



Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacy

COVID-19 Vaccines: A Review of Recent Updates

March 10, 2022

For Every Pharmacist. For All of Pharmacy.

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Sandra Leal, PharmD, MPH, FAPhA, CDCES
President
American Pharmacists Association

Host and Moderator

Today's Webinar

Discuss the **latest information** on COVID-19 vaccine recommendations, including the **effectiveness, protection, and timing** for booster and additional doses, as well as what to expect about the **Novavax COVID-19 vaccine**.



**Colonel (Ret.) John Grabenstein,
RPh, PhD, FAPhA**

Director, Scientific Communications
Immunize.org

President
Vaccine Dynamics

Speaker



Stephan Foster, PharmD, FAPhA

Former APhA Liaison to ACIP
CAPT (Ret.), U.S.P.H.S.

Speaker



Mitch Rothholz, RPh, MBA

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Dan Zlott, PharmD, BCOP

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Subject Matter Expert: Q&A



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Senior Director, Regulatory Policy
American Pharmacists Association

Subject Matter Expert: Q&A

Format for Today's Webinar

1:00pm: Introductions

1:05pm: Discussion with John Grabenstein & Steve Foster

1:30pm: Open Forum Discussion: Share Your Questions & Thoughts

1:50pm: Review of APhA's Ongoing Activities & What's Coming

Open Forum Ground Rules

- Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion.
- We will try to get to as many comments and questions as possible!
- Refer to the **Handout** in the GoToWebinar toolbar to access today's slides and links to resources.
- This webinar recording will be made available.

Discussion with John Grabenstein & Steve Foster

Discuss the latest information on COVID-19 vaccine recommendations, including the effectiveness, protection, and timing for booster and additional doses, as well as what to expect about the Novavax COVID-19 vaccine.

Novavax COVID-19 Vaccine Candidate

Synonyms	NVX-Cov2373, Nuvaxovid, Covovax (In India)
Type	Spike protein subunit with adjuvant
Adjuvant	Matrix-M – 40-nm particles based on saponin extracted from Quillaja saponaria + cholesterol + phospholipid
Production	Baculovirus/Sf9-cell expression system (analogous to Sanofi’s FluBlok influenza vaccine)
Dosage Form	Suspension, 5 mcg protein + 50 mcg Matrix-M per 0.5 mL
Clinical Trials of Efficacy	Phase 2: n=15,000, UK and South Africa, start Aug’20; Phase 3: n=29,960, US and México, start Dec’20, PREVENT-19
Regimen	Days 0 + 21, 0.5 mL, intramuscular
Age Cohort	18+ y/o
Status	Filing with FDA requesting EUA, 31 Jan 2022 WHO EUL Listing, 17 Dec 2021 Emergency Access: Canada, Australia, EU, Switzerland, UK, et cetera

Source: *Novavax Reports*

COVID-19 Vaccines: Product Descriptions

Vaccine Sponsor	Pfizer-BioNTech	ModernaTX USA	Janssen (J&J)	Novavax
Designator	BNT162b2, tozinameran, <i>Comirnaty</i>	mRNA-1273, elasomeran, <i>Spikevax</i>	Ad26.CoV2.S	NVX-CoV2373 <i>Nuvaxovid</i>
Vaccine Type	mRNA	mRNA	Adenovirus 26 vector	Protein subunit + adjuvant
Product Features	Lipid nanoparticle dispersion	Lipid nanoparticle dispersion	Replication-incompetent adenovirus type 26	Spike subunit + Matrix-M
Production Medium (origin)	Cell free (synthetic)	Cell free (synthetic)	PER.C6 (human)	Baculovirus/Sf9 cells (insect)
Dose	30 mcg in 0.3 mL	100 mcg in 0.5 mL	5×10^{10} viral particles in 0.5 mL	5 mcg in 0.5 mL + 50 mcg Matrix-M
Priming Regimen	IM: Days 0 + 21	IM: Days 0 + 28	IM: Day 0	IM: Days 0 + 21
Packaging	Frozen liquid. Multidose vial, no preservative	Frozen liquid. Multidose vial, no preservative	Liquid suspension. Multidose vial, no preservative	Liquid suspension. Likely multidose vial, Likely no preservative
Storage & Handling	Ultra-freeze. Limited refrigeration	Freeze. Limited refrigeration	Refrigerate	Refrigerate

Sources: FDA and company reports.

