Draft ESRD Medication Reconciliation and Management Technical Expert Panel Summary Report

July 19, 2017

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ESRD Medication Reconciliation and Management (MRM) Technical Expert Panel Summary

The Centers for Medicare & Medicaid Services (CMS) contracted with The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to maintain and develop quality measures for dialysis facilities, pertaining to their care of End-Stage Renal Disease (ESRD) patients on chronic dialysis. UM-KECC was tasked with developing quality measures related to medication reconciliation and management for individuals with ESRD who are receiving dialysis. Following the CMS Measures Blueprint process, a Technical Expert Panel (TEP) was convened to provide expert and stakeholder input to the development of potential measures. This report describes the deliberations of the Medication Reconciliation and Management (MRM) TEP.

Technical Expert Panel Objectives

The objectives of the ESRD MRM TEP are described in a charter that was reviewed and approved by the TEP members. The TEP was tasked with applying available evidence and their expert opinions to formulate recommendations to UM-KECC regarding the development of new measures and the identification of important quality gaps relating to MRM. The TEP was asked to provide, where appropriate, specifications for draft quality measures. Criteria for recommended measures include that they be evidence based, scientifically acceptable (reliable and valid), feasible without creating undue burden for dialysis facilities, and usable by CMS, providers, and the public. These are the criteria used by CMS and the National Quality Forum in evaluating quality measures.

Technical Expert Panel Meeting

The Medication Reconciliation and Management (MRM) TEP met in Baltimore, Maryland on July 19, 2017.

A public call for nominations was released in March 2017. The TEP was comprised of individuals with the following areas of expertise or experiential perspectives:

- Clinical pharmacists
- Nephrologists
- Nurses /Dialysis Nurses
- Consumer/patient/family (caregiver) perspective
- Health care disparities
- Performance measurement
- Quality improvement
- Purchaser perspective

The following individuals were selected to serve on the TEP:

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Disclosed
Jane Davis, DNP, CRNP Nurse Practitioner	Division of Nephrology University of Alabama Birmingham Birmingham, AL	Yes, Speaker's bureau for Amgen
Richard Faris, PhD MSc RPh Vice President Clinical Strategy and Services	DaVita Rx Denver, CO	Yes, Employed by DaVita Rx
Renee Garrick, M.D., FACP Executive Medical Director Medical Director, Dialysis Services	Westchester Medical Center Valhalla, New York Dialysis Clinic, Inc, Bradhurst Dialysis	None
Jeffrey Hymes, MD Sr. Vice President, Chief Medical Officer, Chair Pharmacy and Therapeutics Committee Ambulatory Active Courtesy Staff	Fresenius Medical Services Franklin, TN Centennial Medical Center, Nashville, Tennessee St. Thomas Hospital, Nashville, Tennessee	Yes, employed and shareholder of Fresenius
Justin Iorii Motivational Speaker and Patient/Advocate	Justin's Kidney Inc Las Vegas, NV Dialysis Patient Citizens	None
Harold Manley, Pharm.D., FASN, FCCP TEP Chair Senior Pharmacy Director ; Nephrology Pharmacotherapy Specialist	Dialysis Clinic, Inc (DCI) Albany, NY	Yes, served on the Kidney Care Quality Alliance Committee that created the NQF measures the TEP will review

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Disclosed
Bill Murray Former self-employee Patient/Advocate	National Kidney Foundation Delaware	None
Amy Pai, Pharm.D., BCPS, FASN, FCCP, FNKF Associate Professor Nephrology Pharmacotherapy Specialist	University of Michigan College of Pharmacy University of Michigan Outpatient Hemodialysis Ann Arbor, MI	None
Nancy Pelfrey, MSN, ACNP-BC, CNN-NP Nurse Practitioner – Virtual Outcomes Manager	Reliant Renal Care Fairview, NC	None
Maile Robb Patient/Advocate	Forum of ESRD Networks Reno, NV	None
Patricia (Patty) Seo-Mayer, Pediatric Nephrologist & Associate Program Director	Inova Fairfax Hospital, Falls Church VA	Consultant for Achillion Pharmaceuticals on limited project: June 2016- May 2017
Wendy St. Peter, Pharm.D. Professor Professor, Researcher Nephrology Pharmacotherapy Specialist	College of Pharmacy, University of Minnesota Minneapolis, MN	None
Tosha Whitley, RN Clinical Director of Quality Initiatives	Northwest Kidney Centers Seattle, WA	None
Contractor Staff		

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Disclosed
Jonathan Segal, MD, MS	*Associate Professor of Nephrology,* Internal Medicine/Nephrology, University of Michigan, Kidney Epidemiology and Cost Center	None
Abhijit Naik, MD,	*Assistant Professor of Nephrology,* Internal Medicine/Nephrology, University of Michigan, Kidney Epidemiology and Cost Center	None
Jian Kang, PhD	*Professor of Biostatistics,* Department of Biostatistics, University of Michigan, Kidney Epidemiology and Cost Center	None
Xi Wang, MPH	*Research Analyst,* University of Michigan, Kidney Epidemiology and Cost Center	None
Jennifer Sardone, BA, PMP	*Project Manager/ Research Analyst,* University of Michigan, Kidney Epidemiology and Cost Center	None
Mimi Dalaly, MPH	*Research Analyst,* University of Michigan, Kidney Epidemiology and Cost Center	None

1. Introduction

Clinicians need to be aware of what medications a patient is taking before any changes can be made or new medications initiated. This can be a challenge since individuals with end stage renal disease who are receiving dialysis have a high medication burden with an average of 12 different prescriptions per day[1]. The financial burden, both for patients and payers is also substantial; with 77% of ESRD patients enrolled in Medicare part D, total estimated expenditures for enrollees reached $2.7 billion in 2014 for prescription medications[2].

Medication-related problems, such as adverse drug reactions or over/under utilization, occur frequently in the dialysis setting and are often related to gaps in medical information transfer. Identifying these issues has the potential to reduce hospitalizations, improve quality of life, and use health care resources more efficiently. In a randomized controlled trial, dialysis patients assigned to receive medication reconciliation and management of medication related problems by a clinical pharmacist used 14% fewer medications and had almost half as many hospitalizations at the end of the two year intervention compared to the usual-care group[3]. However, systematic medication reconciliation and review is not routinely performed in most dialysis clinics due to lack of staff training, limited interfaces in electronic health information between care facilities (outpatient dialysis facilities, hospitals, skilled nursing facilities, and rehabilitation centers), and absence of clinical pharmacists in most dialysis facilities[4]. Because of the frequent contact between dialysis facilities and patients, medication reconciliation and review as a means to reduce medication related problems may represent an opportunity to improve quality of care.

[1] Manley et al. Nephrol Dial Transplant 19:1842– 1848, 2004.

[2] United States Renal Data System. 2016 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016.

[3] Pai et al. Pharmacotherapy 2009;29(12):1433–1440

[4] Pai et al. CJASN 2013 as doi: 10.2215/CJN.01420213

Specific TEP objectives include:

- Review of existing National Quality Forum (NQF) endorsed measures that incorporate Medication Reconciliation in this or other care settings (e.g. Medication Reconciliation for Patients Receiving Care at Dialysis Facilities, NQF #2988; Medication Reconciliation Post-Discharge (MRP), NQF #0554)
- Examination of data sources and availability
- Consideration of the components of the reconciliation and review processes including frequency that they are performed, providers who are eligible to complete the tasks, and the necessary steps to do so.
- Consideration of medication management as it relates to the reconciliation process and how that might be incorporated into a measure.
- Develop one or more measures of medication reconciliation/review with attention to any adjustment or exclusion criteria that may be needed and harmonization with existing measures.

This report summarizes the discussions and recommendations of the Medication Reconciliation and Management (MRM) TEP meeting convened on July 19, 2017 in Baltimore, Maryland. Preparatory teleconference meetings held on June 26, 2017, and July 10, 2017 are detailed in separate reports. The TEP provided advice and expert input on potential quality measures for MRM within the ESRD population. The discussions were informed by a review of relevant literature and existing and related MRM measures as part of an environmental scan conducted by UM-KECC.

During the discussion, the TEP considered:

- Relevant measures endorsed by the National Quality Forum (NQF)
- Components of a potential MRM measure such as when the process should occur, how medication reconciliation should be conducted, which medications to include during a MRM event , and who can conduct the different components of MRM
- The degree to which performance on a measure is under control of the dialysis facility
- The potential need for exclusion criteria and/or risk adjustment
- Data availability and additional analyses

2. Preliminary Activities

2.1 Information Gathering - Environmental Scan and Literature Review

Prior to the in-person TEP meeting, UM-KECC provided TEP members with a summary of published literature (Appendix A) and existing NQF-endorsed measures (Appendix B) relating to medication reconciliation and management. An overview of the literature and current body of evidence was presented during the teleconference meeting on July 10, 2017 and is summarized in a separate report.

2.2 TEP Charter

The ESRD Medication Reconciliation and Management TEP Charter (Appendix C) was distributed to the TEP members for review prior to the in-person meeting and was approved by the TEP members. Dr. Segal

highlighted key elements of the charter and emphasized the aspects of medication management as it relates to medication reconciliation for consideration when drafting a measure(s).

2.3 TEP Teleconference Meetings

On June 26, 2017 a preliminary conference call was held with the TEP. Activities included the introduction of TEP members, discussion of the measure development process, role of the TEP in providing input on potential measures, and approval of the TEP charter (Appendix D). The second teleconference, held on July 10, 2017 consisted of a review of literature by Dr. Manley (TEP chair) and an overview of relevant NQF endorsed measures by Dr. Segal (UM-KECC) (See Appendix E)

3. In-person TEP Meeting

The remainder of the report summarizes TEP deliberations by the agenda topics for the in-person meeting (see Appendix F for agenda).

3.1 Medication Reconciliation, Review, and Management

The TEP Chair began the in-person meeting by providing an overview of medication reconciliation and how it differs from medication management. (See Appendix G for slides presented during in-person meeting).

Medication reconciliation was defined as the process of maintaining the list of medications that the patient is *actually* taking. This includes prescribed medications as well as over-the-counter products such as herbal products and vitamins. Within that process it is important to document medication dose and directions as well as who conducted the reconciliation and when it was done. In response to this, a TEP member clarified that reconciliation is an *action* of comparing what has been prescribed in different care settings along with what the patient is actually taking, and once this is completed comes both the review and then ongoing management. Medication management was noted by another TEP member to be a distinct service from medication review. It was also noted that a more advanced skill set is needed for medication review and management compared to that required for medication reconciliation.

Medication Review was defined as the process of using a reconciled medication list to verify that medications are appropriate *at that moment in time*. The process also involves identifying and resolving medication discrepancies. Of note, when a patient is unable to take a medication that is prescribed (e.g., due to cost or side effects), TEP members indicated that the medication should ultimately be removed from the list and any issues documented in the medical record. The medication list should be reviewed by a provider even if no discrepancies or issues are identified during the reconciliation process. The medication review process was identified as one potential area that could be developed to expand on the existing NQF endorsed measure.

Medication Management implies an ongoing activity and service over time to ensure optimum therapeutic outcomes, monitoring efficacy and safety, and preventing/resolving medication-related problems. Some TEP members supported the concept of focusing on high-risk medications for medication management services.

3.2 Medication Reconciliation and the Medication List

Relative to medication reconciliation and management, a TEP member discussed how providers reconcile a medication list across different care settings. TEP members articulated the importance that the

clinician/staff member understands the difference between *medications prescribed or ordered* and *medications the patient is actually taking*. TEP members stressed the importance of the components associated with a medication list. These include medication name (generic and trade name), indication, dosage, frequency, route of administration, start date, stop date (if applicable), prescriber, reason medication was stopped (if applicable); it was noted that patients may not know or have all of these components available at the time that reconciliation takes place. In response to this, the TEP chair did review the components listed in the KCQA measure, and went on to emphasize that maintenance of the list is accomplished by addressing and trying to resolve all of the discrepancies. Shared responsibility between provider and patient to have the details of the medication prescription available so as to avoid medication-related problems was raised. A TEP member also voiced that the KCQA measure does necessarily result in the most accurate list of medications since it does not include the review component. There was discussion that in-center medications should be included on a medication list, but one TEP member indicated that only home medications should be included.

The question was raised as to whether the medication list should represent what the patient is actually taking versus what a provider intends for the patient to take. This led to discussion about the barriers to completing medication reconciliation process and key aspects of creating and sharing an accurate medication list. Also, the question of whether all patients should be targeted for a measure or whether targeting high risk patients or time periods, as was suggested by one TEP member, would be higher yield. Ultimately the TEP agreed that a balance may need to exist between what medical regimen is best for a patient's health and what regimen is feasible for a patient to take.

Major themes discussed were as follows:

1. **Sharing of information**: Difficulty with information transfer to facilitate medication reconciliation between the hospital, other outpatient providers and the dialysis facility was raised as a particular concern and seen as an important barrier to overcome. The TEP agreed that sharing of information between facilities/providers at the time of a transition of care is extremely important to obtain the most accurate list. A TEP member explained the difficulty in obtaining medical records (e.g., discharge summary, provider notes) from different specialists, let alone a medication list. The TEP also mentioned that sharing of an updated medication list across providers was an important final component of the process.

2. **Patient Engagement:** The TEP chair asked how do we better engage patients to obtain the most accurate list of medications and how do we help patients understand that value of this process. A TEP member suggested that facilities use patient advocates when necessary to help during the reconciliation process, sitting with patients and going over their medications. This technique may help patients be more open about the medications they are taking versus the medications they are supposed to take compared to doing this with one of the facility staff (i.e., patients may not readily disclose that they are taking a family member's medication to a nurse, but may be more willing to do so with a patient advocate). This may help with completing the task in a non-judgmental way since patients may be hesitant to discuss certain medications they are taking (e.g., HIV medications) or that they are unable to afford some of their prescriptions. Variation in the level of patient engagement in the medication reconciliation process was discussed. Specifically, a TEP member

reported that patients can sign off quarterly on a medication list, but they may or may not have reviewed that list carefully.

3. **Trained Professionals:** TEP members also acknowledged that different skill sets are needed between reconciliation and the review/management components. The reconciliation process can be completed by either trained nurses or pharmacy technicians. Time constraints and other competing responsibilities were noted as a potential barrier for nurses to complete this task. The TEP agreed that medication review/management needs to be performed by either a physician, pharmacist, advanced nurse practitioner, or physician's assistant. It was noted that these four disciplines were best suited to understand the various medications patients could be taking outside of what is prescribed at the facility particularly in relationship to drug interactions, dosing etc. The role of provider bias was raised as a potential problem with the process.

4. **Data Sources**: Prescription fulfillment data from a source such as SureScripts was brought up as a way to aid facility staff in the reconciliation process. Limitations of Medicare Part D data were reviewed including the time lag of claims-based data. Other prescription data, such as SureScripts, was noted to have a much shorter delay. Furthermore, lack of an electronic resource was seen as a barrier by one TEP member who noted that facility staff may not have the time or take the effort to thoroughly engage in the reconciliation process. Information from other touchpoints such as hospitals, pharmacies, and other outpatient providers are needed to accurately perform medication reconciliation.

5. **Frequency**: The TEP discussed completing the reconciliation process for all new patients. One TEP member noted that having the patient come to the facility ahead of the first treatment to complete the process had been helpful. Reconciling the medication list after hospitalization or discharge from a skilled nursing facility was also raised as a critical time point, as well as any time the interdisciplinary team deemed a patient unstable. TEP members also felt that building in a regular review for stable patients, such as quarterly, in addition to these ad-hoc events was important.

6. **Setting**: Discussion about the optimal setting for medication reconciliation raised the issue of privacy in the unit. While some patients may be comfortable doing it chair-side, others may want a private room at the clinic to discuss, or prefer to discuss on the telephone. A TEP member noted that if done over the phone, there is the advantage of having access to medication bottles or pill boxes at home. A separate visit to the facility was not deemed to be feasible and it was stressed that providing patients options for the venue (e.g., chairside, private conference room in clinic, telephone) to do reconciliation was important. Video conference was raised as a novel way to complete the task. The value of having patient advocates help in the reconciliation process was raised since dialysis patients may be more honest with peers compared to providers.

7. **Detailed Process Description**: Having a detailed process to perform medication reconciliation accurately and consistently was noted to be important and not addressed by current measures. Training of facility staff to perform medication reconciliation correctly was seen as a critical step by some TEP members.

