

2021

Vaccination Toolkit

Developed by the Forum of ESRD
Networks' Medical Advisory Council
(MAC)

This toolkit for health providers and practitioners is a reference tool that provides information about vaccination requirements for kidney patients in the dialysis facility.

Tell us what you think!

Please take a moment to complete a short questionnaire about this Toolkit. We appreciate your insight and suggestions to make our resources better.

<https://www.surveymonkey.com/r/ForumResEval>



This toolkit was developed by members of the Forum of ESRD Networks' Medical Advisory Council (MAC). The Council members who participated in the original project and the 2020 and 2021 revisions are listed below.

Authors - 2009

Stuart Goldstein, MD - Subcommittee Chair

Baylor College of Medicine
Texas Children's Hospital
Houston, Texas
ESRD Network 14

James McCarthy, MD

Mayo Clinic Dialysis
Rochester, Minnesota
ESRD Network 11

Richard Paul, MD

Piedmont Nephrology
Hickory, North Carolina
ESRD Network 6

Darlene Rodgers, BSN, RN, CNN, CPHQ

Intermountain ESRD Network, Inc.
Lakewood, Colorado
ESRD Network 15

Authors & Peer Reviewers – 2020 & 2021 Revisions

Ramin Sam, MD – Subcommittee Chair

Zuckerberg San Francisco General Hospital
University of California, San Francisco
San Francisco, California
ESRD Network 17

Lynda K. Ball, MSN, RN, CNN

Health Services Advisory Group (HSAG)
Oklahoma City, Oklahoma
ESRD Network 13

David Henner, DO

Berkshire Medical Center
Pittsfield, Massachusetts
ESRD Network 1

Stephanie Huskey, RN, CDN

QSource
Kansas City, Missouri
ESRD Network 12

Kamyar Kalantar-Zadeh, MD, MPH, PhD

Univ. of California Irvine, School of Medicine
Orange, California
ESRD Network 18

Jane Wilson, MSN, RN, CNN, RD

Health Services Advisory Group (HSAG)
Burlingame, California
ESRD Network 17

Daniel L. Landry, DO, FASN

Baystate Medical Center
Springfield, MA
ESRD Network 1

This toolkit was formatted by Forum Coordinator Bonnie L. Freshly, Med, CMP. (2009)

This toolkit was formatted by Forum Coordinator Dee LeDuc. (2020, 2021)

The toolkit was amended in 2021 to include a section about the COVID-19 vaccination (pg. 6-10).

Note: Some tools contained in this toolkit were originally created by the ESRD Networks. Several resources were provided by the Safe & Timely Immunizations Coalition (STC).

All materials herein were developed by The Forum of ESRD Networks ("The Forum") in cooperation with the ESRD Networks. The Forum and contributors hereby provide limited permission for the user of this information to reproduce, retransmit, or reprint for such user's or other individual's or entities' own personal use (and for such personal use only) provided credit is given and copies are not intended for sale. Use or inclusion of any portion of this document in another work intended for commercial use is prohibited without prior written consent of the Forum and its contributors before any material is reproduced, retransmitted, or reprinted. All other rights reserved.

The Forum is providing information and services as a benefit and service. The Forum makes no representations about the suitability of this information and these services for any purpose. The Forum is not responsible for any material posted by any third party, and The Forum specifically disclaims any and all liability for any claims or damages that result from any posting by third parties. The Forum is not liable to anyone for inaccuracies, errors, or omissions with respect to any material or the transmission or delivery of any material obtained from The Forum; any injury and/or damage to persons or property as a matter of products liability, negligence, or otherwise from any use or operation of any methods, products, instructions, or ideas contained in the material herein.

This Toolkit is a guide, created by experienced professionals using the available evidence, produced by the Medical Advisory Council (MAC) of the Forum of ESRD Networks. The MAC anticipates revisions and additions to the Toolkit overtime. The Toolkit is meant as a resource and should not be referenced as a regulatory statement. As with other MAC Toolkits this document is meant to help guide medical directors in meeting their obligations.

Table of Contents

GENERAL INFORMATION

Introduction	4
Pneumococcal Vaccination.....	5
Influenza Vaccination	6
COVID-19 Vaccination for patients receiving dialysis therapy	6
Other vaccinations not routinely give during dialysis	11
Vaccinating the transplant patient.....	12
How to Use this Toolkit	13
Quality Assessment & Performance Improvement Plan: Patient Immunization	14
Example: Vaccination Action Plan Template.....	15

DATA TOOLS

Immunization Data Collection Tool	18
Immunization Monthly Intervention Tracking Tool	19

RESOURCES AND REFERENCES

Quality Assessment and Performance Improvement (QAPI) for ESRD Medical Directors	22
Pneumonia Vaccine Protocol	23
Immunization Resources Available on the Internet	24
CDC Guidelines for Vaccinating Kidney Dialysis Patients & Patients with Chronic Kidney Disease ...	25

INCREASING IMMUNIZATION RATES AMONG DIALYSIS PATIENTS

INTRODUCTION

The goal of this toolkit is to suggest quality improvement approaches that a facility can use to ensure care coordination for patients and increase immunization rates for influenza, pneumococcal disease, and hepatitis B among dialysis patients. The 2008 revision of the ESRD Conditions for Coverage (CfCs) mandates ongoing Quality Assessment and Performance Improvement (QAPI) projects within each facility and places responsibility for the direction of these projects upon the Medical Director. This toolkit provides information, tools and resources to effectively monitor, track, and manage immunization status among patients in the dialysis facility.

Recommendations for vaccinating dialysis patients for hepatitis B, influenza, and pneumonia have not changed to any significant degree from the recommendations in the pamphlet, [*Guidelines for Vaccinating Kidney Dialysis Patients and Patients with Chronic Kidney Disease*](#), which was generated by a Centers for Disease Control and Prevention (CDC) task force in response to a suggestion from the Forum of ESRD Networks in 2012. A copy of this useful document is appended to the end of this toolkit. There have been some changes to influenza and pneumococcal vaccinations in the last 10 years which will be discussed in detail in the next few pages. Some of the salient recommendations from the document, incorporated with some updated information, are summarized here.

- The 23-valent pneumococcal polysaccharide vaccine (PPSV23) has been available for several years for adults on dialysis regardless of age. A single booster injection continues to be recommended if more than 5 years have elapsed since an initial dose. PPSV23 is recommended for any individual with unknown vaccination status.
- PCV13 (Prevnar 13) is a newer pneumococcal vaccine which contains 13 capsular types and is intended for use in conjunction with the 23-valent pneumococcal vaccine to provide enhanced protection against pneumococcal disease.
- Two hepatitis B vaccine formulations suitable for dialysis patients as well as the general public, Recombivax HB[®] (Merck) and Engerix-B[®] (GlaxoSmithKline), are manufactured from viral proteins generated in yeast through recombinant DNA technology. These formulations have replaced older preparations derived from inactivated virus from human serum. Patients on dialysis have subnormal immune responses to these and other vaccines. Because of this, vaccine doses are doubled (i.e., from 20 µg to 40 µg/dose for adults over the age of 20) and additional doses are recommended for each vaccination series (i.e., three doses of Recombivax HB and 4 of Engerix-B). Vaccination is administered in the deltoid muscle, a site which may help to boost the immune response; patients on chronic anticoagulation may receive it subcutaneously, but immune responsiveness may be further impaired. Gluteal administration is not recommended. If seroconversion does

not occur after the first vaccine series, a second attempt is indicated. If a second full hepatitis B vaccine series fails to induce appropriate antibody response (defined as an antibody titer > 10 IU/L), the patient is considered a “non-responder” and need not be subjected to further doses of the vaccine. The overall response rate to vaccination in the dialysis population with these regimens is up to 70%.

- Once seroconversion occurs, patients no longer require monthly monitoring for surface antigenemia but rather can have such testing performed yearly with quantitative surface antibody status. Booster series of the vaccines are administered when titers fall below 10 IU/L. It is also important to refrain from monitoring recently vaccinated patients for hepatitis B surface antigen, since detectable antigen levels may persist for up to 2 weeks after vaccination leading to unnecessary need for isolation and repeat testing. Because of the suboptimal seroconversion response among dialysis patients, it is recommended to immunize previously unvaccinated individuals with advancing chronic kidney disease to both hepatitis B and pneumococcal disease before dialysis dependence occurs.
- As of November of 2017, a third recombinant hepatitis B vaccine has become available in the United States (HepB-CpG; sold as Heplisav-B made by Dynavax). Heplisav-B contains a novel immunostimulatory adjuvant and it requires the administration of only two doses (one month apart) as opposed to the three doses required for the other two vaccines in the general population. A preliminary study showed a higher antibody response rate with 3 doses of HepB-CpG compared to 4 doses of Energix-B in dialysis patients. A more recent study of 119 hemodialysis patients found that 89.3% of patients have Hep BsAb titers greater than 10 mIU/mL after an average of 47 weeks of follow up. In this study 4 doses of HepB-CpG (20 mcg) were given at 0, 4, 8 and 16 weeks. At this time, it seems many dialysis centers are moving to vaccinate all their patients with HepB-CpG routinely.
- Currently the CDC gives an option of using a high dose influenza vaccine for people over the age of 65. The same guidelines hold true for patients on dialysis (limited to dialysis patients over the age of 65).

