

Vaccinations

COVID-19, Influenza, Pneumonia Vaccinations in End-Stage Kidney Disease (ESKD)

February 2022

ESRD NW 10&12/ Telligen QIN/QIO



Housekeeping

- Q & A at the end of presentation
 - Raise hand feature
 - Question box
- Polling questions distributed throughout presentation





Objectives

- 1. Recognize the higher risk of infectious complications among ESKD patients.
- 2. Learn the current vaccination recommendations against COVID-19, Influenza, and Pneumococcal Infections.
- 3. Understand the safety monitoring and benefits of these vaccines, including lower hospitalization rates.



ESRD Network Program Overview

The End Stage Renal Disease Network Organization Program (ESRD Network Program) is a national quality improvement program funded by the Centers for Medicare & Medicaid Services (CMS), a federal agency of the U.S. Department of Health and Human Services.

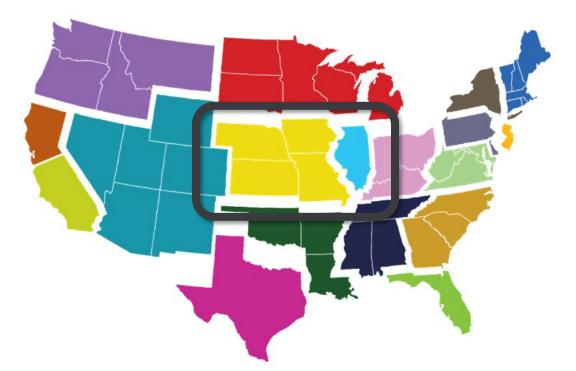
Following passage of the 1972 Amendments to the Social Security Act, in response to the need for effective coordination of ESRD care, hospitals and other health care facilities were organized into networks to enhance the delivery of services to people with ESRD.

In 1978, Public Law 95-292 modified the Social Security Act to allow for the coordination of dialysis and transplant services by linking dialysis facilities, transplant centers, hospitals, patients, physicians, nurses, social workers, and dietitians into Network Coordinating Councils, one for each of 32 administrative areas.

In 1988, CMS consolidated the 32 jurisdictions into 18 geographic areas and awarded contracts to 18 ESRD Network Organizations, now commonly known as ESRD Networks. The ESRD Networks, under the terms of their contracts with CMS, are responsible for: supporting use of the most appropriate treatment modalities to maximize quality of care and quality of life; encouraging treatment providers to support patients' vocational rehabilitation and employment; collecting, validating, and analyzing patient registry data; identifying providers that do not contribute to the achievement of Network goals; and conducting onsite reviews of ESRD providers as necessary.



Qsource ESRD Networks Service Area



ALASKA	PUERTO RICO	U.S. VIRGIN ISLANDS	
HAWAII	GUAM and MARIANA ISLANDS	AMERICAN SAMOA	
		Qsource.	Telligen

Telligen Quality Innovation Network – Quality Improvement Organization (QIN-QIO)

Telligen QIN-QIO brings together Medicare providers, beneficiaries, and communities together in data-driven initiatives that increase patient safety, improve clinical quality, better coordinate post-discharge care, and make communities healthier. Learn more and join us in partnership at <u>Telligen QIN-QIO</u>.



Telligen QIN-QIO is funded by CMS to deliver quality improvement services at no cost to you or your organization. We partner with and leverage local, regional and national expertise with our:

- training, service, and data infrastructure
- education and support through quality improvement learning and action sessions
- peer-to-peer learning through our monthly coalition calls and resource sharing platforms
- technical assistance programs reflecting evidence-based practices



Guest Speaker



Marie Philipneri, MD, PhD.

Professor of Medicine/Nephrology Saint Louis University School of Medicine, Saint Louis, MO.

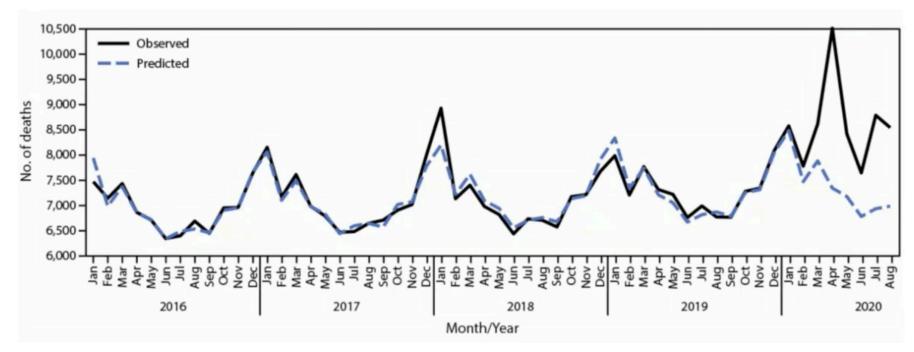


Chronic Kidney Disease and Infection Risk

- Infections are the second most common cause of hospitalization and mortality in end-stage kidney disease (ESKD) patients.
- Dialysis patients have higher annual mortality rates due to sepsis compared to the general population.
- Yet the immune response to most vaccines in dialysis patients are less effective compared to the general population.



Monthly Mortality Among Dialysis Patients in the United States, Jan. 1, 2016–Aug. 31, 2020



Abbreviation: CROWNWeb = Consolidated Renal Operations in a Web-Enabled Network.

* Based on CROWNWeb data from January 1, 2016 through August 31, 2020.

[†] Based on a model fit with monthly data from January 1, 2016 through December 31, 2019.



MMWR Morb Mortal Wkly Rep 2021;70:825–829.

Chronic Kidney Disease and Infections

- 1. Increased susceptibility to infection
 - Older age
 - Co-morbidities (DM, HTN, COPD)
 - Immunodeficiency or immunosuppression
 - Residence in a nursing home and contact during transportation
 - In-center dialysis (high number of personnel and patient contacts)

2. Low response to vaccines

- Lower number of B lymphocyte and CD4+ T lymphocyte
- Reduced T-cell response to antigenic stimuli
- Impaired monocyte functioning and inadequate antigen presentation
- Impaired function of neutrophils

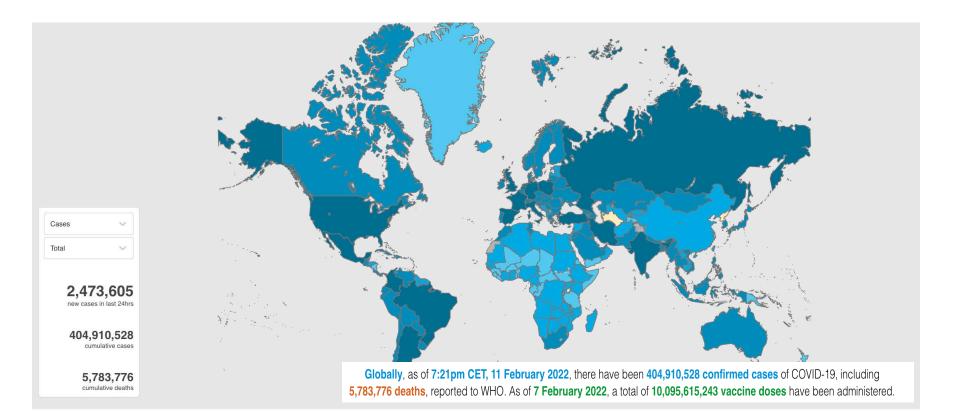
<u>Nat Rev Nephrol.</u> 2021 Oct 11 : 1–2; Clin J Am Soc Nephrol. 2008 Sep; 3(5):1526-33; Clin Exp Nephrol. 2019 Apr; 23(4):437-447; <u>Int J Nephrol Renovasc</u> <u>Dis.</u> 2020; 13: 179–185.



COVID-19 Pandemic



COVID-19 Pandemic: United States at a Glance

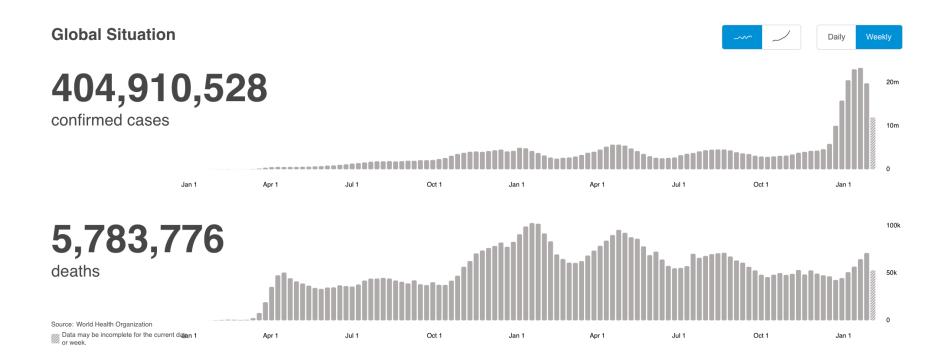


Cases Total (last 30 days): 77,516,009 | **Deaths Total** (last 30 days): 915,425

https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths



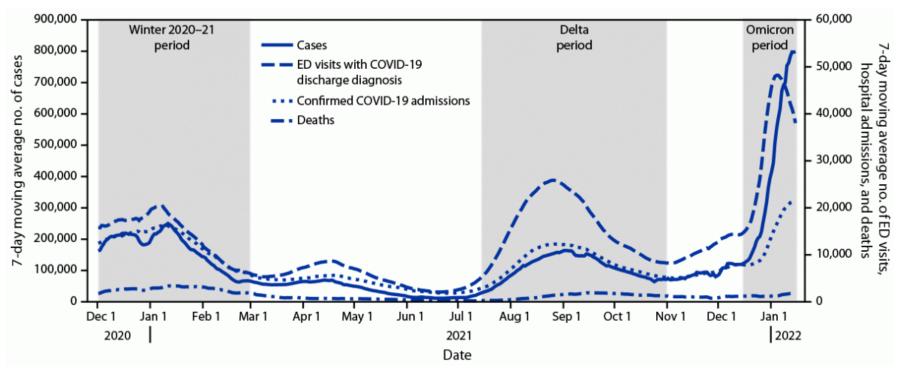
COVID-19 Pandemic



https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths

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Recent COVID-19 Cases and Outcomes



Sources: CDC state-reported data (cases and deaths), Unified Hospital dataset (admissions), and National Syndromic Surveillance Program (ED visits with COVID-19 discharge diagnoses).

