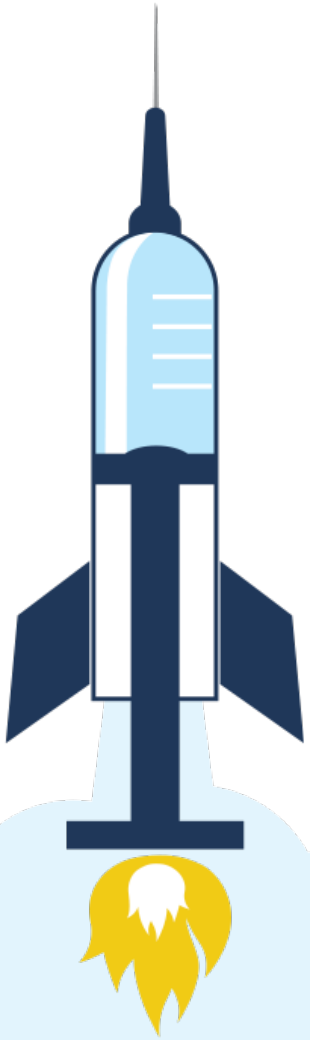
BOOST Education and Office Hours

Karen L. Smith, MD, FAAFP

April 6, 2023



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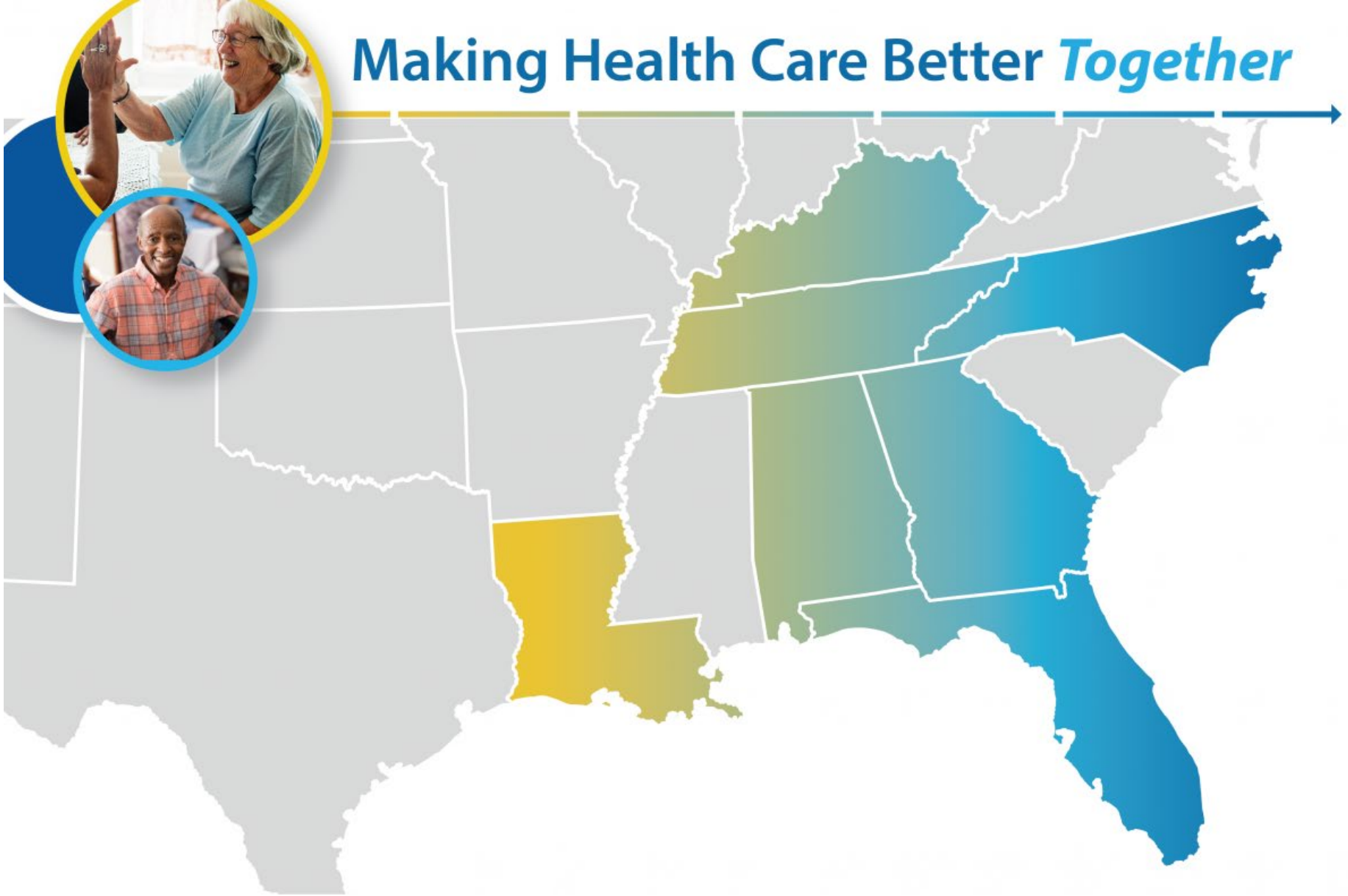