(Reference: Teo EK, Lok ASF. Hepatitis B immunization in adults. In: UpToDate, (www.uptodate.com) Waltham, MA, 2019).

PNEUMOCOCCAL VACCINATION

Since the introduction of PCV13, pneumococcal vaccination has become more complicated. The following principles for pneumococcal vaccination should be considered (see attached pneumonia vaccine protocol on page 23).

- PCV13 (Prevnar) vaccine is only required once in a lifetime.
- It is generally recommended to administer PCV13 vaccine first prior to the administration of PPSV23 (Pneumovax) in the pneumococcal vaccine-naïve patient.

- If PPSV23 is administered first, PCV13 vaccine should not be given until at least a full year following PPSV23 vaccine administration.
- PPSV23 can be given as many as three times in a lifetime, however, only one dose of PPSV23 is needed after the age of 65 (regardless of how many previous doses the patient has received).
- PPSV23 vaccine can be given after 8 weeks have passed since giving PCV13 vaccine.
- PPSV23 vaccine is re-administered every 5 years after giving first dose in patients less than 65 years of age (up to 3 doses)

When considering the above guidelines, it is generally recommended to administer PCV13 vaccine first prior to the administration of PPSV23 in the pneumococcal-naïve patient.

INFLUENZA VACCINATION

Influenza vaccination is recommended by the CDC to be given before the end of October in the United States. Some dialysis chains penalize the metrics of dialysis units that have failed to administer the vaccine by the end of September. There is data to suggest that giving the vaccine earlier (i.e., August) will result in waning of its effectiveness towards the end of the influenza season. At this time, data is lacking to compare the effectiveness of the vaccine (especially at the end of the influenza season) if it is given in September as compared to giving it later in the season (e.g., October), although it is important to note that influenza cases have been reported as early as October in some years. Regardless, if the patient has not had the influenza vaccine, it should be given even if it is late in the influenza season (e.g., February). High dose influenza vaccine should be considered for patients over the age of 65.

([Reference](#): Morbidity and Mortality weekly report August 23, 2019, Prevention and control of seasonal influenza with vaccines: Recommendations of the advisory committee on immunization practices – United States, 2019-20 influenza season).

COVID-19 VACCINATION FOR PATIENTS RECEIVING DIALYSIS THERAPY

Novel coronavirus disease 2019 (COVID-19) is a highly infectious, rapidly spreading viral disease with an alarming case fatality rate up to 5% in the end-stage kidney disease population.^{1,2} COVID-19 infection first affected dialysis patients in China and South Korea in January and February 2020. By March 2020, the first cases of COVID-19 among US dialysis were reported in Washington state, Southern California, and New York City.

The first reported dialysis patient infected by COVID-19 and reported as a stand-alone case report was a 56-year-old non-diabetic male with ESRD secondary to IgA nephropathy undergoing thrice-weekly maintenance hemodialysis for 3 years, who presented to an urgent care, 3 emergency rooms, 1 cardiology clinic, and 2 dialysis centers in California and Utah, prior to his diagnosis of

COVID-19 infection. During this interval, he reported nausea, vomiting, diarrhea, and low-grade fevers but was not suspected of COVID-19 infection until he developed respiratory symptoms and was admitted to the hospital. Imaging studies upon admission were consistent with bilateral interstitial pneumonia. Within the first 24 hours, he deteriorated quickly and developed acute respiratory distress syndrome (ARDS), requiring intubation, and increasing respiratory support and did not survive.¹

It is notable that the mortality rate for dialysis patients infected with COVID-19 has been significantly higher than that of the general population.³ During the COVID-19 pandemic in 2020 and throughout the first half of 2021, as many as 25% of all estimated 550,000 dialysis patients in the USA are thought to have been infected.⁴ The strongest risk factors associated with higher likelihood of COVID-19 infection among ESRD patients include exposure to infected persons at home, failure to maintain social distancing, or failure to use appropriate personal protective equipment (PPE)/surgical face mask. After stringent infection prevention steps were taken, the incidence of in-center transmission of COVID-19 fell in US dialysis clinics,³ while it is unclear whether these measures had a bearing on the high mortality of COVID-19 infected dialysis patients.

The Centers for Disease Control and Prevention (CDC) advises that asymptomatic patients may return to the general population 10 days after first signs of infection (or PCR positivity, whichever first) or 20 days if they are immunocompromised or have severe disease, without the need for further PCR testing. The question as to when COVID-19 infected and recovered dialysis patients can be released from an isolation dialysis unit (or isolation room if a dedicated unit is not available) is less clear. While the general consensus for timing of an asymptomatic dialysis patient to return to their home outpatient facility is currently 10 days after the emergence of first symptoms, there are reports of prolonged viral shedding in immunocompromised patients (including those on dialysis) leading some dialysis organizations to requiring 14-21 days. Testing COVID-19 PCR to document a negative result prior to readmission to the home dialysis unit is not necessary given that many COVID-19 infected patients may have persistently positive PCR tests weeks to months following recovery despite no longer being infectious.⁴

Many persons (including ESRD patients) may continue to suffer from general symptoms (e.g., fatigue, shortness of breath, difficulty with concentration or ‘brain fog’) following acute COVID-19 infection, often referred to as the long-hauler syndrome. There remains a paucity of evidence regarding the cause of these challenging sequelae, however, many medical centers throughout the country are actively studying this condition and offering emotional as well as physician support for these survivors.

Home dialysis (including peritoneal dialysis or hemodialysis) is more likely to ensure social distancing and lower the risk of exposure to COVID-19 infected patients. During COVID-19 surges some medical centers reinvigorated urgent start acute peritoneal dialysis for management of acute kidney injury (AKI) at a time where there was a shortage of dialysis staff, supplies and machines. There were even reports of nephrologists making their own dialysate for purposes of providing continuous renal replacement therapy. While the development of long-term dialysis needs for patients with COVID-19 induced AKI are relatively low, there are some patients who may have protracted AKI and continue to require dialysis after hospital discharge in ambulatory dialysis clinics.


Mass-vaccination of adults >18 years of age in the US starting in December 2020 has had a major impact on controlling the rate of COVID-19 infection (see [Table 1](#)). Despite reassurances by manufacturers regarding safety and efficacy of the mRNA based COVID-19 vaccines and other non-mRNA vaccines, emerging studies suggest varying degrees of post-vaccine immunity in patients with ESRD including dialysis dependent and kidney transplanted patients.⁵ Similarly, the rates of sero-protection after influenza vaccination in patients on dialysis are reported to vary from 33% to 80%.³ At the time of this writing, there is preliminary data indicating that dialysis patients have adequate antibody response (82-95%) albeit with reduced degree of antibody titer when compared to healthy control subjects. The degree of immune response following a 2-dose series of mRNA vaccine appears much lower when kidney transplant recipients are considered, further indicating an urgency to encourage vaccination in advanced CKD and dialysis patients prior to transplantation. Likewise, it remains unclear regarding the duration of immunity following the currently recommended 2-dose mRNA vaccine series or after natural COVID-19 infection.

Table 1. COVID-19 Vaccine Efficacy in the General Population as of early 2021

Vaccine	Type	Doses	Efficacy	Trial Size	Variant Protection	US Authorization
Pfizer	mRNA	2	95% ¹	44K	UK/SA ⁴	Yes (16+)
Moderna	mRNA	2	94% ²	30K	UK/SA ⁴	Yes (18+)
J&J	Adenovirus vector (DNA)	1	72%	44K	57% SA ⁵	Yes (18+)
Novavax	Protein	2	89% ³	15K	86% UK ⁵ 60% SA ⁵	No
Astra-Zeneca	Adenovirus vector (DNA)	2	62%	9K	75% UK ⁵ 22% SA ⁵	No

COVID-19 vaccination may be associated with flu-like symptoms including fevers, chills, malaise and muscle ache within the first 24 to 48 hours in a third to half of ESRD patients who receive the mRNA vaccines.^{6,7} Effective management of side-effects after COVID-19 vaccinations is not clear. Despite these side-effects all dialysis patients should be proactively encouraged to receive complete COVID-19 vaccinations using educational posters and flyers (see Figures 1 and 2).

Figure 1: An example of a poster for the dialysis facility to encourage COVID-19 vaccination.



Why get vaccinated against COVID-19?

COVID-19 is a serious malady:

1. Highly infectious (including delta variant)
2. Post-COVID syndrome: “long hauler COVID”, brain fog
3. Re-infection is possible
4. Hospitalization, ventilation/ECMO/CRRT, poor outcomes
5. Recurring epidemics possible




Figure 2: An educational flyer for the dialysis facilities to encourage COVID-19 vaccination (produced with permission from Dr. D. Landry) available for download from the [Forum website](#).

Medical Advisory Council (MAC)

THE NATIONAL
FORUM
OF ESRD NETWORKS

What Kidney Patients Need to Know about the COVID-19 Vaccine

- People who are older or have chronic health conditions such as kidney failure appear to be at highest risk for having the severe form of the infection.
- Compared to the general population, COVID-19 infections appear to be more common in dialysis patients AND the risk of dying from COVID-19 infection appears to be higher.
- Vaccines are used to help teach our body's immune system to fight off specific infections and the COVID-19 vaccine can help protect you from the virus.

