them at risk for polypharmacy and medication-related problems. Dialysis patients typically have 10 to 12 prescription medications, resulting in an average burden of 19 pills per day. These prescriptions arise from an average of 4 to 5 different prescribers.31 Many of the oral medications are large pills that may be difficult to swallow.32-34

Polypharmacy has been variously defined as the use of multiple medications, potentially inappropriate multiple medications, and the use of multiple pharmacies.35 Each of the items forming these definitions has been associated with poor outcomes, including higher costs, higher rates of adverse drug reactions, reduced medication adherence, lower quality of life, and increased hospitalizations and mortality.36-39 Most dialysis patients interact with multiple health care providers, increasing the risk for using multiple pharmacies and the risk for therapeutic duplication of medications.40 Polypharmacy, combined with a high pill burden, may have a considerable impact on medication adherence.41-43 Programs geared toward the reduction of polypharmacy can be effective independently of other medication management programs (reviewed in 31). Deprescribing is the process of tapering, stopping, or withdrawing drugs with the goal of managing polypharmacy and improving outcomes.44 A recent quality improvement study demonstrated that a targeted deprescribing program reduced inappropriate use of quinine, diuretics, α1-blockers, and proton pump inhibitors among hemodialysis patients.45

Medication-related problems are often defined as “undesirable events experienced by the patient that involve, or are suspected to involve, drug therapy and that interferes with achieving the desired goals of therapy.”46(p 143) Medication-related problems can be further classified into groups, such as issues with dosing, adverse drug reactions, high-risk medication identification, and drug-drug interactions.47 Medication-related problems are both common and costly; a review of more than 677,000 elderly patients receiving prescriptions through Medicare Part D in 2008 revealed that nearly one-third were receiving medications deemed potentially inappropriate for this age group.48 A recent systematic review of both prospective and retrospective studies showed that the median rate of hospital readmissions due to medications was 21% (range, 3%-64%), with a median of 69% of readmissions (range, 5%-87%) considered preventable.2 Recent estimates suggest that 2.4% to 4.1% of all hospitalizations are related to possible adverse drug events and poor adherence, and a high proportion of adverse drug events (up to 69%) are thought to be preventable.21

Disease-specific programs that allow for pharmacist review of medications may be able to reduce medication-related problems and improve outcomes.47 For example, one study of more than 120,000 incident hemodialysis patients found that digoxin use was associated with a 28% increased risk for death, and that an elevated serum digoxin concentration was significantly associated with mortality, most markedly in patients with lower predialysis serum potassium levels.49 A recent review found guideline nonadherence in dosing for kidney function ranges from 19% to as high as 67%.50

In the dialysis setting, studies have supported the use of medication therapy management as an effective tool for the identification and resolution of medication-related problems.22,51 In a 2-year randomized controlled trial, 104 hemodialysis patients were either given in-depth bimonthly medication therapy management conducted by a clinical pharmacist (pharmaceutical care) or brief medication therapy reviews conducted by a nurse (usual care). The pharmaceutical care group was associated with fewer hospitalizations per year.52 Similarly, a meta-analysis of dialysis patients who had been discharged from the hospital within the prior 30 days found that those who underwent a pharmacist-led medication therapy management encounter tended to have lower rates of rehospitalization than those who did not.53

**A KIDNEY PHARMACY QUALITY PYRAMID**

In the rest of this article, we describe a dialysis pharmacy-focused quality pyramid (Fig 1), similar in concept and design to a previously developed dialysis-focused quality pyramid.54 The programs and initiatives included in the pyramid are based on the latest clinical evidence and are mapped to dialysis-specific outcomes that are most likely to be affected by optimal pharmacy care. The pyramid is intended to provide a framework to guide a dialysis organization, health care providers, and/or clinicians with...
respect to an optimal medication management approach for dialysis patients. Ultimately, the goal of the pyramid is to improve the patient’s health and quality of life by increasing adherence while reducing polypharmacy and identifying and resolving medication-related problems. These aims are achieved by leveraging specially designed medication management programs within the pyramid structure.

The “Fundamental Programs” at the base of the pyramid support patient safety, program quality, and the overall patient and prescriber experience, representing the baseline level of care that must be delivered. Without these programs, the chances of successfully improving dialysis patient outcomes through medication management are slim.

Medication reconciliation, or the process of creating an accurate list of the medications a patient is taking, is the key process that paves the way for optimizing medication management. Medication reconciliation programs should be offered in accordance with CMS and other governing body requirements, but with an eye toward creating encounters that maximize clinical benefit. Medication reconciliation may be most effective when carried out by pharmacy personnel who are familiar with trade name and generic medications and understand how best to develop a reconciled list. Patients considered to be high risk due to being new to dialysis, having recently been discharged from the hospital or a rehabilitation or nursing facility, or having a particularly high number of medications should be prioritized. Such patients may be particularly likely to have received inappropriate medications or conflicting/unclear medication instructions arising from contact with more than 1 prescriber; such issues should be a particular focus for the medication reconciliation. Engagement with nondialysis providers may be of particular importance in this circumstance. Personnel conducting medication reconciliation should be trained in behavioral and motivational interview techniques. Toolkits are available to assist dialysis units in developing a robust medication reconciliation process. Patients need to be educated to bring their medications to dialysis at least monthly or after a hospitalization so that medication reconciliation can be efficiently accomplished. The patient should be given a copy of their reconciled list to share with other prescribers.

