



September 2022

# NovaVax and Bivalent COVID-19 Booster Vaccine Update

Virginia Academy of Family Physicians (VAFP)

In Partnership with the Virginia Department of Health (VDH)

# Introduction

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*VAFP & VDH encourage that **all Virginia health professionals vaccinate all eligible patients**, which includes providing the COVID-19 vaccine via routine patient care.*

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**David S. Gregory, M.D., FAFP**

President, Virginia Academy of Family Physicians

# Speakers

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**Chelsea Sprouse, PharmD, BCACP**

Adult Vaccine Coordinator  
Virginia Department of Health



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**Chris Ghaemmaghmi, MD, FACEP**

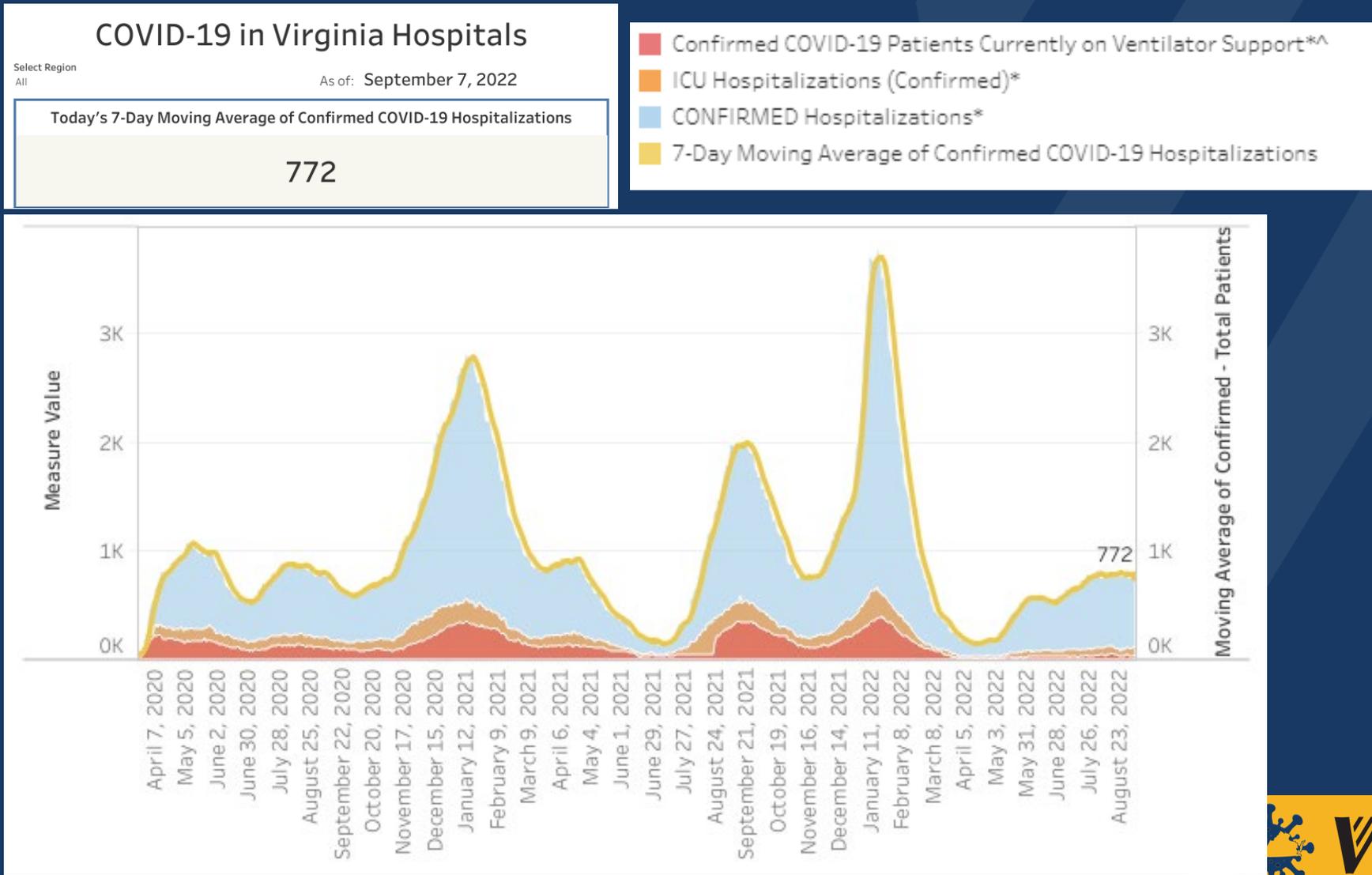
Physician Specialist  
Virginia Department of Health  
Professor of Emergency and Internal Medicine  
UVA School of Medicine