COVID-19 Vaccines: Clinical Trial Data

Vaccine Sponsor	Pfizer-BioNTech	ModernaTX USA	Janssen (J&J)	Novavax
Designator	BNT162b2	mRNA-1273	Ad26.CoV2.S	NVX-Cov2373
Vaccine Type	mRNA	mRNA	Adenovirus 26 vector	Protein subunit + adjuvant
Priming Regimen	Days 0 + 21	Days 0 + 28	Day 0	Days 0 + 21
# of Volunteers	12-55, 56-85: 40,277	18-64, 65+: 30,351	18-59, 60+: 43,783	18-64, 65+: 29,960
Efficacy, overall	95.0% (CI: 90, 98%), 7+ d after Dose 2	94.1% (CI: 89, 97%), 14+ d after Dose 2	66.9% (CI: 59, 73%), 14+ d after Dose 1	90.4% (CI: 83, 95%) 7+ d after Dose 2
Efficacy, stratified by age	56+ y: 94% (81, 99%) 16—55: 96% (89, 99%)	65+ y: 86% (61, 96%) 18—64: 96% (91, 98%)	60+ y: 76% (62, 86%) 18—59: 64% (54, 72%)	18—64: 92% (84, 95)
Additional analyses	Severe: 89% (20, 99%)	Severe: 100% (CI n/a)	Severe: 85% (54, 97%)	Moderate to severe: 100% (87, 100%)
				Dunkle. <i>NEJM</i> 2022:531
Safety Experience	100s of millions of doses	100s of millions of doses	10s of millions of doses	~ millions of doses

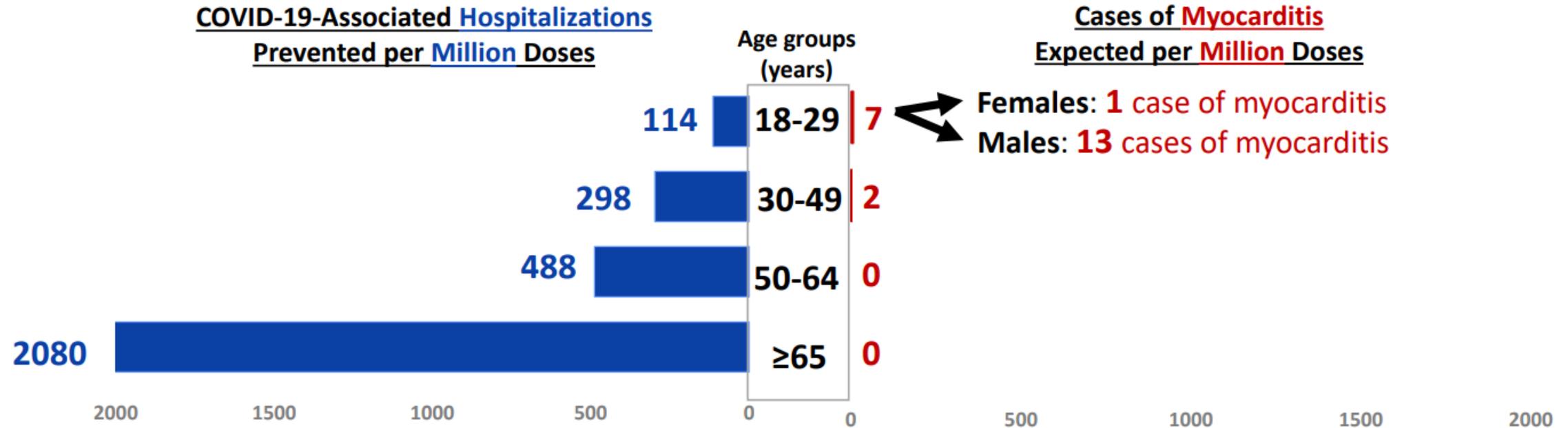
Benefits and risks after Pfizer-BioNTech COVID-19 booster dose