Despite recently seeing the highest reported numbers of Omicron COVID-19 cases and hospitalizations during the pandemic, disease severity indicators including length of stay, ICU admission, and death, were lower than during previous pandemic peaks.



MMWR Morb Mortal Wkly Rep 2022;71:146–152.

COVID-19 Is a Multi-System Disease

- Numerous short- and long-term complications involving almost all organ systems have been reported in COVID-19 patients.
- Data from a prospective, multi-center cohort study involving 302 healthcare facilities suggested that 49.7% of patients admitted with COVID-19 had at least one in-hospital complication

The most commonly involved systems were:



Renal (24.3%)



Respiratory (18.4%)



Neurological (4.3%)





Cardiovascular (12.3%)

Future Virol. 2021 Oct : 10.2217/fvl-2021-0200 (PMID: 34777553)



COVID-19 Is a Multi-System Disease

- **Renal:** acute kidney injury, glomerulonephritis, thrombotic microangiopathy
- **Respiratory:** barotrauma, sepsis, and fungal infection (pulmonary aspergillosis)
- **Cardiac**: myocardial injury, arrhythmia, heart failure, acute coronary syndrome
- Neurological: stroke, cerebral venous thrombosis, delirium, and psychiatric.
- Hematological: venous and arterial thromboembolism, thrombocytopenia
- GI: hemorrhage, mesenteric ischemia, acute liver injury, Clostridium difficile
- Neuromuscular and Musculoskeletal: critical illness myo-neuropathy, myositis
- Endocrine: diabetic ketoacidosis (DKA), hyperosmolar hyperglycemia, severe insulin resistance adrenal insufficiency
- **Dermatologic**: vesicular, urticarial, morbilliform eruptions, erythema multiforme
- **Rheumatologic**: hyper-inflammatory syndrome, vasculitis, reactive arthritis

COVID-19 Infection Risk in Dialysis Patients

Dialysis patients are at high risk for serious illness and death related to COVID-19. Reported statistics include:







COVID-19 Vaccines

COVID-19 vaccines help our bodies develop immunity to the virus that causes COVID-19 without us having to get the illness.

1. mRNA Vaccines

(Pfizer-BioNTech or Moderna)

2. <u>Vector Vaccines</u>

(Johnson & Johnson's Janssen)

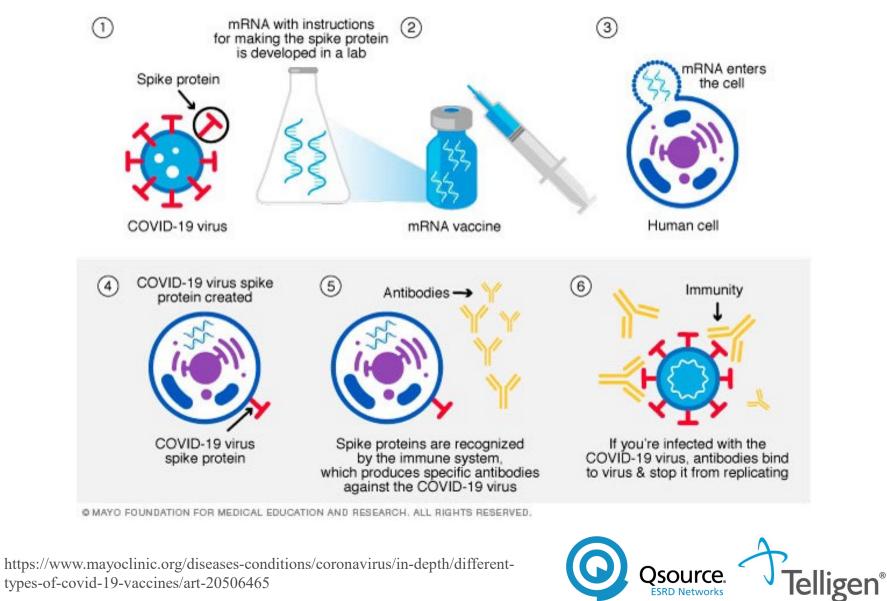
3. Protein Subunit Vaccines (vaccines under development, e.g., Novavax)





19

Messenger RNA (mRNA) Vaccine



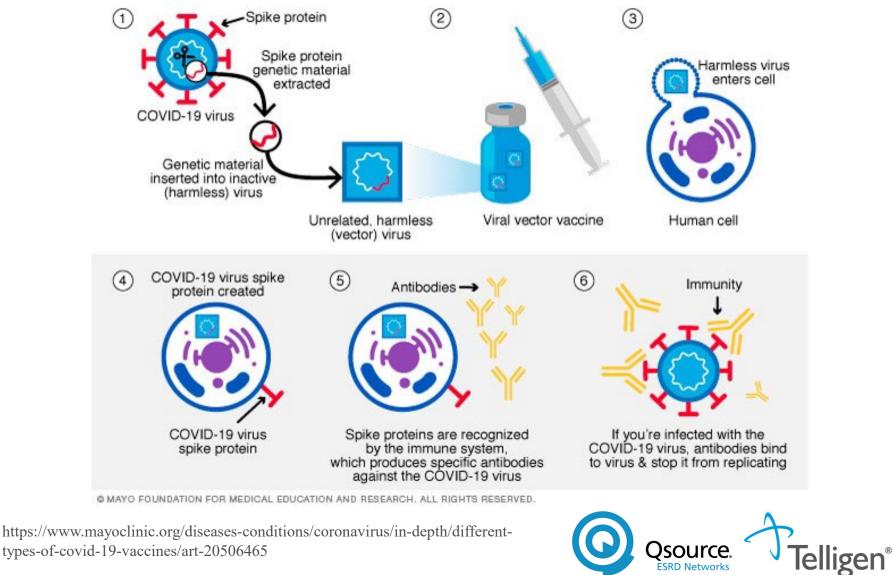
Messenger RNA (mRNA) Vaccine



Mayo Clinic Insights: How mRNA Vaccines Work accessed from https://youtu.be/RvR_yf_haqQ



