# Overview Of Immune Response to the COVID-19 Vaccination Among Hemodialysis Patients

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## Abstract

Globally, over 100 million confirmed cases of COVID-19 have been reported. The virus that causes COVID-19 is designated SARS-CoV-2; previously, it was referred to as 2019-nCoV. At the end of 2019, cases have been reported in all continents. The main aim of the COVID-19 vaccine is to establish immunity to the spike protein of SARS-CoV-2. Immune system dysfunction is one of the serious complications of chronic kidney disease (CKD). On the other hand, the immune system has a central role in the initiation and progression of this disease by promoting and persistence of systemic inflammation. Patients with end stage renal disease (ESRD) are particularly vulnerable to severe COVID-19 due to the older age and high frequency of comorbidity, such as diabetes and hypertension, in this population. This study aimed to review the immune response following vaccination with the COVID-19 vaccines in patients on maintenance HD and the factors associated with it.



**KeyWords:**Hemodialysis Patients; COVID-19; Vaccination; Immune Response
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## Introduction

Coronaviruses are important human and animal pathogens. At the end of 2019, a novel coronavirus was identified as the cause of a cluster of pneumonia. It rapidly spread, resulting in an epidemic throughout China, followed by a global pandemic (1). Coronaviruses (CoVs) have pricky spikes that project from their surface, enveloped RNA viruses, are characterized by club-like spikes that project from their surface, they have a unique replicating process. These viruses are the cause of many types of diseases in mammals and birds leading to enteritis in cows and pigs and upper respiratory infection in humans which may be fatal (2).

Many people are asymptomatic of their CKD, and present after change findings from screening tests for example, through a routine medical examination or check-up or not until they become unwell with advanced CKD. However, depending on the cause of CKD, some people have symptoms directly as a result of their impaired kidney function. Patient may develop complications like high blood pressure, anemia, weak bones, poor nutritional health and nerve damage (3). Patients with ESRD have been disproportionately impacted by the pandemic due in part to their burden of comorbidities. In addition, globally, most patients with ESRD receive in-center HD, which limits their ability to observe physical isolation for infection control (4).

Impact of HD patients on immunity:

Proteinuria, malnutrition, iron overload, alternation of vitamin D level, dialysis processes, chronic inflammation, disruption in the balance between the production of free radicals and antioxidant defenses and uremic toxin affect the immune system. Proteinuria has a crucial role in immune system by reducing many immune components, like adaptor proteins and antibodies (5).CKD reduces bone marrow cell proliferation, leading to decreased number of immune cells and anemia. Iron overload as a consequence of excessive intravenous iron administration disrupts phagocytic activity and microbial killing capability of macrophages and neutrophils, CD4+ T cell depletion and expansion of CD8+CD28− T cells.

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Another complication of elevated iron levels is the development of pro-inflammatory M1 macrophages, which cause augmentation of local inflammation, oxidative stress, and inhibition of injury healing; all of them can contribute to atherosclerosis and CKD progression. Alteration of vitamin D and parathyroid (PTH) hormone levels results in dysfunction of immune cells (6).

Increased PTH levels cause raising cytosolic calcium concentrations, which in combination, decrease PMN phagocytosis capacity, B cell proliferation and antibody production (7). Vitamin D is a potent immunomodulator and plays an important role in controlling immune effector responses, especially during infection or vaccination, by repressing the production of Th1-related cytokines and suppression of inflammatory macrophages. It also can inhibit all of the inflammation processes involved in the pathogenesis of CKD. Vitamin D deficiency may be related to reduce survival in the CKD patients in stages 3 to 5 of the disease. Malnutrition, iron overload, increased intracellular calcium, dialysis process, and uremic toxins are involved in the dysfunction of PMN, T lymphocyte, and monocytes (8).

Prolonged dialysis is associated with developing infective endocarditis, peritonitis, and pneumonia, which are risk factors for mortality in dialysis patients by decreased phagocytic function. In order to prevent infections, it is recommended these patients should be vaccinated against common infectious diseases. Increased number of Th17 cells and decreased number of Treg cells were also observed in patients undergoing HD. The persistent systemic inflammation culminates in the immunosuppressed state in CKD (9).