About Alliant Health Solutions

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Karen L. Smith, MD, FAAFP

FAMILY PHYSICIAN

Dr. Karen L. Smith is a family physician in Raeford, North Carolina. She has successfully implemented population health strategies with telehealth as part of her delivery of care since 2003, providing acute, chronic, and preventive services from birth to the end of life. She also became involved with the North Carolina Academy of Family Physicians and the North Carolina Medical Society. She is actively engaged with the American Academy of Family Physicians and is an AAFP Board of Directors member. In addition, she serves on the North Carolina Medical Society Board of Directors and is a state delegate to the American Medical Association. She served the state of North Carolina with 13 years of service to the Division of Medical Assistance Advisory Board and the North Carolina Institute of Medicine.

Dr. Smith is actively engaged with the Old North State Medical Society, exemplified by her team's community response during the Covid public health emergency. She worked with the Alliant Quality Improvement Organization to engage and assist other doctors with the Merit Incentive Payment System as part of the Medicare Access and CHIP Reauthorization Act of 2015. She accepted the appointments to connect with the national advisory groups for the Office of the National Coordinator as HIT Vanguard Fellow and CMS Quality Payment Program Physician Champion.

Recently, her work with the American Medical Association as Physician Champion for the Diabetes Prevention Program allowed her to provide viable workflow options for practices to create accessible, quality, efficient, and cost-wise strategies.
Dr. Smith is active in health care transformation as a medical director for the Aledade physician-led accountable care organization and Vaxcare North Carolina. Dr. Smith was named North Carolina Family Physician of the Year in 2016 and American Academy of Family Physicians of the Year in 2017.

Contact: https://karensmithmd.com/

Objectives

- Understand the need for COVID boosters to reduce disease and hospitalization
- Understand the need for taking bivalent boosters regardless of previous vaccination status to ensure better outcomes with the current state of COVID-19 variants
- How to address the fears of patients and families against the COVID-19 vaccination

“My 96-year-old Mom has COVID-19”

A longtime patient and friend presented to the office in late January with the unsettling news of her 96-year-old mother’s hospitalization due to complications of COVID-19 Pneumonia. Six months prior, her mother was physically, mentally, and emotionally engaged until an injury warranted rehabilitation services at the local skilled nursing facility. Both she and her mother were fully COVID-19 vaccinated with receipt of the primary series. Her mother did not receive the Bivalent Booster vaccine before hospital admission for management of her unexpected injury. Despite respiratory and contact preventive measures, the daughter noted altered mental status, fever, and poor intake, prompting emergency room evaluation. She was started on an outpatient regimen for COVID-19 with a suboptimal response, then intensive care intervention, where she transitioned just shy of her 97th birthday.