For every million doses of vaccine given

Scenario:

- VE for hospitalization averaged from four platforms¹
- Boost to 95% VE for hospitalization
- **Myocarditis risk equivalent to risk after 1st and 2nd dose averaged**

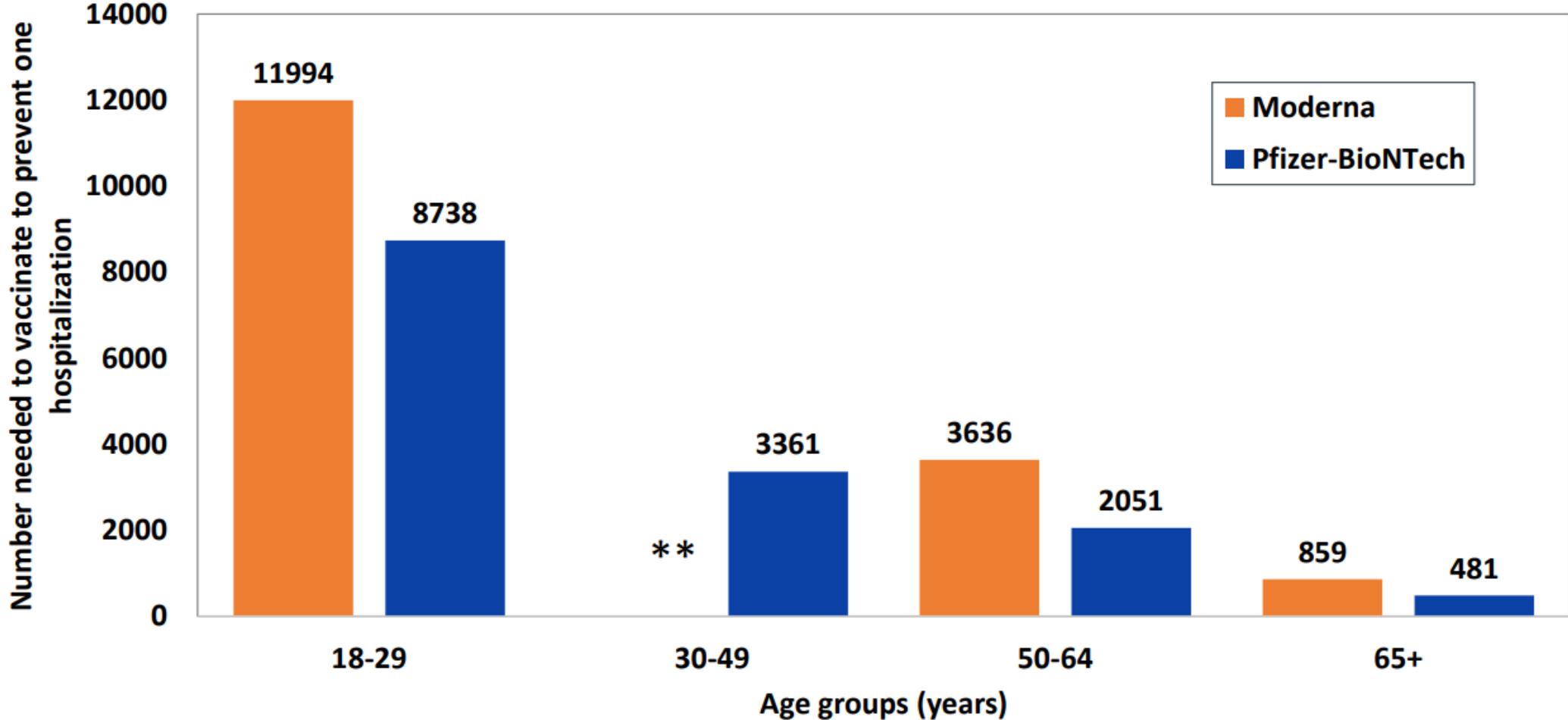
Age Group	VE for hospitalization
18 – 29 years	90.7%
30 – 49 years	90.2%
50 – 64 years	91.1%
≥65 years	85.1%



