

MARYLAND COMMISSION ON KIDNEY DISEASE

THE CONNECTION

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CHAIRMAN'S REPORT

The calendar year of 2018 was a very productive and stimulating one for us. Not only did the Commission certify 6 new dialysis facilities in the State of Maryland, we surveyed 98 dialysis facilities and transplant centers, carefully scrutinizing the corrective plans of action. Many hours were devoted to exploring solutions to the two most frequent citations: 1) poor hand hygiene and 2) staffing violations. Moreover, the Commission resolved 22 patient complaints, in addition to an alarming increase in the number of patient discharge requests. The commission had robust discussions with the members of the community and patient representatives about the urgency of these issues. It was universally agreed that a facility would be resurveyed within an appropriate allotted time frame to guarantee compliance with the Plan of Correction in which they had submitted. Resurveying units offers one mechanism where by a facility's progress in implementing changes in the POC can be measured. Ideally, this action will foster accountability to the commission and ultimately the patients.

Speaking of accountability, and, in accordance with our mandate to help set the standards for the practice of chronic dialysis that reflect new and emerging trends, we fully support initiatives that embrace practices of *patient engagement*. It is well established that patients with end stage kidney disease (ESKD) are at a much higher risk for psychosocial problems, diminished quality of life, and premature death than the general population. A growing body of evidence shows that patients who are engaged in their own care have better health outcomes. Training patients with chronic kidney disease and ESKD to manage their illness

is effective at increasing functioning and improved decision making, reducing pain, and reducing health care costs; ultimately this leads to improved health outcomes. Simultaneously, improved support of patients as self-managers is warranted. If we expect patients to play a more active role in their own care, then providers should also develop tools to measure the effectiveness of any interventions.

Tools which may help achieve this goal include, but are not limited to:

- Patient advocates
- Formal mentor training
- Peer to peer mentor groups
- Access self-surveillance teaching
- Online and telephone support groups
- Patient meetings led by the dialysis team
- Routine patient education activities/handouts
- Comprehensive care plan meetings with patient involvement

In practice, attention should be given to those interventions that are most practical for patients and workflows at the units. The formal support of clinicians, medical directors and administrators in adopting this aim will set the bar for the quality of care and patient involvement. Parenthetically, the level of the patient engagement has been proposed as a leading outcome for quality improvement, accountability, and potential rewards to leading facilities. **Continued on Page 2** ➡

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COMMISSION MEETINGS



The Commission on Kidney Disease will meet on the following dates in 2019:

April 25, 2019

July 25, 2019

October 24, 2019

The Commission meets at the

Department of Health,
4201 Patterson Avenue Baltimore, MD 21215.

The Open Session of the meeting begins at 2:00pm and is open to the public. For further information regarding these meetings, please contact the Commission office at (410) 764 - 4799.

COMMISSION NEWS

CITATION FREE SURVEYS

The Commission is commending a record number of facilities for achieving citation free surveys:

- ◆ Davita Home Downtown
- ◆ FMC LaPlata
- ◆ Davita Charles County
- ◆ IDF Garrett Center
- ◆ NxStage Baltimore West
- ◆ Johns Hopkins Transplant Center
- ◆ University of Maryland Transplant Center
- ◆ ARA Ellicott City
- ◆ ARA Salisbury
- ◆ NxStage Baltimore North
- ◆ IDF Calvert Center
- ◆ Davita Queenstown
- ◆ FMC Middleriver
- ◆ Renal Care of Seat Pleasant
- ◆ Davita Ridge Road
- ◆ FMC Nashua Court
- ◆ Davita Middlebrook
- ◆ Davita Carroll County
- ◆ FMC Greenspring
- ◆ Davita Washington County

It is an achievable goal, and should be the goal of each facility.



NEWLY CERTIFIED FACILITIES:

- ◆ Davita Ridge Road
- ◆ Davita Laurel Lakes
- ◆ ARA Salisbury
- ◆ Davita Gaithersburg
- ◆ Davita Edgewood

These facilities have been certified and are in good standing.

COMMISSION WEBSITE

health.maryland.gov/mdckd
Find the latest Commission information: meeting dates, new facility information, complaint forms, regulations, Governor's report and past and current newsletters.

The Chairman's Report (Continued from page 1)

Both the American Association of Kidney Patients (AAKP) and National Kidney Foundation (NKF) are leaders in kidney patient centric practices. They provide educational tools for patients and families to transform the patient role to engaged partners, rather than passive recipients in healthcare decision

making. Their organizations have improved the lives and well beings of kidney patients, and continue to be valuable resources for patients and providers.