# Objectives

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1. Provide current overview of COVID-19 in Virginia: Epidemiology and Prevention
2. Identify NovaVax and bivalent booster COVID-19 vaccine candidates
3. Differentiate between COVID-19 booster immunization schedules for individual patients
4. Review administration, storage and handling of NovaVax and bivalent booster COVID-19 vaccines

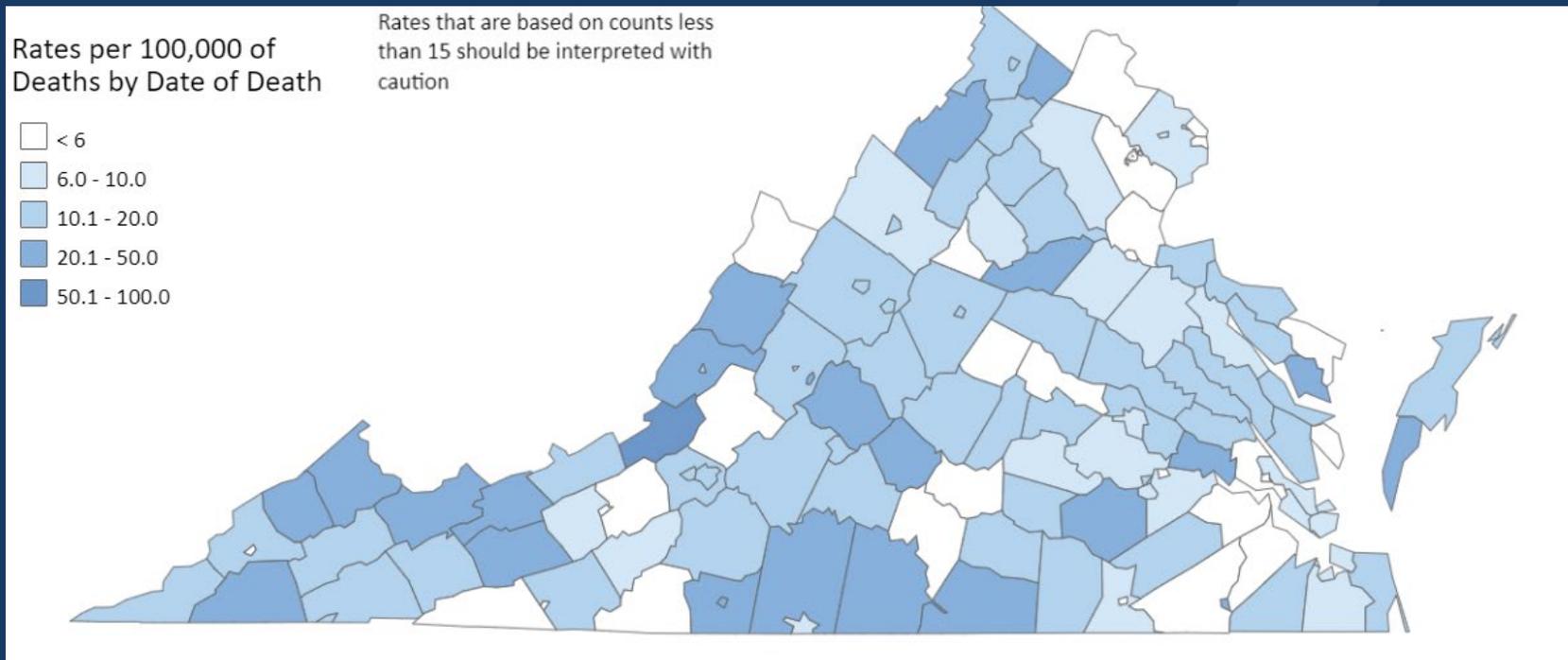
# COVID-19 Hospitalizations in VA - VHHA