Terms for Vaccine Effectiveness

"Vaccine effectiveness is a measure of how well vaccination protects people against health outcomes such as infection, symptomatic illness, hospitalization, and death. Vaccine effectiveness is generally measured by comparing the frequency of health outcomes in vaccinated and unvaccinated people."

"**Absolute vaccine** effectiveness is a term that can be applied when the study compares vaccinated people to unvaccinated people."

Last Updated Mar. 23, 2023

Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

Vaccine Effectiveness

- Host-related factors, such as age, presence of underlying medical conditions (e.g., diabetes, cancer), and history of prior infection
- Pathogen-related factors, such as the virus variant(s) circulating
- Vaccine-related factors, such as type of vaccine and time since vaccination

Last Updated Mar. 23, 2023

Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

COVID-19 Vaccine Effectiveness

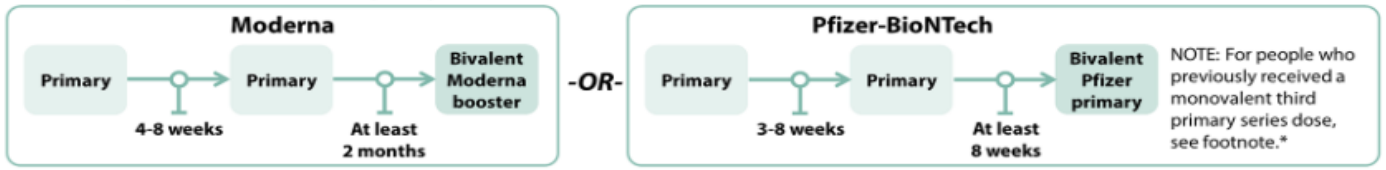
CDC studies published from October 2022-February 2023 on COVID-19 vaccine effectiveness among adults found:

- Vaccine effectiveness data show that bivalent COVID-19 vaccines add protection against illness with Omicron XBB/XBB.1.5-related variants among people who previously received 2, 3, or 4 doses of the monovalent COVID-19 vaccines.
  - CDC found that the bivalent COVID-19 vaccine provides added protection against symptomatic infection with Omicron XBB/XBB.1.5-related variants in people who had previously received two to four doses of the monovalent COVID-19 vaccine.
- The bivalent booster cuts the risk of having to visit an emergency department, urgent care facility, or hospital due to COVID-19 by half or more for most people.
- Bivalent boosters provide protection against severe COVID-19 resulting in hospitalizations.
  - People should also consider other prevention strategies, such as wearing masks in indoor public spaces and improving ventilation (e.g., opening windows) when respiratory virus circulation is high, especially in areas where COVID-19 Community Levels are high.
- Vaccine effectiveness of 2 or 3 doses of the monovalent COVID-19 vaccine mRNA vaccines against COVID-19-associated hospitalization decreased with time since vaccination during periods of both BA.1/BA.2 and BA.4/BA.5 circulation.
  - The overall vaccine effectiveness of three doses of an mRNA COVID-19 vaccine against COVID-19–associated hospitalization was 69% during the BA.1/BA.2 period; it was 31% during the BA.4/BA.5 period.
  - Additionally, protection against hospitalization in the first four months after the third dose of vaccine during the BA.4/BA.5 period was 60% and decreased to 29% after four months.
- Protection among people with weakened immune systems during Omicron predominance was moderate after a 3-dose primary series or booster dose.
  - Adding a third dose to the primary series for adults with immunocompromising conditions increased vaccine effectiveness against hospitalization from 40% to 67% during the BA.1 period. However, during the more recent Omicron BA.2/BA.2.12.1 and BA.4/BA.5 periods, the third dose was only 32% effective against hospitalization after 90 days or more. This number increased to 43% after a fourth dose.
  - To further boost protection, consider early use of antivirals and nonpharmaceutical interventions (e.g., well-fitting, high-quality masks or respirators).

