The Executive Order on Advancing American Kidney Health and its Impact on Renal Care Innovation

On July 10th, 2019 the White House issued the Executive Order pertaining to Advancing American Kidney Health (AAKH)[[1]](#footnote-1). Outlined in the purpose are the statistics and motives that drove the issue of the order; kidney disease is the ninth leading cause of death in the US with approximately 37 million Americans suffering from chronic kidney disease (CKD) and more than 726,000 having end-stage renal disease (ESRD)[[2]](#footnote-2). The order states that the current state of care for patients with CKD and ESRD is unacceptable, citing too many at-risk patients progress into late-stage kidney failure, high mortality rate, and expensive treatments that do not produce an acceptable quality of life.

The general policy missions of the Executive order include the reduction of the risk of kidney failure, improvement of access to and quality of person-centered treatment options, and increased access to kidney transplant. It outlines several goals including reducing the number of Americans developing ESRD by 25% by 2030, achieving 80% of new dialysis patients in 2025 receiving home dialysis or transplant, and doubling the number of kidneys available for transplant by 2030.

The AAKH order is composed of nine discrete sections.  The first two sections outline the need to improve kidney care, and the policy objective as stated above.  The following six sections detail the action items, including establishment of initiatives, proposal of models and regulations, and execution of exploratory studies by several federal agencies.  The final section states the general provisions reflected in all executive orders, i.e. accordance with current laws and federal guidelines. The purpose of this paper’s analysis is to examine the effects directly related to the six sections (sections 3-8) regarding policy directives.  This is not an exhaustive list on current, long-running initiatives related to prevention of, care for, and resolution of kidney disease. There are many efforts within government entities such as the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid (CMS) that aspire to positively affect kidney health.  Private foundations such as the National Kidney Foundation (NKF) and American Society of Nephrology (ASN) are also engaged in the process to advance kidney health policies. We aim to work within the scope of the Executive Order, its action, and how we, as biomedical engineers, fit into it.

Section three of AAKH directed HHS to launch an awareness initiative aiming to support research on the following topics within 120 days:

* “preventing, treating, and slowing the progression of kidney disease”
* “improving kidney transplantation”
* “educating patients and providers about the consequences of kidney disease1”

On November 4, 2019, HHS announced a partnership with the ASN, a professional nephrologist society, and patient-focused NKF[[3]](#footnote-3). HHS hopes that the collaboration will cast a wide net of education and awareness for patients, clinicians, and companies.  Due to the holistic nature of kidney disease, comorbidities are common and are considered risk factors. With the ASN and NKF, patients will have a better chance of being made aware of these risk factors for kidney disease before the progression into ESRD.

The CDC has been managing the CKD Initiative since 2006, providing information about the prevalence of CKD.  As a part of this executive-directed effort, the CDC plans on enhancing its surveillance of CKD and collaborating with other government agencies and universities for epidemiological studies and screening[[4]](#footnote-4). Through its sub-agency, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the NIH currently funds studies on Acute Kidney Injury (AKI), CKD, ESRD, and kidney epidemiology[[5]](#footnote-5).  NIDDK also funds the annual U.S. Renal Data System Report, which provides a vast wealth of information including CKD statistics, financial burden on CMS, and long-term disease trends.  One of the larger foci of awareness will be towards diabetic and hypertensive patients, where CKD prevalence is 36% and 31%, respectively. This compares poorly to the national average CKD prevalence of approximately 15%[[6]](#footnote-6). HHS emphasized its efforts to enhance accessibility of CKD detection and prevention by partnering with communities via the CDC and NIH.

Payment models largely influence how CKD patients receive care.  Even though many CKD patients are covered under Medicare, health providers always discover the ways to make the most profit in accordance with the current payment model.  The present model, the Comprehensive ESRD Care (CEC) model, began in 2015 and resulted in lower spending and improved quality of care. However, it fell short in aiding the patient throughout the continuum of renal care, especially pre-ESRD (CKD stages 4 and 5) care.