1. Scobie et al., COVID-NET, VISION, IVY Network

COVID-NET hospitalization rates from the week of August 21, 2021; Myocarditis rates from VAERS data through August 18, 2021

Number needed to vaccinate with booster dose to prevent one hospitalization over 6 months



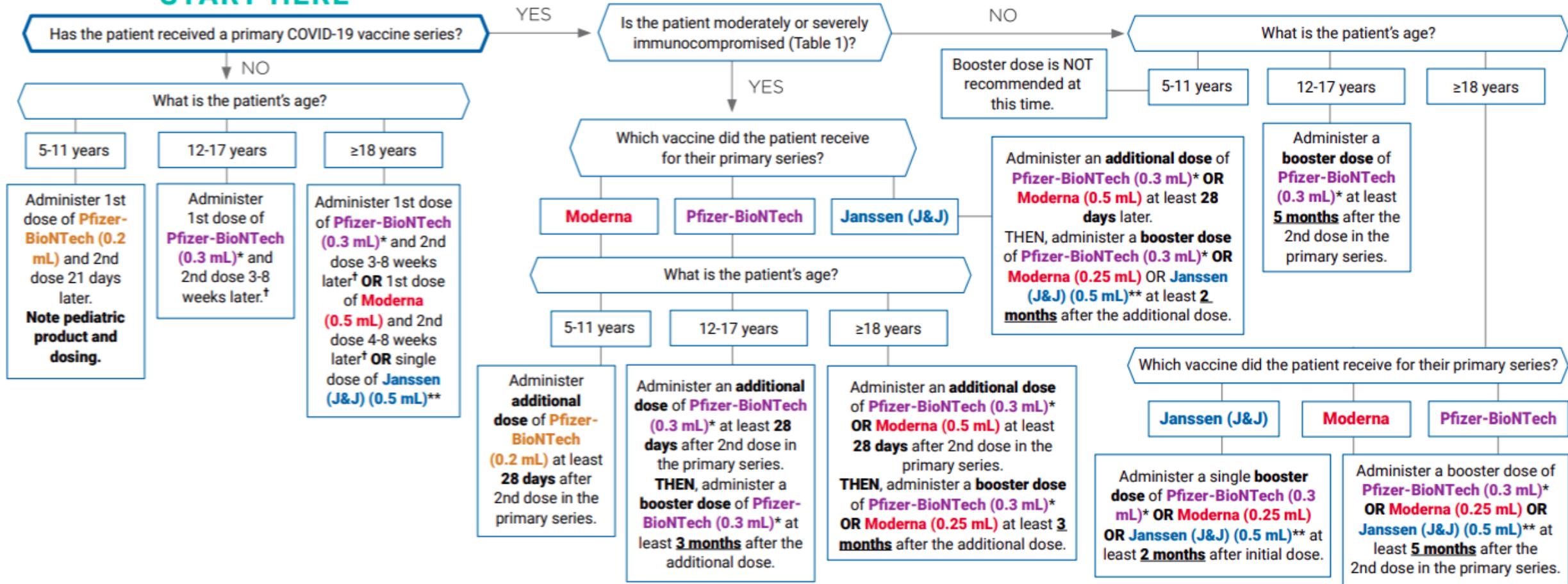
** Not estimable due to pre-booster efficacy estimated at >95%

