

## Advancing American Kidney Health Perspective from Fresenius Medical Care

Robert J. Kossmann<sup>1</sup> and Eric D. Weinhandl<sup>1,2</sup>

CJASN 14: 1811–1813, 2019. doi: <https://doi.org/10.2215/CJN.10370819>

CKD is a unique character on the stage of noncommunicable diseases in the United States: high prevalence (>20% in adults), significant expense to public payers (\$114 billion among Medicare fee-for-service enrollees), and relatively little investment in research (\$29 per patient in National Institutes of Health spending). Although CKD risk factors, including diabetes and hypertension, have garnered justifiable attention, CKD itself has not attracted the same level of attention as heart disease or cancer. The Executive Order (EO) on Advancing American Kidney Health presents a unique opportunity to focus attention on CKD and reset expectations about health care delivery and clinical outcomes in the later stages of CKD. The EO includes three aims: (1) by 2030, to decrease by 25% the number of new patients with ESKD; (2) by 2025, to have 80% of new patients with ESKD undergo either home dialysis or a pre-emptive transplant; and (3) by 2030, to double the number of organs available for kidney transplant. From a clinical perspective, these are very ambitious goals; meeting them will require creativity and investment from the entire kidney care community, including patients, nephrologists, dialysis providers, transplant providers, and the Centers for Medicare & Medicaid Services (CMS).

The first EO goal—to reduce the number of new patients with ESKD by 25%—should be placed in perspective. The US Renal Data System reported 125,000 new patients with ESKD in each of 2015 and 2016 (1). McCullough *et al.* (2) forecasted a 15% increase in the incidence of ESKD between 2015 and 2030. With projected growth of the United States population to 355 million in 2030, around 157,000 new patients with ESKD can be expected. Thus, the first goal of the EO translates to only 118,000 new patients in 2030. How can this be accomplished? Pharmacologic therapy continues to hold promise. Angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers are used by only 36% of patients with diagnosed CKD, despite strong evidence of ESKD risk reduction in CKD with diabetes and/or proteinuria (3). Canagliflozin, a sodium-glucose cotransporter 2 inhibitor, was recently shown to reduce ESKD risk by 32% in CKD stages 2 and 3 with albuminuria (4). In CKD stages 4 and 5, the prevalence of anemia, acidosis, hyperphosphatemia, and hyperparathyroidism is markedly higher (5). Intensive medical management of these abnormalities, control of BP, and avoidance of nephrotoxic

medications in later stages of CKD may stabilize kidney function. Voluntary CMS payment models, including Comprehensive Kidney Care Contracting models, may break the wall that has historically separated nondialysis-dependent CKD and ESKD by creating shared financial accountability among nephrologists and dialysis providers and implicit incentives to slow the progression toward ESKD.

The second EO goal—to have 80% of new patients with ESKD undergo either home dialysis or a pre-emptive transplant—fits squarely in the partnership of nephrologists and dialysis providers. In the United States, only 2.8% of new patients with ESKD receive a pre-emptive transplant (1). Even reaching the level of the United Kingdom, where 8.8% receive a pre-emptive transplant, the United States would need to have 78% of patients initiating dialysis treated at home. Currently, that number is 12%. Can dialysis initiation be dramatically changed in <6 years? The answer requires a precise definition of home dialysis. Among patients now initiating dialysis, home dialysis is essentially synonymous with self-care peritoneal dialysis (PD) in a private residence. Assisted PD is available in many countries, but it is not reimbursed in the United States. Home hemodialysis (HD) is prescribed in <1% of patients initiating dialysis in the United States, the United Kingdom, and Canada. Prescribing home dialysis to most patients initiating dialysis in the future will certainly require medically complex patients to dialyze at home, likely with assistance, and likely require unprecedented utilization of home HD (at or shortly after) dialysis initiation.

There seems to be ample demand for home dialysis if patients are educated about the therapy. Comprehensive predialysis tele-education may increase home dialysis adoption; tele-education can be scaled to size with limited marginal cost (6). In transitional care units, which are emerging across the country, patients are educated during multiple weeks of in-center HD about all dialytic modalities as well as kidney transplantation. In some units, patients may undergo more than three sessions per week and even use home HD equipment. In transitional care units, >30% of patients may select home dialysis (7). Another approach is to initiate PD in patients who present with ESKD in the hospital; outcomes with this approach compare favorably with outcomes after initiation of in-center HD with a central venous catheter (8). Yet another

<sup>1</sup>Chief Medical Officer, Fresenius Medical Care North America, Waltham, Massachusetts; and

<sup>2</sup>Department of Pharmaceutical Care and Health Systems, University of Minnesota, Minneapolis, Minnesota

### Correspondence:

Dr. Robert J. Kossmann, Fresenius Medical Care North America, 920 Winter Street, Waltham, MA 02451. Email: [robert.kossmann@fmc-na.com](mailto:robert.kossmann@fmc-na.com)

approach not contemplated in the EO is self-care dialysis in a health care facility. Regardless of specific models of care, growing home dialysis will require investment in infrastructure, including physicians (nephrologists and surgeons), nurses, technicians, equipment manufacturing, and supply delivery. Furthermore, reducing attrition from home dialysis will require investment in telemedicine tools that enhance the medical relationship between patients and dialysis providers.