# COVID-19 Deaths in Virginia - Last 13-weeks

Number of New Cases Reported	1,826	Number of New Deaths Reported	30
7-Day Average Number of Daily New Cases Reported	2,017.7	7-Day Average Number of Daily New Deaths Reported:	16
Total Cases*	2,054,230	Total Deaths	21,529

Last updated September 7, 2022



# COVID-19 Vaccinations in Virginia

**Total Doses Administered - 16,612,456**

People Vaccinated with at Least One Dose*	% of the Population Vaccinated with at Least One Dose	People Fully Vaccinated^	% of the Population Fully Vaccinated	Booster/ Additional Doses Administered**
<b>7,092,452</b>	<b>82.6%</b>	<b>6,224,662</b>	<b>72.5%</b>	<b>3,707,295</b>
<small>% of the Adult (18+) Population Vaccinated with at Least One Dose</small> <b>92.5%</b>		<small>% of the Adult (18+) Population Fully Vaccinated</small> <b>81.3%</b>		

Last updated September 7, 2022

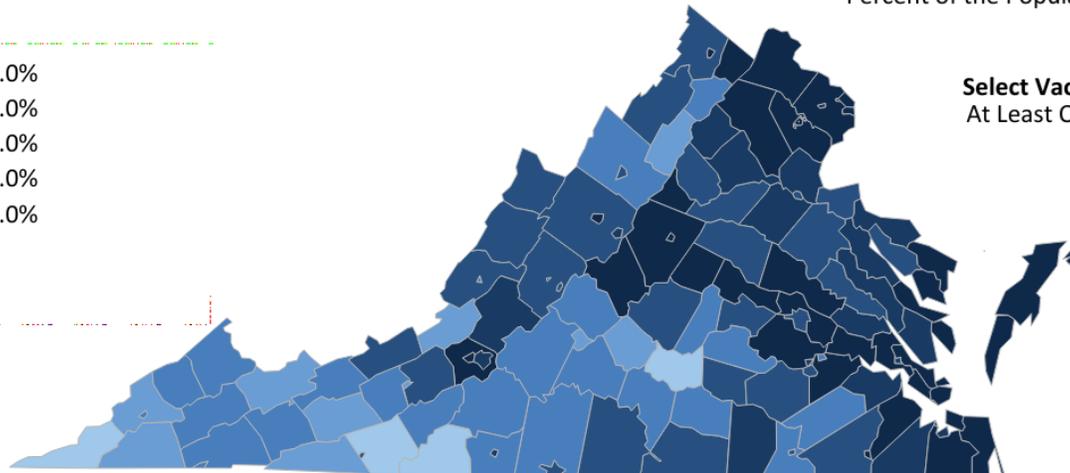
## People Vaccinated by Locality of Residence and Vaccination Status - Percent of the Population

Percent of the Population with At Least One Dose

- 45.1% - 50.0%
- 50.1% - 55.0%
- 55.1% - 60.0%
- 60.1% - 65.0%
- 65.1% - 70.0%
- 70.1+%

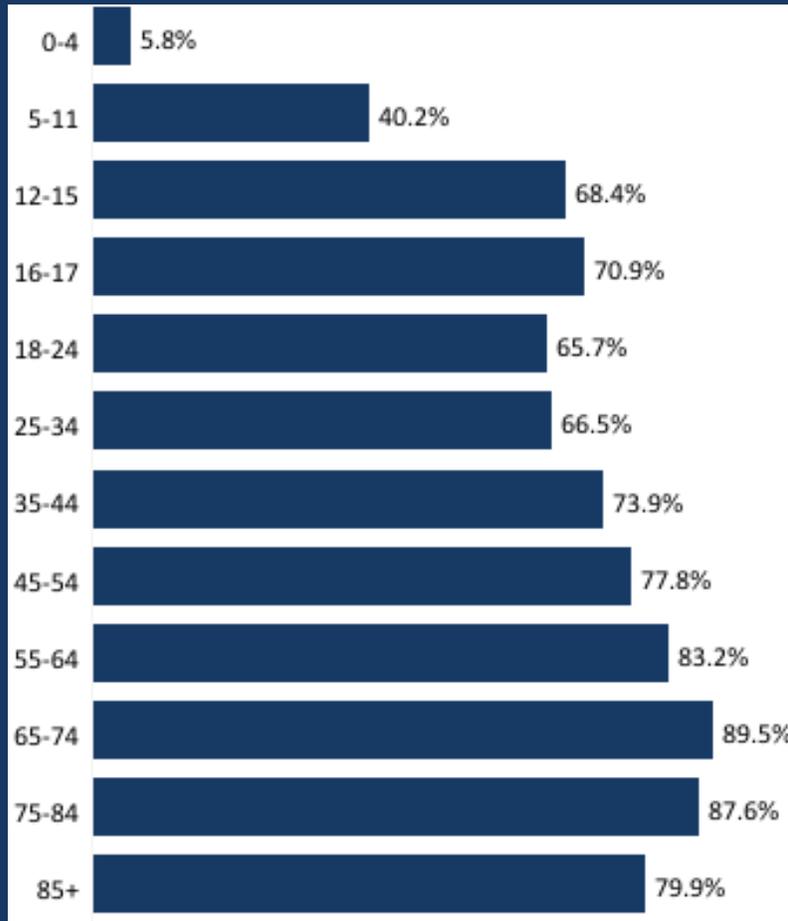
Select Counts, Rates, or Percents  
Percent of the Population