COVID-19 Vaccines: Effectiveness and Boosters

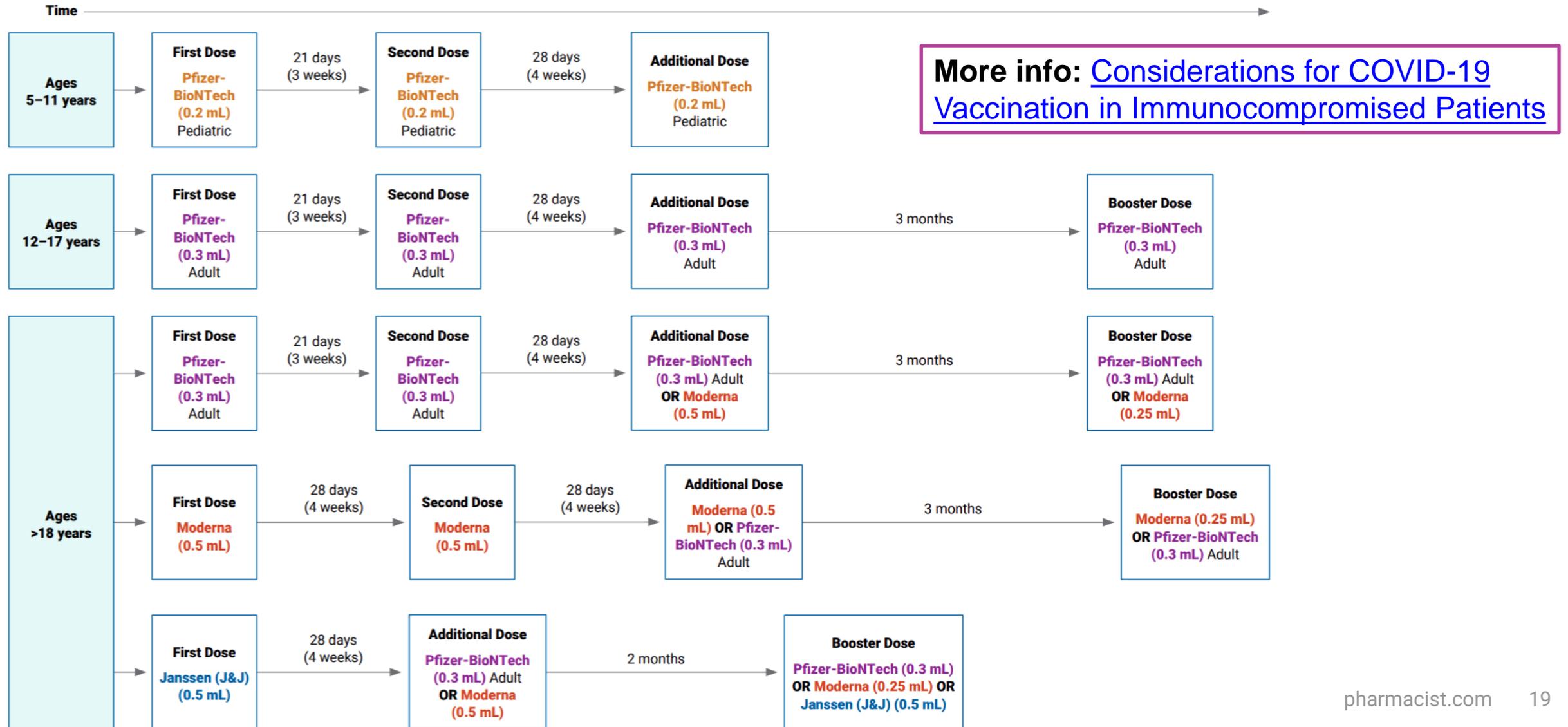
- CDC. Data Supporting Need for a Booster Shot. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>
- Oliver S. Updates to the Evidence to Recommendation Framework: Pfizer-BioNTech and Moderna COVID-19 vaccine booster doses. Presentation to ACIP, 19 Nov 2021. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf>

COVID-19 Vaccine Algorithm

START HERE



Age-specific COVID-19 vaccine recommendations for moderate and severely immunocompromised individuals



Updated COVID-19 Vaccine Timing for *Certain* Individuals

Primary series vaccine manufacturer	Age group	Number of doses in primary series	Number of booster doses	Interval between 1 st and 2 nd dose *	Interval between primary series and booster dose
Pfizer-BioNTech	5–11 years	2	NA	3 weeks	N/A
Pfizer-BioNTech	≥12 years	2	1	3-8 weeks**	≥5 months
Moderna	≥18 years	2	1	4-8 weeks**	≥5 months
Janssen	≥18 years	1	1	NA	≥2 months

*For the vaccination schedule for people who are moderately or severely immunocompromised, see [Table 3](#).

