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The Executive Order on Kidney Care: We Need to Do Much More to Win the Battle Against Kidney Disease

Janet Handal[1,2]

[1]New York, New York, USA

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My family is an Alport's family; as such, I have a lot of experience with end-stage renal disease (ESRD), dialysis, and transplants. There are 7 transplant recipients (9 transplants) among the 20 children of 4 Alport's siblings. All but 1 received their kidneys from deceased donors.

My generation was the first that had access to dialysis when ESRD occurred; we are now in our 50s and 60s. In the next generation, 5 daughters are of childbearing age. So I am eager to see improvements in the care of patients with kidney disease. I welcome most of the proposals organized under the July 10, 2019, Presidential Executive Order on Advancing American Kidney Health,[1] but I know there is much more that can and should be done.

At the current rate of funding and level of research into kidney disease, and the unacceptable numbers of people dying while waiting for an implant, makes it obvious that we're losing the battle against kidney disease.

Nephrologists, as the medical experts who face desperate patients every day in their practice, can be a driving force in bringing about change in how kidney disease is treated, researched, and funded. Our futures, and those of all people facing kidney disease, are dependent on radical changes in the way things are done. The current norm is unacceptable.

Dramatically Increase Funding for Research

Dialysis costs in the United States alone were $42 billion in 2018.[2] The amount of money put forward to stimulate innovation in the Executive Order is practically de minimis: the KidneyX Accelerator's total prize money is only $2.57 million. This is not nearly enough.

By contrast, investment in biotech by corporations and venture capitalists in 2018 was $8 billion by corporations[3] and $10 billion by venture funds.[4] The government should fund at least $250 million per year beyond the funding already provided to The National Institute of Diabetes and Digestive and Kidney Diseases for the next 10 years for innovations to move the needle forward on kidney care. It should also generously fund fetal tissue research and loosen regulations so that research in this area can be fruitful. I urge the National Kidney Foundation to accelerate its pressure on the government to provide this funding.

Invest in New Technologies

Investment should be made in technologies to create replacement organs such as those generated from 3-dimensional printers or grown from human stem cells and artificial kidneys. Gene studies should be further developed to understand possible genetic aspects of kidney disease, including diabetic nephropathy and hypertensive nephropathy, in gene therapies to treat genetically based chronic kidney disease, such as Alport's and polycystic disease, and in innovative new dialysis methods.

It should set aside follow-on funding for projects with promising results, similar to venture capital funding, in which venture groups reserve capital in their funds for future investments in their portfolio companies to sustain growth.

There should be a close connection between the Department of Health and Human Services/Centers for Medicare and Medicaid Services (CMS) funding and Small Business Innovation Research grants, which can further fund development and commercialization. Part of the funds set aside for innovation should be used to identify and develop

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Correspondence: E-mail: janetbhandal@gmail.com

[2]JH is a technology consultant in New York, NY. She is a former Advisory Board member of the Rogosin Institute, New York, NY, and formerly was Chief Information Officer of Save Lives Now NY, an organ donation advocacy group.

information channels with venture capital, device manufacturers, and pharmaceutical companies, so that high potential research can have an expedited access to new funding for commercialization. Patient innovation prizes should be doubled and the total prize money increased by a factor of 5. Money should be set aside to market these prizes to patients with ESRD, so that they are aware of the competition.

Patient Education

Major public awareness campaigns should be launched to raise awareness about the causes and effects of chronic kidney disease, diabetes, and high blood pressure and their interrelationships, and to encourage a healthy lifestyle. People should develop an awareness regarding screening for these diseases, so that they know to ask for it. Doctors who receive CMS payments for kidney patients should be required to deliver standard education for patients with chronic kidney disease at Stage IIIb about kidney disease, its causes, and what hastens or slows progression. Doctors need to discuss different dialysis modalities with their pros and cons and transplants as a treatment for ESRD.

I was astonished to learn at my required pretransplant education session that some patients listing for transplantation had been on dialysis for 4 or more years, and their doctors had never mentioned transplantation as a treatment. This, to me is immoral. These education modules should be made available online. Doctors should be able to request written materials they can share with their patients on diagnosis. Additional education materials should be developed for social media outlets. I would suggest piloting gamification of the impact of various diets and exercise levels on obesity, diabetes, kidney disease, and expected mortality.

Patient Incentives

Just as different approaches to physician payments are being piloted, I think that patients should be incentivized through a tax credit or payment or another mechanism to make healthy choices, such as attaining and maintaining healthy weights and exercise levels and for each year beyond the statistical progression projects that their kidney disease does not progress from Stage IIIa to Stage IV and beyond.

Those in ESRD should be incentivized to try home peritoneal dialysis first if they are medically suitable for this type of dialysis. Because of the cost differential and savings to the government, with peritoneal dialysis costing $53,000[5] and in-center hemodialysis costing $83,000, patients should get a tax credit or refund for a portion of the savings in year 2 and beyond.