Select Vaccination Status  
At Least One Dose

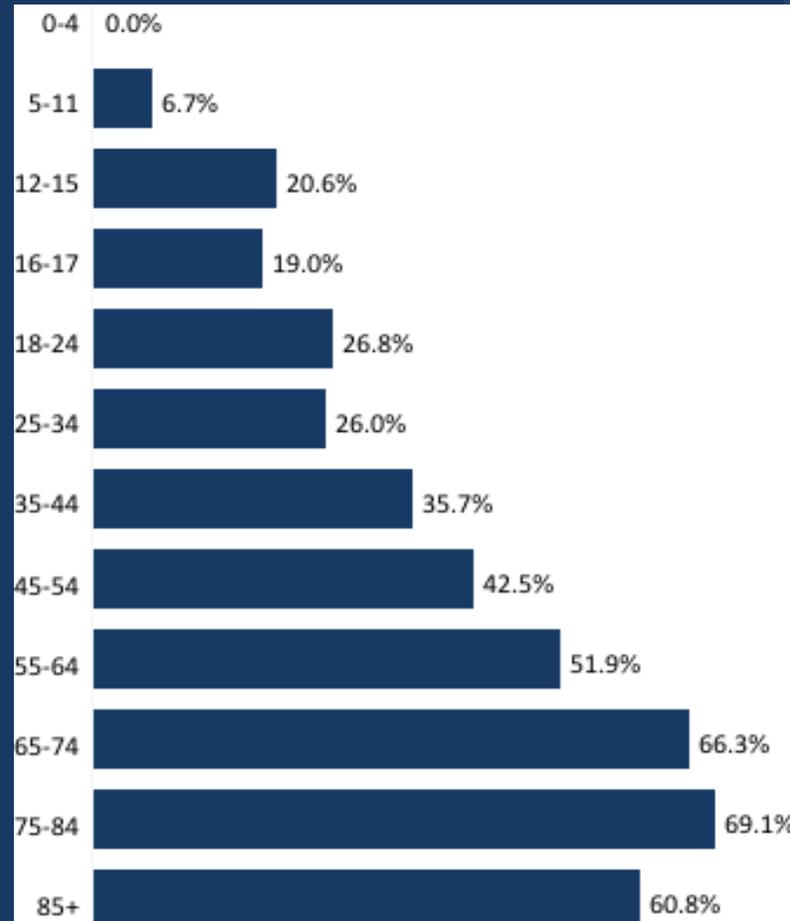


# COVID-19 Vaccination Status by Age Group

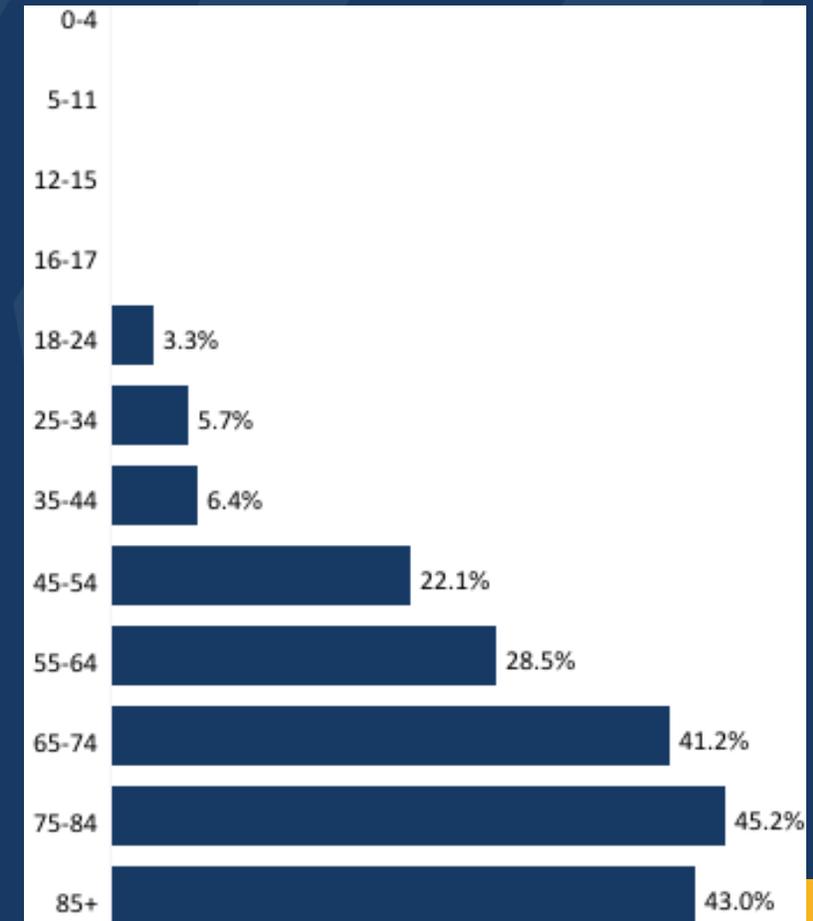
## Fully Vaccinated



## First Booster



## Second Booster



# Overview of Newly Available Vaccines

	<b>NovaVax</b>	<b>Moderna Bivalent Booster</b>	<b>Pfizer-BioNTech Bivalent Booster</b>
<b>Eligibility</b>	ages 12 and older	ages 18 and older	ages 12 and older
<b>Series</b>	2 dose primary series (not authorized for boosters)	Single booster dose	Single booster dose
<b>Interval</b>	Second dose should be administered 3-8 weeks after the first dose	Single booster dose administered at least 2 months after: <ul style="list-style-type: none"> <li>● completion of primary series OR</li> <li>● receipt of most recent monovalent booster dose</li> </ul>	
<b>Vial Color</b>	Royal Blue Cap	Dark blue vial cap with gray label border	Gray vial cap with gray label border
<b>Dose Volume</b>	0.5 mL	0.5 mL	0.3 mL

# **COVID-19 Vaccines: Novavax**

# Novavax Background Information

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Novavax is authorized by FDA and **recommended** by CDC for a **2-dose primary series for 12 years of age and up**. Since Novavax is a monovalent vaccine, it can only be used for the primary series in unvaccinated individuals and cannot be used for booster doses.

- NovaVax offers a **new opportunity for primary series vaccinations**
- NovaVax may be an **opportunity** for **individuals hesitant about the new mRNA technology** and those **who prefer traditional vaccines**
- Novavax technology:
  - [Protein subunit vaccine](#) **contains spike proteins** of the SARS-CoV-2 virus
  - Also **contains an adjuvant** that helps the immune system respond to the spike protein
  - After learning how to respond to the spike protein, the immune system will be able to respond quickly to the actual virus spike protein and protect against COVID-19