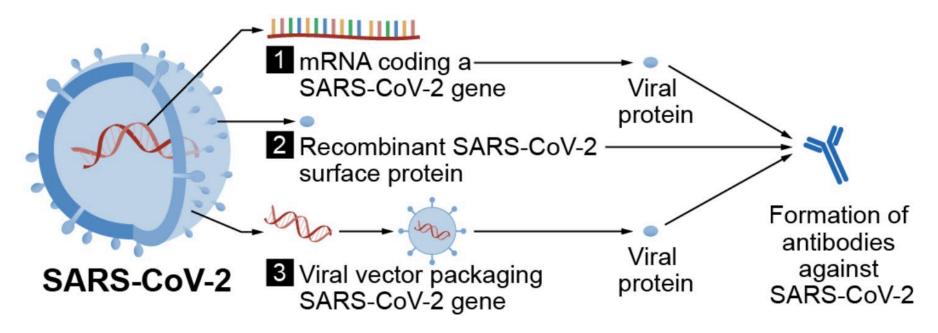
Viral Vector Vaccine



ESRD Networks

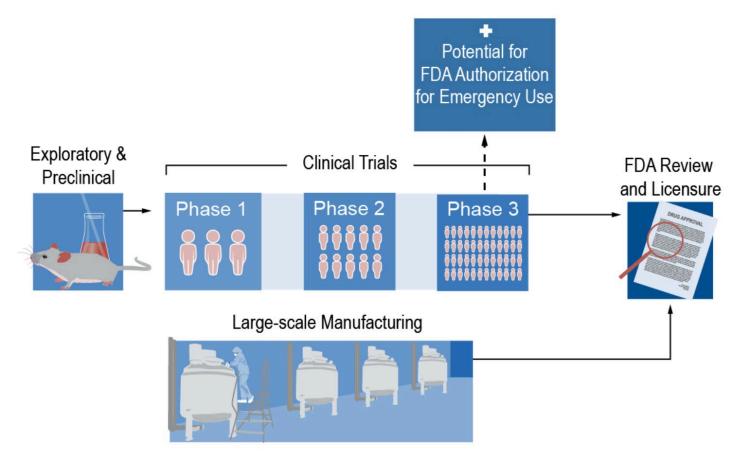
types-of-covid-19-vaccines/art-20506465

COVID-19 Vaccine Use Different Mechanisms



Source: GAO analysis of The Pharmaceutical Journal infographic. | GAO-20-583SP



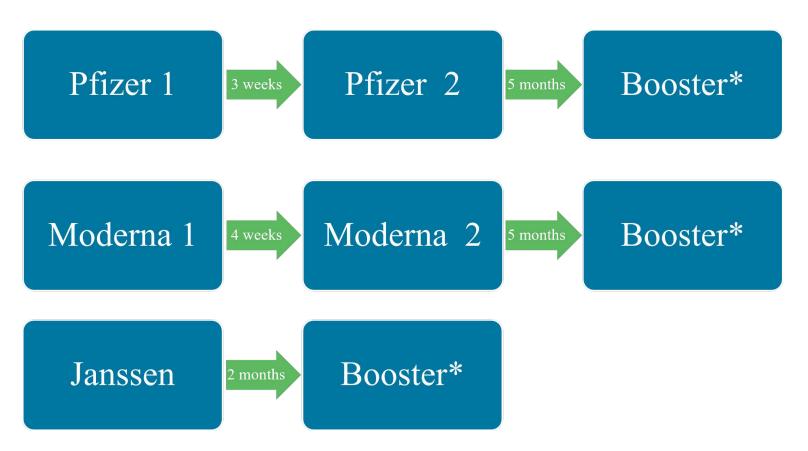


Source: GAO analysis of Food and Drug Administration (FDA), Pharmaceutical Research and Manufacturers of America, and Operation Warp Speed information. | GAO-20-583SP

GAO-20-583SP COVID-19 Vaccine Development: https://www.gao.gov/products/gao-20-583sp



COVID-19 Vaccine Dosing Recommendations



*Booster: mRNA vaccine is preferred over Janssen vaccine.

1 Additional mRNA primary dose in immunocompromised people 28 days after 2nd dose.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#covid19-vaccines



Benefits of COVID-19 Vaccine

A COVID-19 Vaccine Might:

- Prevent us from getting COVID-19 or from becoming seriously ill or dying due to COVID-19.
- Lesson the risk of spreading the virus that causes COVID-19 to others.
- Add to the number of people in the community who are protected from getting COVID-19 — contributing to herd immunity and making it harder for the disease to spread within communities.
- Prevent the virus that causes COVID-19 from spreading and replicating, which allows it to mutate and possibly become more resistant to vaccines.



Reducing COVID-19 Hospitalizations



Effectiveness of Vaccination for Preventing Hospitalization

13 States*, February-April 2021

Age (years)	Pfizer-BioNTech (%)	Moderna (%)	Janssen J & J (%)
65–74	96	96	84
>=75	91	96	85

*California, Colorado, Connecticut, Georgia, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah

MMWR Morb Mortal Wkly Rep 2021;70:1088-1093

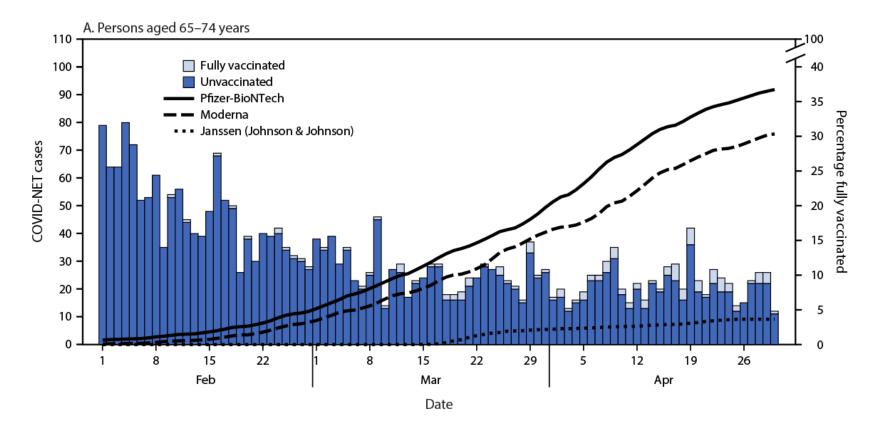
5 Veterans Affairs Medical Centers, February 1–August 6, 2021

Age (years)	mRNA vaccine effectives in preventing hospitalization (%)	
18-64	95	
>=65	80	
Overall	87	

MMWR Morb Mortal Wkly Rep 2021;70:1294–1299



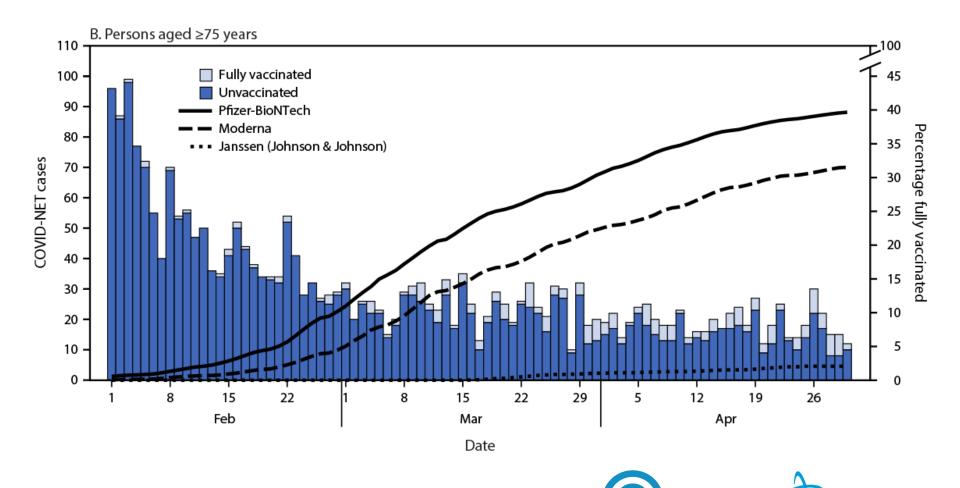
COVID-NET* Cases and Full Vaccination Coverage Among Persons Aged **65–74 Years** — 13 States, Feb. 1–Apr. 30, 2021



COVID-NET data included in this analysis were from the following states: California, Colorado, Connecticut, Georgia, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah.

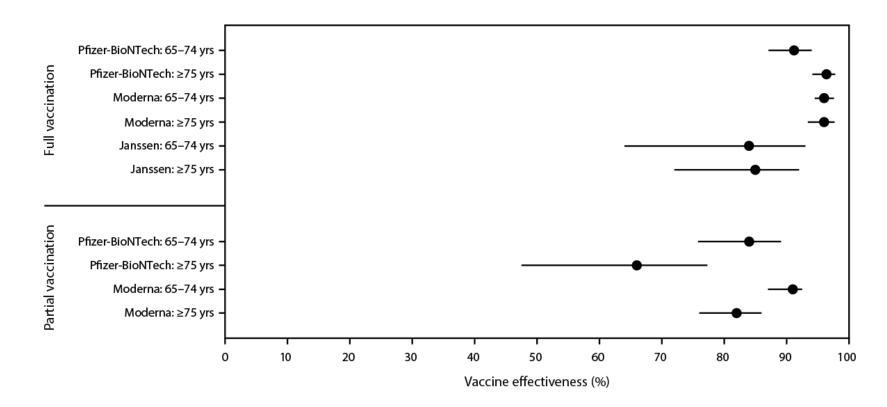


COVID-NET* Cases and Full Vaccination Coverage Among Persons Aged **≥75 Years** (B) — 13 States, Feb. 1–Apr. 30, 2021



igen

Estimates of Vaccine Effectiveness In Preventing COVID-19–Associated Hospitalization Among Patients Aged **≥65 Years** (Feb. 1–Apr. 30, 2021)



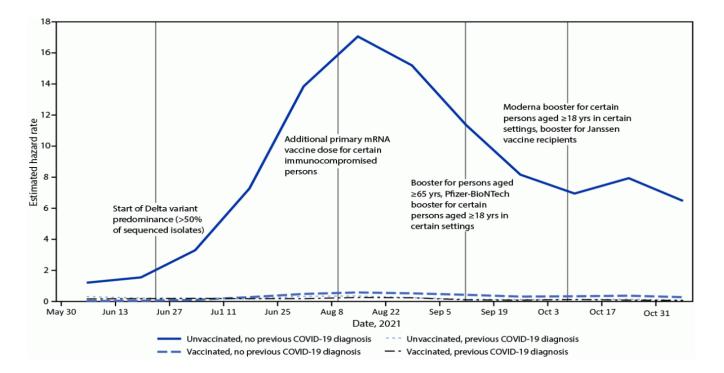
for the COVID-NET catchment area, by vaccine product and age group using the screening method — COVID-NET, 13 states,*

MMWR Morb Mortal Wkly Rep 2021;70:1088-1093



Incident Laboratory-Confirmed COVID-19-Associated Hospitalizations

Incident laboratory-confirmed COVID-19-associated hospitalizations among immunologic cohorts defined by vaccination and previous diagnosis histories — California, May 30–November 13, 2021

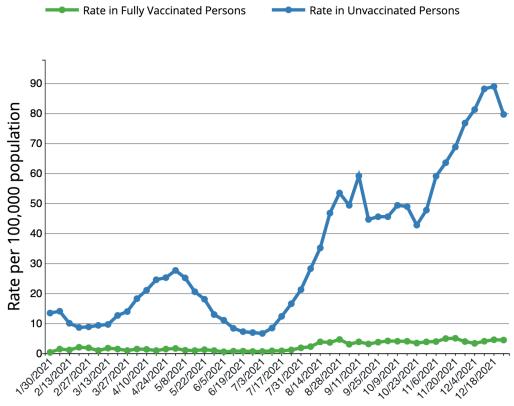


Estimated hazard rate is laboratory-confirmed COVID-19-associated hospitalizations per 100,000 person-days visualized at midpoint of each reporting interval.