An **8-week interval may be optimal for people ages 12 years through 64 years, and especially for males ages 12 through 39 years, who are not moderately or severely immunocompromised. A **shorter interval** (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second dose remains the recommended interval for: people who are moderately or severely immunocompromised; adults ages 65 years and older; and others who need early protection due to increased concern about community transmission or risk of severe disease.

Table 1. Immunization schedule for persons 5 years of age and older

Recipient Age	Product ^{††}	Persons Who ARE NOT Moderately or Severely Immunocompromised		Persons Who ARE Moderately or Severely Immunocompromised	
		Primary Series ^{†§}	Booster Dose ^{†¶}	Primary Series ^{†§}	Booster Dose ^{†¶}
Type: mRNA vaccine					
5–11 years	Pfizer-BioNTech Ages: 5–11 years Orange cap	2 doses. Separate: Dose 1 and 2 by at least 3 weeks ^{**}	Not recommended	3 doses. Separate: Dose 1 and 2 by at least 3 weeks. Dose 2 and 3 by at least 4 weeks.	Not recommended
12–17 years	Pfizer-BioNTech Ages: 12 years and older Gray cap or Purple cap	2 doses. Separate: Dose 1 and 2 by at least 3 - 8 weeks. ^{**}	At least 5 months after Dose 2	3 doses. Separate: Dose 1 and 2 by at least 3 weeks. Dose 2 and 3 by at least 4 weeks.	At least 12 weeks after Dose 3
18 years and older	Pfizer-BioNTech Ages: 12 years and older Gray cap or Purple cap	2 doses. Separate: Dose 1 and 2 by at least 3 - 8 weeks. ^{**}	At least 5 months after Dose 2	3 doses. Separate: Dose 1 and 2 by at least 3 weeks. Dose 2 and 3 by at least 4 weeks.	At least 12 weeks after Dose 3
	Moderna	2 doses. Separate: Dose 1 and 2 by at least 4 - 8 weeks. ^{**}	At least 5 months after Dose 2	3 doses. Separate: Dose 1 and 2 by at least 4 weeks. Dose 2 and 3 by at least 4 weeks.	At least 12 weeks after Dose 3
Recipient Age	Product ^{††}	Persons Who ARE NOT Moderately or Severely Immunocompromised		Persons Who ARE Moderately or Severely Immunocompromised	
		Primary Series ^{†§}	Booster Dose ^{†¶}	Primary Series ^{†§}	Booster Dose ^{†¶}
Type: Viral vector vaccine					
18 years and older	Janssen ^{††}	1 dose	At least 8 weeks after Dose 1	2 doses. Separate: Dose 1 and 2 by at least 28 days ^{††} . Dose 2 MUST be a mRNA vaccine	At least 8 weeks after Dose 2

More info: [COVID-19 Immunization Schedule for Ages 5 Years and Older](#)

Discussion with **John Grabenstein & Steve Foster**

Discuss the latest information on COVID-19 vaccine recommendations, including the effectiveness, protection, and timing for booster and additional doses, as well as what to expect about the Novavax COVID-19 vaccine.

Recommended Adult Immunization Schedule for ages 19 years or older

UNITED STATES
2022

How to use the adult immunization schedule

- 1** Determine recommended vaccinations by age (**Table 1**)
- 2** Assess need for additional recommended vaccinations by medical condition or other indication (**Table 2**)
- 3** Review vaccine types, frequencies, intervals, and considerations for special situations (**Notes**)
- 4** Review contraindications and precautions for vaccine types (**Appendix**)

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American College of Physicians (www.acponline.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), and American Academy of Physician Associates (www.aapa.org), and Society for Healthcare Epidemiology of America (www.shea-online.org).