The Quality Insights Renal Network 5 recognizes the importance of patient engagement to help contain costs, increase patient and provider satisfaction, and improve outcomes. Quality Insights Renal Network 5 provides and encourages all facilities to participate in the ENGAGE Initiative, which promotes improved relations among patients and providers.

Similarly, the United Network for Organ Sharing (UNOS) is devising ways to make patient engagement more of a priority. A focus on recruitment and education of patient representatives on the various committees is currently underway. The FDA is likewise committed to shifting the focus of drug and device development to include a more patient centric focus in which patients function as key collaborators in research and in policies which directly impact them.

In closing, I would like to take this opportunity to acknowledge the vital service work provided by Donna Adcock, Commission Nurse Surveyor, Eva Schwartz, Executive Director, Leslie Schulman, AAG, Dr. Jeremy Yospin, past Chairman, and the rest of our loyal Commissioners for their dedication of time and expertise to carry out the Mission to which we have been charged. The Committee appreciates the close affiliation with the Maryland Board of Nursing, and Office of Healthcare Quality, and the Quality Insights Renal Network 5 which help endorse rapid responses to complaints, thus promoting enhanced patient care. I implore the nephrology community to join our commission meetings and share your experience in adopting patient engagement best practices.

By: Dr. Donna Hanes

The Kidney Disease Program

The Kidney Disease Program (KDP) is a 100% state funded Program; however, 98% of the recipients certified with KDP are eligible for Medicare, which pays 80% of covered charges. Even though KDP does not receive federal funding directly, the Program indirectly benefits from Medicare which is federally funded dollars. There are several KDP reimbursable services that are not covered by Medicare.

The following is a comprehensive description of the ESRD services KDP pays for that Medicare does not:

KDP pays for the first three months of a recipient's end-stage renal disease care and treatment beginning with the first chronic maintenance dialysis prior to Medicare eligibility. (Note: Medicare, on the basis of ESRD, does not become effective until the patient has been on dialysis for three months. The average number of dialysis treatments received per month is 13 which are necessary to maintain life. These costs are extremely expensive. During the first three months, KDP pays at the rate of 100% of the Medicare approved rates.)

KDP pays for the insertion of the shunt/fistula access surgery that is essential to a patient receiving outpatient maintenance dialysis. A patient cannot receive dialysis until the access surgery is performed.

After the Medicare effective date is determined, Medicare reimburses at a rate of 80% of approved costs. KDP pays the remaining 20%. For those recipients not eligible for Medicare, KDP pays at the rate of 100% of the Medicaid approved rates.

KDP pays for a recipient's pre-transplant dental treatment that is essential prior to transplantation.

It is also important to note that the transplant centers may not allow an end stage renal disease (ESRD) patient to be placed on

a transplant wait list until the patient is certified with KDP. This is to ensure that the transplant patients will be able to obtain their anti-rejection (immunosuppressant) drugs to prevent their kidney transplant from rejecting. The anti-rejection drugs are extremely expensive. The Medicare Part D and commercial Rx insurance plans, only pay a percentage of these drugs.

If a patient is eligible for Medicare, on the basis of their ESRD (end stage renal disease), Medicare will only pay for their treatment and transplant drugs for 36 months after the date of their transplant. KDP will continue to pay beyond the 36 month Medicare coverage period. There is no time limit to a recipient's KDP certification period as long as they reapply annually and pay their program participation fee. If a recipient is unable to obtain/afford their immunosuppressant (anti-rejection) drugs and discontinue their medication, their kidney transplant will fail.

Kidney Disease Program Financial Assistance and Coverage

The KDP reimburses for treatment directly related to a recipient's ESRD or a condition that is a direct result of the recipient's ESRD. The KDP does not make direct payments to recipients.

The Kidney Disease Program is a payer of last resort which provides financial assistance to certified Maryland end-stage renal disease patients according to defined criteria.

Benefits:

- Coverage for the first 3 month of a patient's end-stage renal disease care and treatment beginning with the first chronic maintenance dialysis prior to Medicare eligibility
- Payment for Medicare deductible and co-

insurance

- Coverage of approved physician services at the approved rates
- Prescription coverage for medication on the Kidney Disease Program Reimbursable Drug List
- Post renal transplant coverage of certain immunosuppressant drugs for the life of the graft
- Coverage of certain special services or expenses when such services/expenses are required as a direct result of the patient's end-stage renal disease (preauthorization is required)
- Renal transplantation services at transplant centers located outside of Maryland (preauthorization is required)
- Transient dialysis (preauthorization is required)
- Pre-renal transplant dental services (preauthorization is required)
- Ancillary supplies for home intravenous antibiotic therapy (preauthorization is required)
- Durable medical equipment and disposable medical supplies used in the home (preauthorization is required)
- One pair of eyeglasses, one time only (preauthorization is required)