MMWR Morb Mortal Wkly Rep 2022;71:125-131



Age-Adjusted Rates of COVID-19-Associated Hospitalizations by Vaccination Status in Adults Ages ≥18 Years, January–December 2021

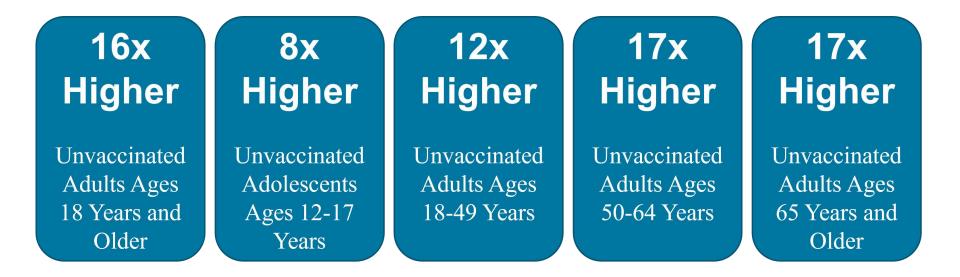


Week

https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination



COVID-19-Associated Hospitalization Rates Among Unvaccinated Compared to Fully Vaccinated Adults (December 2021)

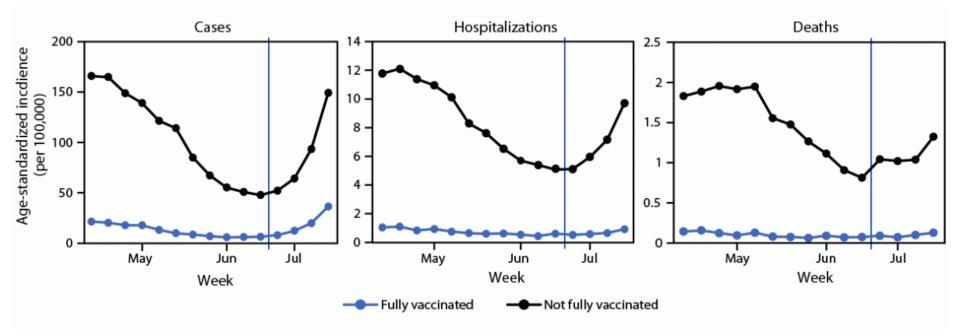


https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination



Weekly Trends by Vaccination Status

Weekly Trends in Age-Standardized Incidence* of COVID-19 Cases, Hospitalizations,[†] and Deaths,[§] by Vaccination Status — 13 U.S. Jurisdictions,** April 4–July 17, 2021



Rates are standardized by age, according to the enumerated 2000 U.S. Census age distribution. Blue vertical lines indicate when the B.1.617.2 (delta) variant reached a threshold of >50%, using weighted estimates for 13 jurisdictions combined.

MMWR Morb Mortal Wkly Rep 2021;70:1284–1290.



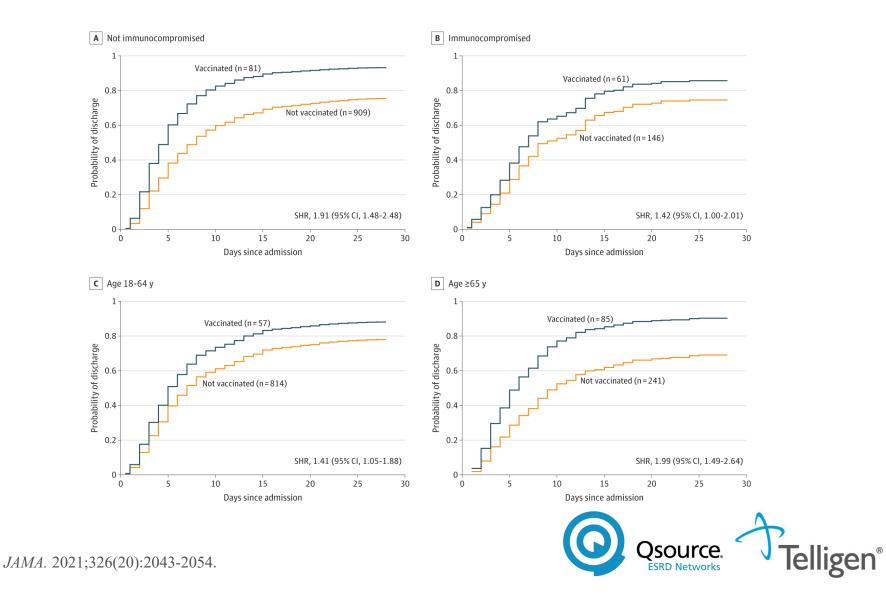
COVID-19 Vaccination Status and Disease Severity

In a case-control study (4513 hospitalized adults from 18 US states), <u>fully vaccinated</u> <u>individuals</u> had lower risk of hospitalization with a COVID-19 diagnosis and progression to death or invasive mechanical ventilation.

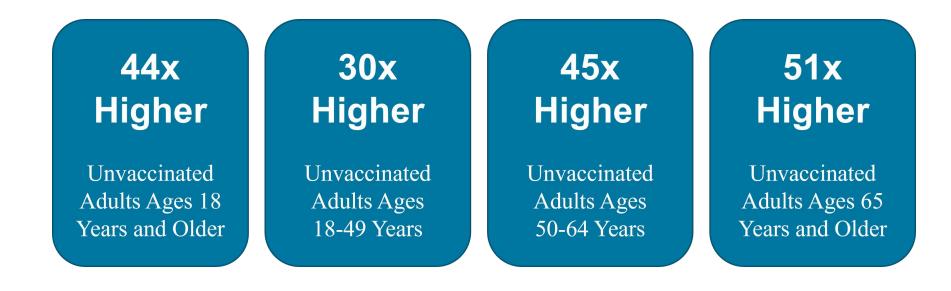
	Adjusted Odds Ratio (AOR)		
	Fully vaccinated	NOT fully vaccinated	
Hospitalization with a COVID-19 diagnosis compared with an alternate diagnosis	0.15	1	
Progression to death or invasive mechanical ventilation	0.33	1	



Hospital Discharge Rates for Adults Hospitalized With COVID-19



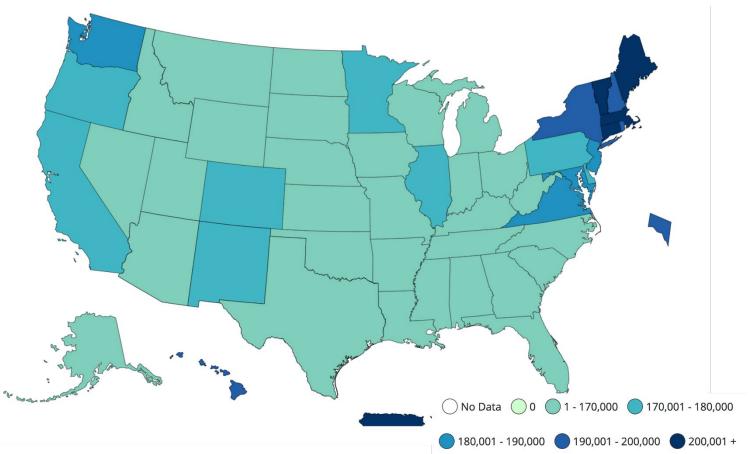
COVID-19-Associated Hospitalization Rates By Vaccination And Additional or Booster Dose Status In Adults (December 2021)*



https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination



COVID-19 Vaccination Rates



Total Doses Administered Reported to the CDC by State/Territory and for Select Federal Entities per 100,000 of the Total Population

https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-totaladmin-rate-total accessed on February 17, 2022



Infection- and Vaccine-Induced Immunity

- Infection with SARS-CoV-2 and vaccination can each result in a lower risk of subsequent infection with antigenically similar variants for at least 6 months.
- COVID-19 vaccination in previously infected individuals significantly enhances their immune response and effectively reduces the risk of subsequent infection
- Data suggests that people with history of COVID-19 infection and then receive mRNA vaccines produce very high levels of antibodies that are likely effective against current and, possibly, future variants. Some scientists call this hybrid immunity. Further research is needed.
- Nearly half of previously infected adults in the US have not been vaccinated.