3.3 Medication Review and Management

In addition to medication reconciliation, the TEP transitioned to discussing broader aspects of medication review and management including both the processes and responsibilities associated with this complex task. The TEP agreed that a physician, physician assistant, nurse practitioner, or pharmacist should be the providers responsible for medication review and management.

3.3a Medication Review

The TEP reviewed the Medication Review measure that was created by the KCQA workgroup. This was a process measure whereby the percentage of patient months where a medication review was performed and documented by an eligible professional. The review consisted of components such as whether there is an appropriate indication for the medication, any drug interactions, and adverse events. Adequate resources for this task was noted to be a potential barrier. It was noted that the ESRD Conditions for Coverage V-tag V506 specifies that a medication history be obtained as part of the comprehensive patient assessment by the interdisciplinary team and that this review include all medications taken with an eye towards identifying any adverse effects, interaction, and demonstration of continued need. The timing of medication review was discussed and one TEP member suggested that this process be done at critical time periods such as within 30 days of admission to the facility or post hospitalization, rather than monthly. Unstable patients were also discussed as being an at-risk group to focus on as defined by hospitalization >15 days or more than 3 hospitalizations in a month. Similar to the medication reconciliation process, TEP members also felt that building in a regular review for stable patients, such as quarterly, in addition to these ad-hoc events was important. Several TEP members noted that the medication review process cannot be performed by typical facility staff such as a nurse or technician, which makes it less attractive as a facility-level measure, as opposed to a provider-level measure. Despite this limitation, many TEP members agreed that it was worth considering further as a possible area for measure development.

3.3b Medication Management

One TEP member suggested that the process of medication management be limited to targeted medications that are relevant to dialysis patients. Potential categories of medications to target included antihypertensive, phosphate binders, diabetes medications, anticoagulants, and those that place patients at a risk for falling. The group suggested that they could develop a list of “high-risk” medications if there was further interest in restricting the categories of medications considered for review or management. There was concern raised about leaving out some medications from this process and separate concerns about how to regulate the activity of non-dialysis facility staff (e.g. physicians or mid-level providers). A TEP member reminded that group that a significant proportion of dialysis patients have Medicare Part D which does support medication management services and questioned whether these resources could be leveraged by the facility to enroll patients for this service. It was later noted that approximately 70% of Medicare dialysis patients are enrolled in a Part D plan, but only 15% of those plans are targeting ESRD as an indication for MTM services. It was also recognized that having nephrologists manage medications that were prescribed by other providers presented a logistic challenge. However, a TEP member noted that proactive patients can be helpful in driving some of this communication and it was suggested that the nephrologists and the dialysis facility are best suited to assume the responsibility for this task, despite the difficulties. A TEP member questioned the amount of leverage that a facility can exert on the providers to complete the task.

The TEP discussed that having a pharmacist or pharmacy technician in the dialysis facility could have a significant impact on effective medication management. A TEP member suggested that a creative solution may involve having Medicare Part D plans opt out of MTM services for dialysis patients, and those funds could be applied to Medicare Part B to support having a pharmacist in the dialysis facility provide those MTM services. It was suggested that the group propose to CMS that pharmacists should be included on the list of required dialysis facility staff that is outlined in the CMS Conditions for Coverage. A TEP member noted that transplant facilities are required to have a pharmacist participate in care and that dialysis facilities should be similarly considered. Pediatric pharmacists were noted to have value in catching many errors related to drug dosing. Given the number of new medications that are entering clinical practice, it was suggested that a pharmacist may be better suited to address dose adjustments and interactions compared to a dialysis nurse or even some nephrologists who may not be as familiar with newer medications.

Using EMR systems to identify drug interactions, allergies, and other problems to then alert provider of an issue was suggested as one tool that could aid in the MTM process.

Overall the TEP did support the concept that medication management was a valuable service although there was not consensus on whether a measure could be drafted for this complex task. Barriers identified were management of medications that are either outside the scope of nephrology practice and/or prescribed by other providers as well as difficulties in communication with other providers. Tracking over time when and how providers are doing medication management was raised as an additional difficulty. It was recognized that additional focused discussion would be needed if further consideration was going to be given to developing a medication management measure. A suggestion was made to focus on high risk patients and/or high risk medications if a measure is developed for medication management.

3.4 Potential Quality Measures

During the course of discussion, several potential measure topics were discussed. These included:

1. Percentage of the Medication List that has discrepancies: Four main medication record discrepancy categories were presented: 1) No longer taking medication, 2) Medication not in record, 3) Change in medication dose and 4) change in medication frequency. Identifying discrepancies may be an opportunity to better understand why a patient is taking a medication differently than prescribed. The discrepancies could be categorized into several basic types. However, it was noted by one TEP member that it would take a provider (MD or mid-level provider) to resolve those discrepancies with the patient. Shared decision making between providers and patients was brought up as an area of potential interest to CMS and a potential way to transition into resolving medication record discrepancies. Ultimately, the percentage of patients taking medications as prescribed was not seen as a marker of facility quality, since in many instances identifying that a discrepancy exists, such as after hospitalization, could in fact be a desired outcome. In addition, some TEP members indicated that there would be limited ability for facility staff to impact this outcome.
2. Clinical outcomes tied to medications reconciliation were discussed. Hospitalization was one such outcome and the TEP chair shared data related to medication-related hospitalizations. Failure of medication reconciliation was a common etiology for both index hospitalizations and re-

admissions. One TEP member noted that there are no other ESRD measures that tie processes to outcomes such as hospitalizations. It was also noted that there are already measures related to hospitalization, transfusion, and a phosphorus reporting measure.

3. Days to reconcile medication list post hospital discharge: It was noted that reconciliation after a care transition, such as hospital or skilled nursing facility discharge, was a measure that the KCQA workgroup had developed. Sharing of information between the hospital and dialysis facility was viewed as problematic. Engaging patients in the process to help with providing discharge summaries to facilities was discussed as well as the hospital's responsibility in providing that information.
4. Proportion of medication lists that have all data elements completed. One TEP member proposed that a measure could evaluate how complete the details are for each medication listed in terms of dose, frequency, route, and indication. Concern was raised that this information is not readily available for medications that are prescribed outside of the dialysis facility and would be burdensome for electronic queries to be created to aid in this process.
5. Facility provided medication list: Patient deliverables in the Medication Therapy Management Program (MTMP) under Medicare Part D has clearly defined deliverables that could be used as a construct for dialysis facilities. A personalized medication list is one of the deliverables and the TEP chair reviewed the format and components with the group. Name of medication, how it is to be taken, indication for use, prescribing provider, date prescribed are all critical components that should be present on a medication list. Providing the updated medication list after the reconciliation and review process in a format that is easy to understand was suggested as a facility metric and there was agreement from the TEP that this was an important patient deliverable.
6. Proportion of Medicare patients that are enrolled in a Part D plan that targets MTMP services for ESRD patients. Given the current small number of patients that have potential access to these services, the impact was unknown, but felt to be limited. Additional concerns related to whether the actual MTMP services provided through Part D plans would address specific issues related to ESRD as opposed to more broad-based MTMP services. Since the reimbursement for Part D MTMP is a separate payment, a carve-out would be needed to have Part D MTMP services provided in the dialysis facility.

3.5 Measure Specifications

The TEP focused discussion on developing a measure for the number of patients at the facility who had a medication review completed and were given an updated medication list that had any discrepancies resolved to the best of the provider's ability. This measure requires three essential components to be completed to receive credit: Medication Reconciliation, Medication Review, and receipt of an updated medication list by the patient. The following details were discussed:

- Medication Reconciliation: the measure begins with the medication reconciliation process. The following individuals were identified as being able to complete this step: RN, Pharmacy technician, Pharmacist, Physician, or Advanced Practice Provider (Nurse Practitioner or Physician Assistant). During the medication reconciliation process, discrepancies between what has been prescribed and what is being taken by the patient should be flagged for Medication Review.

- Medication Review: The following individuals were identified as being able to complete this step: Pharmacist, Physician, or Advanced Practice Provider (Nurse Practitioner or Physician Assistant). During the review process, a TEP member noted that the dialysis providers have a responsibility to resolve any identified discrepancies to the best of their ability, and it was recognized that not all discrepancies may be able to be addressed.
- Medication List: The TEP did not want to give patients a list of medications that had been reconciled, but did not yet have discrepancies resolved. In addition, several TEP members expressed concern about documenting a dose of a medication on the medication list that was different than what was prescribed, even if it more accurately reflected what the patient was actually taking. The TEP debated how best to report medications that were being taken differently than prescribed (e.g., taken once per day rather than twice per day). Many TEP members felt that if the patient was taking the medication, it should be recorded as prescribed, and that most EMR allow for comments to explain any discrepancies. Ultimately, this level of detail was considered to be a best-practice recommendation, rather than an intrinsic portion of the measure. Overall, the group acknowledged that the dialysis facility may not be able to resolve all discrepancies, but that the process of generating an updated medication list provides an opportunity for discourse between patient and provider. TEP members noted that it was important to specify the components required on the medication list, although it was acknowledged that some of the formatting or components displayed may be subject to local EMR system limitations.
- Frequency: the TEP agreed that completing this task monthly may be too often, and that medication reconciliation should occur at least quarterly for stable patients. Transitions of care were also recognized as a time when this needed to be done and include, but are not limited to: Initiation of dialysis, modality change, hospital or skilled nursing facility discharge.
- Time Frame for completing measure: two different time frames were discussed. For unstable patients or those with a transition of care, 8 days to complete the task was seen as optimal. For example, if a patient receives dialysis on a Mon/Wed/Fri schedule, and the process begins on a Monday, then the facility needs to provide the patient with an updated medication list that has been reconciled and reviewed with discrepancies addressed by no later than the following Monday. For new patients to the facility and stable patients undergoing quarterly review 30 days was recommended to align with common workflows in the dialysis facility. The same time frame is expected for both home and in-center dialysis patients and it was recognized that using alternate methods (e.g., telephone, video conference and mail) may be required for home patients.
- Exclusion Criteria: Patients would be excluded from the measure if they are transient, readmitted to the hospital within 8 days of discharge, or are actively enrolled in hospice.

3.6 Final Comments

The TEP acknowledged that there is some tension between the capacity of facility staff to accomplish medication reconciliation, review, and management tasks versus the responsibility of providers who follow patients at the facility. A TEP member noted that cooperation between patients and staff is needed if there is to be success.

The TEP also recognized the current gap in care and stated that funding should be made available to support nephrology trained pharmacists in dialysis facilities to facilitate the medication reconciliation and management process.

Having read-only access to inpatient EMR was also felt to be critical in providing continuity of care and assisting in the medication reconciliation and review process.

Bilateral communication amongst providers in and out of the dialysis facility was voiced as an important component of the reconciliation process. There was discussion about whether the facility should be responsible for sending the reviewed medication list to primary care or specialists. Ultimately, a TEP member indicated that having a patient bring the updated medication list at the time of an encounter with another provider would likely be the best route of communication.

4. Post-TEP Public Comment Period

One public comment was received:

Hi, I am Kathy Lester, I am a council to the Kidney Care Partners, and very much appreciate the opportunity to listen in on the TEP and provide comments. I think most of you know who KCP is, but we represent stakeholders in the ESRD community, focused primarily on dialysis, but expanding our interest in transplant and other areas now to include the facilities, the manufacturers, the patient advocacy organizations and the health care professional's organizations. We began the process which has become the Kidney Care Quality Alliance back in 2005. So, as we look at this area, it's very important; we put together a dialysis quality measure blueprint and medication management, reconciliation, review, was at the top of our list which is why you see the KCQA measure kind of engulfing the NQF process today. We urge the TEP to recommend the KCQA medication measure. I think there were questions about it earlier, so I just wanted to clarify this is in fact an NQF endorsed measure that does apply to the pediatric population as well, so it is across the board to all patients. I thought it was a fascinating discussion today, and I would offer one point of concern which I think you have debated well, that it is very important for this industry that doesn't have a lot of innovation to make sure that well-meaning steps don't have the end to the consequence of squelching innovation. So, when you think about outlining processes or specifying technologies I would caution or urge you to think about being a little more high level and general rather than being so in the weeds because as you see the measures that exist today it absolutely drives what the facilities will do. Not allowing for that innovation will be an unintended consequence that none of us would like to have. I also really wanted to pick up on the point that you made, again, just now, about sharing data. I started working with KCP in 2003 and the dialysis industry in 2000 and this issue has been on my plate since 2000. We have asked for it to be added to the hospital conditions for participation to require them to share with SNIFs and with other post-acute settings, but it has never been extended to dialysis so we applaud you for making a recommendation if you do go there to include that discharge data to make sure that dialysis facilities are treated like other healthcare providers and that information does flow to them. And, then finally, as you consider your work, you look at the NQF criteria and that's very important to us, near and dear to our hearts, and I think you are focused on the right things around feasibility and actionability, those have really risen to the top of our measure development work, and whether it is our patient organizations and facilities, everyone wants to make sure that the measures are actionable and lead to a real outcome, because they do take funding from other areas, so as you look at this, I think what makes sense to focus on

where those areas will actually improve outcomes. There were a lot of aspirational goals here today, but as KCP would recommend, starting in a very specific area where you can make change, make that change, and allow that measure to grow overtime. So again, thank you for the comments and taking this important area under consideration and we are always happy to help provide any background or information that you all might need in this process as well.

5. Summary and Conclusions

5.1 Summary

After review of the literature and existing NQF endorsed measures, the TEP considered several possibilities for additional measure development and proposed a measure to evaluate the number of patients who had both medication reconciliation and review completed and received an updated medication list as a deliverable. Adding the review component where medication discrepancies are resolved to the best of the provider's ability as well as giving the updated medication list to the patients, were noted to be two areas where the proposed measure would build on the current NQF endorsed medication reconciliation measure.

While the TEP agreed that medication management is a valuable service, consensus was not reached as to how a quality measure could be framed around this process. It was suggested that starting with high risk medications and/or high risk patients may be one way to begin a medication management measure. The TEP agreed that additional follow up discussion would be needed in this area.

5.2 Follow-up Needs

It is anticipated a follow-up teleconference will be held in the Fall (2017) to further identify and refine draft measure specifications.

6. Appendices

a) TEP Charter
b) Environmental Scan
c) Literature Review
d) In-person meeting slide presentation
e) Teleconference minutes (June 26, 2017)
f) Teleconference minutes (July 10, 2017)
g) Teleconference Minutes (September 25, 2017)

TECHNICAL EXPERT PANEL CHARTER

Project Title:

End-Stage Renal Disease Medication Reconciliation & Management

Dates:

March – December 2017

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop a quality measure(s) related to medication reconciliation and management. The contract name is End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support. The contract number is HHSM-500-2013-13017I. As part of its measure development process, CMS asks measure developers to convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

Medication reconciliation is a process by which an accurate medication list can be created, whereas medication management optimizes drug therapy to improve patient outcomes and minimize drug related problems. In a dialysis facility, this can be a complex task given that there are often multiple prescribers involved and medication regimens are often changed during times of care transition such as at hospital discharge. The CMS Conditions for Coverage specify that it is incumbent upon facility staff to obtain an accurate medication history as part of the patient assessment, however medication discrepancies remain common and impact patient safety as well as cost of care.

Project Objectives:

The University of Michigan Kidney Epidemiology and Cost Center, through its contract with the Centers for Medicare and Medicaid Services, will convene a technical expert panel (TEP) to inform the development of a quality measure(s) related to medication reconciliation and management in dialysis facilities.

Clinicians need to be aware of what medications a patient is prescribed before any changes can be made or new medications initiated. This can be a challenge since individuals with end stage renal disease who are receiving dialysis have a high medication burden with an average of 12 different prescriptions per day[1]. The financial burden, both for patients and payers is also substantial; with 77% of ESRD patients enrolled in Medicare part D, total estimated expenditures for enrollees

[1] Manley et al. Nephrol Dial Transplant 19:1842– 1848, 2004.

reached $2.7 billion in 2014 for prescription medications[2]. Medication related problems, such as adverse drug reactions or over/under utilization, occur frequently in the dialysis setting and are often related to gaps in medical information transfer. Identifying these issues has the potential to reduce hospitalizations, improve quality of life, and use health care resources more efficiently. In a randomized controlled trial, dialysis patients assigned to receive medication reconciliation and management of medication related problems by a clinical pharmacist used 14% fewer medications and had almost half as many hospitalizations at the end of the two year intervention compared to the usual-care group[3]. However, systematic medication reconciliation is not routinely performed in most dialysis clinics due to lack of staff training, limited interfaces in electronic health information between care facilities (outpatient dialysis facilities, hospitals, skilled nursing facilities, and rehabilitation centers), and absence of clinical pharmacists in most dialysis facilities[4]. Because of the frequent contact between dialysis facilities and patients, medication reconciliation and management as a means to reduce medication related problems may represent an opportunity to improve quality of care.