NK cells counts are diminished and also there are modulated phenotypic, cytotoxic and migratory features in HD patients, which are associated with the incidence of cardiovascular, cancer, infection and pregnancy disorders in uremic patients. The density of Langerhans cells in the skin of uremic patients is reduced that might contribute to the reduced vaccination responses in these patients. The numbers of CD14+CD16++ monocytes and CD4+CD28– T cells are increased that could explain the high incidence of cardiovascular disease in ESRD patients (10).

Serum MBL level is declined in peritoneal dialysis and HD patients and probably is accompanied by increased susceptibility to infection. Also, increased MBL level in HD patients was associated with the management of patients and prediction of kidney allograft survival (11).

Patients with chronic HD had lymphopenia and diminished numbers of both CD4 and CD8 T cells and their proliferative response upon stimulation was decreased. The maturation of subsets of Th cells is impaired in HD patients that maybe due to protein-energy wasting (PEW) (12).

Increased suppressor activity of T cell has been observed in uremic patients. Uremia is accompanied by reduction in the number and function of lymphoid cells, whereas numbers of myeloid cells are normal or increased. Patients with ESRD manifest increased numbers of specific proinflammatory subsets of T cells and monocytes (Figure 1). Thus, an immunosuppressed state, leading to increased susceptibility to infection, may lead to chronic inflammation and that inflammation may also ensue as a consequence of a state of immunoactivation. In addition, external factors, such as the dialysis procedure, dialysis access infections, medication, and PEW, may activate or inhibit the immune system (13).



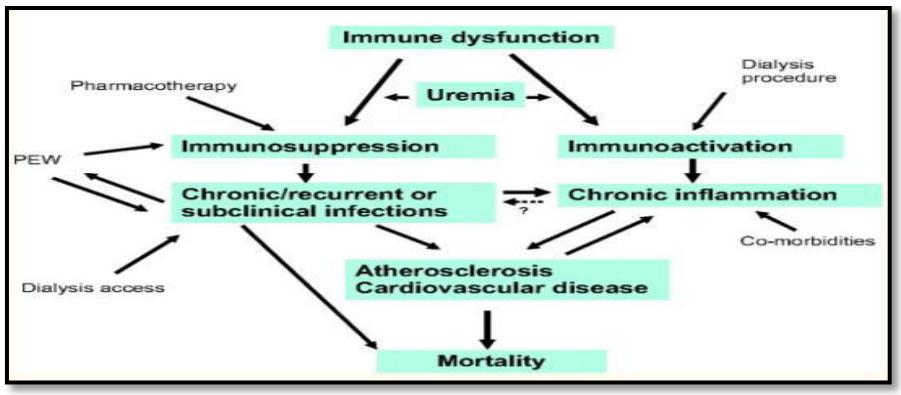


**Figure 1: Potential links between immune dysfunction in uremia, infection, inflammation,**

**increased risk of atherosclerosis and cardiovascular disease (13).**

## COVID-19 in CKD and HD patients

Patients with ESRD have been disproportionately impacted by the pandemic due in part to their burden of comorbidities. In addition, globally, most patients with ESRD receive in-center HD, which limits their ability to observe physical isolation for infection control (4).

Patients with ESRD are particularly vulnerable to severe COVID-19 due to the older age and high frequency of comorbidity, such as diabetes and hypertension, in this population. Of the patients with ESRD, patients who receive dialysis at home, either HD or peritoneal dialysis, may be at a lower risk of developing COVID-19 compared with patients receiving in-center HD (14).

This was demonstrated in one study in which patients receiving in-center dialysis had an approximately twofold greater risk of infection compared with patients receiving home dialysis (15).

In another study of 818 peritoneal dialysis patients who were followed for four months, eight patients (0.9 percent) were diagnosed with COVID-19 after measures to limit exposure were instituted, a rate much lower than that reported among in-center HD patients. In addition, in the United States, hospitalizations related to COVID-19 were three- to four-fold greater among patients receiving HD compared with patients receiving peritoneal dialysis (16).