# Novavax has been used in 40 countries

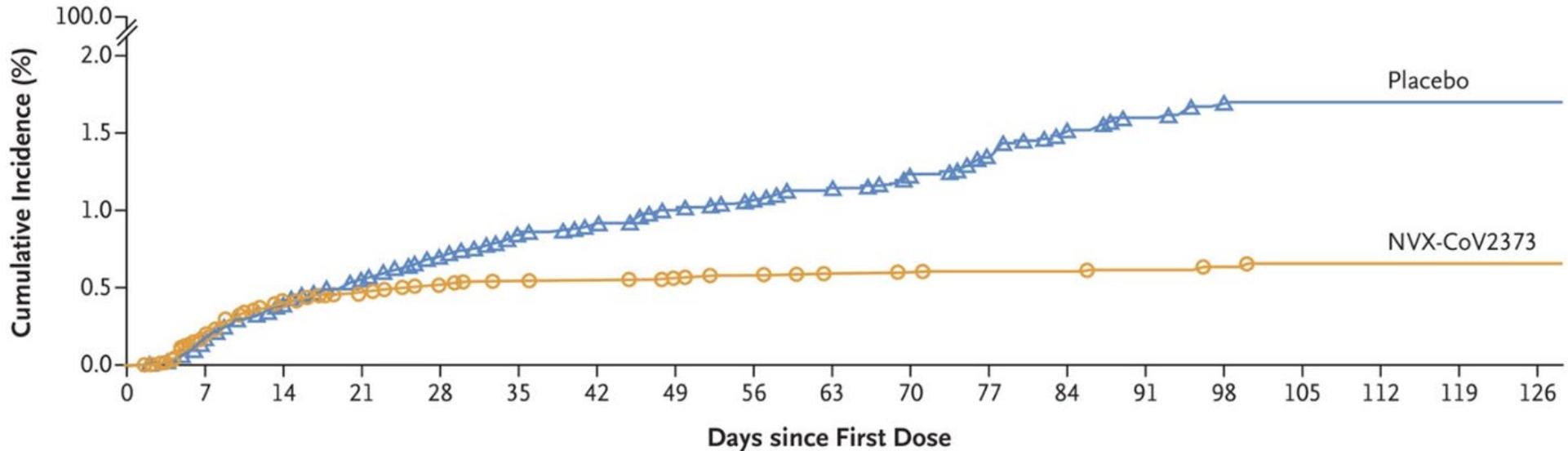
- Novavax COVID-19 vaccine is **already being used to prevent COVID-19 in 40 other countries**
- In **November 2021**, countries around the world, starting with Indonesia and the Philippines, began granting authorizations for the vaccine.

Other countries who have approved the vaccine include:

Australia	Denmark	Ireland	New Zealand	Slovenia
Austria	Estonia	Italy	Norway	Spain
Belgium	Finland	Latvia	Poland	Sweden
Bulgaria	France	Liechtenstein	Portugal	Switzerland
Canada	Germany	Lithuania	Republic of Korea	Taiwan
Croatia	Greece	Luxembourg	Romania	United Kingdom of Great Britain
Cyprus	Hungary	Malta	Singapore	Northern Ireland
Czechia	Iceland	Netherlands	Slovakia	

# Efficacy and Safety of NVX-CoV2373 in Adults in the United States and Mexico

**A Analysis with Surveillance Starting at First Dose (Full Analysis Population)**



**No. at Risk**

Placebo	9,868	9,797	9,715	9,648	9,416	9,187	8,823	8,500	8,167	7,881	7,578	6,821	5,750	4,625	3,575	2,675	1,529	649	385
NVX-CoV2373	19,714	19,581	19,457	19,352	18,996	18,749	18,379	18,104	17,668	17,347	16,972	15,504	13,148	10,689	8,110	6,002	3,195	1,152	561

**No. of Events**

Placebo	0	16	38	54	68	82	88	96	101	107	114	122	133	137	141	141	141	141	141
NVX-CoV2373	0	39	81	91	101	106	107	110	112	115	116	117	117	118	120	121	121	121	121