Specific objectives include:

- Review of existing NQF endorsed measures that incorporate Medication Reconciliation in this or other care settings (e.g. Medication Reconciliation for Patients Receiving Care at Dialysis Facilities, NQF #2988; Medication Reconciliation Post-Discharge (MRP), NQF #0554)
- Examination of data sources and availability
- Consideration of the components of the reconciliation process including frequency that it is performed, providers who are eligible to complete the task, and the necessary steps to do so.
- Consideration of medication management as it relates to the reconciliation process and how that might be incorporated into a measure.
- Develop one or more measures of medication reconciliation and management with attention to any adjustment or exclusion criteria that may be needed and harmonization with existing measures.

TEP Objectives:

The TEP will use existing data and their expert opinion to formulate recommendations to UM-KECC regarding the development of new measures that address important quality gaps in medication reconciliation and management. Recommended measures should be evidence based, scientifically acceptable (reliable and valid), feasible, and usable by CMS, providers, and the public. Key objectives include obtaining TEP input on the following:

- Draft measures including defining denominator, numerator and potential exclusion criteria
- Consideration of risk adjustment (e.g., certain chronic conditions)
- Determine to what extent a new measure(s) can be harmonized with existing measures.

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[2] United States Renal Data System. 2016 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016.

[3] Pai et al. Pharmacotherapy 2009;29(12):1433–1440

[4] Pai et al. CJASN 2013 as doi: 10.2215/CJN.01420213

Scope of Responsibilities:

The role of each TEP member is to provide advisory input to UM-KECC.

Role of UM-KECC: As the CMS measure developer contractor, UM-KECC has a responsibility to support the development of quality measures for ESRD patients. The UM-KECC moderators will work with the TEP chair(s) to ensure the panel discussions focus on the development of draft measure specifications, as recommended to the contractor. During discussions, UM-KECC moderators may advise the TEP and chair(s) on the needs and requirements of the CMS contract and the timeline, and may provide specific guidance and criteria that must be met with respect to CMS and NQF review of revised candidate measures reflecting prevalent comorbidities.

Role of TEP chair(s): Prior to the in-person TEP meeting, one or two TEP members are designated as the chair(s) by the measure contractor and CMS. The TEP chair(s) are responsible, in partnership with the moderator, for directing the TEP to meet the expectations for TEP members, including provision of advice to the contractor regarding measure specifications.

Duties and Role of TEP members: According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to review any existing measures, provide input as to data sources and feasibility, and to suggest measure specifications. TEP members are expected to attend conference calls in 2017, and attend one in-person meeting in June of 2017 (specific dates to be determined) in Baltimore, MD, and be available for additional follow-up teleconferences and correspondence as needed in order to support the submission and review of the candidate measure(s) by NQF. Some follow up activities may be needed after testing has occurred.

The TEP will review, edit (if necessary), and adopt a final charter at the first teleconference. A discussion of the overall tasks of the TEP and the goals/objectives of the ESRD Medication Reconciliation quality measurement project will be described. TEP members will be provided with a summary of peer reviewed literature and other related quality measures prior to the in-person meeting. TEP members will have the opportunity to submit additional studies to be included in the literature review. A review of the CMS and NQF measure development criteria will also be covered during the teleconference.

During the In-Person Meeting: The TEP will review evidence to determine the basis of support for proposed measure(s). The key deliverables of the TEP at the in-person meeting include:

- Recommending draft measure specifications,
- Assisting in completing the necessary documentation forms to support submission of the measures to CMS for review, and to the NQF for endorsement
- As needed TEP members may be asked to provide input to UM-KECC as they prepare responses to NQF and public comments

At the end of the in-person meeting the TEP chair(s) and TEP members will prepare a summary of recommendations. As necessary, the TEP chair(s) will have additional contact with UM-KECC moderators to work through any other issues. This will include votes for draft and final measures. After the In-Person Meeting (approximately June 2017): TEP members will review a summary

report of the TEP meeting discussions, recommendations, draft measure specifications, and other necessary documentation forms required for submission to the NQF for endorsement.

Guiding Principles:

Potential TEP members must be aware that:

- Participation on the Technical Expert Panel is voluntary.
- Input will be recorded in the meeting minutes.
- Proceedings of the in-person meeting will be summarized in a report that is disclosed to the general public.
- Potential patient participants may keep their names confidential, if they wish to do so.
- If a TEP member has chosen to disclose private, personal data, that material and those communications are not covered by patient-provider confidentiality.
- All questions about confidentiality will be answered by the TEP organizers.
- All potential TEP members must disclose any current and past activities that may pose a potential conflict of interest for performing the tasks required of the TEP.
- All potential TEP members must commit to the expected time frame outlined for the TEP.
- All issues included in the TEP summary report will be voted on by the TEP members
- Counts of the votes and written opinions of the TEP members will be included, if requested.

Estimated Number and Frequency of Meetings:

- TEP members should expect to come together for one to three (1 – 2 hour) teleconference calls prior to the in-person meeting held June 2017, in Baltimore, MD.
- One one-day in-person meeting (June 2017)
- After the in-person meeting, additional conference calls may be needed.

Date Approved by TEP: TBD

TEP Membership: TBD

Expiration Notice: This notice expires on December 31, 2017

End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support

Medication Reconciliation and Management Technical Expert Panel

Relevant NQF Measures

Contents

Measure Title	**NQF #2988 Medication Reconciliation for Patients Receiving Care at Dialysis Facilities**
Measure Developer	Kidney Care Quality Alliance (KCQA)
Measure Description	Percentage of patient-months for which medication reconciliation* was performed and documented by an eligible professional.** * "Medication reconciliation" is defined as the process of creating the most accurate list of all home medications that the patient is taking, including name, indication, dosage, frequency, and route, by comparing the most recent medication list in the dialysis medical record to one or more external list(s) of medications obtained from a patient or caregiver (including patient-/caregiver-provided "brown bag" information), pharmacotherapy information network (e.g., Surescripts), hospital, or other provider. ** For the purposes of medication reconciliation, "eligible professional" is defined as: physician, RN, ARNP, PA, pharmacist, or pharmacy technician.
Numerator	Number of patient-months for which medication reconciliation was performed and documented by an eligible professional during the reporting period. The medication reconciliation MUST: • Include the name or other unique identifier of the eligible professional; AND • Include the date of the reconciliation; AND

	• Address ALL known home medications (prescriptions, over-the-counters, herbals, vitamin/mineral/dietary (nutritional) supplements, and medical marijuana); AND • Address for EACH home medication: Medication name(1), indication(2), dosage(2), frequency(2), route of administration(2), start and end date (if applicable)(2), discontinuation date (if applicable)(2), reason medication was stopped or discontinued (if applicable)(2), and identification of individual who authorized stoppage or discontinuation of medication (if applicable)(2); AND • List any allergies, intolerances, or adverse drug events experienced by the patient.
Denominator	Total number of patient-months for all patients permanently assigned to a dialysis facility during the reporting period.
Exclusions	In-center patients who receive < 7 hemodialysis treatments in the facility during the reporting month.
NQF Endorsed	Yes, Updated 01/27/2017
Clinical Condition	Renal, Renal: End Stage Renal Disease (ESRD)
Risk Adjusted	No
Link	http://www.qualityforum.org/QPS/2988

Measure Title	**NQF #0554 Medication Reconciliation Post-Discharge (MRP)**
Measure Developer	National Committee for Quality Assurance
Measure Description	The percentage of discharges during the first 11 months of the measurement year (e.g., January 1–December 1) for patients 66 years of age and older for whom medications were reconciled on or within 30 days of discharge.
Numerator	Medication reconciliation conducted by a prescribing practitioner, clinical pharmacist or registered nurse on or within 30 days of discharge.
Denominator	Acute or non-acute inpatient discharge during the first 11 months of the measurement year (e.g., January 1 to December 1) for patients who are 66 years and older as of the end of the measurement year.
Exclusions	N/A
NQF Endorsed	Endorsed 8/5/2009, Endorsement REMOVED February 23, 2016
Clinical Condition	
Risk Adjusted	No
Link	http://www.qualityforum.org/QPS/0554

End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support

Medication Reconciliation and Management Technical Expert Panel Annotated Bibliography

Literature Review Summary

UM-KECC's Literature Review and Environmental Scan supporting the Medication Reconciliation and Management Technical Expert Panel began in February of 2017. For this review, a series of searches were undertaken iteratively to identify pertinent PubMed and Google Scholer content describing medication reconciliation and medication therapy management among patients with end stage renal disease. The first PubMed search was executed in February 2017 based on the search criteria established by the group. Initial PubMed search results were screened for general topic applicability prior to a focused review by two clinician investigators associated with the team. The PubMed search was limited to articles published in the English language with the following search crtieria: ("kidney failure, chronic"[MeSH Terms] OR ("kidney"[All Fields] AND "failure"[All Fields] AND "chronic"[All Fields]) OR "chronic kidney failure"[All Fields] OR "esrd"[All Fields]) AND ("medication therapy management"[MeSH Terms] OR ("medication"[All Fields] AND "therapy"[All Fields] AND "management"[All Fields]) OR "medication therapy management"[All Fields]). A total of 171 articles were initially identified. An additional search using the Medical Subject Headings (MeSH) was completed with: "Medication Reconciliation"[Mesh] AND ("Renal Dialysis"[Mesh] OR "Kidney Failure, Chronic"[Mesh]) and returned an additional 8 articles. The titles and abstract were reviewed for relevancy and 26 were selected for inclusion. References from these articles were reviewed for additional relevant material as well as PubMed author searches for additional citations. This review resulted in a final list of 32 articles for inclusion in the bibliography.

Annotated Bibliography

Aspden T, Wolley MJ, Ma TM, et al. **Understanding barriers to optimal medication management for those requiring long-term dialysis: rationale and design for an observational study, and a quantitative description of study variables and data**. *BMC Nephrol 2015;16:102 doi: 10.1186/s12882-015-0097-2.*

Abstract: BACKGROUND: Rates of medication non-adherence in dialysis patients are high, and improving adherence is likely to improve outcomes. Few data are available regarding factors associated with medication adherence in dialysis patients, and these data are needed to inform effective intervention strategies. METHODS/DESIGN: This is an observational cross-sectional study of a multi-ethnic dialysis cohort from New Zealand, with the main data collection tool being an interviewer-assisted survey. A total of 100 participants were randomly sampled from a single centre, with selection stratified by ethnicity and dialysis modality (facility versus home). The main outcome measure is self-reported medication adherence using the Morisky 8-Item Medication Adherence Scale (MMAS-8). Study data include demographic, clinical, social and psychometric characteristics, the latter being constructs of health literacy, medication knowledge, beliefs about medications, and illness perceptions. Psychometric constructs were assessed through the following survey instruments; health literacy screening questions, the Medication Knowledge Evaluation Tool (Okuyan et al.), the Beliefs about Medication Questionnaire (Horne et al.), the Brief Illness Perception Questionnaire (Broadbent et al.). Using the study data, reliability analysis for internal consistency is satisfactory for the scales evaluating health literacy, medication knowledge, and beliefs about medications, with Chronbach's alpha > 0.7 for all. Reliability analysis indicated poor internal consistency for scales relating to illness perceptions. MMAS-8 and all psychometric scores are normally distributed in the study data. DISCUSSION: This study will provide important information on the factors involved in medication non-adherence in New Zealand dialysis patients. The resulting knowledge will inform long-term initiatives to reduce medication non-adherence in dialysis patients, and help ensure that they are addressing appropriate and evidence based targets for intervention.

Browne T, Merighi JR. **Barriers to adult hemodialysis patients' self-management of oral medications**. *Am J Kidney Dis 2010;56(3):547-57 doi: 10.1053/j.ajkd.2010.03.002.*

Abstract: Hemodialysis patients use a variety of oral medications on a daily basis to control their kidney disease and comorbid illnesses. Under the new paradigm of kidney disease care for dialysis units outlined in the 2008 US Centers for Medicare & Medicaid Services Conditions for Coverage, there has been a formal shift in the role of the hemodialysis patient from a passive participant in care planning to a fully collaborative member of the interdisciplinary team. In the chronic disease care field, the focus from patient compliance or patient adherence to patient self-management complements this paradigm shift in dialysis care. In this narrative review, we discuss key barriers to adult hemodialysis patient self-management of oral medications that include pill burden, demographic and socioeconomic variables, psychosocial factors, health literacy, patient satisfaction, and health beliefs. We further examine these barriers in the context of the 2008 Medicare Conditions for Coverage. To promote hemodialysis patients' self-

management of oral medication regimens, additional research and behavioral interventions are needed to help hemodialysis patients overcome obstacles that impede their ability to effectively manage chronic illness and improve health outcomes.

Cardone KE, Bacchus S, Assimon MM, Pai AB, Manley HJ. **Medication-related problems in CKD**. *Adv Chronic Kidney Dis 2010;17(5):404-12 doi: 10.1053/j.ackd.2010.06.004.*

Abstract: Patients with CKD are often prescribed heterogeneous medications to treat disease-associated comorbidities, to slow down progression of the disease, and to minimize morbidity and mortality rates. However, the medication regimens of this population are very complex, leading to an increased potential for medication-related problems (MRPs). As kidney function declines, the type and amount of medications a patient consumes increases, thereby putting them at a higher risk for MRPs. MRPs have been known to be associated with morbidity, mortality, and a lower quality of life. This review will summarize data on the prevalence and effect of MRPs, and strategies that can be used by clinicians to reduce and resolve MRPs.

Cardone KE, Manley HJ, Grabe DW, Meola S, Hoy CD, Bailie GR. **Quantifying home medication regimen changes and quality of life in patients receiving nocturnal home hemodialysis**. *Hemodial Int 2011; 15: 234–242.*

Abstract: Medication regimen simplification may improve adherence in end-stage kidney disease. The effect of nocturnal home hemodialysis (NHHD) on medication burden is unknown. A retrospective pilot study of NHHD patients was conducted. Medication information was collected at baseline, NHHD start, and at 3, 6, 12, 18, and 24 months. SF-36 scores were collected at baseline, 6, 12, and 24 months. The number of medications, pill burden, and number of administrations per day were determined. Medication Regimen Complexity Index was used at each time point as a comparator. Medications for anemia, mineral and bone disorders (MBD), cardiovascular (CV) disease, infection, and vitamins were analyzed for number of medications and pill burden. Thirty-five patients were included. Patients used 10.5 ± 4.4 medications at baseline and 11.8 ± 4.7 at the end of the study (P=NS). Regarding the number of medications, anemia medications, anti-infectives, and vitamins increased; MBD and CV medications decreased by the end of the study. Total pill burden did not change over 24 months, nor did anemia pill burden. Mineral bone disorder and CV pill burden decreased, and vitamins and anti-infective pill burden increased. Daily medication administration times decreased significantly from 5.0 ± 1.5 to 3.6 ± 1.5 by 24 months. Switching to NHHD was associated with a significant increase in Medication Regimen Complexity Index at 24 months (P<0.05). SF-36 scores increased significantly once patients began on NHHD. No measure of medication regimen complexity was correlated with the SF-36 score. Medication burden changes over time after starting NHHD. It is unknown what effect NHHD has on adherence or medication costs, and warrants further study in a prospective comparative investigation.

Chan WW, Mahalingam G, Richardson RM, Fernandes OA, Battistella M. **A formal medication reconciliation programme in a haemodialysis unit can identify medication discrepancies and**

potentially prevent adverse drug events. *J Ren Care 2015 Jun;41(2):104-9. doi: 10.1111/jorc.12107. Epub 2015 Feb 19.*

Abstract BACKGROUND: Patients on haemodialysis have been identified as high-risk for medication discrepancies and adverse drug events. Medication reconciliation is an important patient safety initiative to prevent adverse drug events. The primary objective of our study was to determine the number and types of medication discrepancies and drug therapy problems (DTPs) identified in patients on haemodialysis. Our second objective was to assess the potential clinical impact and severity of all unintentional medication discrepancies identified.