The reported prevalence of COVID-19 among patients receiving in-center HD is higher but largely mirrors the general population within a given region. In a United States study of over 28,000 randomly selected patients from approximately 1300 dialysis facilities, 8 to 9 percent of the blood samples were positive for the SARS-CoV-2 antibody. There was an increased likelihood of SARS-CoV-2 antibody positivity among residents of neighborhoods that were majority Black and Hispanic (2 or 3 times higher), lower income (two times higher), and more densely populated (10 times higher) (17).

In a French registry study with data collected from all 1245 dialysis units in the country, approximately 3 percent of patients were reported to have COVID-19. The prevalence varied between <1 to 10 percent depending upon the region (15).

In other study from areas of widespread disease in the United Kingdom, 20 to 22 percent of patients receiving maintenance HD were positive for SARS-CoV-2. Approximately 36 percent of patients were positive for the SARS-CoV-2 antibody, suggesting a prior infection (18).

In a Spanish study of 192 dialysis patients who underwent polymerase chain reaction (PCR) testing for SARS-CoV-2, 19 percent tested positive (12 percent were symptomatic). Risk factors for COVID-19 identified in this study included sharing transport to the dialysis center, living in a nursing home, and being hospitalized within two weeks prior to the test (19).

Patients with ESRD may also be at an increased risk of dying from COVID-19. In one study, for example, nearly one-third of hospitalized dialysis patients with COVID-19 died (20). In another study, one-half of critically ill dialysis patients died within 28 days of admission to the intensive care unit (ICU). The overall mortality among dialysis patients with COVID-19 was approximately 20 percent (14). A mortality rate of up to 32 percent was reported in a study from an area where regional prevalence of COVID-19 was high (21).

Mortality rates among ESRD patients in 2020 exceeded the rates of these patients in prior years, presumably due to additional deaths related to COVID-19. Between February and August 2020, an estimated excess of 9 to 13 deaths occurred per 1000 ESRD patients (22).



## Testing for COVID-19 in CKD and HD patients

COVID-19 is confirmed in a patient receiving HD at the facility, the measures apply if a HD facility is dialyzing more than one patient with suspected or confirmed COVID-19, an attempt should be made to cohort these patients, as well as the health care personnel caring for them, together in the same section of the unit and/or on the same shift (eg, schedule all such patients for the last shift of the day). This includes recommendations on personal protective equipment. Routine cleaning and disinfection are appropriate for COVID-19 in dialysis settings. Any surface, supplies, or equipment (eg, dialysis machine) located within six feet of symptomatic patients should be disinfected or discarded (4).

## Patients receiving home HD dialysis & hospitalized patients

An approach to patients receiving home dialysis is as follows during the COVID-19 pandemic, patients receiving dialysis at home HD dialysis should have their regular follow-up visits by telemedicine or in-

person, depending upon their health, the regional prevalence of COVID-19, and their personal risk of acquiring COVID-19. In addition, home visits by health care professionals should be minimized (4).

The American Society of Nephrology has issued guidelines for nephrology clinicians caring for hospitalized patients who require dialysis for ESRD. In addition, the CDC has issued guidance for care of hospitalized patients, which are applicable for those hospitalized with kidney disease. These guidelines continue to evolve and are frequently updated. Understandably, the execution of some of these guidelines will be limited by policies enforced at the level of any institution. However, when possible, adherence to these guidelines is encouraged (23).

Patients with COVID-19 who are undergoing dialysis should be co-localized on a floor or ICU, when possible. Co-localization within adjacent rooms can enable one dialysis nurse to simultaneously deliver dialysis for more than one patient.When possible, patients with suspected or confirmed COVID-19 who are not critically ill should be dialyzed in their own isolation room rather than being transported to the inpatient dialysis unit. Where available, telemedicine interfaces with a camera should be used to troubleshoot alarms from outside the room and to minimize the need for the dialysis nurse or the nephrologist to enter an isolation room (4).