Some important things to know about the vaccine:

- COVID-19 vaccines DO NOT cause COVID-19 infection. None of the COVID-19 vaccines currently in development, or in use in the United States, contain the live virus that causes COVID-19.
- The COVID-19 vaccine can cause some side effects including injection site pain, muscle aches, fever.
- These symptoms are normal and are a sign that the body is building up your defenses against infection (immunity) but you still must let your dialysis team know if you have any of these symptoms.

After getting a vaccine, continue to practice precautions

- It takes a few weeks for the body to build immunity after vaccination as it is possible to become infected either during or after receiving your vaccine.
- Even after vaccination, continue to wear a mask, wash your hands often, and stay socially distant from others.

ACT NOW!

WASH & COVER COVID-19 TEST REPORT ACCESS SERVICES

Image credit: CDC/WHO

The CDC recommends:

- Get vaccinated to help prevent you and others from getting sick with COVID-19.
- People who have had COVID-19 should still get vaccinated.
- Visit the Centers for Disease Control and Prevention (CDC) website for up-to-date information at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits/fact.html>.

Be a Health Hero at your dialysis center

- It is critically important that you wear a mask during your entire dialysis treatment!
- Practice good hand hygiene. Care for and clean your access.
- Don't skip treatments. If you don't feel well, call your clinic for guidance.




Image credit: CDC/WHO

"I might mess up. I carry bleach in my purse and can just use that to bring me!" - Pam B.

"I love interacting with others. However, I practice social distancing and always avoid large crowds!" - Patricia M.

"As an in-center patient I attend clinic 3 times a week. Following CDC Guidelines I've kept myself safe. COVID-19 is not!" - Stephanie D.

"I see the virus more than the vaccine. Will to minimize side effects one step after 2nd shot and two steps after second. So glad I got the vaccine. If you can get through dialysis you can get through the vaccine!" - Terry D.

"I received my second shot two weeks ago, and since then I feel a heavy weight has been lifted from my body. I am happy to have received the vaccine and am confident by the many lives we've lost. I believe that getting vaccinated is how we stop this tragic wave of pain created by COVID-19!" - Gary M.

"Due to our underlying health issues, we do not want to wait COVID-19 to us."
1. Get vaccinated. 2. Wear a mask. 3. Stay on dialysis!" - Terry D.

Image credit: CDC/WHO

THE NATIONAL FORUM OF ESRD NETWORKS
Inspired by members of the National Kidney Foundation
Member: 2021
www.kidneyforum.org



As of the time of this writing, it remains unclear how dialysis clinics should ideally screen patients who have developed symptoms after COVID-19 vaccination, however, general consensus has recommended that fever and any symptom potentially consistent with COVID-19 be considered as a possible infection until proven otherwise. Full antibody response appears to occur 14 days after second mRNA vaccine dose, but it is currently unclear whether dialysis or transplant patients would benefit from extra vaccine doses if they fail to respond to the initial series. It is generally believed that the risks of COVID-19 in the dialysis population exceeds the potential risk of the vaccine and that the safety and efficacy of currently deployed vaccines for dialysis patients are acceptable.

As of May 2021, the CDC Division of Healthcare Quality Promotion recommends proactive reporting of "Weekly Cumulative COVID-19 Vaccination Data". The objective of this initiative is to ensure that dialysis facilities can confidently report cumulative COVID-19 vaccination data for future analyses. *Cumulative vaccination data* are the total number of individuals who have ever received COVID-19 vaccine since it became available in December 2020. *Incident vaccination data* are the number of new individuals who received COVID-19 vaccine in a specific week.

References:

1. Ferrey AJ, Choi G, Hanna RM, Chang Y, Tantisattamo E, Ivaturi K, Park E, Nguyen L, Wang B, Tonthat S, Rhee CM, Reddy U, Lau WL, Huang SS, Gohil S, Amin AN, Hsieh L, Cheng TT, Lee RA and Kalantar-Zadeh K. A Case of Novel Coronavirus Disease 19 in a Chronic Hemodialysis Patient Presenting with Gastroenteritis and Developing Severe Pulmonary Disease. *Am J Nephrol.* 2020;51(5):337-342. doi: 10.1159/000507417. PubMed PMID: 32222713; PMCID: PMC7179539. URL: <https://www.ncbi.nlm.nih.gov/pubmed/32222713>.
2. Ferrey AJ, Hanna R, Reddy UG, Tantisattamo E, Kalantar-Zadeh K and Amin AN. Novel therapeutic approaches for COVID-19 in chronic kidney disease and transplant. *Curr Opin Nephrol Hypertens.* 2021;30(1):47-53. doi: 10.1097/MNH.0000000000000671. PubMed PMID: 33186223. URL: <https://www.ncbi.nlm.nih.gov/pubmed/33186223>.
3. Ziembra R, Campbell KN, Yang TH, Schaeffer SE, Mayo KM, McGann P, Quinn S, Roach J and Huff ED. Excess Death Estimates in Patients with End-Stage Renal Disease - United States, February-August 2020. *MMWR Morb Mortal Wkly Rep.* 2021;70(22):825-829. doi: 10.15585/mmwr.mm7022e2. PubMed PMID: 34081687; PMCID: PMC8174675 Journal Editors form for disclosure of potential conflicts of interest. Kelly M. Mayo is a current member of the National Forum of ESRD Networks Board of Directors. No other potential conflicts of interest were disclosed. URL: <https://www.ncbi.nlm.nih.gov/pubmed/34081687>.
4. Klinger AS and Silberzweig J. COVID-19 and Dialysis Patients: Unsolved Problems in Early 2021. *J Am Soc Nephrol.* 2021;32(5):1018-1020. doi: 10.1681/ASN.2020121766. PubMed PMID: 33637517. URL: <https://www.ncbi.nlm.nih.gov/pubmed/33637517>.
5. Kho MML, Reinders MEJ, Baan CC, van Baarle D, Bemelman FJ, Diavatopoulos DA, Gansevoort RT, van der Klis FRM, Koopmans MPG, Messchendorp AL, van der Molen RG, Remmerswaal EBM, Rots N, Vart P, de Vries RD, Hilbrands LB, Sanders JF and Collaborators R. The RECOVAC IR study: the immune response and safety of the mRNA-1273 COVID-19 vaccine in patients with chronic kidney disease, on dialysis, or living with a kidney transplant - a prospective, controlled, multicenter observational cohort by the RENal patients COVID-19 VACcination (RECOVAC) consortium COVID-19 VACcination (RECOVAC) consortium. *Nephrol Dial Transplant.* 2021. doi: 10.1093/ndt/gfab186. PubMed PMID: 34038554. URL: <https://www.ncbi.nlm.nih.gov/pubmed/34038554>.
6. Torreggiani M, Bianchi S, Fois A, Fessi H and Piccoli GB. Neutralizing SARS-CoV-2 antibody response in dialysis patients after the first dose of the BNT162b2 mRNA COVID-19 vaccine: the war is far from being won. *Kidney Int.* 2021;99(6):1494-1496. doi: 10.1016/j.kint.2021.04.010. PubMed PMID: 33887320; PMCID: PMC8055923. URL: <https://www.ncbi.nlm.nih.gov/pubmed/33887320>.
7. Pamplona GM, Sullivan T and Kotanko P. COVID-19 Vaccination Acceptance and Hesitancy in Dialysis Staff: First Results From New York City. *Kidney Int Rep.* 2021;6(4):1192-1193. doi: 10.1016/j.ekir.2021.02.001. PubMed PMID: 33615048; PMCID: PMC7879030. URL: <https://www.ncbi.nlm.nih.gov/pubmed/33615048>

OTHER VACCINATIONS NOT ROUTINELY GIVEN DURING DIALYSIS

In general recommendations for these vaccines in the dialysis population are the same as those for the general population with most not having been studied extensively in this specific population of patients.

- Herpes zoster: The two vaccines against herpes zoster currently available include a recombinant zoster vaccine (RZV) and a live zoster vaccine (LZV). RZV is recommended for patients over the age of 50 and consists of two dose series (at least 2 months apart). LZV is given to patients over the age of 60 and consist of only one dose. RZV was introduced to the market after LZV was routinely given but has been shown to be more efficacious and for the most part is the recommended herpes zoster vaccine at this time. RZV is given intramuscularly, whereas LZV is given subcutaneously. Patients who are having active zoster infection should have their infection cleared prior to being vaccinated (some have suggested waiting as long as one year). If a patient has received LZV in the past, it is possible to revaccinate them with RZV (as it is more efficacious) after 8 weeks have passed.

(Reference: Albrecht MA, Levin MJ. Vaccination for the prevention of shingles (herpes zoster). In: UpToDate, (www.uptodate.com) Waltham, MA, 2019).