Science brief: SARS-CoV-2 infection-induced and vaccine-induced immunity. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html

MMWR Morb Mortal Wkly Rep, 2021. 70(32): p. 1081-1083



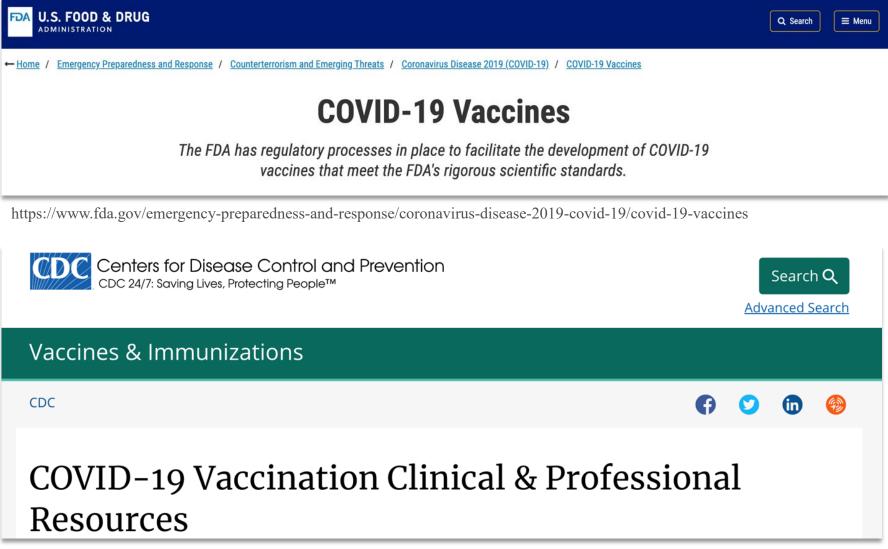
Vaccine Safety Monitoring

CDC's **Immunization Safety Office (ISO)** conducts four primary vaccine safety activities:

- 1) Vaccine Adverse Event Reporting System (VAERS)
- 2) Vaccine Safety Datalink (VSD)
- 3) Clinical Immunization Safety Assessment (CISA) Project
- 4) Emergency Preparedness and Vaccine Safety



Updated Information on COVID-19 Vaccination



https://www.cdc.gov/vaccines/covid-19/index.html

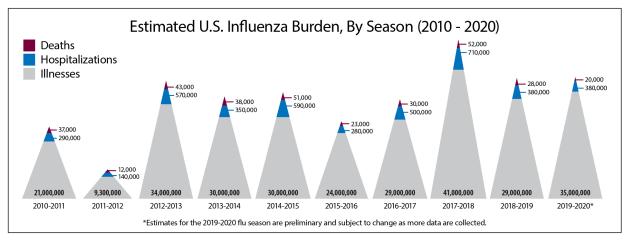
Influenza Vaccination



Estimated Range of Annual Flu Burden in the United States, 2010-2011 Through 2019-2020 Influenza Seasons

Influenza can be associated with serious illnesses, hospitalizations, and deaths.

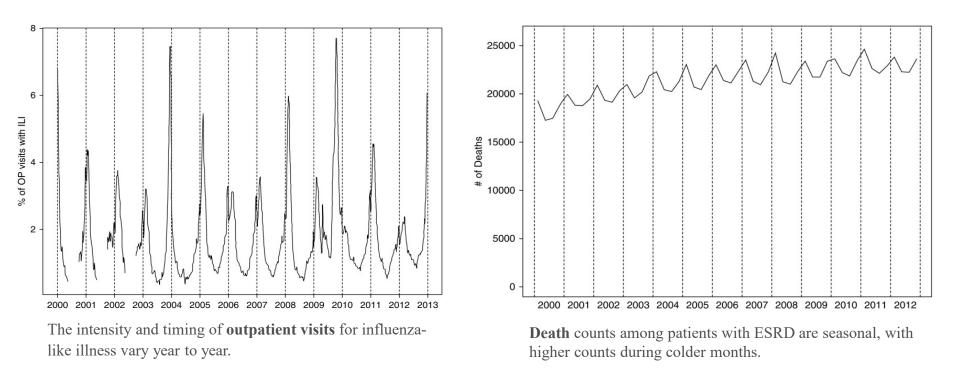




The burden of influenza disease in the United States can vary widely and is determined by a number of factors:

- Characteristics of circulating viruses
- Timing of the season
- How well the vaccine is working to protect against illness
- How many people got vaccinated

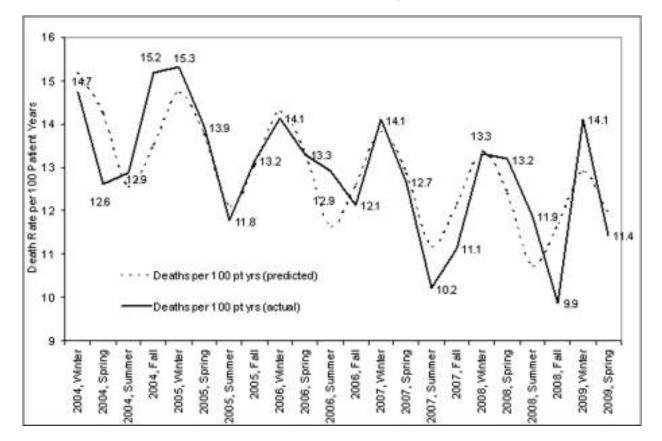
Influenza-Like Illness (ILI) in the ESRD Population



Deaths and ILI office visits peak during colder months each year. The intensity and timing of ILI is associated with similar intensity and timing in deaths in ESRD patients. Therefore, each 1% increase in quarterly ILI was associated with **1.5-2.0%** increase in relative mortality.



Seasonal Variations in Mortality



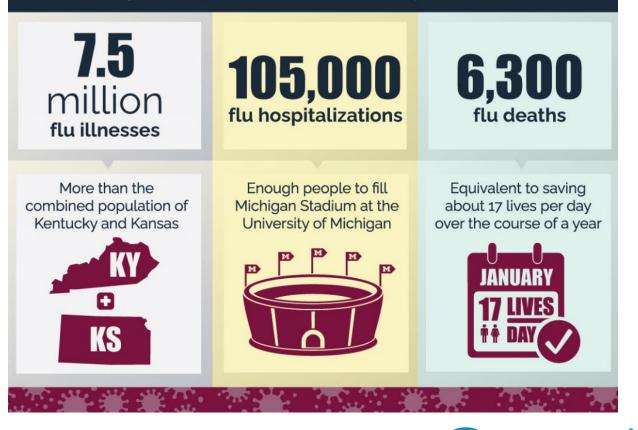
15,056 patients of 51 Renal Research Institute clinics from six states of varying climates in the United States. Mortality differences were related to seasonality of physiologic and laboratory parameters.

Clin J Am Soc Nephrol. 2012 Jan; 7(1): 108-115.



According to CDC Data, Estimated Influenza Disease Burden Averted by Vaccination (2019-2020)

Nearly 52% of the U.S. population aged 6 months and older got a flu vaccine during the 2019-2020 flu season, and this prevented an estimated:



https://www.cdc.gov/flu/about/burden-averted/2019-2020.htm

CDC Yearly Lab Work on Flu Viruses

More than 1 million patient specimens are tested in clinical labs participating in CDC domestic disease surveillance.*

About 100,000 specimens are tested in 93 state/local public health labs.

CDC conducts full genetic sequencing on about 7,000 flu viruses each year.

CDC tests about 2,000 flu viruses to determine their immune properties.

CDC prepares as many as 50 viruses for possible use in vaccine production.

*Influenza data current as of 2020-2021, as reported by CDC's Influenza Division, National Center for Immunization and Respiratory Diseases (NCIRD)





Influenza Vaccines for the 2021-2022 Flu Season

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on March 5, 2021.

All flu vaccines will be **quadrivalent** (four component), which is designed to protect against four different flu viruses as follows:

an A/Victoria/2570/2019 (H1N1) pdm09-like virus; an A/Cambodia/e0826360/2020 (H3N2)-like virus; a B/Washington/02/2019- like virus (B/Victoria lineage); a B/Phuket/3073/2013-like virus (B/Yamagata lineage)

TWO Influenza A TWO Influenza B

Most flu shots and the nasal spray flu vaccine are manufactured using egg-based technology. An egg-free (**cell-based**) quadrivalent vaccine is also available.

https://www.cdc.gov/flu/season/faq-flu-season-2021-2022.htm#what-virus https://www.fda.gov/vaccines-blood-biologics/lot-release/influenza-vaccine-2021-2022-season



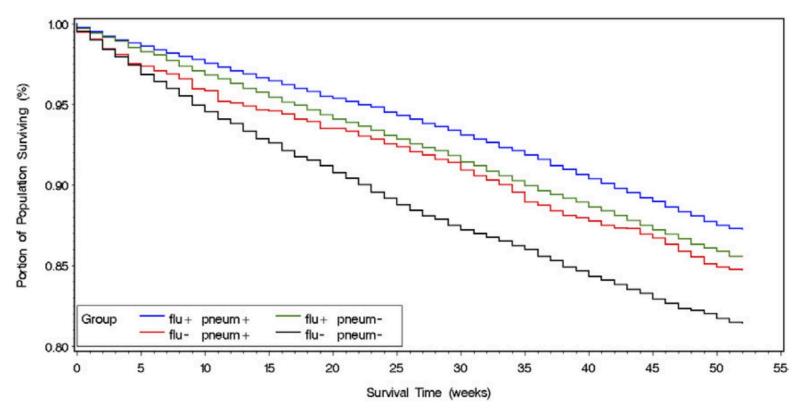
Influenza Vaccines for the 2021-2022 Flu Season

Injectable (FLU shots)	Nasal Spray
Inactivated influenza vaccines (IIV4s)	the live attenuated influenza vaccine
Recombinant influenza vaccine (RIV4)	(LAIV4),

- The CDC recommends annual flu vaccination for everyone 6 months and older, with <u>few exceptions</u>.
- <u>Only</u> the **injectable** flu vaccine is recommended for patients with kidney disease.
- The recombinant influenza vaccine is approved for people aged 18 years and older, and the adjuvanted and <u>high-dose</u> inactivated vaccines are approved for people 65 years and older.
- September and October are generally good times to be vaccinated against flu.