In the early part of the pandemic, there was concern about the presence of SARS-CoV-2 in the spent peritoneal dialysate of patients with COVID-19 and about the proper method of disposal of such dialysate. This was based on an early report of a patient who had SARS-CoV-2 detected in their peritoneal dialysate. Thus, additional disinfection of the spent peritoneal dialysate with sodium hypochlorite or other measures is likely not necessary (24).

Additionally, the use of erythropoiesis-stimulating agents (ESAs) for the treatment of anemia is controversial among patients with ESRD who are diagnosed with COVID-19. ESAs may theoretically increase the prothrombotic risk posed by COVID-19, whereas withholding ESAs may precipitate or worsen anemia. There are no rigorous studies to guide management of anemia in this setting (25).

## Impact of COVID-19 vaccination on HD patients

COVID-19 pandemic has had a huge impact on health and economics because of its rapid spread and multiple mutant variants since 2020. The spectrum of COVID-19 varies from asymptomatic carriers to multiorgan dysfunction, including ARDS and AKI. SARS-CoV-2, the etiological agent of COVID-19, enter cells via the interaction between its spike protein and ACE-2 and thereby induces systemic inflammation and organ dysfunction by activating the NF-kB-associated inflammasome and producing a downstream cytokine storm (26).



The high-risk groups for SARS-CoV-2 -mediated critical illness include those with obesity, diabetes mellitus, advanced age and HD. Among the patients with CKD, the percentage of patients with critical illness was higher than that in the other groups because of the multiple comorbidities and the impaired immune system in CKD patients with varying CKD stages and even in patients undergoing kidney transplantation (KT) (27).

Beyond isolation with adequate social distancing and personal protective equipment, vaccination is a cornerstone strategy for lowering the incidence of critical illness during the COVID-19 pandemic. Currently, the techniques for SARS-CoV-2 vaccines include targeting inactive SARS-CoV-2, vectors carrying the nucleic acid for the spike protein, attenuated virus, a protein fragment of SARS-CoV-2, messenger RNA of SARS-CoV-2 carried by lipidic microparticles or the DNA sequence carried by an adenovirus (Figure 2) (28).

In addition to these direct effects, the pandemic may have indirect effects on the psychosocial health of patients on in-center chronic HD, even if they are not infected with COVID-19. These effects may be particularly overwhelming in a patient population that already has a disproportionately high burden of symptoms such as depression and anxiety (29).

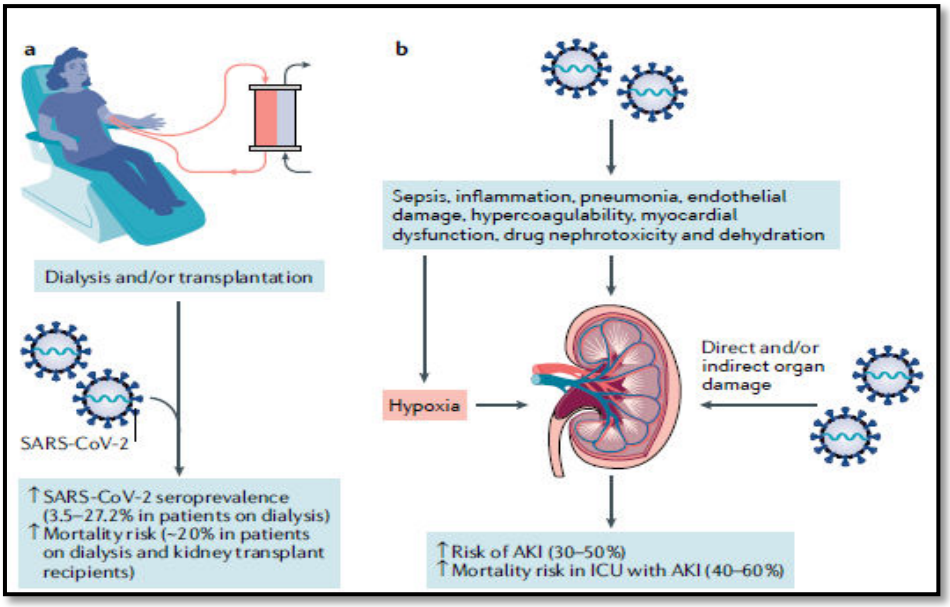


**Figure 2: The impact of COVID-19 on the kidneys; (a) patients on in- centre dialysis and kidney transplant recipients are at increased risk of community exposure to SARS- CoV-2 infection and COVID-19- associated mortality, (b) Acute kidney injury (AKI) is also an important complication of severe COVID-19, likely as a consequence of multifactorial processes, and is associated with an increased risk of mortality (28).**