- Tetanus, diphtheria and acellular pertussis (Tdap): There are currently two available vaccines for adults (Adacel and Boostrix) given as 0.5 mL intramuscular injections. In addition, there are two vaccines intended for infants and children (Daptacel and Infanrix). For the most part the adult vaccines are once in a lifetime single injection except that pregnant patient should receive a dose with each pregnancy. Repeat vaccinations are in general not harmful but not indicated except a second dose of Adacel after > 8 years from the initial dose may be given routinely.
- In cases of wounds requiring prophylaxis a dose of tetanus and diphtheria toxoid (Td) vaccine should be given unless there is no documented history of Tdap vaccination previously. In addition, Td vaccine should be routinely given every 10 years.
- Pertussis is a highly contagious disease causing prolonged cough which used to be seen only in children pre-vaccination era but now is not uncommon in adults. The incidence of pertussis infections is on the rise thus making it more important to vaccinate everyone who is a candidate. Sustained immunity to pertussis following vaccine does not appear to be lifelong, necessitating at least one dose of Tdap after the age of 11.
(Reference: Diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP and Tdap): Drug information. In: UpToDate (www.uptodate.com) Waltham, MA, 2019).
- Measles, mumps and rubella (MMR) vaccine: Immunity rates to these diseases is high after just one dose of the vaccine and even higher after two doses. The vaccine is now routinely given to children at 12-15 months after birth and the second dose at 4-6 years of age. People who were born before 1957 are usually not vaccinated but can be assumed to have had natural infection and immunity. The immunity to these vaccines usually wanes some with time but protection from infection may be longer lasting than serological conversion. The measles component of the vaccine is a live attenuated virus while the other two components are recombinant vaccines. In cases of outbreaks of measles or rubella, two doses of MMR vaccines given at least 28 days apart should be given to people who are incompletely immunized. However, in cases of mumps outbreaks, additionally a third dose of the MMR vaccine should be given to people who already have had two complete doses of the vaccine previously.
(Reference: Hibbard PL. Measles, mumps, and rubella immunization in adults. In: UpToDate (www.uptodate.com) Waltham, MA, 2019).
- One should follow recommendations for the general population for giving other vaccines to dialysis patients including cholera, hepatitis A, haemophilus, papillomavirus, Japanese encephalitis virus, meningococcal, rabies, and yellow fever vaccines until further data.

(Reference: Krueger KM, Ison MG, Ghossein C. Practical guide to vaccination in all stages of CKD, including patients treated by dialysis or kidney transplantation. Am J Kidney Dis 2019 (epub ahead of print).

VACCINATING THE TRANSPLANT PATIENT

Guidelines for vaccinating the kidney transplant patient are similar to those of the general population except for the following:

- Vaccination pre-transplant is preferred if possible as response rates may be better
- Vaccinating close contacts of transplant patients is important with regards to prevention
- Patients with kidney transplant should avoid being vaccinated with a live attenuated vaccine as much as possible. These include the live herpes zoster vaccine, the MMR vaccine (the measles portion but they are all combined), Cholera vaccine, and the yellow fever vaccine.
- Vaccinations should be delayed until at least 3-6 months have passed since the kidney transplant, if possible, as the high dose immunosuppression at the beginning of the transplant is likely making the immune response not as likely to respond.
- Transplant patients who receive eculizumab should be vaccinated for the meningococcus vaccine at least 2 weeks prior to receiving the drug if possible.

(Reference: Krueger KM, Ison MG, Ghossein C. Practical guide to vaccination in all stages of CKD, including patients treated by dialysis or kidney transplantation. Am J Kidney Dis 2019 (epub ahead of print).

HOW TO USE THIS TOOLKIT

There are many different practice patterns, resources, and non-facility factors that contribute to the complexity of caring for dialysis patients. This toolkit can help the facility staff understand and improve its own processes. Each facility will need to determine its own goals, challenges, and solutions. Note that the Medical Director is charged with the leadership role in quality improvement, and that all personnel have important roles and responsibilities when it comes to managing patients' immunizations.

Below provides an example of a QAPI for immunizations. Below the QAPI example, there are supporting templates for tracking immunization performance improvement; these templates have been adapted from those used by the Safe and Timely Immunization Coalition, a project initiated by ESRD Network 6, in conjunction with Networks 11 and 15 and the support of Centers for Medicare & Medicaid Services (CMS). There is an Excel spreadsheet titled, *Immunization Data Collection Tool* on page 14, which can be used by the facility to record and update vaccination information on individual patients. It is recommended to save an electronic copy of *the Immunization Data Collection Tool* and update it periodically. Monthly updates on vaccination progress, may be generated with the including tools. To obtain additional information on QAPI development and maintenance, download the Forum of ESRD Network QAPI toolkit [here](#).

Any materials can be downloaded, revised, printed, and distributed without restriction to meet the needs of the facility.

Quality Assessment & Performance Improvement Plan: Patient Immunization

Completing *and* implementing an effective data driven quality improvement plan is one way to drive sustained improvement. These plans are successful when they include each component of the quality improvement process and incorporate ongoing participation from the entire interdisciplinary team (IDT). Please use the following strategies as you develop a quality improvement plan for your facility:

- **Goal:** Define the desired outcome area currently not being met. **Example: 100% of eligible patients will receive the influenza immunization during the 2019-20 season.**
- **Problem Statement:** Define the problem that has prevented goal from being met, remembering that your facility could have multiple problem statements for one outcome area. **Example: Patients are refusing the influenza immunization.**
- **Multidisciplinary Team:** Determine the team members necessary to improve the outcome identified in the problem statement. **Example: medical director, nurse manager, social worker, governing body, attending nephrologists, dialysis nurses, patient care technicians.**
- **Root Causes:** Determine the underlying causes that have led to the problem. **Example: Lack of patient education regarding the importance of the influenza immunization.**
- **Action Plan Implementation Steps:** Determine what steps need to be taken to address the problem and its root causes. For each step, determine what team member(s) are primarily responsible for completing the task, what date the task should begin, and an estimated date for completing the task.
Example: Step 1. Address barriers and misconceptions related to the influenza immunization.
Responsible team member(s): Lucy Luck, RN and Joe Smile, PCT
Start Date: October 1, 2019
Estimated completed date: October 5, 2019, and incorporate into monthly care conferences.
- **Evaluation:** Determine a timeframe and structure for how each action plan step will be evaluated. During task evaluation, tasks may need to be revised or changed to facilitate further improvement. **Example: Bring list of current patients that have not received the influenza immunization to the monthly plan of care (POC) meeting for the team to review; and report changes in immunization status at POC meeting. Give positive feedback to patients when they receive the influenza immunization.**

VACCINATION ACTION PLAN TEMPLATE WORKSHEET

Use the Vaccination Action Plan Template in QAPI to formulate an action plan to improve the percentage of patients immunized within a specific timeframe. Additionally, this template is intended to identify facility barriers to increasing the number of vaccinated patients and to delineate staff roles and dates for achieving the facility immunization goal(s).

Problem Statement: _____% Currently meeting goal (updated monthly)						Facility Name:
Goal for Improvement:						Facility Provider Number:
Date Required-Needed Resources:						Person completing report:
Root Causes-Barriers:						Date:
Actions Already in Place:						I have reviewed this action plan
						(Medical Director Signature)
						(Administrator Signature)
Action Plan Implementation Steps	Team Members (Note responsible member)	Start Date	Estimated Completion Date	Checkpoint Dates	Date Completed	Comments (Status, outcomes, disposition, etc.)

VACCINATION ACTION PLAN – This is an EXAMPLE and not a complete Action Plan

Problem Statement: Only 45% of the patients in the facility received the influenza immunization in 2018. The Healthy People 2020 goal is 90%.						Facility Name: XYZ Dialysis Facility Provider Number: 098765 Name of Person Completing Report: Janie Doe Date: May 1, 2019 I have reviewed this Action Plan: _____ Medical Director _____ Administrator
Goal for Improvement: Increase the percentage of patients receiving the influenza immunization by 45 percentage points in the 2019-2020 influenza season; rate will be equal to or greater than 90%.						
Data Required/Needed Resources: Number of patients receiving influenza immunization, tracking mechanism, personnel time and commitment to the project, patient education resources regarding the need for immunization, physician orders for immunization						
Root Causes-Barriers: <ul style="list-style-type: none"> Lack of patient/staff education regarding the importance of vaccination of kidney patients Lack of documentation of immunizations including those given outside of the dialysis facility Refusal of vaccine by patients who do not want to receive the immunization. 						
Actions Already in Place: The facility does not currently have an immunization program. Patients are encouraged to seek immunization outside the dialysis facility.						
ACTION PLAN IMPLEMENTATION STEPS	RESPONSIBLE TEAM MEMBER	START DATE	ESTIMATED COMPLETION DATE	CHECKPOINT DATE	DATE COMPLETED	COMMENTS (STATUS, OUTCOMES, EVALUATION, ETC.)
Enlist the support of the Medical Director and the other facility Nephrologists for an influenza immunization program.	Facility Administrator	May 2, 2019	May 5, 2019	May 4, 2019	May 4, 2019	Medical Director and attending Nephrologists approve of an influenza immunization program within the facility. The MDs have agreed to participate on the QI team and are interested in discussing standing orders for immunization of their patients.
Establish current immunization status for all patients-did they receive the influenza immunization in the past year?	Facility RNs	May 10, 2019	May 30, 2019	May 20, 2019	May 28, 2019	Immunization status verified for all patients. The 45% rate thought to be accurate in the problem statement was found to be inaccurate. The actual immunization rate is 40%.
Develop an education program for patients and staff regarding influenza immunization-secure education materials, schedule learning sessions, and document all education efforts for both patients and staff. Determine when vaccine can be ordered and storage requirements. Confirm standing orders and consent requirements. Research documentation/tracking.	Facility Nurse Manager / Educator	May 30, 2019	Jun 30, 2019	Jun 25, 2019	Jun 30, 2019	Resources gathered for patient and staff education. Educational materials reviewed by the QI team. Staff education in-services scheduled to impress upon staff the importance of patient and staff immunization. Patient "Education Days" scheduled. Nurse Manager is looking into when vaccine can be ordered for the upcoming flu season and will confirm storage requirements. MDs contacted regarding standing orders. The Administrator is in the process of researching a documentation/tracking tool for all immunizations.