Section four of AAKH directed HHS to propose a payment model to identify and treat at-risk populations earlier in kidney disease development.  As a result, HHS suggested the optional, nephrology-specific Kidney Care First (KCF) model[[7]](#footnote-7). Under KCF, nephrologists would receive Medicare Capitated (per head) Payments (MCPs) for CKD stages 4 and 5 and ESRD medical care.  Payments would be adjusted based upon quality of care rendered (i.e. patient long-term trends and outcomes) and the number of patients managed.  Nephrology practices aiming to align and become a “KCF practice” face a number of requirements including:

* Primarily cater to Medicare beneficiaries - 500 late stage CKD and 200 ESRD Medicare patients seen over each six-month period
* Receive a majority of revenue from nephrology services rendered
* Receive a majority of revenue from Medicare payments
* Support EMR exchange with other health systems
* Assume financial risk and make Medicare repayments if directed
* Lie within a single KCF market area

KCF practices will be paid for two “Evaluation and Management” (E&M) visits with CKD stages 4 and 5 patients per six months, incentivizing better care for patients pre-ESRD and pre-dialysis.  The model also includes payment information for ESRD and dialysis patients, incentivizing frequent checkups. Finally, patients that receive transplants will result in a capitated bonus for the KCF practice.  KCF practices will also be encouraged, through bonus payments, to provide kidney disease education, Telehealth, home visits, and home care services7.

Once practices have aligned under the KCF model, their performance will be measured based upon quality and utilization measures.  Medicare payments will be adjusted based upon measures compared to all other KCF practices. Top-ranked KCF practices will see up to a 20% Medicare payment bonus and the bottom-ranked KCF practices must pay a penalty up to 8% of estimated revenue, said to cap at -20% of Medicare payments.  Low performing practices may recover some of these payments by reaching increased improvement targets over the following six-month period. With KCF slated to begin in 2020, this optional model aims to enhance the monetary benefit that nephrology practices see from providing care pre-ESRD, correcting weaknesses of the CEC model[[8]](#footnote-8).

Section five of AAKH focuses on increasing home dialysis and kidney transplants through a range of mandatory and optional payment models also starting in 2020.  The sole proposed mandatory model, ESRD Treatment Choices (ETC), shall be randomly applied to Dialysis facilities and healthcare providers, encompassing 50% of Medicare patients.  The ETC model will be similarly alignment-based in that there are “rules to play the game” but the MCP adjustments will incentivize home dialysis and kidney transplantation[[9]](#footnote-9).  While the home dialysis adjustment is strictly a positive one, an additional performance-based adjustment can positively or negatively adjust MCPs based upon dialysis claims, home dialysis rates, and transplant rates.  ETC also incentivizes kidney disease education and waives the past restriction that it must come from a registered clinician (MD, PA, NP, CNS), opening up more avenues to educate patients.

The final three optional Comprehensive Kidney Care Contracting (CKCC) payment models are intended for groups of healthcare providers, called Kidney Contracting Entities (KCE).  KCEs must include nephrologists and transplant providers; dialysis facilities and other healthcare providers are optional. Similar to KCF, all CKCC models refocus kidney care to include CKD stages 4 and 5 in the continuum.  The CKCC models also include the same MCP adjustments as KCF, however the models differ in the amount of financial risk that is assumed by the KCEs. The three options include the Graduated, Professional, and Global CKCC models.  The Graduated CKCC model is the least risky; it involves one introductory year with up to a 40% “shared savings rate” followed by years with up to 50% “shared savings rate” and 30% “shared losses rate” in the total value of Medicare payments.  The Professional CKCC model steps up the risk with a 50%/50% shared savings and losses rate, respectively. The Global option is the riskiest, with a 100%/100% shared savings and losses rate, respectively8.  KCEs able to provide quality kidney care while operating at low cost will benefit the most in these models.

Payment model descriptions are undoubtedly complex (and among the worst abusers of alphabet soup -- in the leaderboards with scientific journal articles).  However, strict definition of payment can shape healthcare and, transitively, patient outcomes. With a stronger focus on earlier advanced CKD care, emphasis on home dialysis, and the importance of transplantation, kidney disease has a greater chance at being effectively managed and patients will have better outcomes.  Financial encouragement could also spur innovation in the business of kidney care, leading to better or more convenient healthcare. Telehealth is an excellent example of this phenomena.

Section six of AAKH encourages the development of an artificial kidney (AK). Within 120 days of the order, it sought to increase cooperation between AK developers and the FDA to accelerate and gain premarket approval of AKs. It also expanded an organization called the Kidney Innovation Accelerator or KidneyX, a private-public partnership between HHS and the American Society of Nephrology that encourages innovative solutions through collaboration of patients, health professionals, innovators, industry, and government to improve the quality of life for people living with kidney diseases.[[10]](#footnote-10) KidneyX also seeks to promote coordination across the HHS agencies, including CMS, FDA, and NIH, to clarify a path towards commercialization and patient access to innovative products. It also commits itself to raising public awareness of the severity of kidney failure as a disease and create a sense of urgency to develop new ways to prevent, diagnose, or treat kidney diseases. Phase 1 of the inaugural KidneyX Prize competition named “Reinventing Dialysis” encouraged innovators to design possible solutions that can replicate normal kidney functions and improve patient quality of life, awarding 15 prizes of $75,000 each in April 2019. Phase 2 proposals for the building and testing of prototype solutions that can replicate normal kidney functions or improve dialysis access are due January 31, 2020.