Of course, patients initiating dialysis constitute a subset of all patients on dialysis. Although home dialysis utilization in the dialysis population is not an expressed aim of the EO, utilization in the population is a meaningful measure and a key component of the ESKD Treatment Choices (ETC) model, a mandatory CMS payment model for dialysis facilities and nephrologists caring for Medicare Part B enrollees. The ETC model evaluates home dialysis and kidney transplant rates among Part B enrollees attributed to a dialysis facility and assigns bonuses and penalties—the latter tentatively beginning in July 2021—to reimbursement for all dialysis treatments both in the facility and at home. We support the dual intent of the ETC model: kidney transplant is the recommended kidney replacement therapy in ESKD, and home dialysis can improve clinical outcomes and quality of life. However, the model extends the long-standing CMS practice of evaluating performance within individual health care facilities. This is a major problem. Dialysis facilities may be certified to offer home dialysis, but not all are. In our analysis of 2017 Medicare Part B claims, we found that 54% of facilities with  $\geq 11$  patient-years had no claims for home dialysis. Some of these facilities are certified to offer home dialysis and could increase utilization. However, the more important fact is that dialysis providers and nephrologists typically offer home dialysis in a subset of facilities that serve patients across a broad area so that home dialysis resources—especially staff—can be concentrated. The PD literature includes many studies that identify positive associations between program volume and clinical outcomes. Home dialysis utilization should be measured in multifacility groups (e.g., all facilities operated by a dialysis provider in a predefined area). Transplant rates must be measured in such groups because of statistical limitations regarding trend analysis: in our analysis of claims, we found that 84% of facilities observed fewer than or equal to two transplants among all patients on dialysis in the facility during 2017. Furthermore, large penalties for low utilization of home dialysis may be imprudent. Home dialysis generally requires stable housing, with plumbing infrastructure and enough square footage for supply storage. In highly urban markets, such housing is in shorter supply. In most rural markets, there is practical access to only one dialysis facility. Reimbursement penalties should not endanger access to dialysis in either type of market.

The third EO goal—to double the number of organs available for kidney transplant—is a formidable challenge. According to Dialysis Facility Report data, only 20% of patients on dialysis age  $< 75$  years old were on the kidney transplant waitlist at the end of 2017. Dialysis providers should resolve to educate all patients about kidney transplant and ensure that interested patients are referred for transplant evaluation and fully evaluated. However, the supply of organs is a serious constraint. Kidney

transplant volume has been steadily increasing since 2014, mostly due to growth of deceased donation. To further increase transplant volume, the kidney discard rate could be targeted. A recent analysis of kidney discard rates in France and the United States suggested that applying French-based practice patterns in the United States could result in 1600 additional transplants per year (9). Some countries use opt-out systems for deceased donation. To increase the rate of living donation, initiatives that facilitate both donor identification and engagement may yield significant gains (10).

The EO on Advancing American Kidney Health is a turning point in the history of CKD. Dialysis providers in partnership with nephrologists must be active participants in changing the face of kidney care through increasing kidney transplants and home dialysis utilization. That work has already begun. Fresenius Medical Care North America has acquired NxStage Medical, constructed a large manufacturing and distribution facility for PD supplies, opened many transitional care units, launched a cloud platform to improve monitoring of patients on home dialysis, and expanded professional education about home dialysis. From 2018 to 2019, numbers of patients on PD and patients on home HD in facilities operated by the ten largest dialysis providers increased by 8% and 13%, respectively (11). From that perspective, it is critically important that new policy, including CMS payment models, catalyze momentum around home dialysis and more importantly, improve clinical outcomes and quality of life in patients with ESKD.

#### Acknowledgments

The content of this article does not reflect the views or opinions of the American Society of Nephrology (ASN) or *CJASN*. Responsibility for the information and views expressed therein lies entirely with the author(s).

#### Disclosures

Dr. Kossmann and Dr. Weinhandl are employees of Fresenius Medical Care North America.

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Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).