Reimbursement for access surgery required by a recipient for dialysis treatment even though the access surgery may predate the recipients date of certification for KDP benefits



CKD AND ESRD IN THE GOVERNMENT SPOTLIGHT

Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD) are in the spotlight again by The Centers for Medicare & Medicaid Services (CMS) and Health and Human Services (HHS). The HHS Director, the CMS Administrator and Deputy Administrator, and Director of Center for Medicare and Medicaid Innovation (CMMI) are focused on kidney care and improving treatment options, reducing financial burdens and empowering consumers by discussing the need for improvement in current policies and a call for innovation at high impact events such as The CMS Quality Conference, the NKF meeting and the Office of the National Coordinator for Health Information Technology (ONC) Annual Conference and The New York Times.

National Health Policy

In recent remarks to the National Kidney Foundation (NKF) on March 4, 2019 made by Alex M. Azar II, Secretary of HHS the current status of CKD and future focus were highlighted. *"Today, I want to lay out what it would look like to pay for kidney health, rather than kidney disease- and pay for Americans with kidney disease to actually get good outcomes, rather than the endless, life-consuming procedures that you all know so well."* He went on to pointedly describe the outcome failures in kidney care policies that include: 30 million people in the US with CKD and that it is the ninth leading cause of death, over 100,000 people on the transplant waitlist and the huge financial burden of CKD costing \$79 billion and an additional \$34 billion for ESRD making up 20 percent of the Medicare budget.¹ He highlighted options for treatment focusing on improved detection and slowing of progression of CKD, increasing pre-emptive transplants and increasing the use of home modalities.

Seema Verma, Administrator CMS was quoted in an article in *The New York Times* "A lot of the way the program has been set up, it creates perverse incentives to actually keep people

in an institutional setting" She discussed trial payment designs to improve care in early CKD, increase access to kidney transplants and favor home dialysis over clinic-based treatment.²

Adam Boehler, Deputy Administrator and Director of CMMI in remarks to the Healthcare Information and Management Systems Society (HIMSS) on February 15, 2019 stated *"We do not think the state of kidney care is acceptable"* and shared similar remarks of trial payment design to improve care in early CKD, increase access to kidney transplants, and favor home dialysis over clinical-based treatment.

He went on to say *"What you really want is the prevention of ESRD from developing..." "If it develops, you want [patients to have a] transplant wherever possible; if not, [treatment] at home wherever possible. It should be a last resort that people go to a dialysis center."*

Quality Insights Kidney Care Focus

The focus is clear from national health policy leaders that we must improve home modality penetration and increase the number of transplanted kidney patients in the ESRD setting. Network 5's Scope of Work, as determined by CMS, directs the 2019 quality improvement activities focusing on patient safety, improving the number of patients dialyzing at home, and increasing the number of people on the kidney transplant waitlist. These quality improvement activities align with the call to improve consumer empowerment, focusing on patient and family centered care. Patient engagement activities are weaved throughout all of Network 5's quality improvement activities, including partnering with patients in monthly facility quality meetings, peer mentoring, and shared education. For more information and resources related to patient engagement, visit <https://www.qirn5.org/Ongoing-Projects/Patient-Engagement.aspx>.

Quality Improvement Activities (QIAs)



Promote Home Dialysis QIA

The Promote Home Dialysis QIA focuses on identifying barriers and implementing targeted interventions to increase the number of patients dialyzing at home. The intent of the QIA is to promote early referral to home modalities and assist patients and providers in initiating home therapies. The project will run from January through September of 2019. The scope of the project is 30 percent of the Network service area. This is the second year of this QIA working with 102 facilities across the Network service area. The clinical outcome goal is to demonstrate at least a 2 percentage point increase in the rate of patients that start home dialysis by September 2019. Facilities were issued a facility goal based on historical data in CROWNWeb which translates to approximately 65 patients per month among the facilities enrolled in the QIA needed to start home training to reach the 2 percent increase. Intervention aimed at providing support to the Home Modality Campaign include: Match-D Tool training and talking with patients regarding their options for home modalities, how to host a healthy lobby day and empowering home patients to assist with sharing their experience with in-center clinic based patients.