## COVID-19 vaccines of choice in preventing HD patients from critical illness

The main aim of the COVID-19 vaccine is to establish immunity to the spike protein of SARS-CoV-2. For humans or mice, immunity to the S-protein could be induced by exposure to the full-length S-protein or the extracellular domain of the S-protein (Figure 3) (29). For SARS-CoV, a viral vector with the RNA expression receptor binding domain for the S protein served as the strategy for the development of the antibody. Moreover, for SARSCoV, the S-protein of Tor2, GD03T13, and SZ3 within the S1 domain induced monoclonal antibodies with high affinity for the receptor binding protein for the S-protein. In this manner, the neutralizing antibody could decrease the entry of SARS-CoV (30).

## 1.Replication-defective viral vector carrying pathogen gene(s)

In the SARS-CoV era, the most commonly used viral vectors included adenovirus, lentivirus, measle virus, poxvirus, rhabdovirus and alphavirus. Adenovirus-based vectors have served as the most dominant vectors during COVID-19 vaccine development. ChAdOx-1 uses the full-length codon for the S-protein with a tissue plasminogen activator leader sequence. The prime-boosting strategy can elicit IgG against the spike protein (31). AD26.COV.S, which uses adenovirus vector 26 with a full-length codon for the S-protein, is injected viral particles and thereby induces an immune response. Recombinant AD26 (rAd26) and AD5 (rAd5), which carry SARS-CoV-2 full-length glycoprotein S, are given viral particles and thereby induce an immune response (32).

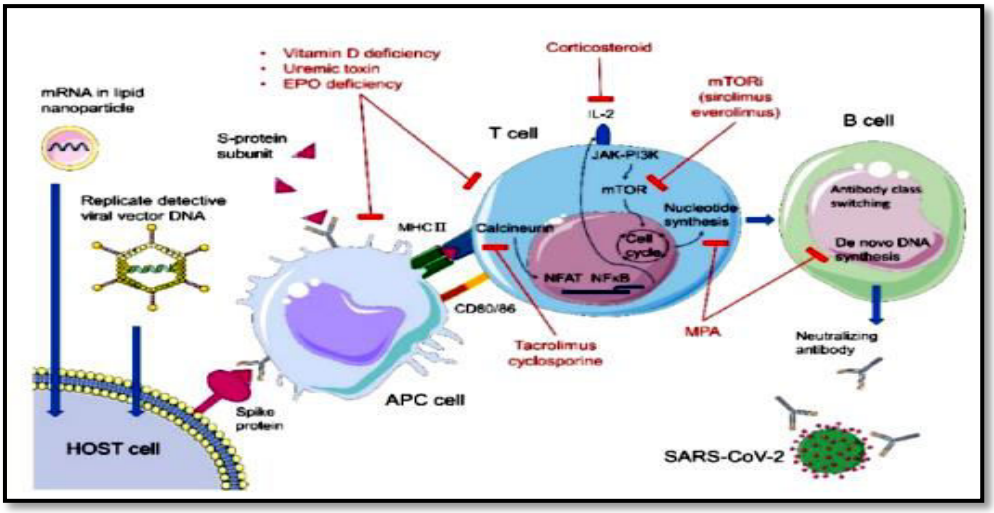


**Figure 3: The mechanism of the impaired generation of neutralizing antibody after SARS-CoV-2 vaccine injection in HD patients. Antigen presenting cell (APC); IL2: interleukin 2; JAK-PI3K: Janus-activated kinase/phosphoinositide 3-kinase pathway; MHC: major histocompatibility complex (30).**