• • •
**DATA
TOOLS**
• • •

IMMUNIZATION DATA COLLECTION TOOL

Download the Immunization Data Collection Tool excel spreadsheet from the [Forum website](#) and customize the form to your facility.

Facility Name		Number of patients		Immunization Data Collection Tool																				
Terrapin Station		8																						
Contact Name		Phone Number																						
David Lemeux		1-800-Dead-Net																						
INSTRUCTIONS: Use the codes at right to indicate immunization status for influenza, pneumococcal pneumonia, hepatitis B, and COVID-19. Codes 3, 7, 9 and 10 indicate opportunities to improve individual patient immunization status.				IMMUNIZATION CODES: 1. YES, received at this facility 2. YES, received at another location 3. YES, but surface antibody negative after 1 series (Hep B only) 4. YES, but persistent anti-HBs negative after 2 vaccine series (Hep B only) 5. NO, surface antigen positive (Hep B only) 6. NO, patient immune (hep B only) 7. NO, not received, pt refused 8. NO, not received, pt allergic 9. NO, not offered or other reason 10. Unknown																				
Immunization		Influenza		Pnevrax (PCV-13)		Pneumovax (PPSV-23)					Hepatitis B					COVID-19								
Patient Name		During the current Influenza season (enter code 1, 2, or 7-10)	Received 13-valent vaccine at least 8 weeks prior to PPSV-23 (enter code 1, 2, or 7-10)	Date patient received dose MM/DD/YYYY	Received 23-valent vaccine (enter code 1, 2, or 7-10)	Date most recent dose MM/DD/YYYY	Years since PPSV-23 dose?	Patient DOB MM/DD/YYYY	Patient Age	If patient <65 and >5 years since last vaccine, received booster (enter code 1, 2, 7-10)?	If patient >65, received vaccine (enter code 1, 2, 7-10)?	Type of Hepatitis B vaccine (I.e. Energix, Hepsilav)	Patient has received complete series (enter code 1 to 10)	Date patient completed series MM/DD/YYYY	Patient has received partial series (enter 1, 2, or 3 doses)	Date of most recent dose MM/DD/YYYY	Patient received 2nd complete series (enter 1 if yes)	Date patient completed 2nd series MM/DD/YYYY	Patient received booster dose (enter 1 if Yes)	Date patient received booster MM/DD/YYYY	Type of COVID-19 vaccine (Pfizer, Moderna, J&J)	Patient Received COVID Vaccine (enter code 1, 2, 7-10)	Patient completed COVID vaccine (enter code 1, 2, 7-10 for series if applicable)	Date p-compl COV vacc MM/DD/
Total Number of Patients		6																						
Patients vaccinated (codes 1-4) (#)		5	6		5					1	4		4				1		1					5
Percentage vaccinated (%)		83%	100%		83%					#DIV/0!	#DIV/0!		67%				17%		17%					83%
Vaccine candidates (codes 3,7,9,10)		1	0		1					0	0		1										1	1
Percent vaccine eligible		17%	0%		17%					#DIV/0!	#DIV/0!		17%										17%	17%
Vaccination in progress (code 7)																3								
Percent in progress															50%									
Vaccination not indicated (4,5,6 or 8)		0											3											
Percent not indicated		0%											50%											

MONTHLY INTERVENTION TRACKING TOOL

Update this tracking tool on a monthly basis to evaluate progress towards your immunization goal(s) and to identify potential areas for improvement. Review your action plan progress with your IDT by using this tool each month during QAPI.

Facility Name: Provider Number: Month: Due Date:

Date Action Plan Submitted: _____

Action Plan Accepted: Yes No

If no, date action plan will be resubmitted: _____

Action Plan Progress

Action Plan Influenza Immunization Goal: _____%

A. Number of patients on facility census as of (date): _____

B. Of the patients on the facility census, number that were vaccinated for influenza this season (regardless of where the vaccine was given): _____

Remember to include patients who received their influenza vaccine somewhere other than this facility!

C. Percent of patients vaccinated (number of vaccinated patients/facility census x 100):
_____ %

1. Outline the progress your facility has made toward implementation of each action plan step (be specific):

2. Has your facility made any changes to its immunization policies/procedures to achieve the facility immunization goal(s)?

Yes No

If yes, what are the changes?

- 3. Has your facility instituted a program to educate **staff** about influenza immunization?
 Yes No
- 4. Has your facility instituted a program to educate **patients** about influenza immunization?
 Yes No
- 5. For patients who refuse the immunization (not based on medical contraindications) are you providing additional information/education related to the influenza immunization?
 Yes No

If yes, did any of these patients decided to be vaccinated?

- Yes No

- 6. Has your facility reached the influenza immunization goal you set in your action plan?
 Yes No

If no, what actions are planned to achieve the immunization goal?

- 7. Does your facility have any additional issues or questions that you would like the Network to address regarding immunizations?
 Yes No

If yes, please be specific.



RESOURCES AND REFERENCES



QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI) FOR THE ESRD MEDICAL DIRECTOR

Medical Directors set the course for their dialysis center. Patients and staff members rely on the Medical Director to lead effectively. The CfCs released on 4/15/08 by CMS has updated the responsibilities of ESRD facility Medical Directors. As Pay for Performance (P4P) becomes a reality, it is increasingly important for facilities to achieve and sustain clinical performance targets in order to receive reimbursement. Medical Directors are encouraged to read carefully and become very familiar with the current Conditions.

The Medical Director has operational responsibility for the QAPI program and ensures that program data is used to develop actions to improve quality of care and must ensure that the facility's QAPI program is effectively developed, implemented, maintained, and periodically evaluated. The dialysis facility must maintain and demonstrate evidence of its QAPI program for review by CMS.

We encourage you to review the Forum's Medical Director Toolkit and QAPI Toolkit which provide greater detail about the Medical Director's role. The Toolkits are available as a free download at the [Forum website](#).

The table below contains a breakdown of some Medical Director QAPI and responsibilities.

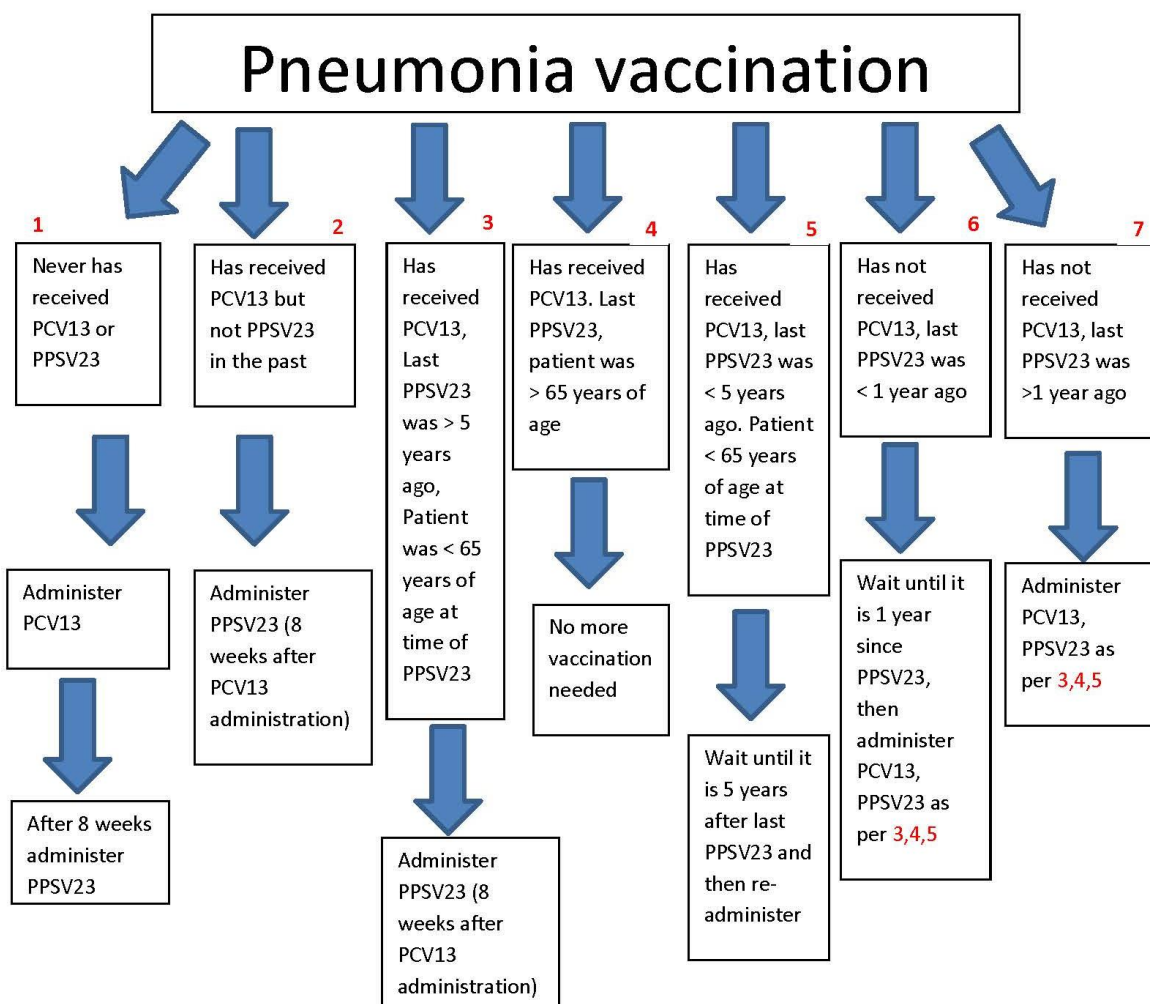
Patient Clinical Outcomes	Reuse & Water Treatment	Patient Safety & Satisfaction	Staff Training	Involuntary Discharge of Patients	Oversight of Attending Physicians	Biohazard & Infection Control	Facility Policies & Procedures
Adequacy of dialysis	Reuse program	Medical injuries	Ensure that staff receive appropriate education and training to competently perform job	Written and signed order from both Med. Dir. and attending physician prior to discharge	Inform medical staff of facility P&P including QAPI	Adverse events	Participate in developing P&P
Nutritional status	Deviations from AAMI standards (corrective action plan)	Medical errors		(Note: The new *discharge/transfer process is very lengthy, specific, and progressive.)	Written and signed order from both Med. Dir. and attending physician prior to pt discharge	Infection control issues	Assure the attending physicians & other staff adhere to P&P
Mineral metabolism	Water treatment equipment	Patient satisfaction					
Anemia management	Pt did not reach target weight	Grievances			Assure the attending physicians adhere to P&P		
Vascular access							