Centers for Disease Control and Prevention. COVID Data Tracker. Atlanta, GA: US Department of Health and Human Services, CDC; 2023, April 03. https://covid.cdc.gov/covid-data-tracker

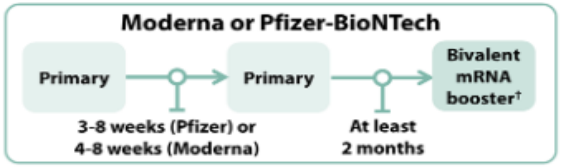
COVID-19 Vaccination Schedule Infographic for People who are NOT Moderately or Severely Immunocompromised

People ages 6 months through 4 years

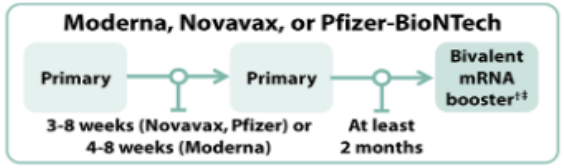


People age 5 years

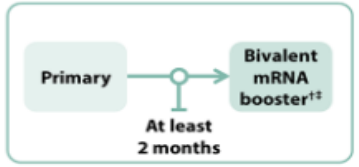
People ages 6 through 11 years



People ages 12 years and older



People ages 18 years and older who previously received Janssen primary series dose§



* People ages 6 months–4 years who previously completed a 3-dose monovalent Pfizer-BioNTech primary series are authorized to receive 1 bivalent Pfizer-BioNTech booster dose at least 2 months after completion of the monovalent primary series.

† For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

‡ A monovalent Novavax booster dose may be used in limited situations in people ages 18 years and older who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered **at least 6 months** after completion of a primary series.

§ Janssen COVID-19 Vaccine should only be used in certain limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a

COVID-19 Vaccine

Interim COVID-19 Immunization Schedule for Persons 6 Months of Age and Older

Table 2. **Immunization Schedule for Persons 18 Years of Age**

Type	Age	For Most People		Those Who **ARE** Moderately or Severely Immunocompromised	
		Doses	Interval Between Doses*	Doses	Interval Between Doses
Moderna	**18 years and older**	**Primary series†: MONOVALENT VACCINE** (Red capped vial with a blue-bordered label)			
		Dose 1 to 2	At least 4–8 weeks‡	Dose 1 to 2	At least 4 weeks
				Dose 2 to 3	At least 4 weeks
		Booster dose§: BIVALENT VACCINE (Blue capped vial with a gray-bordered label)			
		Dose 2 to 3	At least 8 weeks (2 months)	Dose 3 to 4	At least 8 weeks (2 months)
Pfizer-BioNTech	**18 years and older**	**Primary series†: MONOVALENT VACCINE** (Gray capped vial with a gray-bordered label)			
		Dose 1 to 2	At least 3-8 weeks‡	Dose 1 to 2	At least 3 weeks
				Dose 2 to 3	At least 4 weeks
		Booster dose§: BIVALENT VACCINE (Gray capped vial with a gray-bordered label)			
		Dose 2 to 3	At least 8 weeks (2 months)	Dose 3 to 4	At least 8 weeks (2 months)
Novavax	**18 years and older**	**Primary series†: MONOVALENT VACCINE**			
		Dose 1 to 2	At least 3–8 weeks‡	Dose 1 to 2	At least 3 weeks
		Booster dose§: BIVALENT VACCINE Moderna or Pfizer-BioNTech bivalent COVID-19 vaccine should be used for the booster dose.			
		Dose 2 to 3	At least 8 weeks (2 months)	Dose 2 to 3	At least 8 weeks (2 months)
Janssen	**18 years and older**	**Primary series: MONOVALENT VACCINE** Janssen COVID-19 vaccine is authorized for use in certain limited situations due to safety considerations.¶			
		Booster dose§: BIVALENT mRNA VACCINE Moderna or Pfizer-BioNTech bivalent COVID-19 vaccine should be used for the booster dose.			
		Administer a single booster dose at least 8 weeks (2 months) after the previous dose.			

* Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).
† Complete the primary series with same product. If the vaccine product previously administered cannot be determined, is no longer available or contraindicated, any age-appropriate monovalent COVID-19 vaccine may be administered at least 28 days after the first dose to complete the primary series. Moderna or Pfizer-BioNTech bivalent COVID-19 vaccine can be administered for the booster dose, regardless of the primary series product.
‡ An 8-week interval between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it may reduce the small risk of myocarditis and pericarditis associated with these vaccines. A shorter interval (4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.
§ A single Novavax booster dose (instead of a bivalent mRNA booster dose) may be given to persons 18 years of age or older who have not received a previous booster dose in **limited situations**. These situations are 1. an mRNA vaccine is contraindicated, or not available or 2. the recipient is unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose. Administer the booster dose at least 6 months after the last primary series dose.
¶ For guidance on use of Janssen vaccine and retrospective record review, scheduling and administration see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A

CDC Resources

CDC COVID-19 vaccine clinical training and materials

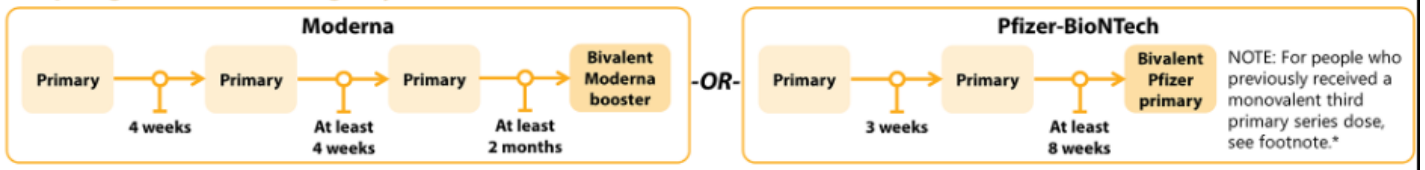
CDC Interim Clinical Considerations for the Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

CDC Vaccine administration clinical materials

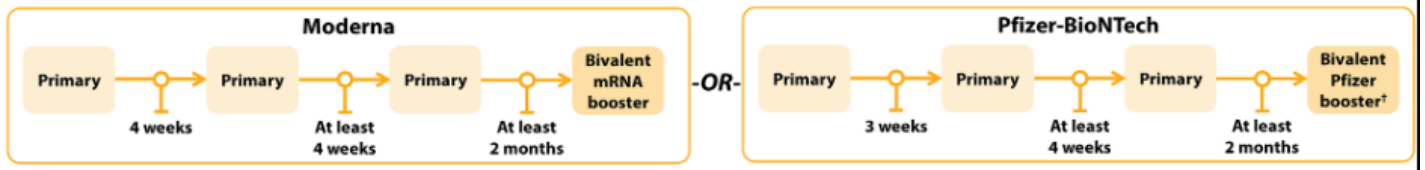
CDC Vaccine Storage and Handling Toolkit

COVID-19 Vaccination Schedule Infographic for People who ARE Moderately or Severely Immunocompromised