# Efficacy and Safety of NVX-CoV2373 in Adults in the United States and Mexico

Analysis Group	NVX-CoV2373	Placebo	Vaccine Efficacy (95% CI)
<b>Per-protocol efficacy analysis population</b>	14/17, 312 (0.1)	63/8140 (0.8)	<b>90.4</b> (82.9-94.6)
<b>Full Analysis population</b>	16/18, 584 (0.1)	69/9144 (0.8)	<b>89.3</b> (81.6-93.8)
<b>Age of 18-64 yr</b>	12/15, 264 (0.1)	61/7194 (0.8)	<b>91.5</b> (84.2-95.4)
<b>Male</b>	5/9050 (0.1)	23/4131 (0.6)	<b>90.9</b> (76.0-96.5)
<b>Female</b>	9/8262 (0.1)	40/4009 (1.0)	<b>90.0</b> (79.3-95.1)
<b>White</b>	12/13,140 (0.1)	48/6184 (0.8)	<b>89.4</b> (80.0-94.4)
<b>Black</b>	0/1893 (0.0)	7/905 (0.8)	<b>100.0</b> (67.9-100.0)
<b>Hispanic or Latino</b>	8/3733 (0.2)	11/1751 (0.6)	<b>67.3</b> (18.7-86.8)
<b>Country; United States</b>	14/16,294 (0.1)	62/7638 (0.8)	<b>90.4</b> (82.8-94.6)
<b>Has Coexisting Conditions</b>	7/8109 (0.1)	34/3910 (0.9)	<b>90.8</b> (79.2-95.9)
<b>No Coexisting Conditions</b>	7/9203 (0.1)	29/4230 (0.7)	<b>89.9</b> (77.1-95.6)
<b>At high risk for COVID-19</b>	13/16,493 (0.1)	13/16,493 (0.1)	<b>91.0</b> (83.6-95.0)

# NovaVax: Safety Profile/Adverse Effects

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- **Myocarditis and Pericarditis:** Clinical trials data provide evidence for increased risks of myocarditis and pericarditis
- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to vaccination.
- **Limitations of Vaccine Effectiveness:** Novavax may not protect all vaccine recipients.
- **Additional side effects:** Injection site reactions, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, fever, chills, lymphadenopathy-related reactions

# Novavax: Clinical Information

- Authorized for use in people **12 years and older**
- Anyone who **is NOT immunocompromised**: timing between the 2 doses is **3-8 weeks**
- Anyone who **is immunocompromised, wanting better protection due to high levels of community transmission, or people aged 65 years and older**, should get the second dose **3 weeks** after the first dose
- **A bivalent mRNA booster is recommended** at least **2 months after** completion of **primary series**

Novavax								
Age indication	Vaccine composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster dose	
					Dose	Injection volume	Dose	Injection volume
12 years and older	Monovalent	Royal blue	No color	No	5 µg rS and 50 µg of Matrix-M™ adjuvant	0.5 mL	NA	NA

# Novavax: Storage & Handling

## Storing Vaccine

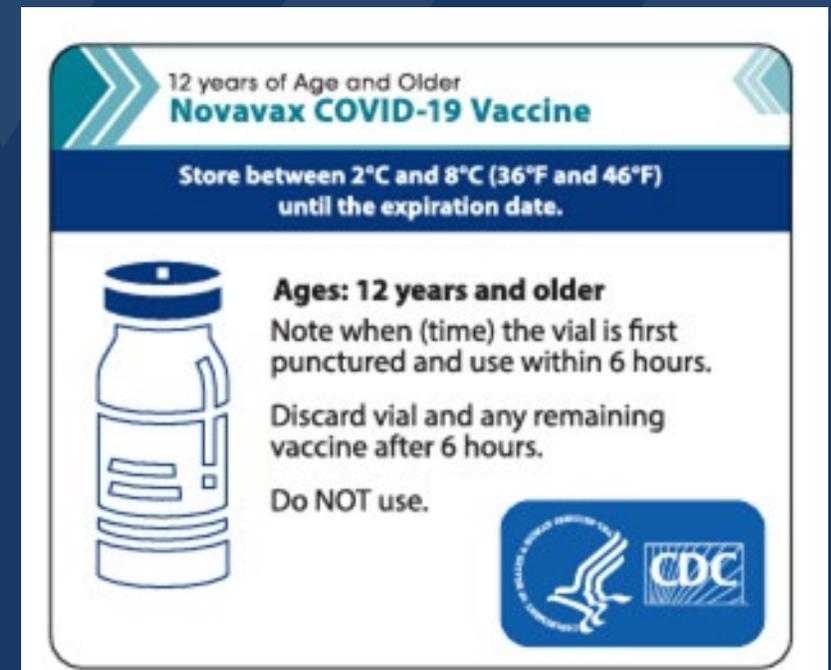
- Store unpunctured vials between 2°C and 8°C (36°F and 46°F) until the expiration date. Do not freeze.
- Store vaccine in the original packaging. Protect from light.