PNEUMONIA VACCINATION PROTOCOL

Use this Pneumonia Vaccination Protocol with your facility staff to determine timing, type and appropriateness of pneumonia vaccination administration. This protocol is available as a pdf download from the Forum website [here](#).

Pneumonia vaccine protocol

1. In order to do pneumonia vaccination we need a record of the previous vaccinations patients have received.
2. Prevnar 13 vaccine is only given once in life time of the patient
3. PPSV23 vaccine can be given as many as 3 times in the life of the patient
4. Prevnar 13 vaccine cannot be given up to a year after receiving PPSV23 vaccine. As such this vaccine should be given first if possible.
5. PPSV23 can be given as early as 8 weeks after giving Prevnar 13.
6. PPSV23 is re-administered 5 years after giving first dose in patients less than 65 year of age and then again after age of 65, assuming at least 5 years elapsed since the last dose.
7. After age 65, only one dose of PPSV23 is necessary.



IMMUNIZATION RESOURCES AVAILABLE ON THE INTERNET

Numerous resources related to immunizations and immunization processes are available on the internet from the ESRD Networks as well as the Centers for Disease Control and Prevention (CDC), the national Immunization Action Coalition (IAC) and the Centers for Medicare & Medicaid Services (CMS).

ESRD NETWORK WEBSITES:

Network 1:	https://network1.esrd.ipro.org/
Network 2:	https://network2.esrd.ipro.org/
Network 3:	https://www.qirn3.org/home.aspx/
Network 4:	https://www.qirn4.org/Home.aspx
Network 5:	https://www.qirn5.org/home.aspx
Network 6:	https://network6.esrd.ipro.org/
Network 7:	https://www.hsag.com/es/esrd-networks/esrd-network-7/
Network 8:	https://www.esrdnetwork8.org/
Network 9:	https://network9.esrd.ipro.org/
Network 10:	https://www.esrdnetwork10.org/
Network 11:	https://www.midwestkidneynetwork.org/
Network 12:	https://esrdnetwork12.org/
Network 13:	https://www.hsag.com/esrdnetwork13
Network 14:	https://www.esrdnetwork.org/
Network 15:	https://www.hsag.com/esrdnetwork15
Network 16:	https://nwrn.org/
Network 17:	https://www.hsag.com/esrdnetwork17
Network 18:	https://www.hsag.com/en/esrd-networks/esrd-network-18

OTHER RESOURCES AVAILABLE:

Centers for Disease Control and Prevention (CDC) – Vaccination Information Sheets (VIS) are required to be provided to patients and staff receiving an immunization.

<https://www.cdc.gov/vaccines/hcp/vis/index.html>

[Centers for Disease Control \(CDC\) MMWR August 23, 2019 - Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, 2019-2020 Influenza Season.](https://www.cdc.gov/mmwr/volumes/68/rr/pdfs/rr6803-H.pdf)

<https://www.cdc.gov/mmwr/volumes/68/rr/pdfs/rr6803-H.pdf>

National Immunization Program (<http://www.cdc.gov/vaccines/>) - This is a portion of the CDC Web site that is specifically geared to healthcare professionals and has a plethora of immunization resources.

Immunization Action Coalition (<http://www.immunize.org>) - Vaccination information for healthcare professionals including a directory of available resources across the Internet. This site contains the ability to subscribe for immunization alerts and new practice recommendations.

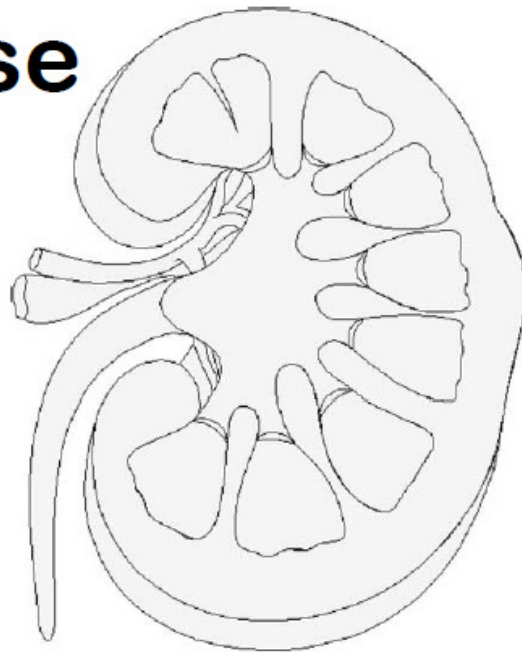
CDC Guidelines for Vaccinating Kidney Dialysis Patients and Patients with Chronic Kidney Disease (December 2012, reviewed July 2015)

<https://www.cdc.gov/vaccines/pubs/downloads/dialysis-guide-2012.pdf>

Under CMS contract #HHSM-500-2006-NW015C, ESRD Network #15 created a spreadsheet-based immunization tracking form, the Multiple Immunization Monitoring Instrument (MIMI). This resource has been updated by the Forum of ESRD Networks and is available on the Forum of ESRD Networks website at:

<https://esrdnetworks.org/toolkits/professional-toolkits/vaccination-toolkit/>

Guidelines for Vaccinating
Kidney Dialysis Patients and
**Patients with Chronic
Kidney Disease**



summarized from
**Recommendations of the Advisory Committee on
Immunization Practices (ACIP)**



December 2012

This summary is not meant to apply to chronic kidney disease patients who are recently post-transplant. These patients are considered more significantly immunosuppressed than those who have only chronic kidney disease, with or without dialysis. The childhood and adult immunization schedules and a comprehensive listing of current ACIP recommendations can be found at <http://www.cdc.gov/vaccines/>

Prepared by:
Carolyn Chi, B.S.
Priti Patel, M.D., M.P.H.
Tamara Pilishvili, M.P.H.
Matt Moore, M.D.
Trudy Murphy, M.D.
Ray Strikas, M.D., M.P.H.

Guidelines for Vaccinating Dialysis Patients and Patients with Chronic Kidney Disease

summarized from

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

December 2012

This summary is not meant to apply to chronic kidney disease patients who are recently post-transplant. These patients are considered more significantly immunosuppressed than those who have only chronic kidney disease, with or without dialysis.

Vaccination of Dialysis Patients and Patients with Chronic Kidney Disease (CKD)

Determination of chronic kidney disease is important to the vaccine provider because incidence or severity of some vaccine-preventable diseases is higher in persons with altered immunocompetence*; therefore, certain vaccines (e.g., inactivated influenza vaccine and pneumococcal vaccines) are recommended specifically for persons with immune compromise. In addition, vaccines might be less effective during a period of altered immunocompetence. Inactivated vaccines administered during a period of altered immunocompetence might need to be repeated. Because secondary antibody responses are less affected by immune compromise than primary antibody responses, immunization strategies should be formulated early in the course of progressive renal disease to maximize likelihood of vaccine-induced immunity. This approach is particularly important if transplantation and chronic immunosuppressive therapy are being considered.¹ Live vaccines might need to be deferred if severe immune compromise is present; persons with altered immunocompetence might be at increased risk for an adverse reaction after administration of live, attenuated vaccines because of uninhibited replication.² However, the majority of persons with CKD (regardless of CKD stage) have sufficient immune function to safely receive all live vaccines for which an inactivated vaccine is not an alternative.

* “Altered immunocompetence” will be used in this document synonymously with immunosuppression and immunocompromise.