Mortality by Influenza and Pneumococcal Vaccination Status



Abbreviations: flu= influenza; pneum= pneumococcal.



Am J Kidney Dis. 2012;60(6):959-965.

How Influenza (Flu) Viruses Can Change: "Drift" and "Shift"

Flu viruses are constantly changing. They can change in two ways.

- Antigenic Drift It consists of small changes (or mutations) in the genes of influenza viruses that can lead to changes in the surface proteins of the virus.
- Antigenic **Shift** An abrupt, major change in a flu A virus, resulting in new surface proteins in flu viruses that infect humans.

While flu viruses change all the time due to antigenic drift, antigenic shift happens less frequently.

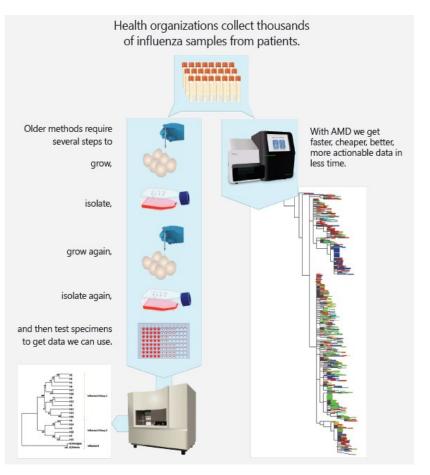
Type A viruses undergo <u>both</u> antigenic <u>drift and shift</u> and are the only flu viruses known to cause pandemics, while flu type B viruses change only by the more gradual process of antigenic drift.



Improved Flu Surveillance

- Developing the annual flu shot is a yearround process (surveillance etc.).
- Older genetic sequencing methods require specimens taken from patients to be grown in culture to create a virus isolate that can then be sequenced.
- With Advanced Molecular Detection (AMD), specimens can be sequenced directly, without first growing them in culture.
- CDC performs "next generation sequencing" on close to 7,000 influenza viruses annually.
- The time-saving benefit has reduced the response time to flu outbreaks.

https://www.cdc.gov/amd/what-we-do/improvingvaccines.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Famd%2Fproje ct-summaries%2Finfluenza-vaccines.html





Pneumonia Vaccination



Pneumococcal Infections

- *Streptococcus pneumoniae* is an endemic global pathogen that causes a wide range of clinical disease in children and adults.
- <u>Noninvasive</u> pneumococcal disease includes otitis, sinusitis, and community-acquired pneumonia. Pneumococcal pneumonia results in 400,000 hospitalizations annually in the United States; mortality ranges from 5 to 7%.
- Pneumococcus is the most common cause of community-acquired pneumonia in adults (at least 25% of documented cases).



Pneumococcal Infections (Cont.)

Invasive pneumococcal diseases include:

Bacteremia

Endocarditis

- Empyema
- Meningitis

Osteomyelitis

The majority of these cases start with streptococcal pneumonia as a primary focus.

They carry significant mortality risk (up to 10% for meningitis and 15% for bacteremia), and survivors can be left with significant sequelae (e.g., hearing loss, seizures, blindness, or paralysis).



Pneumococcal Infection and Kidney Disease

- People with chronic kidney disease are at a greater risk for pneumococcal disease, and prone to its complications.
- Overall, the mortality rate from pneumonia is **14–16-fold** higher in patients on dialysis than in the general population.
- In a USRDS study that included an incident dialysis cohort of nearly 300,000 patients, one in five (21%) developed pneumonia within 1 year of starting dialysis, and 42% of these individuals required hospitalization.



Risk Factors for Pneumonia

A total of 15,562 patients with CKD and 62,109 individuals without CKD (matched for age and gender) were taken as subjects in the Longitudinal Health Insurance Database of Taiwan National Insurance from 1996 to 2010. CKD was associated with increased risk of pneumonia.

Risk Factors	Pneumonia (Overall) aHR (95% CI)	Pneumonia (Outpatient) aHR (95% CI)	Pneumonia (Inpatient) aHR (95% CI)			
CKD	1.97 (1.89-2.05)	1.40 (1.31–1.49)	2.17 (2.07-2.29)			
Age (every 10 additional years)	1.05(1.05 - 1.05)	1.02(1.02 - 1.03)	1.07(1.07 - 1.07)			
Male	1.24(1.20-1.29)	1.13(1.07 - 1.19)	1.37 (1.31-1.44)			
Hypertension	1.09(1.04 - 1.15)	1.03(0.96-1.11)	1.10(1.04 - 1.16)			
Diabetes	1.29 (1.24-1.34)	1.12(1.05-1.19)	1.22(1.14 - 1.30)			
CVD	1.08 (1.07-1.14)	1.11 (1.04-1.20)	1.10(1.04 - 1.16)			
Asthma	1.39 (1.32-1.46)	1.66 (1.53-1.79)	1.20 (1.12-1.28)			
COPD	1.60 (1.54-1.67)	1.89 (1.77-2.02)	1.41 (1.34-1.49)			

aHR = adjusted hazard ratio (adjusted for age, sex, diabetes, hypertension, CVD, asthma, and COPD), CI = confidence interval, CKD = chronic kidney disease, COPD = chronic obstructive pulmonary disease, CVD = cardiovascular disease.



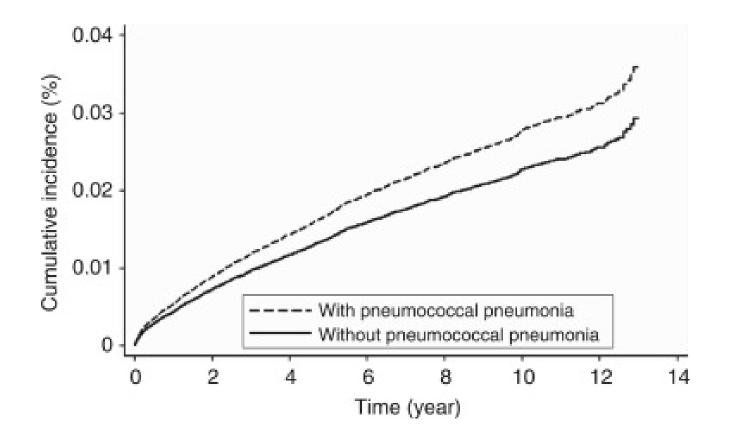
Pulmonary Infections in Hemodialysis Patients

The following factors might explain the increased susceptibility:

- Transient hypoxemia during the dialysis procedure
- Exposure to other patients and healthcare personnel
- Transportation to and from dialysis
- Weakened immune system
- Co-morbidities



Pneumococcal Pneumonia Infection Is Associated With End-Stage Kidney Disease in Adult Hospitalized Patients





Kidney International 2014 861023-1030DOI: (10.1038/ki.2014.79)

Pneumococcal Vaccines

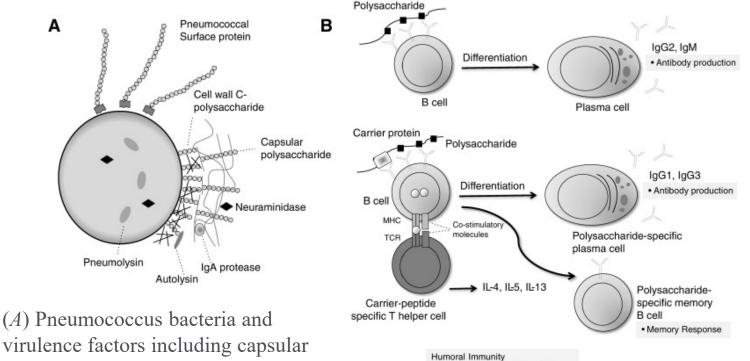
Until recently, the 13-valent pneumococcal conjugate vaccine (PCV13) and the 23valent pneumococcal polysaccharide vaccine (PPSV23) were recommended for U.S. adults. Recommendations vary by age and risk groups.

PCV13 (conjugate)	PPSV23 (polysaccharide)
Covers against 13 serotypes and uses modified	Consists of pneumococcal polysaccharide antigens
non-toxic mutant of the Diphtheria toxin as the	covering 23 serotypes and stimulates a <u>T-cell</u>
carrier protein . PCV stimulates a T-cell-dependent	independent, relatively transient antibody
longer-term response. Efficacious against	response due to lack of immunological memory.
nonbacteremic pneumonia.	

Pneumococcal polysaccharide (PPSV23) vaccination was <u>not</u> highly protective against pneumococcal pneumonia without bacteremia. Introduction of PCVs has resulted in major reductions of pneumococcal disease burden.

MMWR Morb Mortal Wkly Rep 2022;71:109–117; *Hum Vaccin Immunother. 2020 Nov 1; 16(11):2758-2772; Ann Am Thorac Soc. 2016 Jun; 13(6):933-44 ;* N Engl J Med 2003;348:1747-55;–e1497. *Clin Infect Dis* 2019; 69:34–49; <u>Clin Infect Dis.</u> 2021 Oct 1; 73(7): e1489;

Pneumococcal Bacteria and Vaccination Response



Clearance of extracellular pathogen

(*B*) Immune response to polysaccharide and proteinpolysaccharide conjugate vaccines.