METHODS: Patients in an academic haemodialysis unit were interviewed to obtain a best possible medication history (BPMH) between May and August 2010. The BPMH was documented and discrepancies were identified, classified and resolved with the interprofessional team. An interprofessional panel conducted a discrepancy clinical impact assessment for potential adverse drug events.

RESULTS: Two hundred and twenty-eight patients on haemodialysis were interviewed and 512 discrepancies were identified for 151 patients (3.4 discrepancies per patient). Of these, 174 (34%) were undocumented intentional discrepancies and 338 (66%) were unintentional discrepancies. The unintentional discrepancies were classified as 21% omissions, 36% commissions and 43% incorrect dose/frequency. Most drug therapy problems were related to patient taking a medication that was not indicated (25%), medication required but patient not taking (25%), patient not willing to take the medication as prescribed (28%) or incorrect dosing of a drug (20%). Overall, 6% of discrepancies were classified as clinically significant potential adverse drug events.

CONCLUSION: Medication discrepancies appear to be common in patients on haemodialysis. Formal interprofessional medication reconciliation practice models are essential to identify discrepancies and prevent patients from experiencing adverse drug events.

Chiu YW, TeitelbaumI, Misra M, De Leon EM, Adzize T,Mehrotra R. **Pill burden, adherence, hyperphosphatemia, and quality of life in maintenance dialysis patients.** *Clin J Am Soc Nephrol 2009; 4: 1089–1096.*

Abstract BACKGROUND AND OBJECTIVES: Dialysis patients have a high burden of co-existing diseases, poor health-related quality of life (HR-QOL), and are prescribed many medications. There are no data on daily pill burden and its relationship to HR-QOL and adherence to therapy.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Two hundred and thirty-three prevalent, chronic dialysis patients from three units in different geographic areas in the United States underwent a single, cross-sectional assessment of total daily pill burden and that from phosphate binders. HR-QOL, adherence to phosphate binders, and serum phosphorus levels were the three main outcome measures studied.

RESULTS: The median daily pill burden was 19; in one-quarter of subjects, it exceeded 25 pills/d. Higher pill burden was independently associated with lower physical component summary scale scores on HR-QOL on both univariate and multivariate analyses. Phosphate binders accounted for about one-half of the daily pill burden; 62% of the participants were nonadherent. There was a modest relationship between pill burden from phosphate binders and adherence and serum phosphorus levels; these associations persisted on multivariate analyses. There was no relationship between adherence and serum phosphorus levels.

CONCLUSIONS: The daily pill burden in dialysis patients is one of the highest reported to date in any chronic disease state. Higher pill burden is associated with lower HR-QOL. There are many reasons for uncontrolled serum phosphorus levels; increasing the number of prescribed pills does not seem to improve control and may come at the cost of poorer HR-QOL.

Cohen-Glickman I, Haviv YS, Cohen MJ. **Summary adherence estimates do not portray the true incongruity between drug intake, nurse documentation and physicians' orders**. *BMC Nephrol 2014;15:170 doi: 10.1186/1471-2369-15-170.*

Abstract: BACKGROUND: Hemodialysis patients (HD) need to adhere to a complex medication regimen. Because their daily pill burden is one of the highest reported, poor compliance is a major cause of therapeutic failure. The primary aim of this study was to define patterns of medication prescription, intake and documentation among HD patients. METHODS: HD patients treated between 2007 and 2009 and assigned to the largest health service provider in Israel were randomly selected. Drug practices were abstracted from their records and compared to electronic pharmacy data. The discrepancy between drug intake reports and the actual purchase was measured to estimate adherence. Drug purchase, intake report and physician order were plotted in complementing diagrams to appreciate consistency and discrepancy patterns. RESULTS: The study included full analysis of 75 patients. The mean overall drug adherence was 56.7% (95% CI 53.6-59.9%), varying among drug families and over time. Often, there was a systematic disengagement between the nurses' documentation and the actual patient purchase. Specifically, we observed either different quantities of medication use, improper documentation of a non-purchased drug, drug purchase without nurse documentation and futile physician attempts to modify prescriptions of unpurchased medication. We found a high rate of physician order turbulence for active vitamin D and calcium. CONCLUSIONS: Drug prescription, documentation and adherence are incongruent and their mismatches are diverse. Summary estimates do not divulge the extent of these disparities. These system-wide communication failures compromise patient care. Strategies to promote system reconciliation and reasonable medication prescription are in need.

Gonzalez Lopez A, Nava Rebollo A, Andres Martin B, et al. **Degree of adherence and knowledge prior to medication reconciliation in patients on peritoneal dialysis**. *Nefrologia 2016;36(4):459-60 doi: 10.1016/j.nefro.2015.10.021.*

Abstract: None –Letter to the Editor.

Ibrahim N, Wong IC, Patey S, Tomlin S, Sinha MD, Jani Y. **Drug related problem in children with chronic kidney disease.** *Pediatr Nephrol 2013*; *28: 25–31.*

Abstract Drug therapies in the management of chronic kidney disease (CKD) are complex and specialised and have a high potential for drug-related problem (DRP). In adult CKD populations, the identification and resolution of DRP has been shown to have beneficial effects on disease management, adherence and knowledge of treatment, patient's quality of life, hospitalisation rate and length of stay and cost to the healthcare system. The focus of this article is the review of published studies on DRP in children with CKD. There is a lack of information on the epidemiology of DRP in this patient group, and research in this area is therefore needed to better understand and manage DRP in children with CKD.

Impicciatore P, Choonara I, Clarkson A, Provasi D, Pandolfini C, Bonati M. **Incidence of adverse drug reactions in paediatric in/out-patients: A systematic review and meta-analysis of prospective studies**. *Br J Clin Pharmacol 2001; 52: 77–83.*

Abstract AIMS: To explore the usefulness of data derived from observational studies on adverse drug reactions (ADRs) in defining and preventing the risk of pharmacological interventions in children in different health care settings.

METHODS: A systematic review of studies on ADRs in hospitalized children, in outpatient children, and on ADRs causing paediatric hospital admissions was performed. Studies were identified through a search of the MEDLINE and EMBASE databases. The inclusion criteria required that the population was not selected for particular conditions or drug exposure and prospective monitoring was used for identifying ADRs. Data were analysed by a random-effects model.

RESULTS: Seventeen prospective studies were included. In hospitalized children, the overall incidence of ADRs was 9.53% (95% confidence interval [CI], 6.81, 12.26); severe reactions accounted for 12.29% (95%CI, 8.43,16.17) of the total. The overall rate of paediatric hospital admissions due to ADRs was 2.09% (95%CI, 1.02, 3.77); 39.3% (95%CI, 30.7,47.9) of the ADRs causing hospital admissions were life threatening reactions. For outpatient children the overall incidence of ADRs was 1.46% (95%CI, 0.7, 3.03).

CONCLUSIONS: The results show that ADRs in children are a significant public health issue. The completeness and accuracy of prescription reporting as well as clinical information from studies was a rarity, making it difficult for health practitioners to implement evidence based preventive

strategies. Further, methodologically sound drug surveillance studies are necessary for an effective promotion of a safer use of drugs in children.

Isetts BJ, Schondelmeyer SW, Artz MB, Lenarz LA, Heaton AH, Wadd WB, Brown LM, Cipolle RJ. **Clinical and economic outcomes of medication therapy management services: The Minnesota experience.** *J Am Pharm Assoc (2003) 48: 203–211, 2008.*

Abstract OBJECTIVES: To (1) provide medication therapy management (MTM) services to patients, (2) measure the clinical effects associated with the provision of MTM services, (3) measure the percent of patients achieving Healthcare Effectiveness Data and Information Set (HEDIS) goals for hypertension and hyperlipidemia in the MTM services intervention group in relationship to a comparison group who did not receive MTM services, and (4) compare patients' total health expenditures for the year before and after receiving MTM services.

DESIGN: Prospective study.

SETTING: Six ambulatory clinics in Minnesota from August 1, 2001, to July 31, 2002.

PATIENTS: 285 intervention group patients with at least 1 of 12 medical conditions using prestudy health claims; 126 comparison group patients with hypertension and 126 patients with hyperlipidemia were selected among 9 clinics without MTM services for HEDIS analysis.

INTERVENTION: MTM services provided by pharmacists to BlueCross BlueShield health plan beneficiaries in collaboration with primary care providers.

MAIN OUTCOME MEASURES: Drug therapy problems resolved; percentage of patients' goals of therapy achieved and meeting HEDIS measures for hypertension and hypercholesterolemia. Total health expenditures per person were measured for a 1-year period before and after enrolling patients in MTM services.

RESULTS: 637 drug therapy problems were resolved among 285 intervention patients, and the percentage of patients' goals of therapy achieved increased from 76% to 90%. HEDIS measures improved in the intervention group compared with the comparison group for hypertension (71% versus 59%) and cholesterol management (52% versus 30%). Total health expenditures decreased from $11,965 to $8,197 per person (n = 186, P < 0.0001). The reduction in total annual health expenditures exceeded the cost of providing MTM services by more than 12 to 1.

CONCLUSION: Patients receiving face-to-face MTM services provided by pharmacists in collaboration with prescribers experienced improved clinical outcomes and lower total health expenditures. Clinical outcomes of MTM services have chronic care improvement and value-based purchasing implications, and economic outcomes support inclusion of MTM services in health plan design.

Ledger S, Choma G. **Medication reconciliation in hemodialysis patients**. *CANNT J 2008;18(4):41-3.*

Abstract: Medication reconciliation is an effective process to reduce adverse drug events (ADEs) and harm associated with the loss of medication information as patients transfer between health care settings. Patients with end stage renal disease (ESRD) are at a high risk of experiencing drug-related problems (DRPs) because they take many medications, have multiple comorbidities, and require frequent medication changes. We evaluated the potential impact of medication reconciliation and optimization in the ambulatory care setting at the time of patient transfer from an in-centre dialysis unit to a satellite dialysis unit. Overall, 15 patients (78.8%) had at least one unintended medication variance. The majority of unintended variances (56%) were caused by the physician/nurse practitioner (NP) omitting an order for medication that the patient was taking. In this small study, medication reconciliation was effective at identifying and rectifying medication errors and optimizing pharmacotherapy at the time of transfer from an in-centre hemodialysis to a satellite dialysis unit.

Lindberg M, Lindberg P, Wikström B**. Medication discrepancy: A concordance problem between dialysis patients and caregivers**. *Scand J Urol Nephrol 2007;41(6):546-52 doi: 10.1080/00365590701421363.*

Abstract: Objectives. Extensive drug utilization, and non-concordance between the patient and the caregiver about prescriptions and actual medicine intake, are associated with the risk of non-adherence to medication as well as medication-related illness. To achieve reliable estimates of drug use, it is important to consider the patient's self-reported drug utilization as well as to consult his/her medical record. The present multicentre study was conducted with the aim of examining the self-reported drug consumption of dialysis patients and its congruence with medical records. Material and methods. Consumption of pharmaceutical agents was recorded by 204 patients undergoing haemo- or peritoneal dialysis at 10 Swedish clinics. Drug record discrepancies were identified by comparing the self-reported use of prescribed medicines with the subsequently obtained medication lists. Results. The median drug intake was 11 prescribed medicines and by including on-demand drugs this increased to 12. Discrepancies between the self-reported use of prescribed drugs and the medical record were prevalent in 80.4% of cases, with a median of three discrepancies per patient. Conclusions. Dialysis patients have an extensive need for medication but there is an undesirable deviation between consumption and prescription. A single medication list, accessible for the patient and for all prescribers, is a possible solution to achieve concordance but other measures, such as analysis of the reasons for discrepancy and tailored measures, would also benefit concordant medicine-taking.

Manley HJ, Cannella CA, Bailie GR, St Peter WL. **Medication-related problems in ambulatory hemodialysis patients: a pooled analysis**. *Am J Kidney Dis 2005;46(4):669-80 doi: 10.1053/j.ajkd.2005.07.001.*

Abstract: BACKGROUND: Medication-related problems are common in hemodialysis (HD) patients. These patients often require 12 medications to treat 5 to 6 comorbid conditions. Medication-related problem research reports cannot be generalized to the entire HD population

because data are obtained from single centers and limited numbers of patients. We conducted a pooled analysis to gain additional insight into the frequency, type, and severity of medication-related problems and extrapolated the data to the entire US HD population. METHODS: Articles were identified through a MEDLINE search (1962 to March 2004). Seven studies were included in the analysis. Medication-related problems were categorized into the following 9 categories: indication without drug therapy, drug without indication, improper drug selection, subtherapeutic dosage, overdosage, adverse drug reaction, drug interaction, failure to receive drug, and inappropriate laboratory monitoring. A medication-related problem appearance rate was determined. RESULTS: We identified 1,593 medication-related problems in 395 patients (51.2% men; age, 52.4 +/- 8.2 years; 42.7% with diabetes). The most common medication-related problems found were inappropriate laboratory monitoring (23.5%) and indication without drug therapy (16.9%). Dosing errors accounted for 20.4% of medication-related problems (subtherapeutic dosage, 11.2%; overdosage, 9.2%). The medication-related problem appearance rate was 5.75e(-0.37x), where x equals number of months of follow-up (P = 0.02). CONCLUSION: HD patients experience ongoing medication-related problems. Reduction in medication-related problems in dialysis patients may improve quality of life and result in decreased morbidity and mortality. Pharmacists are uniquely trained to detect and manage medication-related problems. Pharmacists should be an integral member of the dialysis health care team.

Manley HJ, Carroll CA. **The clinical and economic impact of pharmaceutical care in end-stage renal disease patients**. *Semin Dial 2002;15(1):45-9.*

Abstract: End-stage renal disease (ESRD) patients are medically complex, require multiple medications for treatments of their various comorbidities, and cost the healthcare system billions of dollars each year. These patients are at risk of drug-related problems (DRPs) that may lead to increased morbidity, mortality, and cost to the healthcare system. Review of the literature demonstrates that pharmaceutical care provided by pharmacists improves ESRD patient care. Pharmacist review of ESRD patients' medication profiles and medical records has shown to be beneficial in identifying and resolving DRPs. Economic analysis suggests that for every $1 spent on pharmaceutical care, the healthcare system saves an estimated $3.98. Provision of pharmaceutical care by pharmacists should be consdiered for all ESRD patients.

Manley HJ, Drayer DK, McClaran M, Bender W, Muther RS. **Drug record discrepancies in an outpatient electronic medical record: frequency, type, and potential impact on patient care at a hemodialysis center**. *Pharmacotherapy 2003;23(2):231-9.*

Abstract: BACKGROUND: Patients who require hemodialysis take many drugs. Electronic drug records may be discrepant with what patients are actually taking. Record discrepancies are a potential source of drug-related problems. We sought to determine the extent to which drug record discrepancies occur in a hemodialysis population. METHODS: This was a prospective observational study of patients enrolled in a pharmacist clinic at an outpatient hemodialysis center from August-December 2001. Patients participated in monthly drug interviews conducted

by a pharmacist, during which patient drug use was determined. Data collected consisted of patient demographics, drug type, and number of drugs. Drug record discrepancies were classified and assigned a potential drug-related problem. Results were compared with the electronic drug record. Patients with documented drug record discrepancies were compared with those patients for whom no discrepancy was identified. RESULTS: Over the 5-month period, 215 drug interviews were conducted in 63 patients. One hundred thirteen drug record discrepancies were identified in 38 patients (60%). Discrepancies (mean +/- SD 1.7 +/- 1.3, range 1-7) were identified during 65 drug interviews (30.2%). Electronic drug records were discrepant by one drug record, two drug records, and more than two drug records 60.0%, 26.2%, and 13.8% of the time, respectively. Drug record discrepancies placed patients at risk for adverse drug events and dosing errors in 49.6% and 34.5%, respectively, of 113 discrepancies. Patient age negatively correlated with the number of drug record discrepancies identified (r = -0.27, p = 0.04). CONCLUSIONS: Drug record discrepancies occur frequently among patients undergoing hemodialysis. Incorporation of a pharmacist into the patient care team may increase the accuracy of the electronic drug record and avert unnecessary drug-related problems.

