Vaccine and The Need to be Heard: Considerations for COVID-19 immunization in ESKD

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The Coronavirus Disease 2019 (COVID-19) pandemic represents an unprecedented challenge in the care of individuals with end stage kidney disease (ESKD) receiving maintenance dialysis. These individuals not only suffer from multiple medical comorbidities, but also need to attend in-center dialysis sessions in an era of social distancing, and in many cases, rely on care partners for daily needs. Herein, we advocate for these vulnerable patients and for their voices to be heard.

“As a home dialysis patient of 11 years I was very concerned when COVID-19 hit the United States. Since January of 2020, I have been following all the public health guidelines to try not to contract the virus. I have been watching the clinical trials for the vaccines since they started. I felt like the vaccine was the only way we were going to get back to a normal life and the only way I was going to be able to not worry about contracting COVID-19 all the time. I live in Florida where there is an executive order that states that hospital providers may also vaccinate persons who they deem extremely vulnerable to COVID-19. However, all the vaccine registration websites state that you must be over 65 to register for an appointment. I received a letter from my doctor stating my medical need for the vaccine as well as a prescription for it. It was still difficult to get an appointment for the vaccine because there is no infrastructure in place for people who are deemed medically needy despite the executive order. My husband ended up going to the different pharmacies around town to explain the situation and see if they could help me figure out how to get an appointment. He happened on one pharmacy that had extra doses from no shows to appointments and they were able to call the regional headquarters and get approval for me to get the vaccine. I have never felt such relief to get a vaccine. While I understand that I will still need
to follow all the public health guidelines, to have that extra layer of protection makes me feel much safer than I did without the vaccine. I am looking forward to my second shot to get the full effect of that protection.”

Patient Interest in COVID-19 Vaccination

This patient offers her perspective on COVID-19 vaccination and a majority of patients share this view. The American Association of Kidney Patients (AAKP) performed an online flash survey in January 2021 with 700 responses. While 85% had not received the vaccine at time of survey, 74% indicated they planned to receive vaccine when available; 78% believed the benefits outweighed the risks. Those unsure of receiving vaccine cited concerns around safety and effectiveness (1). In January 2021, at one dialysis organization with socioeconomic, racial and ethnic diversity similar to metropolitan areas around the United States (US), patients who had not received vaccine were asked if they would receive the COVID vaccine when available. 1094 (72%) reported ‘yes’, 237 (16%) ‘maybe’, and 178 (12%) ‘no’, (2). These rates were higher than polls of the general population, although sampling bias may be playing a role with such a small sample size.

The Advisory Committee on Immunization Practices (ACIP) provided recommendations to the Centers for Disease Control and Prevention (CDC) for COVID-19 vaccination, which federal, state, and local government used for vaccination program implementation. Patients receiving dialysis were not specifically designated in any phase despite increased incidence of disease, risk of hospitalization, and mortality. Some dialysis patients were eligible to receive vaccine in Phase 1a, which included residents of long-term care facilities. However, the majority did not qualify until Phase 1b, which included persons aged 75 and older or Phase 1c, aged 65 or older and those
16-64 with medical conditions (3). Each state has adopted modified versions of these recommendations; while some states have prioritized dialysis patients, patients must review local guidelines to see when they are eligible to receive the vaccine. Nephrologists should be well-familiar with local COVID-19 vaccine information to have informed discussions with their patients.

**Why ESKD patients should receive the COVID-19 vaccine**

Preliminary data from the Centers for Medicare and Medicaid Services (CMS) detailing Medicare claims related to COVID-19 from January 1, 2020 to November 21, 2020 demonstrate that ESKD beneficiaries experience extraordinarily high rates of hospitalization (4,721 per 100,000) in comparison to Medicare beneficiaries over age 65 (732 per 100,000). This holds true even compared to Medicare patients over age 85 who were hospitalized at the rate of 1,436 per 100,000 beneficiaries (4). With regard to mortality, COVID-19 associated mortality in ESKD patients is described as roughly 25% (5). Furthermore, ESKD patients with severe COVID-19 requiring admission to an intensive care unit (ICU), have a staggering 50% mortality at 28 days (6).