MHC = major histocompatibility complex; TCR = T cell receptor.

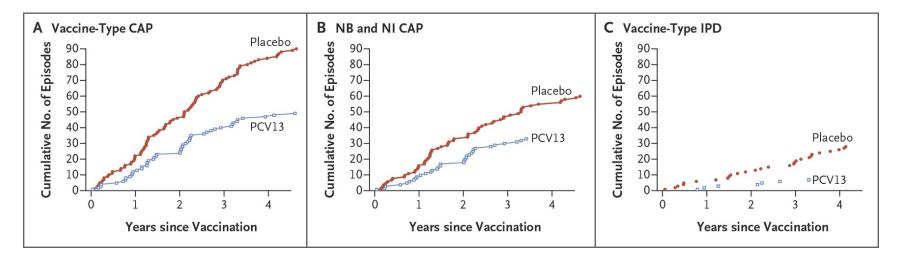
Nat Rev Immunol. 2009 Mar; 9(3):213-20; <u>Ann Am Thorac Soc.</u> 2016 Jun; 13(6): 933–944.

polysaccharide.

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PCV13: Post Hoc Analysis of the Cumulative Episodes of the Primary and Secondary Efficacy End Points

A randomized, double-blind, placebo-controlled trial involving 84,496 adults 65 years of age or older, evaluated the efficacy of 13-valent polysaccharide conjugate vaccine (PCV13) in preventing first episodes of vaccine-type strains of pneumococcal community-acquired pneumonia, nonbacteremic (NB) and noninvasive (NI) pneumococcal community-acquired pneumonia (CAP), and invasive pneumococcal disease (IPD).





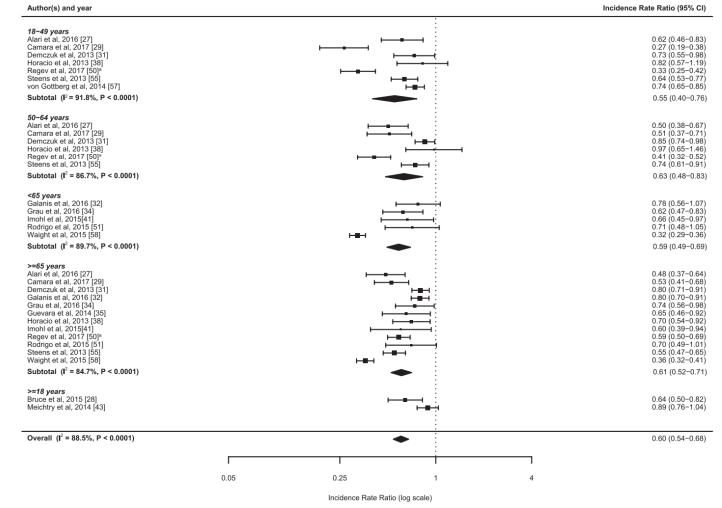
Risk of 7-Valent Polysaccharide Conjugate Vaccine (PCV7) Serotype-Invasive Pneumococcal Disease, Before And After The Introduction Of PCV7

Author(s) and year			Incidence Rate Ratio (95% C
18-49 years Alari et al, 2016 [27] Camara et al, 2017 [29] Demczuk et al, 2013 [31] Horacio et al, 2013 [38] Regev et al, 2017 [50] son Gottberg et al, 2014 [57] Steens et al, 2013 [55]			0.43 (0.27-0.6 0.39 (0.23-0.6 0.98 (0.85-1.1 1.06 (0.65-1.7 0.61 (0.41-0.9 0.69 (0.59-0.8 0.35 (0.21-0.5
Subtotal (I ² = 86.9%, P < 0.0001)			0.61 (0.45-0.8
50-64 years Alari et al. 2016 [27] Camara et al. 2017 [29] Demczuk et al. 2013 [31] Horacio et al. 2013 [38] Regev et al. 2017 [50] ^a Steens et al. 2013 [55]			0.49 (0.33-0.7 0.50 (0.29-0.8 0.83 (0.60-1.1 1.00 (0.59-16 0.34 (0.22-0.5 0.31 (0.20-0.4
Subtotal (I ² = 77.6%, P = 0.0003)			0.53 (0.36-0.7
<65 years Galanis et al, 2016 [32] Grau et al, 2016 [34] Imohl et al, 2015[41] Rodrigo et al, 2015 [51] Waight et al, 2015 [58]			0.36 (0.23-0.5 0.53 (0.36-0.7 0.40 (0.21-0.7 0.33 (0.12-0.8 0.16 (0.12-0.2
Subtotal (I ² = 87.5%, P < 0.0001)			0.49 (0.39-0.6
>=65 years Alari et al, 2016 [27] Camara et al, 2017 [29] Demczuk et al, 2013 [31] Galanis et al, 2013 [32] Grau et al, 2016 [34] Guevara et al, 2014 [35] Horacio et al, 2013 [38] Imohl et al, 2015[41] Regev et al, 2017 [50] Rodrigo et al, 2017 [50] Waight et al, 2015 [58]	Ē		$\begin{array}{c} 0.38 \ (0.26-0.5 \\ 0.49 \ (0.32-0.7 \\ 0.65 \ (0.50-0.8 \\ 0.32 \ (0.27-0.3 \\ 0.51 \ (0.34-0.7 \\ 0.70 \ (0.46-1.0 \\ 0.39 \ (0.29-0.7 \\ 0.70 \ (0.46-1.0 \\ 0.39 \ (0.37-0.6 \\ 0.27 \ (0.14-0.5 \\ 0.35 \ (0.26-0.4 \\ 0.11 \ (0.08-0.1 \ (0.08-0.1 \\ 0.11 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \ (0.08-0.1 \$
Subtotal (I ² = 87.7%, P < 0.0001)			0.39 (0.29-0.5
> =18 years Meichtry et al, 2014 [43]		⊢ ∎→1	0.67 (0.53-0.8
Overall (I ² = 88.6%, P < 0.0001)			0.45 (0.38-0.5
			(
	Γ		
	0.05	0.25 1	4

A pooled analysis of observational studies for all adults.

Clin Infect Dis. 2019 Jun 18;69(1):34-49.

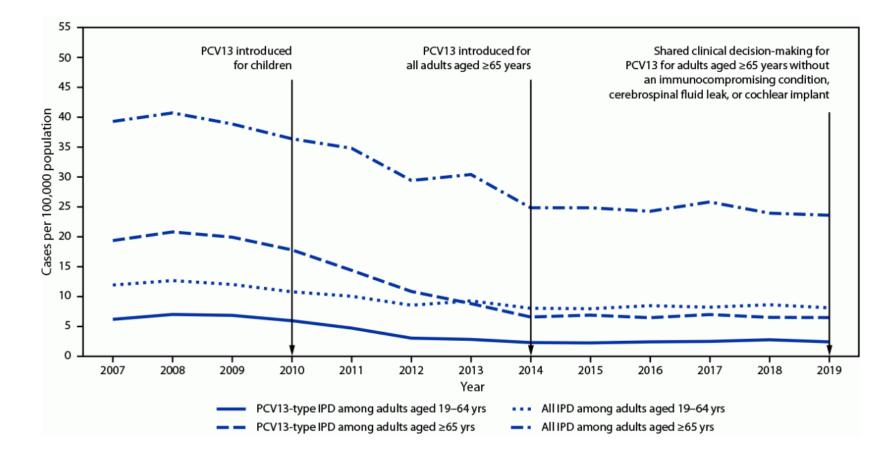
Risk of 13-Valent Pneumococcal Conjugate Vaccine (PCV13) Serotype-Invasive Pneumococcal Disease, Before and After the Introduction Of PCV13



A pooled analysis of observational studies for all adults.

Clin Infect Dis. 2019 Jun 18;69(1):34-49.

Incidence of All Invasive Pneumococcal Disease and 13-Valent Pneumococcal Conjugate Vaccine (PCV13) Timeline





Updated CDC Pneumococcal Vaccination Guide

NEW Vaccines

- 20-valent pneumococcal conjugate vaccine (PCV20 or PREVNAR 20), Pfizer/Wyeth Pharmaceuticals, LLC
 - Licensed for use in adults aged ≥ 18 years on June 8, 2021.
- 15-valent pneumococcal conjugate vaccine (PCV15 or PREVNAR 15), Merck
 - Licensed for use in adults aged ≥ 18 years on July 16, 2021.

On October 20, 2021, the Advisory Committee on Immunization Practices (ACIP) <u>simplified</u> pneumococcal vaccination recommendations across age and risk groups.

15-valent PCV (PCV15) or 20-valent PCV (PCV20) for PCV–naïve adults who are either aged \geq 65 years or aged 19–64 years with certain underlying conditions. When PCV15 is used, it should be followed by a dose of PPSV23, typically \geq 1 year later.