Mason NA. **Polypharmacy and medication-related complications in the chronic kidney disease patient**. *Curr Opin Nephrol Hypertens 2011;20(5):492-7 doi: 10.1097/MNH.0b013e328349c261.*

Abstract: PURPOSE OF REVIEW: Medication-related problems are very common in patients with chronic kidney disease (CKD). Identification, prevention and management of these problems require a comprehensive, interdisciplinary approach. This article reviews the recent literature regarding medication-related problems in CKD and proposes initiatives for addressing these problems through a structured review process and use of patient-centered adherence-promoting strategies. RECENT FINDINGS: Pharmacist-conducted medication review and intervention programs are successful at identifying and resolving medication-related problems in CKD patients. These programs are associated with a reduction in the number of medications and frequency of hospitalization, and are associated with maintenance of quality of life. However, adherence continues to be a major medication-related problem in CKD care. SUMMARY: Structured medication review and assessment of adherence assist in identification and resolution of medication-related problems in CKD. More research is needed on successful methods to improve medication adherence and related health outcomes.

Mason NA, Bakus JL. **Strategies for reducing polypharmacy and other medication-related problems in chronic kidney disease**. *Semin Dial 2010;23(1):55-61 doi: 10.1111/j.1525-139X.2009.00629.x.*

Abstract: Medication-related problems are very common in patients with chronic kidney disease (CKD). These problems are often avoidable and can result in detrimental patient consequences and high financial costs. Despite these risks, it is often medically necessary to prescribe multiple medications to treat the comorbid conditions that accompany CKD. In addition, patients' use of nonprescription medications and changes in pharmacokinetic and pharmacodynamic parameters may further contribute to medication-related problems in CKD, including drug interactions and the need for dosage adjustments. A structured medication assessment process

is one approach to reducing the risks associated with medication-related problems. This multifaceted process involves a comprehensive medication history interview, structured therapy assessment, and open communication between members of the medical team. A detailed description of this process is provided to aid healthcare providers in addressing this important issue.

Mirkov S**. Implementation of a pharmacist medication review clinic for haemodialysis patients**. *N Z Med J 2009;122(1297):25-37.*

Abstract: AIMS: To implement the Pharmacist Medication Review Clinic and establish a sustainable clinical pharmacy service. METHODS: Prospective clinical medication review conducted by trained clinical pharmacists using standardised tools. Pharmacists' intervention included medication recommendation and patient education. RESULTS: From December 2007 to July 2008, medication reviews were conducted with 64 haemodialysis patients. Patients were taking on average 13 medications. Drug-related problems (DRPs) were identified in 92% of medication reviews (a total of 278 DRPs). The major DRP was non-adherence with medication regimen (33%), followed by medication requiring dose decrease (9.3%) and indication requiring new medication (8.6%). The risk factors for multiple DRPs were ethnicity, length of time on dialysis and age. New Zealand (NZ) Maori and Pacific Peoples were more likely to have more than three DRPs compared to patients of European descent. (NZ Maori: OR 7.49, 95%CI 1.15-48.9, p=0.035; Pacific Peoples: OR 5.4, 95%CI 0.96-30.34, p=0.055) and patients who spent 3.5 to 6.3 years on dialysis (OR 7.48, 95%CI 1.45-38.76, p=0.016). Patients older than 55 were less likely to have more than three DRPs compared to younger patients (OR 0.14, 95%CI 0.03-0.69, p=0.016). CONCLUSIONS: Pharmacist-led medication review clinic identified drug-related problems (DRPs) and risk factors for DRPs in haemodialysis patients.

Najafzadeh M, Schnipper JL, Shrank WH, Kymes S, Brennan TA, Choudhry NK. **Economic value of pharmacist-led medication reconciliation for reducing medication errors after hospital discharge.** *Am J Manag Care. 2016 Oct;22(10):654-661.*

Abstract OBJECTIVES: Medication discrepancies at the time of hospital discharge are common and can harm patients. Medication reconciliation by pharmacists has been shown to prevent such discrepancies and the adverse drug events (ADEs) that can result from them. Our objective was to estimate the economic value of non-targeted and targeted medication reconciliation conducted by pharmacists and pharmacy technicians at hospital discharge versus usual care.

STUDY DESIGN: Discrete-event simulation model.

METHODS: We developed a discrete-event simulation model to prospectively model the incidence of drug-related events from a hospital payer's perspective. The model assumptions were based on data published in the peer-reviewed literature. Incidences of medication discrepancies, preventable ADEs, emergency department visits, re-hospitalizations, costs, and net benefit were estimated.

RESULTS: The expected total cost of preventable ADEs was estimated to be $472 (95% credible interval [CI], $247-$778) per patient with usual care. Under the base-case assumption that

medication reconciliation could reduce medication discrepancies by 52%, the cost of preventable ADEs could be reduced to $266 (95% CI, $150-$423), resulting in a net benefit of $206 (95% CI, $73-$373) per patient, after accounting for intervention costs. A medication reconciliation intervention that reduces medication discrepancies by at least 10% could cover the initial cost of intervention. Targeting medication reconciliation to high-risk individuals would achieve a higher net benefit than a nontargeted intervention only if the sensitivity and specificity of a screening tool were at least 90% and 70%, respectively.

CONCLUSIONS: Our study suggests that implementing a pharmacist-led medication reconciliation intervention at hospital discharge could be cost saving compared with usual care.

Pai AB, Boyd A, Chavez A, Manley HJ. **Health-related quality of life is maintained in hemodialysis patients receiving pharmaceutical care: a 2-year randomized, controlled study**. *Hemodial Int 2009;13(1):72-9 doi: 10.1111/j.1542-4758.2009.00328.x.*

Abstract: End-stage renal disease and initiation of hemodialysis (HD) adversely affect health-related quality of life (HRQOL). There are currently no data evaluating the effect of pharmaceutical care (PC) on HRQOL in HD patients. HD patients were randomized to receive PC; one-on-one, in-depth medication reviews conducted by a clinical pharmacist or Standard of Care (SOC); and brief medication reviews conducted by dialysis nurses. The renal quality of life profile (RQLP) was administered at baseline and then at 1 and 2 years after study initiation. The RQLP is a 43-item questionnaire that has 5 dimensions: Eating/Drinking, Physical Activities, Leisure Time, Psychosocial Activities, and Impact of Treatment, where increasing scores reflect worsening of HRQOL. A total of 107 patients were enrolled (SOC: n=46; PC: n=61). Besides gender, there were no differences in the demographics or the baseline total RQLP scores. The mean+/-SD total RQLP scores at Year 1 were significantly worse in SOC compared with PC (88+/-31 vs. 71+/-34, respectively; P=0.03). Significant worsening of Eating and Drinking (5.9+/-3.3 vs. 4.4+/-3.1, respectively; P=0.04), Physical Activities (37+/-13.6 vs. 30+/-16.3, respectively; P=0.04), and Leisure Time scores (8.3+/-3.4 vs. 5.9+/-3.6, respectively; P=0.03) was also observed in the SOC group. After 2 years, only the SOC patients had worsening of Leisure Time (7.5+/-3.0 vs. 5.2+/-3.9, respectively; P=0.04). No other parameters were different between the groups after 2 years. These data indicate that patients who have clinical care provided by pharmacists do not have worsened HRQOL after 1 year and are able to maintain HRQOL for an additional year.

Pai AB, Boyd A, Depczynski J, Chavez IM, Khan N, Manley H. **Reduced drug use and hospitalization rates in patients undergoing hemodialysis who received pharmaceutical care: a 2-year, randomized, controlled study**. *Pharmacotherapy 2009;29(12):1433-40 doi: 10.1592/phco.29.12.1433.*

Abstract: STUDY OBJECTIVE: To investigate the impact of a pharmaceutical care program managed by clinical pharmacists on drug use, drug costs, hospitalization rates, and drug-related problems (DRPs) in ambulatory patients undergoing hemodialysis. DESIGN: Prospective,

randomized, controlled, longitudinal, 2-year pilot study. SETTING: Nonprofit university-affiliated dialysis clinic. PATIENTS: One hundred four patients older than 18 years with end-stage renal disease (ESRD) who were undergoing a stable hemodialysis regimen for at least 3 months. INTERVENTION: Patients were randomly assigned to receive either pharmaceutical care, consisting of one-on-one care, with in-depth drug therapy reviews conducted by a clinical pharmacist (57 patients), or standard of care, consisting of brief drug therapy reviews conducted by a nurse (47 patients). MEASUREMENTS AND MAIN RESULTS: Baseline data on demographic and clinical characteristics were collected. Mean numbers of concomitant drugs, drug costs, hospitalization rates, and lengths of stay were compared between the groups. In the pharmaceutical care group, DRPs were identified and recorded. Baseline age, length of time receiving hemodialysis, and etiology of ESRD were not significantly different between the groups. Mean number of concomitant drugs at baseline was similar between the groups. At the end of the 2-year follow-up, pharmaceutical care was associated with a significant decrease of 14% fewer drugs compared with standard of care, as documented during each drug therapy review ($p<0.05$). There were significantly fewer all-cause hospitalizations among patients assigned to pharmaceutical care compared with those receiving standard of care (mean +/- SD 1.8 +/- 2.4 vs 3.1 +/- 3 hospitalizations, $p=0.02$), and the cumulative time hospitalized was shorter in the pharmaceutical care group compared with the standard of care group (9.7 +/- 14.7 vs 15.5 +/- 16.3 days, $p=0.06$). During the study period, 530 DRPs were identified and resolved. CONCLUSION: Identification and resolution of DRPs through pharmaceutical care resulted in decreased drug use and costs for patients undergoing hemodialysis. Hospitalization rates were significantly lower in the pharmaceutical care group, with a trend toward shorter duration. Provision of pharmaceutical care is associated with tangible benefits on outcomes in ambulatory patients undergoing hemodialysis and should be considered in health care policy decisions.

Pai AB, Cardone KE, Manley HJ, et al. **Medication reconciliation and therapy management in dialysis-dependent patients: need for a systematic approach**. *Clin J Am Soc Nephrol 2013;8(11):1988-99 doi: 10.2215/CJN.01420213.*

Abstract: Patients with ESRD undergoing dialysis have highly complex medication regimens and disproportionately higher total cost of care compared with the general Medicare population. As shown by several studies, dialysis-dependent patients are at especially high risk for medication-related problems. Providing medication reconciliation and therapy management services is critically important to avoid costs associated with medication-related problems, such as adverse drug events and hospitalizations in the ESRD population. The Medicare Modernization Act of 2003 included an unfunded mandate stipulating that medication therapy management be offered to high-risk patients enrolled in Medicare Part D. Medication management services are distinct from the dispensing of medications and involve a complete medication review for all disease states. The dialysis facility is a logical coordination center for medication management services, like medication therapy management, and it is likely the first health care facility that a patient will present to after a care transition. A dedicated and adequately trained clinician, such

as a pharmacist, is needed to provide consistent, high-quality medication management services. Medication reconciliation and medication management services that could consistently and systematically identify and resolve medication-related problems would be likely to improve ESRD patient outcomes and reduce total cost of care. Herein, this work provides a review of available evidence and recommendations for optimal delivery of medication management services to ESRD patients in a dialysis facility-centered model.

Parker WM, Jang SM, Muzzy JD, Cardone KE**. Multidisciplinary views toward pharmacist-delivered medication therapy management services in dialysis facilities**. *J Am Pharm Assoc (2003) 2015;55(4):390-7 doi: 10.1331/JAPhA.2015.14168.*

Abstract: OBJECTIVE: To determine views of staff of dialysis centers toward pharmacist-delivered medication therapy management (MTM) services. DESIGN: Focus group study. SETTING: Three private, nonprofit, outpatient dialysis facilities. PARTICIPANTS: Multidisciplinary dialysis staff. INTERVENTION: Two focus group sessions were conducted using a semistructured interview guide. MAIN OUTCOME MEASURES: Views of staff toward MTM services at a dialysis center. RESULTS: A total of 13 staff members of dialysis centers participated in the study. Participants included nurses, patient care technicians, a social worker, dietitian, and administrative personnel. Key themes included: the need for access to MTM services in dialysis facilities exists; services should include medication reconciliation and patient education; services should be proactive, consistent, individualized, and covered by insurance; and that pharmacists are uniquely suited to provide MTM services. CONCLUSION: Dialysis staff support the integration of MTM services in facilities. Further research is needed to identify barriers and opportunities in the implementation process, including patient perspectives.

Patricia NJ, Foote EF. **A pharmacy-based medication reconciliation and review program in hemodialysis patients: a prospective study**. *Pharm Pract (Granada) 2016;14(3):785 doi: 10.18549/PharmPract.2016.03.785.*

Abstract: BACKGROUND: Hemodialysis (HD) patients are on multiple medications, see many prescribers and have many hospitalizations which put them at risk for medication record discrepancies and medication related problems (MRP). Being able to effectively identify and reconcile these medication issues is crucial in reducing hospitalizations, morbidities, and mortalities. The care of the hemodialysis patients can be enhanced by incorporating a pharmacist into the interprofessional team. There is little data in the literature on medication record discrepancies and MRP's in dialysis patients. OBJECTIVE: The objectives of this research were to determine the types of medication discrepancies and MRPs in dialysis patients and if recommendations for changes based on these findings were accepted by providers. METHODS: Patients were asked to bring medications to the dialysis unit for review. Discrepancy and MRP recommendations were communicated to the unit staff via written progress notes. A follow-up was performed an average of 33 days later to determine if the recommendations were accepted. RESULTS: Overall, in 93 unique patients, 376 discrepancies (3.1 per patient) and 64 MRPs (0.5 per patient) were identified. The most common type of discrepancy and MRP was

drug omission and indication without drug, respectively. Of the total 440 interventions, 77% were ultimately accepted. Discrepancies were more likely to be accepted as compared to MRPs (85% vs. 27%, respectively). CONCLUSION: Medication record discrepancies and MRPs are common in dialysis patients. Recommendations related to discrepancies were more likely to be accepted by the providers as compared to MRPs. Medication records became inaccurate within 12 months. A pharmacy-based medication reconciliation and review program may have an important impact on the care of hemodialysis patients.

Salgado TM, Moles R, Benrimoj SI, Fernandez-Llimos F. **Exploring the role of pharmacists in outpatient dialysis centers: a qualitative study of nephrologist views**. *Nephrol Dial Transplant 2013;28(2):397-404 doi: 10.1093/ndt/gfs436.*

Abstract: BACKGROUND: Implementation of pharmacy services in dialysis centers seems to be limited and requires acceptance from nephrologists. The aim of this study was to explore the opinions of Australian and Portuguese nephrologists toward a potential future provision of clinical pharmacy services in outpatient dialysis centers. METHODS: A qualitative study using semistructured interviews was conducted with a purposeful sample of 7 Australian and 14 Portuguese nephrologists. The audiotaped interviews were transcribed verbatim and thematically analyzed. RESULTS: Three themes emerged from the analysis: 'attitudes of nephrologists towards pharmacist involvement', 'types of pharmacy services' and 'consequences of implementation of pharmacy services'. Australian nephrologists showed positive attitudes and reported several pharmacy services that could be performed by pharmacists in dialysis centers, whereas Portuguese nephrologist views restricted pharmacists to administrative duties. In addition, Portuguese nephrologists showed concerns with professional boundaries and demonstrated lack of awareness and knowledge of pharmacist skills. Pharmacy services suggested by Australian nephrologists included medication review, medication reconciliation, medication history update, patient and staff education, patient compliance improvement and development and implementation of anemia protocols. Nephrologists expected economic benefits from the services implementation by minimizing the inappropriate use of drugs, avoiding medication errors, and reducing drug wastage due to noncompliance. CONCLUSIONS: Australian and Portuguese nephrologists hold different views regarding the future provision of pharmacy services in outpatient dialysis centers. Acceptability seems to be related to a previous acquaintance with pharmacists and pharmacy services. Different health policies in the two countries that promote collaborative practice between physicians and pharmacists may also account for the differences.

Stemer G, Lemmens-Gruber R**. Clinical pharmacy activities in chronic kidney disease and end-stage renal disease patients: a systematic literature review.** *BMC Nephrol. 2011; Jul 22;12:35. doi: 10.1186/1471-2369-12-35.*

Abstract BACKGROUND: Chronic kidney disease (CKD) and end-stage renal disease (ESRD) represent worldwide health problems with an epidemic extent. Therefore, attention must be given to the optimization of patient care, as gaps in the care of CKD and ESRD patients are well documented. As part of a multidisciplinary patient care strategy, clinical pharmacy services have

led to improvements in patient care. The purpose of this study was to summarise the available evidence regarding the role and impact of clinical pharmacy services for these patient populations.