## 2. MRNA vaccines

Both BNT162b2 and mRNA-1273 vaccines are lipid nanoparticle–encapsulated mRNA based vaccines that encode perfusion-stabilized full-length spike proteins. For BNT162b2, the full-length RNA with 2 mutation modified by proline can translate the locked-in perfusion transformation in order to augment the production of neutralizing antibody (33). Based on the current evidence, the titer of neutralizing antibodies might be associated with protection against critical illness created a model for correlating the titer of neutralizing antibodies and the occurrence of severe disease related to SARS-CoV-2 (34). Titer of Ab was negatively associated with severe disease. In the UK, vaccination with either ChAdOx1 or BNT162b2 decreased the occurrence of mild symptoms in individuals with COVID-19, and the protective effects of the vaccine increased in patients after receiving the second dose (35).

## 3. Purified virus components

Beyond the injection of mRNA coding the S-protein with nanoparticles or a viral vector, the subunit of S-protein has been used to induce the development of neutralizing antibodies against SARS-CoV-2 and to block viral entry via human ACE. NVX-CoV2373, as the subunit of the S-protein, is derived from the established baculovirus Spodoptera frugiperda (Sf9) insect cell-expression system. The mutation in the S1/S2 cleavage site makes the protein resistant to protease cleavage and thereby able to bind to hACE with high affinity (36). The adjuvant matrix protein is formulated in the subunit. Such evidence demonstrated that the neutralizing antibody might be negatively associated with severe SARS-CoV-2 infection, and an adequate dose of vaccine was warranted for the prevention of symptomatic COVID-19 infection (34). Among the current vaccines with a 50% protective neutralization level, the vaccines above can induce the development of essential antibodies. Only 0.7% of all subjects enrolled in the BNT162b2 trial had CKD (32).

## COVID-19 vaccine efficacy in HD patients

In clinical trials, the efficacy of vaccination has been assessed in different stages of CKD. Only 39.4% of enrollees had mild to moderate CKD. Regarding immunosuppressive agents, 93.5% of phase III studies excluded participants on immunosuppressive agents. Therefore, assessing the efficacy of the vaccine based on different stages might be difficult (37).

Currently, phase III studies on BNT162b2 (Pfizer), mRNA-1273 (Moderna), AD26.COV.2 (Johnson & Johnson), Novavax and ChAdOx1 nCoV-19 (AstraZeneca) are being conducted. In patients with CKD stage 3–5, the primary etiologies of CKD might influence the efficacy of the vaccine for COVID-19 because immunosuppressive agents might in turn influence adaptive immunity and therefore influence the IgG titer after –vaccination. Some states are prioritizing vaccination to these patients, almost half of whom are also over 65 years of age. A

substantial fraction of persons receiving dialysis, however, belong to racial, ethnic, socioeconomic, cultural, and religious groups more likely to vaccine hesitant (38).

Comorbidity among patients undergoing dialysis is at high rates. Those patients have variable immunosuppression levels in addition to being much more likely to live in a state of permanent caution; therefore, they are at high risk of acquiring SARS-CoV-2 infection and also of mounting severe disease complications. Hemodialysis patients showed an increased case fatality rate (from 20 to 30%) (39).

Therefore, the Food and Drug Administration (FDA) is piloting an independent assessment of the safety as well as efficiency of a booster COVID-19 vaccine dose after receiving the first two doses. Moreover, the Advisory Committee on Immunization Practices (ACIP) will be providing booster dose endorsements based on a comprehensive evaluation of the data (40).

## Conclusion

The COVID-19 pandemic has profound adverse effects on the population on dialysis.

Patients requiring dialysis are at an increased risk of SARS-CoV-2 infection and mortality, and many have experienced psychological distress as well as delayed or suboptimal care.

Patients with persistent poor vaccine responses may be candidates for primary prophylaxis strategies.

Neutralizing monoclonal antibodies may be an attractive option after a high-risk exposure or during the early course of infection.

## conflict of interest.

No

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