Dialysis providers have adjusted safety protocols to comply with public health efforts to ensure that dialysis can be provided while minimizing COVID-19 risk. However, dialysis centers remain densely populated for patients who attend sessions three times per week. Although home dialysis patients do not face the same risks of dialysis in congregate settings, they are subject to the similar underlying comorbidities and have close contact with care partners. (5) The seroprevalence of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antibodies
was between 8-9 percent in a large nationwide sample of ESKD patients in US (7). However, in New York State, seroprevalence rates among those receiving dialysis reached nearly 34% (7).

Despite data demonstrating tremendous COVID-19 related morbidity and mortality among ESKD patients, they have still not been prioritized for vaccination. Promptly vaccinating this vulnerable group is critical. In the US, the Food and Drug Administration (FDA) has issued emergency use authorizations (EUA) for COVID-19 vaccines which have been effective in the general population with minimal side effects (8,9). The American Society of Nephrology (ASN) has recently sent a letter to the White House advocating for direct vaccine allocation to dialysis providers to oversee and implement vaccination within facilities analogous to longstanding hepatitis and influenza vaccination programs (10). Dialysis facilities are a lost opportunity to effectively vaccinate ESKD patients, with staff who are experienced in the provision of other vaccines to ESKD patients. Large public vaccination sites or retail pharmacies are unlikely to be the first choice for ESKD patients looking to be vaccinated. Many patients have long standing relationships with their dialysis unit and team who are uniquely poised to address vaccine hesitancy among patients. Simply observing other ESKD patients receiving vaccine and continuing their usual care is a powerful message to those contemplating vaccination. However, at this time, an initially hesitant patient is left to scramble and call local pharmacies, wait in online queues, or otherwise try to navigate a confusing local vaccine distribution system. Ultimately this serves as a deterrent to well-meaning vaccination efforts.

The COVID-19 vaccines approved in the US thus far have shown greater efficacy and safety than anticipated. The Pfizer and Moderna mRNA vaccines granted EUA in the US showed 94 to 95% efficacy, with few serious adverse events (8,9). The Johnson & Johnson adenovirus vector vaccine was approved for EUA, also with minimal side effects. (11) However, these studies
did not include large numbers of dialysis patients. We know that ESKD patients exhibit a poorer immune responsiveness in several situations, with seroprevalence rates of approximately 50-60% following Hepatitis B vaccination compared to 80-90% in the general US population (12). Approximately 80% of ESKD patients developed antibodies following influenza vaccination (13). ESKD patients may experience decreased immune responsiveness to COVID-19 vaccine similar to Hepatitis B and influenza. Additionally, the durability of any immune response to a COVID-19 vaccine in ESKD patients is not clear. A longitudinal, 3-month serologic assessment of SARS-CoV-2 Infections in a Belgian hemodialysis facility demonstrated a decrease in antibody titer after 3 months following a natural COVID-19 infection (14). If the combination of decreased initial immunogenicity to COVID-19 vaccination as well as a waning response over time is verified for ESKD patients, the dialysis facility is the natural location to administer COVID-19 booster vaccines. With several vaccines receiving EUA by the FDA, it is likely that the vaccine supply in the United States will increase over time (9,10,12). A discussion about which vaccine is preferred for ESKD patients will ensue, however as it stands, ESKD patients have neither easy access to COVID-19 vaccines nor a choice in which vaccine they receive. Given the high risk of morbidity and mortality from COVID-19, ESKD patients should prioritize getting any approved vaccine available at this time.

Summary

Available COVID-19 vaccines are both safe and effective in all subgroups tested in clinical trials published to date. Although ESKD patients on maintenance dialysis were not well-represented, prevailing recommendations are to vaccinate this extremely vulnerable population. Dialysis facilities still represent an untapped resource to quickly and effectively vaccinate ESKD
patients as well as monitor their response to vaccination. As a kidney community it is our obligation to advocate for our patients so that they may emerge from COVID-19 more resilient.

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