METHODS: A literature search was conducted using the Medline, Embase and International Pharmaceutical Abstracts databases to identify relevant studies on the impact of clinical pharmacists on CKD and ESRD patients, regarding disease-oriented and patient-oriented outcomes, and clinical pharmacist interventions on drug-related problems.

RESULTS: Among a total of 21 studies, only four (19%) were controlled trials. The majority of studies were descriptive (67%) and before-after studies (14%). Interventions comprised general clinical pharmacy services with a focus on detecting, resolving and preventing drug-related problems, clinical pharmacy services with a focus on disease management, or clinical pharmacy services with a focus on patient education in order to increase medication knowledge. Anaemia was the most common comorbidity managed by clinical pharmacists, and their involvement led to significant improvement in investigated disease-oriented outcomes, for example, haemoglobin levels. Only four of the studies (including three controlled trials) presented data on patient-oriented outcomes, for example, quality of life and length of hospitalization. Studies investigating the number and type of clinical pharmacist interventions and physician acceptance rates reported a mean acceptance rate of 79%. The most common reported drug-related problems were incorrect dosing, the need for additional pharmacotherapy, and medical record discrepancies.

CONCLUSIONS: Few high-quality trials addressing the benefit and impact of clinical pharmacy services in CKD and ESRD patients have been published. However, all available studies reported some positive impact resulting from clinical pharmacist involvement, including various investigated outcome measures that could be improved. Additional randomised controlled trials investigating patient-oriented outcomes are needed to further determine the role of clinical pharmacists and the benefits of clinical pharmacy services to CKD and ESRD patients.

St Peter WL. **Improving medication safety in chronic kidney disease patients on dialysis through medication reconciliation**. *Adv Chronic Kidney Dis 2010;17(5):413-9 doi: 10.1053/j.ackd.2010.06.001.*

Abstract: Patients with chronic kidney disease on dialysis are prescribed an average of 10 to 12 medications. Most hemodialysis patients encounter health care professionals 3 times a week, and peritoneal dialysis patients at least once a quarter; however, medication-related problems continue to be present in large numbers. A significant proportion of medication-related problems in hospitalized dialysis patients have been attributed to a medical information gap that occurs during transitions between healthcare settings. Information regarding the effect of medication reconciliation on the rates of medication-related errors and outcomes of dialysis patients is sparse. Information from hospital-based medication reconciliation programs suggests that dedicated multidisciplinary medication reconciliation teams using electronic or paper-based medication reconciliation tools can work to reduce medication errors and rates of rehospitalization. The dialysis center staff has intimate knowledge of patient medical histories, comorbid conditions, and dialysis-related medications; dialysis center practitioners are known to

often prescribe other routine medications for patients undergoing dialysis. Therefore, the dialysis center is the most logical place for carrying out medication reconciliation. Data necessary for medication review and reconciliation, and data on the dialysis team's role in reconciling information after care transitions, have been outlined. Reducing medication errors through a systematic multidisciplinary approach may ultimately reduce hospitalization rates. Adequately powered trials are necessary to demonstrate that medication reconciliation can improve dialysis patient outcomes and cost.

St Peter WL**. Management of Polypharmacy in Dialysis Patients**. *Semin Dial 2015;28(4):427-32 doi: 10.1111/sdi.12377.*

Abstract: Most patients receiving dialysis have other common chronic conditions in addition to end-stage renal disease, including hypertension, diabetes, cardiovascular disease, and mineral and bone disorder, all of which require long-term medication management. Dialysis patients take an average of 10-12 prescribed and over-the-counter medications from an average of 4.7 prescribers, and an average of 19 pills per day. Thus, reducing polypharmacy is not adequate as a medication therapy goal for these patients. Instead, the dialysis community should focus on ensuring that all patients receive medications that are appropriate, effective, safe and convenient. Barriers to this include a fragmented health care system with inadequate communication between multiple prescribers and pharmacies, and frequent care transitions between ambulatory care sites (dialysis centre, ambulatory primary care practice, ambulatory specialty practice) and the hospital, skilled nursing facility or long-term care facility. Three distinct processes are necessary to prevent and solve the resultant medication-related problems (and reduce polypharmacy). These are medication reconciliation (creating an accurate medication list that reflects all medications the patients is taking and how they are being taken), medication review (evaluating the list for appropriateness, effectiveness, safety and convenience in conjunction with the patient's health status), and ongoing patient-centred medication therapy management (e.g., developing treatment plans centred on each patient's medication-related goals). A team approach including pharmacists as part of the dialysis team with the dialysis facility as the primary medication home is needed.

St Peter WL, Wazny LD, Patel UD. **New models of chronic kidney disease care including pharmacists: improving medication reconciliation and medication management**. *Curr Opin Nephrol Hypertens 2013;22(6):656-62 doi: 10.1097/MNH.0b013e328365b364.*

Abstract: PURPOSE OF REVIEW: Patients with chronic kidney disease (CKD) 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-centred 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.

Weinhandl ED, Arneson TJ, St Peter WL. **Clinical outcomes associated with receipt of integrated pharmacy services by hemodialysis patients: a quality improvement report**. *Am J Kidney Dis 2013;62(3):557-67 doi: 10.1053/j.ajkd.2013.02.360.*

Abstract: BACKGROUND: Reducing medication-related problems and improving medication adherence in hemodialysis patients may improve clinical outcomes. In 2005, a large US dialysis organization created an integrated pharmacy program for its patients. We aimed to compare the outcomes of hemodialysis patients enrolled in this program and matched control patients. STUDY DESIGN: Quality improvement report. SETTING & PARTICIPANTS: Hemodialysis patients with concurrent Medicare and Medicaid eligibility who chose to receive program services and propensity score-matched controls; the propensity score was an estimated function of demographic characteristics, comorbid conditions, medication exposure, serum concentrations, and vascular access method. QUALITY IMPROVEMENT PLAN: Program services included medication delivery, refill management, medication list reviews, telephonic medication therapy management, and prior authorization assistance. OUTCOMES: Relative rates of death and hospitalization. MEASUREMENTS: Survival estimates calculated with the Kaplan-Meier method; mortality hazards compared with Cox regression; hospitalization rates compared with Poisson regression. RESULTS: In outcome models, there were 8,864 patients receiving integrated pharmacy services and 43,013 matched controls. In intention-to-treat and as-treated analyses, mortality HRs for patients receiving integrated pharmacy services versus matched controls were 0.92 (95% CI, 0.86-0.97) and 0.79 (95% CI, 0.74-0.84), respectively. Corresponding relative rates of hospital admissions were 0.98 (95% CI, 0.95-1.01) and 0.93 (95% CI, 0.90-0.96), respectively, and of hospital days, 0.94 (95% CI, 0.90-0.98) and 0.86 (95% CI, 0.82-0.90), respectively. Cumulative incidences of disenrollment from the pharmacy program were 23.4% at 12 months and 37.0% at 24 months. LIMITATIONS: Patients were not randomly assigned to receive integrated pharmacy services; as-treated analyses may be biased because of informative censoring by disenrollment from the pharmacy program; data regarding use of integrated pharmacy services were lacking. CONCLUSIONS: Receipt of integrated pharmacy services was associated with lower rates of death and hospitalization in hemodialysis patients with concurrent Medicare and Medicaid eligibility. Studies are needed to measure pharmacy program use and assess detailed clinical and economic outcomes.

Weir MR, Fink JC. **Safety of medical therapy in patients with chronic kidney disease and end-stage renal disease.** *Curr Opin Nephrol Hypertens. 2014 May; 23 (3):306-13. doi: 10.1097/01.mnh.0000444912.40418.45.*

Abstract PURPOSE OF REVIEW: Maintaining patient safety is a necessary step to improve healthcare delivery. Patients with chronic kidney disease (CKD) and end-stage renal disease (ESRD) have an increased frequency of adverse safety events largely because of medication errors.

RECENT FINDINGS: CKD and ESRD have several features which threaten patient safety. Reduced glomerular filtration rate affects the clearance of many medications and is also associated with several comorbidities such as diabetes, cardiovascular disease, metabolic bone disease, and anemia. These comorbidities of CKD often increase the complexity of treatment regimens. Patients with ESRD, requiring dialysis or transplantation, have an even greater potential for adverse safety events because of the reliance on renal replacement modalities and the frequent requirements of polypharmacy and potential drug-drug interactions.

SUMMARY: There is an important need to develop strategies to provide inpatient and outpatient management plans to limit the risk of adverse medication errors across a wide range of educational and socioeconomic backgrounds, and a critical need to develop a uniform set of standards for evaluating patient safety in CKD and ESRD as well as appropriate descriptions of the prototypical safety profiles of patients who have CKD, a kidney transplant, or who are on dialysis.

Medication Reconciliation and Management Technical Expert Panel

July 19, 2017

Agenda

8:00 – 8:30	Introductions and COI Disclosure; Overview of objectives for the day
8:30 – 10:15	Measure focus: reconciliation vs. management -- Definition: review, reconciliation, management -- Components of reconciliation and management Potential measure concepts
10:15 – 10:30	BREAK
10:30 – 12:00	Identify candidate measure concepts
12:00 – 1:00	LUNCH

Agenda

1:00 – 3:00	Discussion of measure details
	All medications vs. specific medications
	Measure perspective: facility, patient, others
	Timing / Frequency of measure
	Staff that can perform measure tasks
	Data Sources
	Cost/Burden of measure
	Risk adjustment / Exclusions
	Validity of measure
3:00 – 3:15	BREAK

Agenda

3:15 – 3:45	Wrap-up and Summary of Recommendations Next Steps
3:45 – 4:00	Public Comment Period

TEP Members

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Jane Davis, DNP, CRNP Nurse Practitioner	Division of Nephrology University of Alabama Birmingham Birmingham, AL	Yes, Speaker's bureau for Amgen
Richard Faris, PhD MSc RPh Vice President Clinical Strategy and Services	DaVita Rx Denver, CO	Yes, Employed by DaVita Rx
Renee Garrick, M.D., FACP Executive Medical Director Medical Director, Dialysis Services	Westchester Medical Center Valhalla, New York Dialysis Clinic, Inc, Bradhurst Dialysis	None

TEP Members

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Jeffrey Hymes, MD Sr. Vice President, Chief Medical Officer, Chair Pharmacy and Therapeutics Committee Ambulatory Active Courtesy Staff	Fresenius Medical Services Franklin, TN Centennial Medical Center, Nashville, Tennessee St. Thomas Hospital, Nashville, Tennessee	Yes, employed and shareholder of Fresenius
Justin Iorii Motivational Speaker and Patient/Advocate	Justin's Kidney Inc Las Vegas, NV Dialysis Patient Citizens	
Harold Manley, Pharm.D., FASN, FCCP TEP Chair Director Medication Management & Pharmacovigilance;	Dialysis Clinic, Inc (DCI) Albany, NY	Yes, served on the Kidney Care Quality Alliance Committee that created the NQF measures the TEP will review

TEP Members

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Bill Murray Former self-employee Patient/Advocate	National Kidney Foundation Delaware	None
Amy Pai, Pharm.D., BCPS, FASN, FCCP, FNKF Associate Professor Nephrology Pharmacotherapy Specialist	University of Michigan College of Pharmacy University of Michigan Outpatient Hemodialysis Ann Arbor, MI	None
Nancy Pelfrey, MSN, ACNP-BC, CNN-NP Nurse Practitioner – Virtual Outcomes Manager	Reliant Renal Care Fairview, NC	None

TEP Members

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Maile Robb Patient/Advocate	Forum of ESRD Networks Reno, NV	
Patricia (Patty) Seo-Mayer, Pediatric Nephrologist & Associate Program Director	Inova Fairfax Hospital, Falls Church VA	Consultant for Achillion Pharmaceuticals on limited project: June 2016- May 2017
Wendy St. Peter, Pharm.D. Renal Pharmacist, Professor, Researcher	College of Pharmacy, University of Minnesota Minneapolis, MN	
Tosha Whitley, RN Clinical Director of Quality Initiatives	Northwest Kidney Centers Seattle, WA	

UM-KECC Team

University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) Measure Developer Contractor Staff
Jonathan Segal, MD, *Associate Professor of Nephrology*
Abhijit Naik, MD, *Assistant Professor of Nephrology*
Jian Kang, PhD, *Assistant Professor of Biostatistics*
Xi Wang, MPH, *Research Analyst*
Mimi Dalaly, MPH, *Research Analyst*
Jennifer Sardone, PMP, *Project Manager/ Research Analyst*

Conflicts of Interest

- During the nomination process TEP members are asked to disclose any potential current and past activities that may cause a conflict of interest. If at any time while serving on the TEP, a member's status changes and a potential conflict of interest arises, the TEP member is required to notify the measure developer and the TEP chair.

- Potential for conflicts of interest is not solely a reason to exclude an individual from participation on a TEP, because the membership should also be balanced with applicable points of view and backgrounds. The measure developer should, however, give preference to individuals who will not be inappropriately influenced by any particular special interest

TEP Charter

- Review of existing NQF endorsed measures that incorporate Medication Reconciliation in this or other care settings (e.g. Medication Reconciliation for Patients Receiving Care at Dialysis Facilities, NQF #2988; Medication Reconciliation Post-Discharge (MRP), NQF #0554)
- Examination of data sources and availability
- Consideration of the components of the reconciliation process including frequency that it is performed, providers who are eligible to complete the task, and the necessary steps to do so.
- Consideration of medication management as it relates to the reconciliation process and how that might be incorporated into a measure.
- Develop one or more measures of medication reconciliation and management with attention to any adjustment or exclusion criteria that may be needed and harmonization with existing measures.

Measure Evaluation Criteria

- Evidence:
  - Extent to which the specific measure focus is evidence-based

- Scientific Acceptability:
  - Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care

*National Quality Forum (NQF). "Measure Evaluation Criteria". 2017. Accessed May 17, 2017. http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/Measure_Evaluation_Criteria.aspx

Measure Evaluation Criteria

- Feasibility: Data that are readily available or could be captured without undue burden
- Usability: Stakeholders (e.g., consumers, purchasers, providers, policy makers) can use measure performance results for both accountability and performance improvement
- Comparison to Related or Competing Measures (Harmonization)
  - If there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure

*National Quality Forum (NQF). "Measure Evaluation Criteria". 2017. Accessed May 17, 2017. http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/Measure_Evaluation_Criteria.aspx

Measure Focus

Medication Reconciliation
or
Medication Management

Medication *Reconciliation* ≠ Medication *Management*

The process of *maintaining an accurate medication list* with patient and/or caregiver

- Transitions in care
- Interactions with patients
- Time of initiation or discontinuation medications

Data Recorded

- Rx, OTC, Vitamins, Herbals, Supplements

Opportunity

- Update list of disease state or diagnosis

Professional /clinical *service* by a RPh or qualified HC professional:

- Engage patients
- Ensure appropriate use of medication
- Optimize pharmacological therapy
- Reduce the risk of adverse events
- Improve medication adherence

Service Includes:

- Medication Reconciliation
- Identify Medication-Related Problems
- Recommendations to other health care providers
- Scheduled patient follow up
- Professional documents for patients, HC team & administrators

Potential Measure Concepts

- Reporting of Medication record discrepancy
  - No Longer Taking (taking different from prescribed), not in record, dose change, change in freq.
  - Outcome: % discrepancy
- Time to complete reconciliation
- Post hospitalization medication reconciliation
- Facility provided medication list to patients

Potential Measure Concepts

Lunch

12:00-1:00

Measure	Value	Frequency	What Meds	Responsible party	Deliverable	Measure
Med Recon (list @ point in time what pt is taking)	Yes	Q Qtr; Q transition; Q start Not hospice; not transient	All	RN, Rx Tech, RPh, MD, Adv Prac. Prov.	# & type of discrep & barrier identified flagged on med list (provided to Med Rev resp party)	% pt, % med rec; <8 d to med rec complete post transition, QTR, start
Med Review (approp @point in time taking and what want to take)	Yes	Q qtr; Q transition; Q start Not hospice; not transient	All	RPh, MD, Adv Prac Prov	Document(s?) that lists what pt is *taking* provided to patient **&** what is *prescribed* to take **&** assoc barriers/resolution Give guidance (but attest)	[# pt or # med rev] / opportunity to conduct rev <8 d between transition and med rev complete
Med Mgmt (ongoing – identify MRPs)	yes	TBD - Target meds? High risk? Abx? PolyRx? Beers meds? ESRD must avoid meds? Some freq?		IT to identify – MD, advance prac provider, RPh to resolve	Reports?	Low number better