List of Vaccines and their use for Dialysis or CKD Patients

Vaccine	Recommended for Dialysis or CKD Patients	Recommended for All Adults	May Use if Otherwise Indicated*	Contraindicated
Anthrax			X	
DTaP/Tdap/Td		X	X	
Hib			X	
Hepatitis A			X	
Hepatitis B	X (see p. 4)			
Human papillomavirus			X	
Influenza (TIV)		X (see p. 6)		
Influenza (LAIV)				X (see p. 6)
Japanese Encephalitis			X	
MMR		X	X	
Meningococcal			X	
Pneumococcal	X (see p. 7)			
Polio (IPV)			X	
Rabies			X	
Rotavirus			X	
Smallpox			X	
Typhoid			X	
Varicella		X	X	
Yellow Fever			X	
Zoster			X	

*No specific ACIP recommendation for this vaccine exists for dialysis patients or patients with chronic kidney disease.

NOTES

Hepatitis B Vaccine

"Hepatitis B vaccination is recommended for all susceptible chronic hemodialysis patients. . . Vaccination is recommended for pre-end-stage renal disease patients before they become dialysis dependent, and for peritoneal and home dialysis patients because they might require in-center hemodialysis.

“Patients with uremia who were vaccinated before they required dialysis have been shown to have higher seroprotection rates and antibody titers. The response to hepatitis B vaccination may also be better in children.”¹

Dosage and Schedule

For patients undergoing hemodialysis and for other immunosuppressed patients, higher vaccine dosages or an increased number of doses are recommended. One formulation of hepatitis B vaccine designed for hemodialysis patients and other immunocompromised adults (age ≥ 20 years) patients contains an increased dosage and is administered in a 3 dose schedule (Recombivax HB, 40 $\mu\text{g}/\text{mL}$, Merck & Co., Inc, Whitehouse Station, New Jersey).¹ The other available formulation of hepatitis B vaccine is administered at a double standard dosage in a 4 dose schedule for hemodialysis patients and other immunocompromised adults (age ≥ 20 years) patients (two Engerix-B, 20ug [1.0 mL doses] administered in 1 or 2 injections, GlaxoSmithKline Biologicals, Rixensart, Belgium).³

“If an adult patient begins the vaccine series with a standard dose before beginning hemodialysis treatment, then moves to hemodialysis treatment before completing the series, complete the series using the higher dose recommended for hemodialysis patients. No specific recommendations have been made for higher doses for pediatric hemodialysis patients. If a lower than recommended vaccine dose is administered to either adults or children, the dose should be repeated.”³

Immunogenicity and Duration of Immunity

Compared with immunocompetent adults, hemodialysis patients are less likely to have protective levels of antibody after vaccination with standard vaccine dosages; protective levels of antibody developed in 67%–86% (median: 64%) of adult hemodialysis patients who received 3–4 doses of either vaccine in various dosages and schedules. Higher seroprotection rates have been identified in patients with chronic renal failure, particularly those with mild or moderate renal failure, who were vaccinated before becoming dialysis dependent.⁴

"Limited data are available on the duration of immune memory after hepatitis B vaccination in . . . dialysis patients. No clinically important HBV infections have been documented among immunocompromised persons who maintain protective levels of anti-HBs. . . . However, among hemodialysis patients who respond to the vaccine, clinically significant HBV infection has been documented in persons who have not maintained anti-HBs concentrations of ≥ 10 mIU/mL."⁵

Serologic Testing

Testing after vaccination is recommended for hemodialysis patients to determine their response to the vaccine. Testing should be performed 1-2 months after administration of the last dose of the vaccine series by using a method that allows determination of a protective level of anti-HBs (e.g., ≥ 10 mIU/mL).

"Persons found to have anti-HBs levels of < 10 mIU/mL after the primary vaccine series should be revaccinated with a second hepatitis B vaccination series. Administration of three or four doses on an appropriate schedule followed by anti-HBs testing 1-2 months after the third dose is usually more practical than serologic testing after one or more doses of vaccine."⁴

Persons who do not have a protective concentration of anti-HBs after revaccination should be tested for HBsAg. If the HBsAg test result is positive, the person should receive appropriate

management, and any household, sex, or needle-sharing contacts should be identified and vaccinated. Persons who test negative for HBsAg should be considered susceptible to HBV infection and should be counseled about precautions to prevent HBV infection and the need to obtain HBIG postexposure prophylaxis for any known or likely parenteral exposure to HBsAg positive blood.⁴

Booster Doses

"For hemodialysis patients, the need for booster doses should be assessed by annual testing for antibody to hepatitis B surface antigen (anti-HBs). A booster dose should be administered when anti-HBs levels decline to <10 mIU/mL."⁴

Influenza Vaccine

Inactivated Influenza Vaccine (TIV)

Routine annual influenza vaccination is recommended for all persons aged ≥ 6 months. To permit time for production of protective antibody levels, vaccination optimally should occur before onset of influenza activity in the community. Therefore, vaccination providers should offer vaccination as soon as vaccine is available. Vaccination should be offered throughout the influenza season (i.e., as long as influenza viruses are circulating in the community).⁶

"Routine influenza vaccination is recommended for all persons aged ≥ 6 months. This represents an expansion of the previous recommendations...and is supported by evidence that annual influenza vaccination is a safe and effective preventive health action with potential benefit in all age groups."⁷

"Vaccination to prevent influenza is particularly important for the following persons who are at increased risk for severe complications from influenza or at higher risk for influenza-related outpatient, ED, or hospital visits:...all persons aged ≥ 50 years;... adults and children who have chronic pulmonary (including asthma) or cardiovascular (except isolated hypertension), renal, hepatic... or metabolic disorders (including diabetes mellitus);...residents of nursing homes and other long-term-care facilities; [and] household contacts and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza."⁷

Live, Attenuated Influenza Vaccine (LAIV)

CONTRAINDICATED

"Persons at higher risk for complications of influenza infection because of underlying medical conditions should not receive LAIV. Persons at higher risk for complications of influenza infection because of underlying medical conditions include adults and children with chronic disorders of the pulmonary or cardiovascular systems; adults and children with chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression... and residents of nursing homes and other chronic-care facilities that house persons with chronic medical conditions."⁸

Use of influenza antivirals for persons with impaired renal function⁹

Zanamivir. Limited data are available regarding the safety and efficacy of zanamivir for patients with impaired renal function. Among patients with renal failure who were administered a single intravenous dose of zanamivir, decreases in renal clearance, increases in half-life, and increased systemic exposure to zanamivir were reported. However, a limited number of healthy volunteers who were administered high doses of intravenous zanamivir tolerated systemic levels of zanamivir that were substantially higher than those resulting from administration of zanamivir by oral inhalation at the recommended dose. On the basis of these considerations, the manufacturer recommends no dose adjustment for inhaled zanamivir for a 5-day course of treatment for patients with either mild-to-moderate or severe impairment in renal function.

Oseltamivir. Serum concentrations of oseltamivir carboxylate (GS4071), the active metabolite of oseltamivir, increase with declining renal function. For patients with creatinine clearance of 10-30 mL/min, a reduction of the treatment dosage of oseltamivir to 75 mg once daily and in the chemoprophylaxis dosage to 75 mg every other day is recommended. Treatment or chemoprophylaxis dosing recommendations have been proposed for patients undergoing routine renal dialysis treatment but are based on limited pharmacokinetic data.

Pneumococcal Vaccine

23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)

The 23-valent pneumococcal polysaccharide vaccine (PPSV23; Pneumovax 23, Merck & Co. Inc.) contains 12 of the serotypes included in 13-valent pneumococcal conjugate vaccine (PCV13; Prevnar 13, Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc.), plus 11 additional serotypes. PPSV23 is recommended for prevention of invasive pneumococcal disease (IPD) among all adults aged ≥ 65 years, and for adults at high risk aged 19–64 years. Given the high burden of IPD caused by serotypes in PPSV23 but not in PCV13, broader protection might be provided through use of both pneumococcal vaccines.