A safety and quality board with representation from across the care team should be convened on a routine basis. The board should review matters such as adverse events, new medication offerings, drug warnings, and opportunities to educate patients and prescribers, and prescription dispensing occurrences. A robust medication-related research program and an analytics platform should be maintained to develop new programs, study the impact of current programs, stratify patients by risk, and describe their experience. Monthly reporting of adherence, occurrence of
medication-related problems.35,57 This approach to medication therapy management can improve care coordination, reduce the use of inappropriate drugs, and reduce risk factors for hospitalization. In the era of value-based care, being able to predict which interventions or programs are most likely to be impactful for specific patients is critical to guide resource utilization.60 Medication therapy management should focus on opportunities that generate the greatest impact from a clinical and cost perspective.53,62 Because medication therapy management programs are considered expensive in the capitated fee-for-service landscape, care must be taken to apply them where most beneficial. Target populations may include patients initiating dialysis, those recently discharged from the hospital or other care facilities, those with multiple comorbid conditions, and those with multiple medications, known medication adherence issues, poor health literacy, and/or significant financial constraints.63 Medication therapy management services should aim to increase adherence to medications that, in the context of a patient’s particular circumstances, seem most likely to improve either clinical outcomes or quality of life. For example, renin-angiotensin system antagonists may diminish harmful pathophysiologic processes in some dialysis patients.64-66 In addition, proper use of high-risk medications such as anticoagulants could help avoid complications such as excessive bleeding. Programs that drive selective adherence to critical medications may bring more value than generalized adherence strategies. Adherence technologies such as smart pill bottles and mobile phone apps may also be beneficial, although direct evidence supporting the use of these technologies in the dialysis population is not yet available.

MEASURES OF EFFECTIVENESS

Measures of effectiveness allow for assessment of the impact of the lower tiers of the pyramid on key health outcomes.67 Given that there is significant mortality risk associated with a single missed dialysis treatment68 and hospitalization has long been a surrogate marker for heightened mortality risk, these metrics are important readouts for the efficacy of medication management.
programs. Alleviation of symptoms is important to dialysis patients because this can improve their quality of life. Hemodialysis patients believe that the symptoms of fatigue, insomnia, and muscle cramping should be prioritized for therapeutic intervention, either with improved dialysis methods or with medications. There is a critical need in the dialysis field for the development and implementation of patient-reported outcomes measures to evaluate medication therapies.

**DISCUSSION**

Patients being treated with dialysis take numerous daily medications and are more likely than other patient groups to experience drug-drug interactions and adverse effects due to changes in medication pharmacokinetics and pharmacodynamics in patients with severe decreased kidney function who receive dialytic therapies. Although a growing body of evidence supports the concept that active medication management can increase adherence, reduce medication-related problems, and improve outcomes, these strategies are viewed as costly and are not widely deployed. However, if done effectively, pharmacy-led medication management has the potential to be one of the more cost-effective disease management strategies with the potential to greatly improve outcomes for these complex patients.

Going forward, it will be critical to target resource-intensive medication management programs to patients who are at highest risk for adverse events and who stand to benefit the most from such interventions. Among high-risk patients, the cost of applying medication management programs may be offset by reductions in hospital admissions or readmissions or through reduced medication cost. Recognition of the benefits of a more holistic approach to medication management is reflected in the current trend toward vertical integration of insurers and pharmacy benefit managers. Although there are clear upfront costs with respect to optimization of medication utilization, these may be covered by downstream savings that far outweigh the initial investment. The ability to pay for these programs may be realized further with the merging of pharmacy and medical benefits and a focus on the total cost of care as seen by the recent consolidation of pharmacy benefit managers and payors within the health care landscape.

In contrast to the requirement that Medicare Part D plans offer medication therapy management services, out-of-clinic medication management is currently not included in the dialysis reimbursement bundle. Medication reconciliation services are currently not reimbursed. Rather, they are completed by the dialysis facility nursing staff under the operational and financial constraints of dialysis providers. Medication therapy management and adherence technologies face similar reimbursement challenges. Provision of health technologies and services without discrete reimbursement has been stymied by questions as to whether they may be subject to concern under current Medicare patient inducement limits. For example, if a dialysis provider were to provide a smart pill bottle to improve adherence, it may be viewed as an item of value being bestowed to the patient. The same question applies to medication therapy management programs, which are costly in terms of staff time. Given the potential benefits of these resource-intensive programs, regulatory clarification of the implications of providing such programs to patients is needed, especially as CMS considers adopting quality metrics associated with medication reconciliation and management.

The issues imposed by a fee-for-service payment environment may become less prominent as the ESRD payment system moves toward an integrated care model. ESCO programs, Chronic Condition Special Needs Plans, and future integrated care models in dialysis may overcome these limitations and allow for medication management programs to become more prevalent. The use of medication management programs, particularly in complex patient populations such as those on dialysis, will be a needed tool that can be wielded to influence health care outcomes.

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