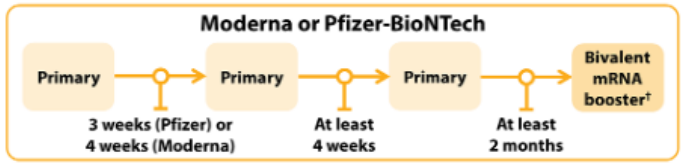
People ages 6 months through 4 years



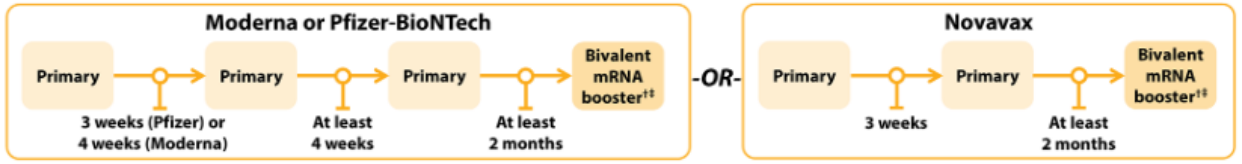
People age 5 years



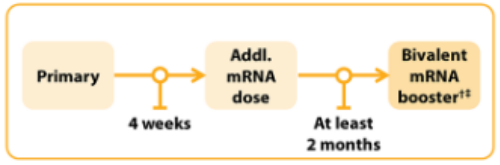
People ages 6 through 11 years



People ages 12 years and older



People ages 18 years and older who previously received Janssen primary series dose§



* People ages 6 months–4 years who previously completed a 3-dose monovalent Pfizer-BioNTech primary series are authorized to receive 1 bivalent Pfizer-BioNTech booster dose at least 2 months after completion of the monovalent primary series.
† For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.
‡ A monovalent Novavax booster dose may be used in limited situations in people ages 18 years and older who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered **at least 6 months** after completion of a primary series.
§ Janssen COVID-19 Vaccine should only be used in certain limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a

COVID-19 Vaccine

Interim COVID-19 Immunization Schedule for Persons 6 Months of Age and Older

Table 3. **COVID-19 Vaccine Products Summary**

Type	Product	Age Indications**	Diluent	Use For:††	Dose/Injection Amount
mRNA vaccine	**MONOVALENT Moderna:** Blue capped vial with magenta-bordered label	6 months through 5 years	NONE	Any dose in the primary series	25 µg/ 0.25 mL
	BIVALENT Moderna: Dark pink capped vial with yellow-bordered label	6 months through 5 years	NONE	Booster dose	10 µg/ 0.2 mL
	MONOVALENT Moderna: Blue capped vial with purple-bordered label	6 through 11 years	NONE	Any dose in the primary series	50 µg/0.5 mL
	BIVALENT Moderna: Blue capped vial with gray-bordered label	6 through 11 years	NONE	Booster dose	25 µg/0.25 mL
	MONOVALENT Moderna: Red capped vial with blue- bordered label	12 years and older	NONE	Any dose in the primary series	100 µg/ 0.5 mL
	BIVALENT Moderna: Blue capped vial with gray-bordered label	12 years and older	NONE	Booster dose	50 µg/0.5 mL
	MONOVALENT Pfizer-BioNTech: Maroon capped vial with maroon-bordered label	6 months through 4 years	2.2 mL 0.9% sodium chloride (normal saline, preservative-free)	Primary series Doses 1 and 2	3 µg/0.2 mL
	BIVALENT Pfizer-BioNTech: Maroon capped vial with maroon-bordered label	6 months through 4 years	2.2 mL 0.9% sodium chloride (normal saline, preservative-free)	Primary series Dose 3	3 µg/0.2 mL
	MONOVALENT Pfizer-BioNTech: Orange capped vial with orange-bordered label	5 through 11 years	1.3 mL 0.9% sodium chloride (normal saline, preservative-free)	Any dose in the primary series	10 µg/0.2 mL
	BIVALENT PFIZER-BIONTECH Orange capped vial with a orange-bordered label	5 through 11 years	1.3 mL 0.9% sodium chloride (normal saline, preservative-free)	Booster dose	10 µg/0.2 mL
	MONOVALENT Pfizer-BioNTech: Gray capped vial with a gray- bordered label	12 years and older	NONE	Any dose in the primary series	30 µg/0.3 mL
	BIVALENT Pfizer-BioNTech: Gray capped vial with gray-bordered label Single-dose Vials and Multidose Vials	12 years and older	NONE	Booster dose	30 µg/0.3 mL
Protein sub unit vaccine	**MONOVALENTNovavax:** Royal blue capped vial	12 years and older	NONE	Any dose in the primary series or as a single booster dose, in **limited situations**, for persons 18 years of age or older	5 µg rS and 50 µg of Matrix-M™ adjuvant/0.5 mL
Viral vector vaccine	**MONOVALENT Janssen:** Blue capped vial	18 years and older	NONE	Janssen COVID-19 vaccine is authorized for use in certain **limited situations** due to safety considerations‡‡	5x1010 viral particles/0.5 mL