Maintain Patient Freedom of Choice Regarding Dialysis

Although it is beneficial to incentivize physicians and patients to have home peritoneal or hemodialysis, it is also important for patients to have the choice of what type of dialysis is best for them given their resources, health, and family situation. Some may not be well enough to do home dialysis or to monitor their own health and know when they need to see a physician, whereas for others, the burden may fall to the family caregiver(s) who may be unable or unwilling to assume this burden.

Physician Best Practices and Training

Just as there are criteria for recommending certain cancer screenings, there should be criteria developed for screening for chronic kidney disease, high blood pressure, and diabetes so that there is earlier detection of these diseases when the best opportunities exist to slow or halt progression. Physicians should be compensated based on wellness of these patients, rather than sickness. They should refer or provide ongoing nutritional and exercise programs, discuss with their patients the benefits and risks of noncompliance, and monitor progress with patients. Residents should receive adequate training so that they are comfortable managing the home dialysis patient.

Living Organ Donation

Living organ donation needs to be encouraged. A major public awareness campaign should be undertaken highlighting that it is a safe procedure because deceased donor organs alone cannot meet the need; only 3 in 1000 deaths happen in a manner that is suitable for organ donation.[6] The Executive Order has tenets to support living donors and I strongly support all of those: to expand the definition of reimbursable allowable costs incurred when donating an organ, raise the limit on the income of donors eligible for reimbursement under the program, allow reimbursement for lost-wage expenses, and provide for reimbursement of child-care and elder-care expenses.

However, more should be done to support and incentivize living donation. The policy of denying living donors access to life insurance should not be permitted. A roll forward tax credit should be provided for living donors, both family and altruistic donors, equal to the CMS annual reimbursement for dialysis patients. Although this is controversial and may require a legislative change, the effect would be to dramatically increase living donations and eliminate the waiting list for kidneys. A similar tax credit should be available for partial liver donation.

Organ Donor Registry

US organ donor registration should be "Opt Out" rather than "Opt In" as it currently is. Registries are administered at the state level, so this may need to be accomplished through legislation and/or new regulations. Research indicates that 95% of people support organ donation, but only 58% are registered. Changing to an "Opt Out" system would rectify this problem.

Organ Procurement Organizations

CMS needs to require public, understandable transparency (in layman's language) of all organ procurement organization (OPO) data, establish minimum performance level requirements, and create a best practices registry for organ procurement, family donor solicitation, and donor registration practices. SWAT-like consulting teams need to work with OPOs to improve performance.

To maintain their contracts, OPOs should be required to have audits and training. Performance goals and timelines should be established for each OPO, especially for recovery of suboptimal organs. The *Washington Post* reported recently on 2 studies that demonstrated that OPOs could have tripled the number of organs for transplantation if they recovered less than perfect organs.[7] With that level of organ recovery, the waiting list could be cleared probably within 3 to 4 years. The *Post*'s own research indicated a greater shortfall in recovery of organs from those older than 50 and a great disparity among the recovery rates among OPOs.

In addition, CMS should audit numbers reported by OPOs to ensure the accuracy and consistency of data, rather than accepting self-reported numbers. Escalating fines should be levied on OPOs that do not meet minimum performance levels. The patient community should have easy access the understandable comparative facts so that they can bring pressure to bear on poorly performing organizations.

I would like to see 1 or more OPOs lose their accreditation so that better-performing OPOs can take over the contracts for that area. For instance, New York City's OPO, LiveOnNY, frequently states that the reason they have the lowest donation rate in the country is because of the diversity of New York City; however, when looking at state registrations in Hawaii, the most diverse state in the country, it has one of the highest registration rates at 61% and California, the second most diverse state, has a registration rate of 47%. New York's is 32%.[8]

Transplant Physician Training and Outcomes Measurement

The *Washington Post* article recommended that the standards by which transplant surgeons are measured should be changed. Currently "surgeons are judged by the 1-year survival rate of their transplant patients—but not by the number of patients who die while waiting for a transplant to come through." The same applies to measures for transplant centers. And additional research should be done to provide physicians with the data to make them comfortable with accepting suboptimal organs. Physicians should get more training to develop skills in working with these organs to get peak performance from them.

Potential Transplant Recipient Education Regarding Suboptimal Organs

Patients need more detailed information in their pretransplant education sessions about the risk/rewards of suboptimal organs and again at the time of an organ offer. However, I believe patients must maintain the right to receive a standard set of information on an offered kidney, to have all questions answered if the information is available, and to reject a kidney if they choose.

I encourage physicians to become more active in the fight against kidney disease and to encourage their patients to do so also. Write Senators Charles Grassley, Patrick Toomey, and Todd Young and demand more funding. Encourage patients to sign up for the National Kidney Foundation newsletter. Many voices together will have a greater impact in pushing the government to increase funding for research and educating patients and for educating the public about kidney disease and living donation. Every day 13 people die waiting for a kidney transplant and 500,000 are receiving dialysis. We owe it to them and future generations to attack this problem with everything we've got.

DISCLOSURE

The author declared no competing interests.

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