The current ACIP PPSV23 recommendations call for vaccination of adults at high risk aged 19–64 years at the time of diagnosis of the high-risk condition. A one-time revaccination dose of PPSV23 is recommended 5 years after the first dose for persons with functional or anatomic asplenia and for immunocompromised persons. All adults are eligible for a dose of PPSV23 at age 65 years, regardless of previous PPSV23 vaccination; however, a minimum interval of 5 years between PPSV23 doses should be maintained.¹⁰

“Vaccination is . . . recommended for immunocompromised adults at increased risk of pneumococcal disease or its complications (e.g., persons with splenic dysfunction or anatomic asplenia, Hodgkin's disease, leukemia, lymphoma, multiple myeloma, chronic renal failure, nephrotic syndrome, or conditions such as organ transplantation associated with immunosuppression).”¹

13-Valent Pneumococcal Conjugate Vaccine (PCV13)

On June 20, 2012, the Advisory Committee on Immunization Practices (ACIP) recommended routine use of 13-valent pneumococcal conjugate vaccine (PCV13) for adults aged ≥ 19 years with immunocompromising conditions (including those with chronic renal failure or nephrotic syndrome), functional or anatomic asplenia, cerebrospinal fluid (CSF) leaks, or cochlear implants. PCV13 should be administered to eligible adults in addition to the 23-valent pneumococcal polysaccharide vaccine (PPSV23), the vaccine currently recommended for these groups of adults.¹⁰

The ACIP recommendation for routine vaccination with PCV13 and the immunization schedules for children aged ≤ 59 months who have not received any previous conjugate vaccine (PCV7) or PCV13 doses are the same as those published previously for PCV7, with PCV13 replacing PCV7 for all doses. For routine immunization of infants, PCV13 is recommended as a 4-dose series at ages 2, 4, 6, and 12--15 months. Infants and children who have received ≥ 1 dose of PCV7 should complete the immunization series with PCV13. A single supplemental dose of PCV13 is recommended for all children aged 14--59 months who have received 4 doses of PCV7 or another age-appropriate, complete PCV7 schedule. For children who have underlying medical conditions, a supplemental PCV13 dose is recommended through age 71 months.¹¹ A single dose of PCV13 may be administered for children aged 6-18 with high-risk conditions such as functional or anatomic asplenia, immunocompromising conditions, cochlear implants, or CSF leaks, regardless of whether they have previously received PCV7 or PPSV23.¹⁰ Children aged 2--18 years with underlying medical conditions also should receive PPSV23 after completing all recommended doses of PCV13.¹¹

Adults with specified immunocompromising conditions who are eligible for pneumococcal vaccine should be vaccinated with PCV13 during their next pneumococcal vaccination opportunity. ACIP recommends that adults aged ≥ 19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23, should receive a dose of PCV13 first, followed by a dose of PPSV23 at least 8 weeks later. Subsequent doses of PPSV23 should follow current PPSV23 recommendations for adults at high risk. Specifically, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19--64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years, or later if at least 5 years have elapsed since their previous PPSV23 dose. For adults aged ≥ 19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, who previously have received ≥ 1 doses of PPSV23 should be given a PCV13 dose ≥ 1 year after the last PPSV23 dose was received. For those who require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23.¹⁰

Tables 1-3 describe the recommended pneumococcal immunization schedule for chronic kidney disease patients (Appendix).

References

1. Recommendations of the Advisory Committee on Immunization Practices (ACIP): Use of Vaccines and Immune Globulins for Persons with Altered Immunocompetence. *MMWR Recommendations and Reports*. Apr 9 1993;42(RR-4):1-18.
2. National Center for Immunization Respiratory Diseases. General Recommendations on Immunization --- Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recommendations and Reports*. Jan 28 2011;60(2):1-64.
3. Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients. *MMWR Recommendations and Reports*. Apr 27 2001;50(RR-5):1-43.
4. Mast EE, Weinbaum CM, Fiore AE, et al. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults. *MMWR Recommendations and Reports*. Dec 8 2006;55(RR-16):1-33.
5. Mast EE, Margolis HS, Fiore AE, et al. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part 1: Immunization of Infants, Children, and Adolescents. *MMWR Recommendations and Reports*. Dec 23 2005;54(RR-16):1-31.
6. Centers for Disease Control and Prevention. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)--United States, 2012-13 Influenza Season. *MMWR Morbidity and Mortality Weekly Report*. Aug 17 2012;61(32):613-618.
7. Fiore AE, Uyeki TM, Broder K, et al. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR Recommendations and Reports*. Aug 6 2010;59(RR-8):1-62.
8. Fiore AE, Shay DK, Broder K, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. *MMWR Recommendations and Reports*. Jul 31 2009;58(RR-8):1-52.
9. Fiore AE, Fry A, Shay D, Gubareva L, Bresee JS, Uyeki TM. Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza --- Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recommendations and Reports*. Jan 21 2011;60(1):1-24.
10. Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morbidity and Mortality Weekly Report*. Oct 12 2012;61:816-819.
11. Nuorti JP, Whitney CG. Prevention of Pneumococcal Disease Among Infants and Children - Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine - Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recommendations and Reports*. Dec 10 2010;59(RR-11):1-18.
12. Nuorti JP, Whitney CG. Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23). *MMWR Morbidity and Mortality Weekly Report*. Sep 3 2010;59(34):1102-1106.

Appendix

Table 1. Guidelines for administering PCV13 and PPSV23 vaccines for infants and children (ages 0-18) with chronic kidney disease

Infants and Children (ages 0-18)				
Vaccination History	Recommended Regimen			Notes
Never vaccinated with PCV7 or PCV13 up to age 59 months	Routine vaccination for PCV13 (4 dose series)	Administer 1 dose of PPSV23 at age ≥ 2 years and ≥ 8 weeks after last indicated dose of PCV13	Administer 1 dose of PPSV23 5 years later	The ACIP recommendation for routine vaccination with PCV13 and the vaccination schedules for infants and toddlers through age 59 months who have not received any previous PCV7 or PCV13 doses are the same as those previously published for PCV7. PCV13 is recommended as a 4-dose series at ages 2, 4, 6, and 12–15 months. ¹¹
Completed all recommended doses of PCV7	Administer 1 dose of PCV13 ≥ 8 weeks later	Administer 1 dose of PPSV23 at age ≥ 2 years and ≥ 8 weeks after last indicated dose of PCV13	Administer 1 dose of PPSV23 5 years later	For children who have underlying medical conditions, a single supplemental PCV13 dose is recommended through 71 months of age. This includes children who have received PPSV23 previously. PCV13 should be administered at least 8 weeks after the most recent dose of PCV7 or PPSV23. This will constitute the final dose of PCV for these children. ¹¹
Children aged 24-71 months who received <3 doses of PCV7 before age 24 months	Administer 2 doses of PCV13 now	Administer 1 dose of PPSV23 ≥ 8 weeks later after last indicated dose of PCV13	Administer 1 dose of PPSV23 5 years later	Children aged 24–71 months with underlying medical conditions who received <3 doses of PCV7 before age 24 months should receive a series of 2 doses of PCV13 followed by 1 dose of PPSV23 administered ≥ 8 weeks later. ¹¹
Children aged 24-71 months who received any incomplete schedule of 3 doses of PCV7 before age 24 months	Administer 1 dose of PCV13 now	Administer 1 dose of PPSV23 ≥ 8 weeks later	Administer 1 dose of PPSV23 5 years later	Children aged 24–71 months with underlying medical conditions who received any incomplete schedule of 3 doses of PCV7 before age 24 months should receive 1 dose of PCV13 followed by 1 dose of PPSV23 administered ≥ 8 weeks later. ¹¹
Completed all recommended doses of PCV13	Administer 1 dose of PPSV23 at age ≥ 2 years and ≥ 8 weeks after last indicated dose of PCV13	Administer 1 dose of PPSV23 5 years later		A second dose of PPSV23 is recommended 5 years after the first dose of PPSV23 for children who have anatomic or functional asplenia, including SCD, HIV infection, or other immunocompromising condition. ¹¹
Children aged 6-18 years who have not received PCV13	Administer 1 dose of PCV13 now			One dose of PCV13 is recommended by ACIP for children aged 6-18 years with high-risk conditions such as functional or anatomic asplenia, immunocompromising conditions, cochlear implants, or CSF leaks. ¹⁰

Table 2. Guidelines for administering PCV13 and PPSV23 vaccines for adults (ages 19-64) with chronic kidney disease

Adults (ages 19-64)				
Vaccination History	Recommended Regimen			Notes
Never vaccinated with PCV13 or PPSV23	Administer 1 dose of PCV13 dose now	Administer 1 dose of PPSV23 \geq 8 weeks later	Administer 1 dose of PPSV23 \geq 5 years later	ACIP recommends that adults aged \geq 19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23, should receive a dose of PCV13 first, followed by a dose of PPSV23 at least 8 weeks later. Subsequent doses of PPSV23 should follow current PPSV23 recommendations for adults at high risk. Specifically, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years, or later if at least 5 years have elapsed since their previous PPSV23 dose. ¹⁰
Previously vaccinated with 1 dose PPSV23 \geq 1 year ago; never vaccinated with PCV13	Administer 1 dose of PCV13 dose now	Administer 1 dose of PPSV23 \geq 8 weeks after PCV13, which must be \geq 5 years after first dose of PPSV23		
Previously vaccinated with 2 doses of PPSV23 (last dose was \geq 1 year ago); never vaccinated with PCV13	Administer 1 dose of PCV13 dose now			
Previously vaccinated with \geq 1 dose PCV13 (\geq 8 weeks ago); never vaccinated with PPSV23	Administer 1 dose of PPSV23 now	Administer 1 dose of PPSV23 \geq 5 years later		
Previously vaccinated with \geq 1 dose PCV13 (\geq 8 weeks ago) and 1 dose PPSV23	Administer 1 dose of PPSV23 \geq 5 years after first PPSV23 dose			

Table 3. Guidelines for administering PCV13 and PPSV23 vaccines for adults (ages 65 and over) with chronic kidney disease

Adults (ages 65 and over)			
Vaccination History	Recommended Regimen		Notes
Never vaccinated with PCV13	Administer 1 dose of PCV13 now	Administer 1 dose of PPSV23 ≥ 8 weeks after PCV13, which must be ≥ 5 years after last dose of PPSV23	All persons should be vaccinated with PPSV23 at age 65 years. Those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose. Those who receive PPSV23 at or after age 65 years should receive only a single dose. ¹²
Previously vaccinated with ≥ 1 dose PCV13 (≥ 8 weeks ago)	Administer 1 dose of PPSV23 now		