Although the FDA has not explicitly stated a public initiative that will work in tandem with AKs, several projects have already spearheaded themselves in this sector. The Kidney Project was started in 2002 by a group of scientists and clinicians from universities and laboratories across the United States with a goal of creating a small, surgically implanted, and self-contained bioartificial kidney to treat ESRD.[[11]](#footnote-11) The project is headed by Dr. Shuvo Roy from the University of California, San Francisco and includes collaborators from Ohio State University, Pennsylvania State University, and privately-owned businesses.[[12]](#footnote-12).

The wearable artificial kidney (WAK), headed by Dr. Victor Gura in Los Angeles, has experienced funding issues as it is not a part of a national project or initiative. Although the WAK won the FDA Innovation 2.0 that got it fast-tracked through the regulatory phase, Dr. Gura still sites lack of venture capital and dialysis industry support as issues when it comes to funding.[[13]](#footnote-13)

Section seven of AAKH focuses on increasing the utilization of available organs. Within 90 days of the issue it sought to enhance the procurement and utilization of organ available through decreased donation by revisiting the Organ Procurement Organization (OPO) rules and evaluation metrics. Within 180 days of the issue it sought to streamline and expedite the process of kidney matching and delivery to reduce the discard rate of donor organs. To date there has not been any government action or statement to this section.

Section eight of AAKH focuses on supporting living organ donors. Within 90 days of the issue it sought to remove financial barriers to living organ donation, modifying the current regulation system to expand the definition of allowable costs that can be reimbursed under several programs and income brackets. To date there has not been any government action or statement to this section.

Effective changes resulting from this executive order will be a mixture of adoption of policy and expedited innovation. It is important to account how we, as biomedical engineers, fit into the executive order and take part in the overarching goal of improving kidney health care. Sections three, six, and seven are rich with opportunities both in established organizations and policies as well as the potential for future developments. In section three, the partnership between major national kidney health organization has encouraged grants such as the NKF’s 2020 Young Investigator Research Grant due in February, 2020 which we, along with Dr. Bowman, are eligible for.[[14]](#footnote-14) On the public/governmental front, the NIDDK has consistent funding opportunities for students, faculty, and established investigators. Studies related to kidney disease are usually part of a very general research problem or jointly investigated with comorbidities of CKD like diabetes.[[15]](#footnote-15)

In section six, the mediation of research funds and grants are primarily found in the expansion of KidneyX. We are primary candidates to participate in Phase II of Reinventing Dialysis where up to three winners will each be awarded $500,000. Along with KidneyX, we could participate in the various AK initiatives, such as the wearable and implantable kidney, nationwide that have been headed by passionate doctors and engineers. There is a general roadmap that is aimed towards engineers and scientists on how to invent AKs within FDA policies to attempt as smooth of transition into market as possible.[[16]](#footnote-16) FDA sponsored awards may allow for inventions to get fast tracked like the WAK, but nothing from the FDA itself has been made public specifically for innovation in AKs.

Although section seven deals with policy in the OPO, the process of kidney matching and transportation is something that can be directly influenced by innovation in technology. Kidney transplantation is by far the most effective, desired, and cost-effective modality of RRT for patients with irreversible CKD. It has the best patient and quality of life outcomes.[[17]](#footnote-17) As outlined in the executive order, removing process inefficiencies in matching and delivery of donor organs will increase rates of acceptance by transplant centers and reduce detrimental effects on organ quality due to prolonged time with reduced or cut-off blood supply. If not by policy, innovators such ourselves immerse ourselves into the biology and engineering of prolonging the viability of tissues and organs after retrieval from the donor. In the case of organ donation, looking to countries such as Spain, which leads the world in organ donation and transplantation, may prove effective in how we treat policy and adoptable biomedical systems engineering in the United States.[[18]](#footnote-18) The Executive Order reinvigorated the renal health care continumm that has remained largely unchained over the past 60 years and we are enthusiastic to see how we, as biomedical engineers, contribute to it.

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