MMWR Morb Mortal Wkly Rep 2022;71:109–117; https://www.cdc.gov/vaccines/vpd/pneumo/hcp/who-when-to-vaccinate.html https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-29/01-Pneumococcal-Poehling-508.pdf https://www.fda.gov/vaccines-blood-biologics/vaccines/prevnar-20

Pneumococcal Vaccines And Target Serotypes

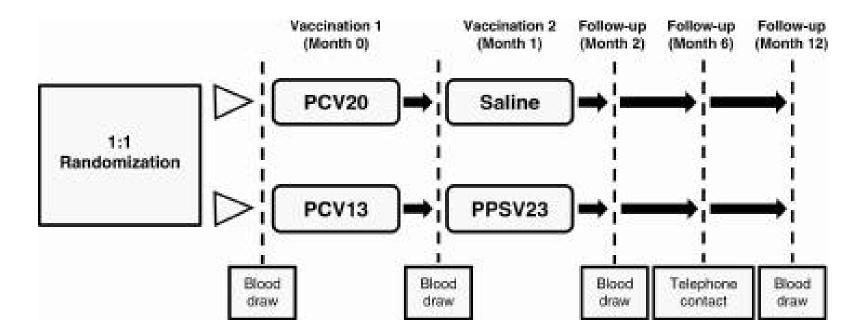
No vaccine is 100% effective at preventing disease, but all three pneumococcal vaccines — Prevnar 13, Prevnar 20, and Pneumovax 23 — are considered safe and effective for helping protect against pneumococcal disease.

PCV13 1 3 4 5 6A 6B 7F 9V 14 18C 19A 19F 23F PSV23 1 3 4 5 6B 7F 9V 14 18C 19A 19F 23F 8 10A 11A 12F 15B 22F 33	PCV20	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	8	10A	11A	12F	15B	22F	33F											
								Ļ					Ļ					Т														
	PCV/13	1	3	4	5	6Δ	6B	7F	9V	14	180	194	19F	23F																		
PPSV/23 1 3 4 5 6B 7E 9V 14 18C 19A 19E 23E 8 10A 11A 12E 15B 22E 33	FCVIS		J	4	5	UA	0D	1	34	14	100	IJA	191	ZJF																		
PPSV/23 1 3 4 5 6B 7E 9V 14 18C 19A 19E 23E 8 10A 11A 12E 15B 22E 33																	\bullet	\bullet	$\mathbf{+}$	\bullet	$\mathbf{\mathbf{\nabla}}$											
	PPSV23	1	3	4	5		6R	7F	٩V	14	180	194	19F	23F	8	10Δ	11 Δ	12F	15E	226	- 33	F	F 2	F 2 9N	E 2 9N 17E 2	E 2 9N 17E 2	E 2 9N 17E 20	E 2 9N 17E 20	E 2 9N 17E 20			

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/24-25/03-Pneumococcal-Watson.pdf



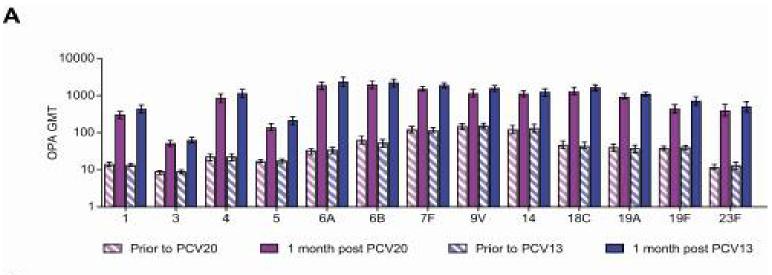
Safety, Tolerability, and Immunogenicity of PCV20 in Adults 60 to 64 Years of Age



202 participants in each arm



Immunogenicity of PCV20 vs PCV13 in Adults 60-64 Years of Age



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GMFRs in I	Functionality	Antibody	From B	laseline	to 1 Mor	nth After	Vaccin	ation						
Serotype		1	3	4	5	8A	68	7F	9V	14	18C	19A	19F	23F
SAME S	GMFR	21.2	6.0	37.8	8.3	58.6	29.6	12.2	7.7	8.5	26.8	23.3	11.8	33.6
PCV20	95% CI	16.96, 26.60	5.02	27.4. 52.10	6.55, 10.54	44.15, 77.73	22.56, 38.96	9.86, 15.22	6.15. 9.57	6.35, 11.26	19.96, 35.85	17.96, 30.19	8.93, 15.47	24.19, 46.54
10000	GMFR	33.5	7.1	51.0	11.6	68.6	38.8	15.8	10.1	9.6	35.2	30.9	18.4	39.8
PCV13	95% CI	25.77, 43.65	5.85. 8.60	36.04. 72.27	9.09, 14.85	49.49, 95.20	28.52. 52.66	12.57, 19.82	7.95, 12.74	7.20, 12.89	26.02, 47.50	23.70, 40.37	14.19, 23.87	28.85, 54.88

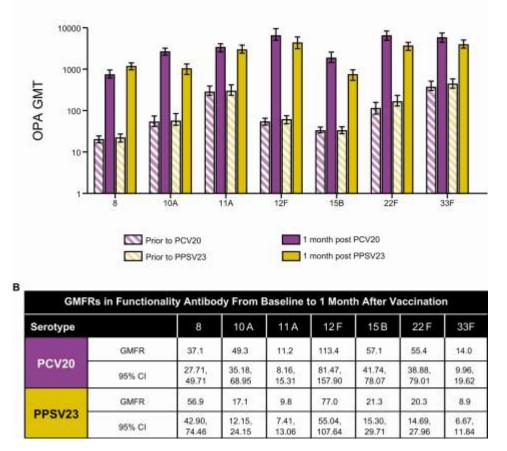
pneumococcal serotype-specific opsonophagocytic activity (OPA) geometric mean titers (GMTs)



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Clin Infect Dis. 2021 Oct 1; 73(7): e1489-e1497.

Immunogenicity of PCV20 vs PPSV23 in Adults 60-64 Years of Ade



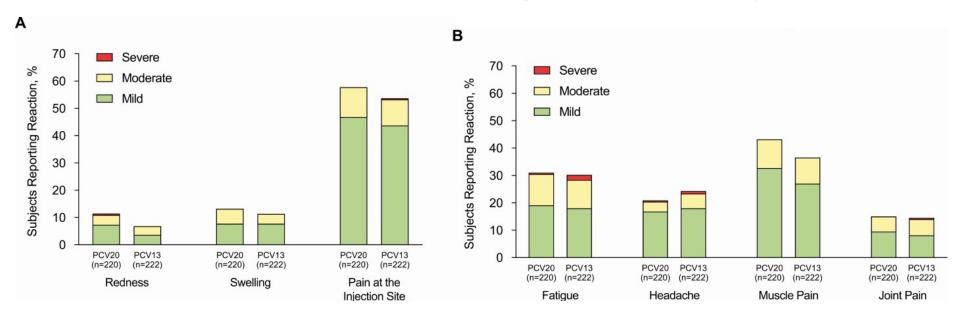
Pneumococcal serotype-specific opsonophagocytic activity (OPA) geometric mean titers (GMTs)



<u>Clin Infect Dis.</u> 2021 Oct 1; 73(7): e1489–e1497.

Prompted Reactogenicity Events

(A) local reactions within 10 days of vaccination



Clin Infect Dis. 2021 Oct 1; 73(7): e1489-e1497.

(B) systemic events within 7 days of vaccination.



Adults 18+ Years With Chronic Kidney Disease

Previous Pneumococcal Vaccine	NEXT Step
None	PCV 20 alone or PCV 15 plus PPSV23 (after 1 year)
PPSV23 only	PCV15 or PCV20 (at least 1 year after most recent PPSV
PCV13 +/- PPSV23	PPSV23 as previously recommended

For adults who have received PCV13 but have not completed their recommended pneumococcal vaccine series with PPSV23, one dose of PCV20 may be used <u>if PPSV23 is not available</u>. If PCV20 is used, their pneumococcal vaccinations are complete.

https://www.cdc.gov/vaccines/vpd/pneumo/hcp/who-when-to-vaccinate.html



Effectiveness and Safety of Pneumococcal Vaccines Used Alone or Combined With Influenza Vaccination in Dialysis Patients: A Systematic Review and Meta-Analysis

Five cohort studies and one quasi-randomized control trial enrolling 394,299 dialysis patients with high to moderate quality were included.

Compared with no vaccination, lower all-cause mortality was observed in those receiving both influenza and pneumococcal vaccines.

Vaccine (s)	Adjusted RR	95% CI
IV and PV	0.71	0.67-0.75
PV alone	0.86	0.78-0.94
IV alone	0.76	0.73-0.79

IV = Influenza vaccine; PV = Pneumococcal vaccine



Conversations About Vaccination



Embrace an attitude of empathy



Ask if they are open to discussion



Respond to questions about vaccines



https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html; *Pediatrics*. 2013;132:1037–46. <u>Hum Vaccin Immunother</u>. 2018; 14(1): 218–224.



Additional Resources



Centers for Disease Control and Prevention CDC 24/7: Saving Lives, Protecting People™



Vaccines & Immunizations

- <u>Centers for Disease Control & Prevention (CDC)</u>
- <u>American Society of Nephrology</u>
- National Kidney Foundation
- ESRD Networks
- State and Local Health Departments
- Numerous Publications
- ...and many more reliable sources (stay up-to-date!)



Q&A





Thank you! Connect with us...

Qsource

Quality Improvement Department: <u>qsource-qidept@qsource.org</u>

Telligen

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