Vaccines in the Adult Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
<i>Haemophilus influenzae</i> type b vaccine	Hib	ActHIB® Hiberix® PedvaxHIB®
Hepatitis A vaccine	HepA	Havrix® Vaqta®
Hepatitis A and hepatitis B vaccine	HepA-HepB	Twinrix®
Hepatitis B vaccine	HepB	Engerix-B® Recombivax HB® HepLisav-B®
Human papillomavirus vaccine	HPV	Gardasil 9®
Influenza vaccine (inactivated)	IIV4	Many brands
Influenza vaccine (live, attenuated)	LAIV4	FluMist® Quadrivalent
Influenza vaccine (recombinant)	RIV4	Flublok® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R II®
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-D MenACWY-CRM MenACWY-TT	Menactra® Menveo® MenQuadfi®
Meningococcal serogroup B vaccine	MenB-4C MenB-FHbp	Bexsero® Trumenba®
Pneumococcal 15-valent conjugate vaccine	PCV15	Vaxneuvance™
Pneumococcal 20-valent conjugate vaccine	PCV20	Prevnar 20™
Pneumococcal 23-valent polysaccharide vaccine	PPSV23	Pneumovax 23®
Tetanus and diphtheria toxoids	Td	Tenivac® Tdvax™
Tetanus and diphtheria toxoids and acellular pertussis vaccine	Tdap	Adacel® Boostrix®
Varicella vaccine	VAR	Varivax®
Zoster vaccine, recombinant	RZV	Shingrix

*Administer recommended vaccines if vaccination history is incomplete or unknown. Do not restart or add doses to vaccine series if there are extended intervals between doses. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to the local or state health department
- Clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

Injury claims

All vaccines included in the adult immunization schedule except pneumococcal 23-valent polysaccharide (PPSV23) and zoster (RZV) vaccines are covered by the Vaccine Injury Compensation Program. Information on how to file a vaccine injury claim is available at www.hrsa.gov/vaccinecompensation.

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.



Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html.

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual
- Travel vaccine recommendations: www.cdc.gov/travel
- Recommended Child and Adolescent Immunization Schedule, United States, 2022: www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
- ACIP Shared Clinical Decision-Making Recommendations: www.cdc.gov/vaccines/acip/acip-scdm-faqs.html



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Scan QR code
for access to
online schedule



CS310021-A

[MMWR - February 18, 2022
Adult Immunization Schedule](#)

Open Forum Discussion: Share Your Questions & Thoughts

Review of APhA's Ongoing Activities & What's Coming

Pharmacist Groups Call On Biden Administration To Remove Limits On Prescribing COVID Treatments

Modification To EUAs For Oral Antivirals Needed To Achieve Potential Of “Test To Treat” Initiative

WASHINGTON, D.C—Today, 14 pharmacy organizations urged the Biden Administration to remove barriers preventing pharmacists from ordering oral antivirals and expand patient access to the “Test to Treat” initiative announced last week during the State of the Union.

In a [letter](#) sent to President Biden, the groups called for the removal of a limitation placed on the emergency use authorization (EUA) of COVID-19 antivirals by the Food and Drug Administration (FDA). The limitation prevents pharmacists from ordering the medications. The groups stressed that limitations in the EUAs for COVID oral antivirals mean that patients in rural and underserved communities will be less likely to benefit from the test to treat approach.

“Despite your statement during the State of the Union, Americans who test positive at a pharmacy will only be able to access time-sensitive oral antivirals, on the spot, from a limited number of pharmacies with in-house access to non-pharmacist prescribers, primarily in metropolitan areas,” the groups noted.

Many states license pharmacists to order medications, either independently or in collaboration with a physician. In September, the Department of Health and Human Services authorized pharmacists in all 50 states to order oral treatments for COVID-19. The EUAs issued in December by the FDA specifically prevent pharmacists from ordering oral antivirals.