** Administer the appropriate vaccine product based on the recipient's age and the vaccine product's indications.
†† COVID-19 vaccines may be administered on the same day as other routinely recommended vaccines, including influenza vaccine.
‡‡ For guidance on use of Janssen vaccine and retrospective record review, scheduling and administration see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A

12/08/2022 CS321629-AV 5

CDC COVID-19 Vaccination Schedule

Ending of the Public Health Emergency?

Based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service (PHS) Act, to expire at the end of the day on May 11, 2023

Feb 9, 2023

FDA's EUAs for COVID-19 products (including tests, vaccines, and treatments) will not be affected. The ending of the COVID-19 PHE will not affect the FDA's ability to authorize various products, including tests, treatments, or vaccines for emergency use. Existing EUAs for COVID-19 products will remain in effect under Section 564 of the Federal Food, Drug, and Cosmetic Act, and the agency may continue to issue new EUAs going forward when the criteria for issuance are met.

Content created by Assistant Secretary for Public Affairs (ASPA)

Content last reviewed February 22, 2023

Masks May Disappear While Collaboration Remains

Teamwork Will Continue

Community Trust for COVID-19 Boosters

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Thank you!

Questions?

Nursing Home and Partnership for Community Health:
CMS 12th SOW GOALS

OPIOID UTILIZATION AND MISUSE

Promote opioid best practices

•

Reduce opioid adverse drug events in all settings

PATIENT SAFETY

Reduce hospitalizations due to c. diff

•

Reduce adverse drug events

•

Reduce facility acquired infections

CHRONIC DISEASE SELF-MANAGEMENT

Increase instances of adequately diagnosed and controlled hypertension

•

Increase use of cardiac rehabilitation programs

•

Reduce instances of uncontrolled diabetes

•

Identify patients at high-risk for kidney disease and improve outcomes

CARE COORDINATION

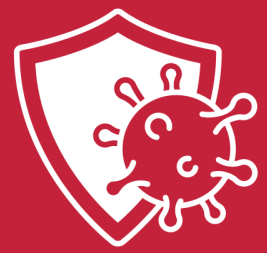
Convene community coalitions

•

Reduce avoidable readmissions, admissions to hospitals and preventable emergency department visits

•

Identify and promote optimal care for super utilizers



COVID-19

Support nursing homes by establishing a safe visitor policy and cohort plan

•

Provide virtual events to support infection control and prevention

•

Support nursing homes and community coalitions with emergency preparedness plans

IMMUNIZATION

Increase influenza, pneumococcal, and COVID-19 vaccination rates

TRAINING

Encourage completion of infection control and prevention trainings by front line clinical and management staff