Med Rec + Rev deliverable attestation – provided med list to patient

Medication	Dose	How prescribed	How taking	comment
Lopressor	100 mg	Twice a day	Once a day	Cannot afford
Sensipar	30 mg	Daily	M, W, F	Makes me nauseous

Measure Details

- All medications vs. specific medications
- Measure perspective: facility, patient, others
- Timing / Frequency of measure
- Staff that can perform measure tasks

Measure Details

- Data Sources
- Cost/Burden of measure
- Risk adjustment / Exclusions
- Validity of measure

Summary of Recommendations

Public Comment

3:45pm – 4:00pm (ET)

Appendix

Existing Measures

Measure Title	Documentation of Current Medications in the Medical Record
Measure Steward	Centers for Medicare & Medicaid Services
Measure Description	Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration
Numerator	Eligible professional attests to documenting, updating, or reviewing a patient´s current medications using all immediate resources available on the date of the encounter.
Denominator	All visits occurring during the 12 month reporting period for patients aged 18 years and older before the start of the measurement period
Exclusions	Patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status.
Risk Adjustment	No
Care Setting	Clinician Office/Clinic
Level of Analysis	Clinician: Individual or group practice
Use in Federal Program	Medicare Physician Quality Reporting System (PQRS), Medicare Shared Savings Program (MSSP), Physician Feedback/Quality and Resource Use Reports (QRUR), Physician Value-Based Payment Modifier (VBM)

NQF #0419

Existing Measures

Measure Title	Care for Older Adults (COA) – Medication Review
Measure Steward	National Committee for Quality Assurance
Measure Description	Percentage of adults 66 years and older who had a medication review during the measurement year; a review of all a patient's medications, including prescription medications, over-the-counter (OTC) medications and herbal or supplemental therapies by a prescribing practitioner or clinical pharmacist.
Numerator	At least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record.
Denominator	All patients 66 and older as of the end (e.g., December 31) of the measurement year.
Exclusions	None
Risk Adjustment	No
Care Setting	Clinician Office/Clinic, Inpatient Rehabilitation Facility, Long Term Acute Care, Nursing Home / SNF
Level of Analysis	Health Plan, Integrated Delivery System
Use in Federal Program	No

NQF #0553

Existing Measures

Measure Title	Antidepressant Medication Management (AMM)
Measure Steward	Centers for Medicare & Medicaid Services
Measure Description	The percentage of patients 18 years of age and older with a diagnosis of major depression and were treated with antidepressant medication, and who remained on an antidepressant medication treatment. Two rates are reported: a) Effective Acute Phase Treatment. The percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b) Effective Continuation Phase Treatment. The percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Numerator	Adults 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment.
Denominator	Patients 18 years of age and older with a diagnosis of major depression and were newly treated with antidepressant medication.
Exclusions	Patients who use hospice services any time during the measurement year. Exclude patients who did not have a diagnosis of major depression in an inpatient, outpatient, ED, intensive outpatient or partial hospitalization setting during the 121-day period from 60 days prior to the IPSD, through the IPSD and the 60 days after the IPSD. Exclude patients who filled a prescription for an antidepressant 105 days prior to the IPSD.
Risk Adjustment	No
Care Setting	Clinician Office/Clinic
Level of Analysis	Health Plan, Integrated Delivery System
Use in Federal Program	Medicaid, Medicare Physician Quality Reporting System (PQRS), Physician Feedback/Quality and Resource Use Reports (QRUR), Physician Value-Based Payment Modifier (VBM), Qualified Health Plan (QHP) Quality Rating System (QRS)

NQF #0105

Existing Measures

Measure Title	Medication Reconciliation Post-Discharge
Measure Steward	National Committee for Quality Assurance
Measure Description	The percentage of discharges for patients 18 years of age and older for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record by a prescribing practitioner, clinical pharmacist or registered nurse.
Numerator	Medication reconciliation conducted by a prescribing practitioner, clinical pharmacist or registered nurse on or within 30 days of discharge. Medication reconciliation is defined as a type of review in which the discharge medications are reconciled with the most recent medication list in the outpatient medical record.
Denominator	All discharges from an in-patient setting for patients who are 18 years and older.
Exclusions	The following exclusions are applicable to the Health Plan Level measure. - Exclude both the initial discharge and the readmission/direct transfer discharge if the readmission/direct transfer discharge occurs after December 1 of the measurement year. - If the discharge is followed by a readmission or direct transfer to an acute or non-acute facility within the 30-day follow-up period, count only the readmission discharge or the discharge from the facility to which the patient was transferred.
Risk Adjustment	No
Care Setting	Clinician Office/Clinic
Level of Analysis	Clinician: Individual, Group/Practice, Health Plan, Integrated Delivery System
Use in Federal Program	Medicare Physician Quality Reporting System (PQRS), Physician Compare, Physician Feedback/Quality and Resource Use Reports (QRUR), Physician Value-Based Payment Modifier (VBM)

NQF #0097

Existing Measures

Measure Title	Medication Reconciliation: Number of Unintentional Medication Discrepancies per Patient
Measure Steward	Brigham and Women´s Hospital
Measure Description	This measure assesses the actual quality of the medication reconciliation process by identifying errors in admission and discharge medication orders due to problems with the medication reconciliation process. The target population is any hospitalized adult patient. The time frame is the hospitalization period.
Numerator	For each sampled inpatient in the denominator, the total number of unintentional medication discrepancies in admission orders plus the total number of unintentional medication discrepancies in discharge orders.
Denominator	The patient denominator includes a random sample of all potential adults admitted to the hospital. Our recommendation is that 25 patients are sampled per month, or approximately 1 patient per weekday.
Exclusions	Patients that are discharged or expire before a gold standard medication list can be obtained.
Risk Adjustment	No
Care Setting	Hospital
Level of Analysis	Facility
Use in Federal Program	No

NQF #2456

Existing Measures

Measure Title	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities
Measure Steward	Kidney Care Quality Alliance (KCQA)
Measure Description	Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional. • "Medication reconciliation" is defined as the process of creating the most accurate list of all home medications that the patient is taking, including name, indication, dosage, frequency, and route, by comparing the most recent medication list in the dialysis medical record to one or more external list(s) of medications obtained from a patient or caregiver (including patient-/caregiver provided "brown bag" information), pharmacotherapy information network (e.g., Surescripts), hospital, or other provider. • For the purposes of medication reconciliation, "eligible professional" is defined as: physician, RN, ARNP, PA, pharmacist, or pharmacy technician.

NQF #2988

Existing Measures

Measure Title	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities
Numerator	Number of patient-months for which medication reconciliation was performed and documented by an eligible professional during the reporting period. The medication reconciliation MUST: • Include the name or other unique identifier of the eligible professional; AND • Include the date of the reconciliation; AND • Address ALL known home medications (prescriptions, over-the-counters, herbals, vitamin/mineral/dietary (nutritional) supplements, and medical marijuana); AND • Address for EACH home medication: Medication name, indication, dosage, frequency, route of administration, start and end date (if applicable), discontinuation date (if applicable), reason medication was stopped or discontinued (if applicable), and identification of individual who authorized stoppage or discontinuation of medication (if applicable); AND • List any allergies, intolerances, or adverse drug events experienced by the patient.

NQF #2988

Existing Measures

Measure Title	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities
Denominator	Total number of patient-months for all patients permanently assigned to a dialysis facility during the reporting period.
Exclusions	In-center patients who receive < 7 hemodialysis treatments in the facility during the reporting month.
Risk Adjustment	No
Care Setting	Dialysis Facility
Level of Analysis	Facility
Use in Federal Program	No

NQF #2988

Medication Related Problems

- Medical indication without drug treatment
- Failure to receive drug
- Suboptimal dose (underdose)
- Overdose
- Drug use without medical indication
- Adverse Drug Reaction
- Drug interaction
- Wrong drug
- Inappropriate laboratory follow up

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ESRD Quality Measure Development, Maintenance, and Support Project
Medical Reconciliation and Management Technical Expert Panel
Conference Call Minutes
June 26, 2017 4:00 – 5:00pm EST

Name	Affiliation
Jane Davis, DNP, CRNP	Division of Nephrology, University of Alabama
Richard Faris, PhD, MSc, RPh	DaVita Rx (through 06/2017)
Renee Garrick, MD FACP	Westchester Medical Center; Dialysis Clinic, Inc.
Jeffrey Hymes, MD	Fresenius Medical Services; Centennial Medical Center
Justin Iorii	Justin's Kidney Inc.; Dialysis Patient Citizens
Harold Manley, Pharm D, FASN, FCCP	Dialysis Clinic Inc.
Bill Murray	National Kidney Foundation
Amy Pai, Pharm D, BCPS, FASN, FCCP	University of Michigan
Nancy Pelfrey MSN, ACNP-BC, CNN-NP	Reliant Renal Care
Maile Robb	Forum of ESRD Networks
Wendy St. Peter, Pharm D	College of Pharmacy, University of Minnesota
Tosha Whitley, RN	Northwest Kidney Centers
Joel Andress	CMS
Elena Balovlenkov	CMS
Jesse Roach	CMS
Abhijit Naik, MD	UM-KECC
Mimi Dalaly, MPH	UM-KECC
Jian Kang, PhD	UM-KECC
Jennifer Sardone, BA, PMP	UM-KECC
Jonathan Segal, MD	UM-KECC
Xi Wang, MPH	UM-KECC

Greeting and Agenda Overview:

a) UM-KECC thanked the TEP members for participating in the measure development process and presented the goals of the meeting agenda.

b) TEP members were reminded that the discussion was open to the public and that the call was being recorded to produce a summary report. Furthermore, it was noted that there would be time for public comment at the end.

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Conflicts of interest:

a) TEP members were reminded that they had filled out a conflict of interest disclosure as part of the application process and that at the in-person meeting there would be an opportunity to present any potential conflicts.

b). Given the potential for the TEP to work together for an extended period of time, members were asked to let UM-KECC know about any changes to potential conflicts of interest that may arise.

Quality Measure Development:

UM-KECC summarized an outline of Quality Measure development process. Briefly, a measure developer like UM-KECC drafts a measure for National Quality Forum (NQF) endorsement and the Centers for Medicare and Medicaid (CMS) selects Measures Under Consideration (MUC) and presents this to the Measures Application Partnership (MAP). MAP includes multiple entities organized through NQF and assists with choosing measures for federal health programs.

Role of Medication Reconciliation and Management TEP:

a). *Role of TEP Members:* TEP members will propose and develop measure concepts, provide information and draft measure specifications, review and approve summary report recommendations, approve final measure specifications, and provide feedback on other documentation required for NQF endorsement. It should be understood that UM-KECC makes recommendations to CMS based on TEP input. Ultimately, it is the responsibility of UM-KECC (measure developer) to explain any variations in the proposed measure from recommendations that the TEP has presented.

b). *Role of UM KECC:* The role of UM KECC is to assist in facilitating discussion and to objectively report on discussions and represent the view of the TEP in the measure development process.

c). *Role of TEP Chair:* Assist in leading discussions, building consensus and gather and focus recommendations from the TEP for measure development. The TEP chair also oversees voting.

Measure Evaluation Criteria:

Five basic domains were presented that are used to evaluate quality measures that are submitted to the National Quality Forum. These include:

i). Evidence, Performance Gap, and Priority (Impact)

ii). Reliability and Validity

iii). Feasibility

iv). Usability

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v). Comparison to Related or Competing Measures: how a proposed measure harmonizes with existing measures

The TEP Charter was reviewed:

a) Review of existing NQF endorsed measures that incorporate Medication Reconciliation in this or other care settings (e.g. Medication Reconciliation for Patients Receiving Care at Dialysis Facilities, NQF #2988; Medication Reconciliation Post-Discharge (MRP), NQF #0554)
b) Examination of data sources and availability
c) Consideration of the components of the reconciliation process including frequency that it is performed, providers who are eligible to complete the task, and the necessary steps to do so.
d) Consideration of medication management as it relates to the reconciliation process and how that might be incorporated into a measure.
e) Develop one or more measures of medication reconciliation and management with attention to any adjustment or exclusion criteria that may be needed and harmonization with existing measures.

Focus topics for discussion were presented including:

a) Incorporation of Medication Management
b) Process vs. Outcome Measure: looking at whether the success of medication reconciliation and management can be detected in hospitalization rates.
c) Perspective: Patient / Facility: Is it possible to create a measure that represents the patient's experience of care.
d) Data Sources: Discussion for sources for data

Discussion/ key points from TEP Members:

a). The group could consider targeting key high-risk medications as an alternative to all medications with the goal towards reducing harm.

b). Appropriate dosing of medications for the level of kidney function should be considered.

c). Dialysis facility staff training for this process was mentioned as an important component that might be included in a measure. The burden on the nursing staff and the education required to complete these tasks was raised for discussion in the setting of limited facility resources.

d). Patient education as part of the medication reconciliation and management process was noted to be important and that the burden should not fall on the facility staff alone.

e). Affordability of medication was brought up as a key reason for why patients may not take medications as prescribed.

f). A TEP member asked whether a medication management measure, similar to one crafted as part of the KCQA measure development process, could be brought forward. UM-KECC confirmed that a

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medication management measure could be considered by the group as a stand-alone concept or be incorporated into a measure that had other components.

g). The differences between a medication list vs medication reconciliation vs medication review were raised and that the challenge will be to create a measure that is not just a "check-box" so that patients can have optimal outcomes.

h). It will be important to look at transitions of care as it relates to data sharing with hospitals, other facilities, nursing homes etc. It was noted that medication changes at hospital discharge are not always communicated effectively to the dialysis facility and patients are not always aware of these changes.

i). Incorporating health information technology as part of the reconciliation process was raised as an important starting point in using multiple sources for the task.

UM-KECC announced that the literature review will be available soon, and if there are any articles that TEP members would like to have added to the collection, please let UM-KECC know.

Public Comment:

a) A brief Public Comment Period was held at the conclusion of the call and no public comments were received.

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ESRD Quality Measure Development, Maintenance, and Support Project
Medical Reconciliation and Management Technical Expert Panel
Conference Call Minutes
July 10, 2017 3:30 – 4:30pm EST

Name	Affiliation
Jane Davis, DNP, CRNP	Division of Nephrology, University of Alabama
Richard Faris, PhD, MSc, RPh	DaVita Rx (through 06/2017)
Renee Garrick, MD FACP	Westchester Medical Center; Dialysis Clinic Inc.
Jeffrey Hymes, MD	Fresenius Medical Services; Centennial Medical Center
Justin Iorii	Justin's Kidney Inc.; Dialysis Patient Citizens
Harold Manley, Pharm D, FASN, FCCP	Dialysis Clinic Inc.
Bill Murray	National Kidney Foundation
Amy Pai, Pharm D, BCPS, FASN, FCCP	University of Michigan
Nancy Pelfrey MSN, ACNP-BC, CNN-NP	Reliant Renal Care
Maile Robb	Forum of ESRD Networks
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Joel Andress	CMS
Elena Balovlenkov	CMS
Abhijit Naik, MD	UM-KECC
Mimi Dalaly, MPH	UM-KECC
Jian Kang, PhD	UM-KECC
Jennifer Sardone, BA, PMP	UM-KECC
Jonathan Segal, MD	UM-KECC
Xi Wang, MPH	UM-KECC

1) Greeting and Agenda Overview:

a) UM-KECC thanked the TEP members for participating in this discussion and presented the goals of the meeting agenda.

b) TEP members were reminded that the discussion was open to the public and that the call was being recorded to produce a summary report. Furthermore, it was noted that there would be time for public comment at the end.

2). Review of Literature:

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The TEP chair gave a framework for the literature review by outlining medication use patterns and medication related issues in ESRD patients, reviewing the differences and similarities of medication management and medication reconciliation, and looking at medication reconciliation and management as it relates specifically to ESRD patients.