Pharmacists are clinically trained medication experts and are the primary health care professionals responsible for ensuring safe medication use, including identifying and mitigating drug interactions associated with oral antiviral medications for COVID-19.

Signatories

- American Society of Health-System Pharmacists (ASHP)
- American Association of Colleges of Pharmacy (AACP)
- American College of Apothecaries (ACA)
- American College of Clinical Pharmacy (ACCP)
- Academy of Managed Care Pharmacy (AMCP)
- American Pharmacists Association (APhA)
- American Society of Consultant Pharmacists (ASCP)
- College of Psychiatric and Neurologic Pharmacists (CPNP)
- Hematology/Oncology Pharmacy Association (HOPA)
- National Alliance of State Pharmacy Associations (NASPA)
- National Association of Boards of Pharmacy (NABP)
- National Community Pharmacists Association (NCPA)
- National Pharmaceutical Association (NPhA)
- Society of Infectious Diseases Pharmacists (SIDP)

<https://www.pharmacist.com/APhA-Press-Releases/pharmacist-groups-call-on-biden-administration-to-remove-limits-on-prescribing-covid-treatments>

New design!

<https://pharmacist.com/Practice/COVID-19/COVID-19-Vaccines>



Current Guidance & Recommendations



**mRNA Vaccines
(Pfizer & Moderna)**



**Viral Vector Vaccines
(Janssen)**



**Protein-Based Vaccines
(Novavax)**



Adolescents & Children



**Immunocompromised
Individuals**



Documentation & Billing



Storage & Administration



Authority



**Implementation
Strategies**



Vaccine Confidence

A_{Ph}A2022 is here!

For the first time since 2019, we're meeting IN PERSON. A_{Ph}A2022 is bringing all of pharmacy together to celebrate our industry's accomplishments and connect with peers across the country to share knowledge and experiences.

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Reimagine.

San Antonio, TX | March 18-21

We're stronger together. For the first time since 2019, we are bringing pharmacists and pharmacy professionals from every practice setting gather to celebrate the industry's accomplishments, provide opportunities for continued growth, and connect with

Keynote Speakers

"This year's A_{Ph}A2022 keynotes will focus on better care for patients and patient care through innovation. We are delighted to have two compelling and engaging general sessions with exciting speakers at A_{Ph}A2022," said Scott Knoer, MS, PharmD, FASHP, A_{Ph}A executive vice president and CEO. "It's wonderful to be back in person, and these two general sessions will energize and engage A_{Ph}A2022 participants."

[VIEW KEYNOTE SPEAKERS >](#)

11 Education Tracks

There is something for everyone with 11 educational and interactive session tracks to choose from. Get access to the latest industry trends, treatment updates, and professional practice guidelines.



[VIEW EDUCATION >](#)

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Networking sessions, lunches, and coffee breaks are all available – and everyone is invited!



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Open Forum Webinars

Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacy are open forum webinars conducted every other Thursday from 1:00 pm–2:00 pm ET. CE will be available during the webinar that takes place on the second Thursday of each month. Each webinar is moderated by APhA President Sandra Leal.

COVID-19 and Other Immunizations: A Review of Recent Updates (February 24)

Discuss recent updates to recommendations for COVID-19 vaccines and other adult vaccines, such as influenza. ([Video](#) – [Slides](#))

COVID-19 Antivirals: Updates and Practical Considerations (February 10)

Discuss pharmacy approaches to dispensing COVID-19 oral antivirals, including key considerations for implementation, patient education, documentation, and billing. ([Video](#) – [Slides](#))

COVID-19 Test and Treat: How to Manage Patients Based on their Results (January 13)

This webinar will review how to manage COVID-19 vaccine options and patient expectations in busy pharmacies and continue to confident recommendations. ([Video](#) – [Slides](#))

Access this webinar and our many others on our [Open Forum Webinars](#) webpage or directly by visiting our [Youtube](#) channel!



Addressing the COVID-19 Crisis: A Webinar Series for Pharmacists

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