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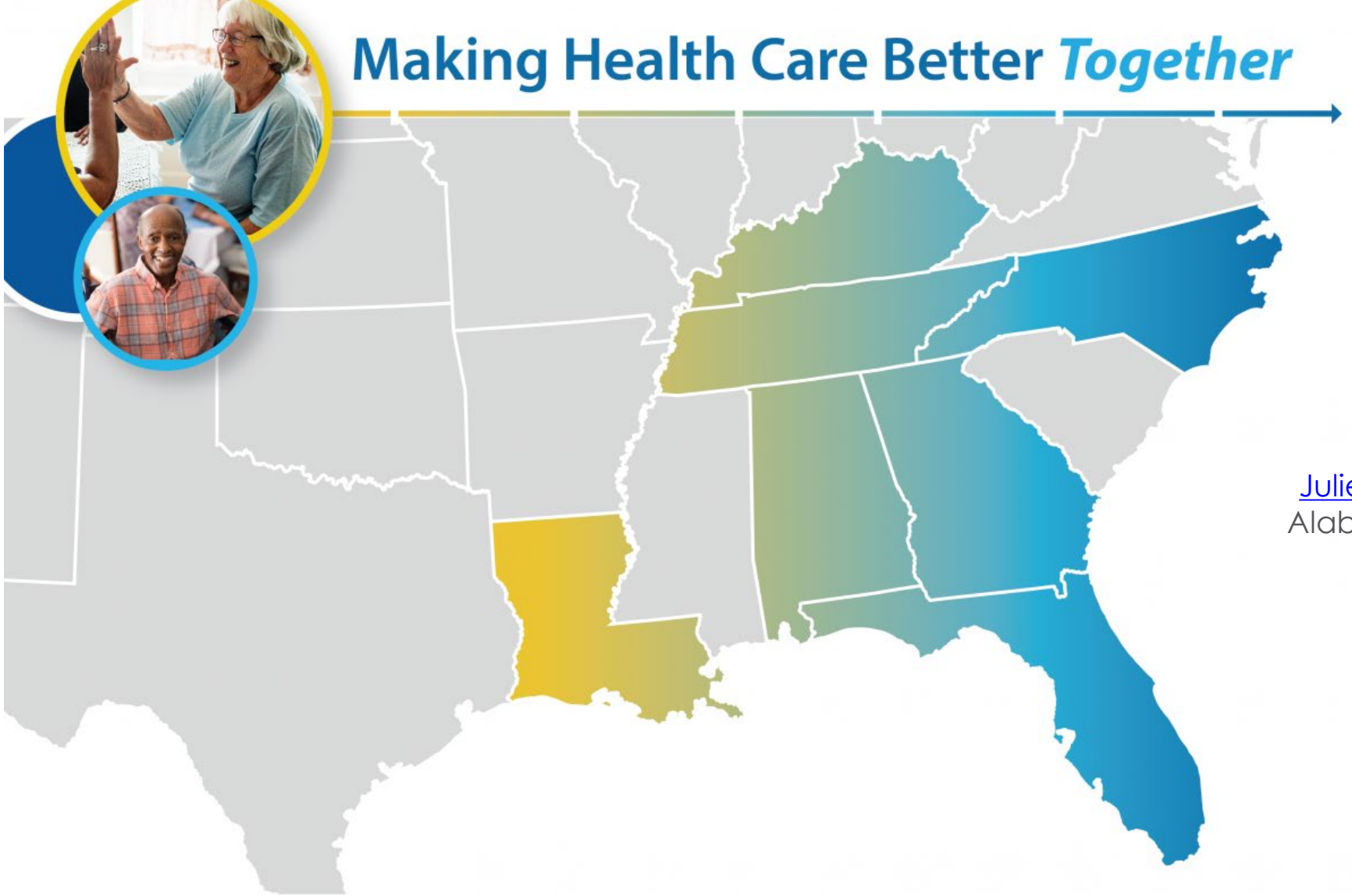

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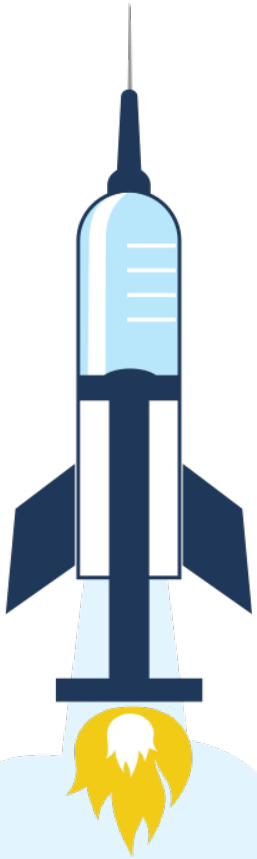

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