The TEP chair summarized medication use and pill burden for ESRD patients, and the different sources of prescribed/non-prescribed medication that patients can take. The differences between medication reconciliation and management were outlined:

Characteristics of Medication Reconciliation [1]

The process of maintaining an accurate medication list with patients and/or caregivers that is performed at care transitions and when medications are initiated/discontinued in addition to other routine patient interactions. This process includes all prescribed medications, over the counter drugs, herbals/supplements. Medication Reconciliation is also an opportune time to maintain an accurate list of problems or diagnoses.

Characteristics of Medication Management:[1]

Medication management is service performed by a pharmacist or other qualified health care professional to engage patients while ensuring appropriate use of medications. This involves optimizing pharmacologic therapy while reducing the risk of adverse events and improving medication adherence. With regards to CMS's medication history elements, *the assessment should demonstrate that all current medications were reviewed for possible adverse effects/ interactions and continued as needed.* [2] This service also includes identifying and resolving any medication related-problems, and making recommendations to other health care providers.

Medication Related Problems (MRPs):

The TEP chair discussed the various medication related problem (MRPs) that can be split up into 9 categories: [3]

1. Medication indication where there is no drug therapy
2. Failure to receive medication (non-adherence, cost)
3. Overdose
4. Under dosing
5. Drug use without indication

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[1] Manley, H. (2017). *Medication Reconciliation and Management Technical Expert Panel Teleconference #2*[PowerPoint slides].
[2] CMS Survey Tool: V506 Immunization history and medication history
[3] American Journal of Kidney Disease 2003; DICP Ann Pharmacotherapy 1990

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6. Adverse drug reactions
7. Adverse drug interactions
8. Wrong drug
9. Inappropriate laboratory follow up

Risk factors for developing medication related problems were discussed. Many patients with ESRD have multiple risk factors for medication related problems such as 3 or more concurrent diseases, multiple medication regimen changes throughout the year, and use of drugs that require therapeutic monitoring. The likelihood of finding at least one medication related problem in these complex patients who have multiple criteria is high.

The TEP chair discussed literature that was a compilation of seven different reports involving various factors associated with medication related problems and their frequency. Two of the most frequent problems were found with inappropriate laboratory monitoring (23.5% of the time) and Indication Without Drugs (IWD) where a patient has a medical problem but is not taking a medication for it (16.9%). Other examples were presented.[4]

Medication Record Discrepancy (MRD)

Medication Record Discrepancies puts patients at risk for adverse outcomes. The TEP chair gave an overview of medication record discrepancies that were categorized and the medication related problems associated with those discrepancies.[5] He described a study from 2016 in which there were 124 medication reconciliations, and of those there were 376 medication discrepancies found, yielding a rate of approximately 3.1 discrepancies per patient.[6]

The TEP chair highlighted communication breakdown as a significant aspect of medication related problems where there are information gaps when care is being transferred between providers. Hospitalizations due to medication related problems are frequent and proactively sharing information between dialysis clinics and other health institutions has been reported to greatly assist with reducing medication record discrepancies and improving patient care.[7]

Medication Therapy Management (MTM):

The TEP chair reviewed the literature indicating that Medication Therapy Management (MTM) can lower medication use, medication costs, and hospitalizations in ESRD patients[8].

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[4] Manley HJ, et al. Am J Kidney Dis, 2005; 46(4):669-80
[5] Manley, HJ. Pharmacotherapy 2003; 23: 231-239
[6] Patricia, NJ., Foote, EF. A pharmacy-based medication reconciliation and review program in hemodialysis patients: a prospective study. *Pharmacy Practice*, 2016 14 (3): 785.
[7] Riley KD, Wazny LD. CANNT J. 2006; 16:24-28; Riley KD, Wazny LD. CANNT J. 2006; 16:24-28
[8] Pai, AB. et al. Reduced drug use and hospitalization rates in patients undergoing hemodialysis who received pharmaceutical care: a 2-year, randomized, controlled study, 2009, *Pharmacotherapy, 29(12): 1433-40.*

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He summarized that medication reconciliation, review, and management process includes assessment of the appropriateness, adherence, accuracy and access of medications.

A TEP member asked if there were any tool-kits that are usable for medication reconciliation; the TEP chair replied that there are Medication Reconciliation tool-kits available and noted one created by the National Forum of ESRD Networks. UM-KECC will amass tool-kits that are available.

Existing Measures:

UM KECC presented a summary of National Quality Forum (NQF) endorsed measures that pertain to aspects of medication reconciliation and management:

1) *Medication Reconciliation for Patients Receiving Care at Dialysis Facilities*[9]*:* This measure is defined as the percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional; the eligible professional is defined as a physician, clinical nurse, physician's assistant, pharmacist or pharmacy technician. The Medication Reconciliation process itself is defined as creating the most accurate list of home medications including the drug name, indication, dosage, frequency etc by comparing the most recent list in the dialysis clinic with one or more external sources. While the drug name is required, other data elements such as dose, frequency, start date etc can be listed as unavailable if the information is unknown. This includes pediatric and adult patients. The denominator is the number of patient-months within the dialysis facility with exclusions.

2) NQF #0419: *Documentation of Current Medication in the Medical Record* [10]*:* percentage of visits for patients (≥ 18 years) in which an eligible professional makes an attestation that they documented current medications, all known prescriptions over the counters, vitamins/herbal medication and nutritional supplements and must have the name, dosage, frequency, and route of administration of the medications

3) NQF #0553, *Care for Older Adults (COA) - Medication Review*[11]*:* Similar to NQF #0419 this measure is focused on the elderly population (≥ 66 years). The measurement includes at minimum one medication review annually by a prescribing practitioner or pharmacist, and the medication list must be included in the patient's medical record.

[9] https://www.qualityforum.org/QPS/2988
[10] https://www.qualityforum.org/QPS/0419
[11] https://www.qualityforum.org/QPS/0553

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4) NQF #0105: *Antidepressant Medication Management (MMW)* [12]*:* In reference to the first Medication Management and Reconciliation call, this measure serve as an example looking at medication measures for targeted indications. Limited to those with a diagnosis of major depression in the adult population; there is a long term and acute phase component.

5) NQF #0097, *Medication Reconciliation Post-Discharge*[13]*:* This measures evaluates the percentage of discharges for adult patients for whom the discharge medication list was reconciled with their current medication list in the outpatient setting by a prescribing practitioner, clinical pharmacist or registered nurse.

6) NQF #2456, *Number of Unintentional Medication Discrepancies per Patient*[14]: This inpatient measure evaluates the quality of the medication reconciliation process by trying to identify errors in the admission or discharge medication orders that would signify underlying problems with the medication reconciliation process. The intention of this measure is to see where errors are occurring in hospitals as a first step towards reducing error rates.

A TEP member asked if there were any measures in this area that were validated for pediatrics. UM-KECC answered there were no pediatric measures found during the environmental scan for medication reconciliation and management.

Another TEP member mentioned a document that is part of the transforming clinical practice initiative and contains a compilation of tested interventions and one was medication reconciliation on transformation of change; the TEP member will send to UM KECC. UM KECC asked if there were any other available resources that the group wanted to share and there were no other comments.

Public Comment: There was no public comment.

[12] https://www.qualityforum.org/QPS/0105
[13] https://www.qualityforum.org/QPS/0097
[14] https://www.qualityforum.org/QPS/2456

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ESRD Quality Measure Development, Maintenance, and Support Project
Medical Reconciliation and Management Technical Expert Panel
Conference Call Minutes
September 25, 2017 3:00 – 4:00pm EST

Name	Affiliation
Jane Davis, DNP, CRNP	Division of Nephrology, University of Alabama at Birmingham
Richard Faris, PhD, MSc, RPh	DaVita Rx (through 06/2017)
Renee Garrick, MD FACP	Westchester Medical Center; Dialysis Clinic, Inc.
Jeffrey Hymes, MD	Fresenius Medical Services; Centennial Medical Center
Harold Manley, Pharm D, FASN, FCCP	Dialysis Clinic Inc.
Bill Murray	National Kidney Foundation
Amy Pai, Pharm D, BCPS, FASN, FCCP	University of Michigan
Nancy Pelfrey MSN, ACNP-BC, CNN-NP	Reliant Renal Care
Maile Robb	Forum of ESRD Networks
Wendy St. Peter, Pharm D	College of Pharmacy, University of Minnesota
Tosha Whitley, RN	Northwest Kidney Centers
Jesse Roach	CMS
Joel Andress	CMS
Elena Balovlenkov	CMS
Abhijit Naik, MD	UM-KECC
Mimi Dalaly, MPH	UM-KECC
Jian Kang, PhD	UM-KECC
Jennifer Sardone, BA, PMP	UM-KECC
Jonathan Segal, MD	UM-KECC
Xi Wang, MPH	UM-KECC

1) Greeting and Agenda Overview:

a) UM-KECC thanked the TEP members for participating in this discussion and presented the goals of the meeting agenda.

b) TEP members were reminded that the discussion was open to the public and that the call was being recorded to produce a summary report. Furthermore, it was noted that there would be time for public comment at the end.

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2). Review of In Person Summary Report

Dr. Segal gave a brief update regarding the in- person TEP summary report and that UM-KECC was working on incorporating feedback given by the TEP. Issues from the summary report will be discussed as part of the agenda for this meeting.

In Person Review and Discussion:

Dr. Segal reviewed the TEP discussion from the in person meeting by noting that dialysis facilities face multiple barriers to completing medication reconciliation and review while recognizing that providers have a responsibility to participate in this process. Pharmacists, although a scarce resource in dialysis facilities, could help fill that gap. Furthermore, adding medication review and providing an updated medication list to the patient were identified by the TEP as opportunities to expand on the existing NQF endorsed Medication Reconciliation measure. Lastly, the timing of when medication reconciliation and review should be performed was discussed during the in-person meeting.

A TEP member asked whether adding medication review to reconciliation was a formal recommendation from the in-person meeting. UM-KECC responded that adding medication review to resolve discrepancies identified as part of the reconciliation process was in fact a formal recommendation that is described in the summary report. Three TEP members raised concerns that the review process reflects a physician behavior rather than something the facility can do and that it would be difficult to incorporate into a facility quality metric. They noted that requiring the physician to lead this process would be challenging from the facility standpoint and may be better captured as a provider-level metric.

Dr. Segal asked if there were comments from TEP members who supported adding the medication review component into the measure. A TEP member voiced that medication review to resolve discrepancies should be included if the deliverable is to be an updated patient medication list. Discussion followed about which physician decisions are considered medication management as opposed to review. A TEP member noted that asking nursing staff to perform medication review would be burdensome because they may not be able to identify or resolve discrepancies.

<u>Medication Review Measure</u>

Dr. Segal presented a working definition for a medication review measure as a starting point for discussion: *Percentage of patient months during which medication reconciliation and review were completed and an updated medication list was provided to the patient.* There were three aspects that occur within this measure to get credit for it: reconciliation, review (resolving discrepancies), and the medication list (the deliverable).

The measure uses the KCQA definition for medication reconciliation, which was reviewed, and TEP members indicated that this was acceptable with no modifications needed. Next, there was discussion

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on whether only home medications should be included or whether in-center medications should be included as well. A TEP member voiced that in-center medications need to be included since other providers should know what medications are being given in the dialysis facility. Other TEP members agreed. However, it was noted that the dose of the in-center medications was less critical, and that it could be listed as the medication name and then "dosed per protocol" so that constant updates would not be needed.

Measure Definitions

The definition for medication review was discussed and defined as: *The process of using a reconciled medication list to verify that medications are appropriate at that moment in time. The process involves identifying and resolving medication discrepancies.* Key components of a medication list was also discussed and included medication name, dose, frequency, route of administration. Some TEP members mentioned that a medication name would be enough to satisfy the measure criteria if the dose and frequency were unknown, but concern was raised that this could set too low of a standard to achieve. Other TEP members voiced the importance of having all the components listed above so that appropriate medication dosing for dialysis patients could be verified. Indicating that the dose is "unknown" may be a way of signaling to other providers that assistance is needed in adding detail to the medication list and it was generally agreed that it would be preferred given the alternative of not listing the medication at all. A TEP member then voiced concern that it would be difficult to generate a meaningful patient medication list if there were numerous unknown components. There was brief discussion about whether it would be helpful to quantify the percentage of unknown elements, but this did not have support from the TEP.

Dr. Segal said that UMKECC would send out an email vote about what could be listed as "unknown" on the medication list.

The TEP also discussed medication start and stop dates, and whether a medication should simply be removed from the list when it is stopped. One TEP member explained that patients sometimes do not know when they started/stopped a medication(s). Another TEP member clarified that the patient list may not need the stop and start dates, however EMR systems should have start and stop dates so that if a medication was tried and not tolerated it would be documented and less likely to be re-prescribed. Other TEP members added that having start/stop dates on the patient list could quickly lead to a complicated, confusing list. A TEP member summarized that they were discussing *two different lists,* a patient medication list that is part of the measure and does not need to have start/stop dates and the facility's EMR medication list, which should have start/stop dates.

Furthermore, Dr. Segal confirmed that the patient medication list should include allergy information, and the TEP agreed.

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Eligible Professionals

Dr. Segal reviewed from the in person meeting who should do medication reconciliation versus medication review. The TEP agreed on this list presented that had been previously discussed.

Measure Specifications

The time period would include 12 months, and the reconciliation/review process would occur upon:

- Admission to the facility: within 13 treatments or 30 days as this aligns with the initial interdisciplinary care plan.
- After a care transition (defined as discharge from a hospital, skilled nursing or rehabilitation facility or a change in dialysis modality). The question was raised as to whether hospital observation stays should be included. A TEP member discussed that observational stays should be classified as hospital discharges within the scope of measure specifications since medication changes could occur. Some of the TEP members voiced agreement, but it was also noted that some observational stays could occur simply because a patient cannot be easily discharged from the ED and that including all observation stays could significantly increase the burden of the measure on dialysis facilities. It was noted that the proportion of observation stays is increasing in recent years relative to the number of admissions and one TEP member commented that the total number of events (observation stays and admissions) may actually be about the same. Therefore, the overall burden may not be increased if observation stays were included. Other TEP members pointed out that neither the patient nor the facility may be aware of how a hospital encounter (observation vs. admission) is classified. The TEP Chair suggested that we start with hospital discharges in the measure and then revisit observational stays in the future. A TEP member suggested that assisted living facilities be added to the list of care transitions and it was suggested that any change in the patient's living situation should be considered.
- Quarterly for stable patients: the process time includes admission to facility.

Furthermore, Dr. Segal reiterated that while the TEP indicated during the in person discussion that this measure should include all patients within the dialysis facility, it was not clear whether UM-KECC can reliably identify hospitalizations in the non-Medicare population.

Denominator:

Total number of patient months for all patients assigned to the facility. Denominator exclusions were discussed and previously *<7 hemodialysis treatments at facility* was considered as a way to avoid transient patients at the facility from counting in the measure. Dr. Segal suggested that the TEP consider increasing that number to *< 13 treatments at facility* since this would align with the above recommendation for new patients to the facility and would also prevent transient patients from being included in the measure.

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Dr. Segal also brought up whether hospice patients should be excluded from the measure, since this had been suggested at the in-person meeting. The TEP agreed that hospice patients should be included in this measure.

Numerator:

The number of patients in the reporting month who had:

Medication Reconciliation performed AND
Medication Review performed AND
Updated Medication list provided to patient

Perform the above when a patient is admitted to a dialysis facility, has a care transition, or if stable, quarterly.

Requires: attestation including the name of provider who completed medication review and the date a reviewed medication list is given to patient.

Dr. Segal ended the discussion and mentioned that he will be emailing the group for a vote and asked if there was any public comments.

Public Comment:

Robin Nishimi (KCQA*): KCQA has attempted a medication reconciliation measure for care transitions and found that physician reliability could not be reached until there was at least 6 months of data that were aggregated, and even then this was not achieved for smaller facilities. The bigger problem was missing data for the actual events, either hospitalizations or observational stays, or the missing date of discharge. We did some follow up with our partners who have access to ESCO claims data in addition to their facility data. For hospitalizations the correct date of discharge matched the claims data 50% to 90% of the time, depending on the facility, so missing data is an issue. For observation stays, the facility records match the claims data less than 5% of the time. I just wanted to let the group know about that, because these events are not required for reporting by dialysis facilities, KCQA determined the validity of the measure was in question, and that underreporting has the potential to be rewarded in this scenario. Facilities that do a good job in capturing the events but miss the eight day window for a few cases could do worse than the facilities that do not capture the events at all. Thank you.*