Increase Transplant Waitlist

The Increase Transplant Waitlist QIA focuses on identifying barriers and implementing targeted interventions to increase the number of patients on the kidney transplant waitlist. The intent of

the QIA is to promote early referral to transplant programs for evaluation and assist patients and providers in identifying barriers and implementing targeted interventions to overcome the barriers. The clinical outcome goal of the QIA is to demonstrate a 2 percentage point increase in the rate of patients placed on the kidney transplant waitlist by September of 2019. Facilities were issued a facility goal based on historical data in UNOS which translates to approximately 67 patients per month among the facilities enrolled in the QIA needed to reach the 2 percentage point increase. Intervention aimed at providing support to the Transplant Campaign include: Identifying Transplant Program criteria that meets the patient's needs, transplant program Scientific Registry of Transplant Recipients (SrTr) data, talking with patients regarding their options for referral to transplant, how to host a healthy lobby day and empowering transplanted patients to assist with sharing their experience with in-center clinic based patients.

For more information about all of the Network's quality improvement activities in 2019, visit <https://www.qirn5.org/Ongoing-Projects.aspx>.

Sources:

¹ <https://www.hhs.gov/about/leadership/secretary/speeches/2019-speeches/remarks-to-the-national-kidney-foundation.html>

² <https://www.nytimes.com/2019/03/04/business/04reuters-usa-healthcare-dialysis.html>

**Submitted by: Quality Insights
Renal Network 5**

A BRIEF OVERVIEW OF KIDNEY TRANSPLANT ALLOCATION, WAIT TIMES AND LIVING DONATION

Kidney transplant is the therapy of choice for most patients with end stage kidney disease. There are close to 90,000 people currently on the waiting list for a kidney transplant. Wait times can vary greatly and is on average 5 years in most states for a deceased donor, and in some states it is closer to 10 years. Important factors that drive the priority on the list are wait time accrued, blood type and immune system activity. Waiting for a long time for a kidney transplant particularly while on dialysis has been shown to be detrimental to a patient's quality of life and life expectancy. Unfortunately about 80% of patients on the list are on dialysis and facing long wait times on the kidney transplant waiting list. The shortage of kidney donors has been a constant for many years, leaving the waiting list practically unchanged year to year, with only approximately 20,000 kidney transplants performed each year and about same number of new registrations for the waiting list per year. Although many efforts have been made to increase the donor pool, less than a third of kidney transplants are from living donors.

In 2014 the Organ Procurement and Transplantation Network kidney transplantation committee implemented a new kidney Allocation System (KAS) to increase accessibility to transplant candidates, considering those candidates that are harder to match due to biologic reasons and addressing inequities resulting from the way wait times were being calculated. KAS uses the Kidney Donor Profile Index (KDPI), a new scoring system developed to determine donor quality- which tells you how long a deceased donor kidney is expected to function relative to all the kidneys recovered in the US in the previous year- the lower the score the longer the expected function. The majority of deceased donor kidneys (65%) have scores between 21-85% and are expected to function for about 9 years.

In an effort to address barriers to transplant referral and listing the KAS also changed the point of start in which transplant candidates can begin to accrue time on the list, making the date of first chronic dialysis as the point of onset once registered on the waiting list. This change has greatly benefited those patients that were on dialysis for years but had not been able to get registered on the waiting list. In Maryland the average wait time is 4-7 years, depending on transplant candidate blood type, with blood group type A and AB waiting the least and group O and B waiting the most. Having a living donor reduces the wait time to the time the recipient and the living donor take to complete the transplant evaluation process. If a recipient and living donor pair are incompatible due to blood type or other biological reasons, they can enter a kidney exchange program, this will allow the donor-recipient pairs to swap with other pairs in the same situation. All medically eligible donor-recipient pairs can participate in the program. There are many transplant centers in the US participating in kidney exchange programs and compatible kidney swaps can come from anywhere in the country.

The best outcomes come from a living donor, and with a living donor, recipients are not subject to the intrinsic constraints of the waiting list, and the wait to a transplant is reduced to the time that will take for the donor and recipient to be evaluated and listed if medically eligible. I encourage all my patients to look at the resources provided by the United Network for Organ Sharing, where they can learn more about the kidney transplant and donation process and start a fruitful conversation with their families, support systems and potential kidney donors.

By: Dr. Nadiesda Costa

Expanding the Kidney Donor Pool with Hepatitis C-Positive Donors

Each year in the U.S., some 500 kidneys are deemed ineligible for donation and are discarded because they came from deceased donors who are hepatitis C-positive. Transplanting these organs into recipients who are virus free has been generally considered too high risk, and only a tiny fraction of patients awaiting kidney transplant are infected with the virus. Now, a recent study led by Johns Hopkins suggests that direct-acting antiviral prophylaxis before and after transplantation could significantly alter the landscape of organ transplantation from hepatitis C-infected donors to noninfected recipients.¹ In a study of 10 virus-free patients who received hepatitis C-infected kidneys, none developed clinical signs of chronic hepatitis C infection in the three months following surgery, and all have continued to remain free of the infection.

New hepatitis C treatments pave the way

Over the last decade, the treatment of hepatitis C has undergone a major transformation, propelled by a generation of new drugs that are more potent and cause fewer side effects. Now, a disease that was previously difficult to treat—requiring weekly injections of drugs with significant toxicities for many patients—and quite challenging to cure, can be treated with drugs that carry few side effects and result in cures for the vast majority of patients.

This paradigm shift led Johns Hopkins physicians Niraj Desai and Christine Durand to explore whether the new hepatitis C drugs—known as direct-acting antivirals (DAAs)—could also be used to improve the utilization of hepatitis C-positive kidneys for transplantation. “In this era of organ shortages, it’s difficult to watch good organs get discarded,” says Durand. “This was a great opportunity to take a neglected public health resource and put it to good use.”

Proof-of-principle study yields dramatic results

Desai, Durand and their colleagues launched an open-label, nonrandomized trial at Johns Hopkins known as EXPANDER (Exploring

Renal Transplants Using Hepatitis C Infected Donors for HCV-Negative Recipients). The team recruited patients over the age of 50, who lacked a living donor and were awaiting kidney transplant, had no history of organ transplant, and were negative for hepatitis C as well as HIV and hepatitis B. Ten patients agreed to participate, with an average age of 71 and an average time on the transplant wait list of four months.

Donor kidneys were recovered from deceased donors ranging in age from 13 to 50. The organs tested positive for hepatitis C and showed no evidence of kidney disease. Donor blood was also analyzed to determine the strain and levels of hepatitis C virus. “These 10 kidneys we used are 10 kidneys that would not have been transplanted outside of this study,” says Desai. “They would have been discarded.”

To provide prophylaxis for hepatitis C, each kidney recipient received a dose of grazoprevir/elbasvir, an oral combination pill, prior to transplant surgery. Following transplant, recipients continued with daily grazoprevir/elbasvir therapy for 12 weeks. Three patients also took a daily dose of sofosbuvir due to the strain of virus found in their donor organ.

In five of the kidney recipients, no hepatitis C RNA could be detected in their blood. In the other patients, low levels of the virus were detected shortly after transplant but then became undetectable within days or a week. Importantly, none of the recipients ever developed any clinical signs of chronic hepatitis C infection, and the kidneys functioned well. At the time of the study’s online publication in the *Annals of Internal Medicine*, all patients were at least a year post-transplant and remained healthy and hepatitis C-free.

Looking ahead

Desai and Durand are deeply encouraged by the EXPANDER trial’s results. They seek to extend their initial findings through a larger, multicenter trial. If this early success continues, it could propel the availability of more organs for the nearly 100,000 people in the U.S. now waiting for a kidney transplant. In addition, this novel approach could be expanded to other organs,

including the heart, liver and lungs.

“Right now, most of the usable organs from donors with hepatitis C are discarded,” says Desai. “Figuring out how to use these kidneys is a way to do more transplants and save more lives.”

Courtesy of Johns Hopkins Medicine Marketing and Communications

SENATE BILL 796- STATE COMMISSION ON KIDNEY DISEASE (COMMISSION)- MEMBERSHIP - REVISIONS- 2019 LEGISLATION

STATUS: Passed as amended. To be effective 7/1/19.

SB 796 will amend Health-General Article, §13-305, Annotated Code of Maryland, in two significant ways regarding Commission membership. First, it will prohibit prospective Governor-appointed Commission member candidates from having direct ownership of more than 30% in renal dialysis or kidney transplant centers that do business in the State. Secondly, the required number of nominated names for each vacancy on the Commission will be reduced from three to two candidates. Impacted by this new law will be the category of nominations to the Commission from: MEDCHI, University of Maryland School of Medicine, The Johns Hopkins School of Medicine and the National Kidney Foundation. It is our hope that these changes will help facilitate the nominations process and the Commission is looking forward to working with the aforementioned organizations, as vacancies become available.

Submitted by:
Eva Schwartz, MS, MT, SBB(ASCP)
Executive Director



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Anthony Gomera,
Kidney transplant recipient.
Read his story at KidneyWalk.org/stories

17th Annual Greater Baltimore Kidney Walk
October 6, 2019 – Registration Begins at 9:00am
The Weinberg Y in Waverly - 900 E. 33rd Street, Baltimore, MD 21228

Register your team today at www.kidneywalk.org For volunteer opportunities contact Kristin Brooks,
Development Director, Kristin.brooks@kidney.org or call 410.494.8545