## Temperature Monitoring

- Storage unit temperatures must be monitored regularly and checked and recorded at the beginning of each workday to determine if any excursions have occurred since the last temperature check.

## Expiration/Beyond Use Date

- Once punctured, Novavax may be kept at room temperature for up to **6 hours**.
  - Vials that have been punctured 20 times should always be discarded.
- ***Novavax Expiry Page Now Available!***
- Novavax was approved for a 9-month refrigerated shelf life, and all Novavax vaccine purchased by USG currently expires February 2023.



# Novavax: Additional Vaccine Product Information

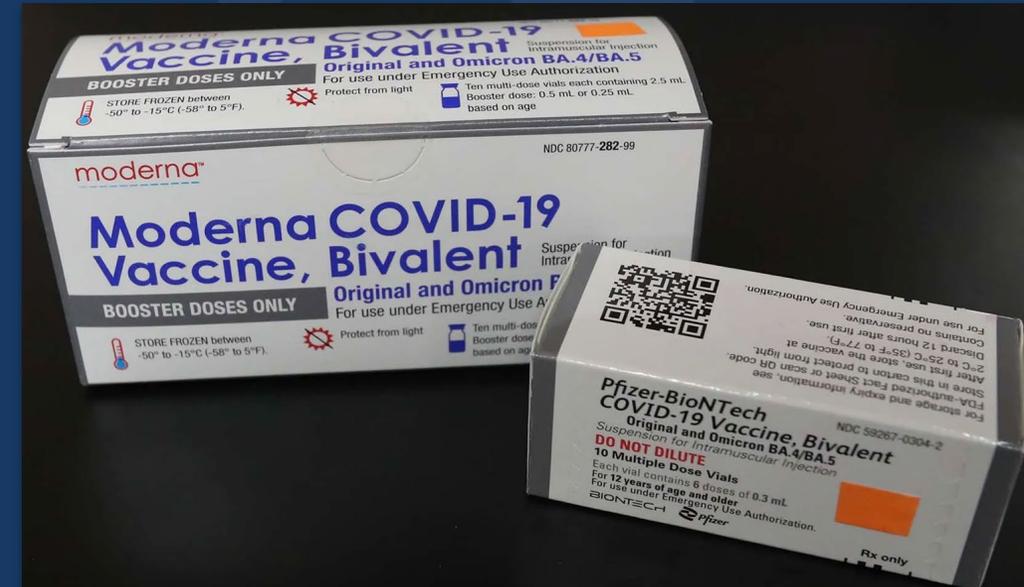
	Novavax
<b>Ancillary Kits</b>	Ancillary supplies will be provided, including a variety of 1-inch & 1.5-inch needles and syringes to support 100 doses of vaccine. Novavax COVID-19 vaccine does not require a diluent.
<b>Shipment</b>	<ul style="list-style-type: none"><li>● Ships under refrigerated temperatures (<b>2 to 8°C</b>)</li><li>● Arrives in a single-use thermal shipper. Do NOT use shipper for extended storage.</li><li>● Once received, vaccines should be put in the refrigerator. Do NOT store in freezer.</li></ul>
<b>Order Quantity</b>	The minimum order quantity is 100 doses. Each multi-dose vial contains 10 doses of 0.5 mL each.
<b>Training</b>	Novavax will be hosting weekly Wednesday (12pm-1pm EST) sessions. Register here: <a href="#">Novavax Office Hours</a>

# **COVID-19 Vaccines: Bivalent Boosters**

# Bivalent Boosters: Background Info

Moderna and Pfizer-BioNTech **bivalent COVID-19 formulations** are **authorized** by the FDA and **recommended** by the CDC **for use in people 12 years and older, as a single booster dose** at least two months following primary or booster vaccination.

- [June 28 FDA](#) Vaccines and Related Biological Products Advisory Committee meeting:
  - Discussed a change to the current vaccine strain composition of COVID-19 vaccines for booster doses for the 2022 fall and winter seasons.
  - Advised manufacturers seeking to update their COVID-19 vaccines that they should **develop modified vaccines that add an Omicron BA.4/BA.5 spike protein component** to the current vaccine composition to create a bivalent booster vaccine.
- CDC recommends **everyone stay up to date with COVID-19 vaccination**, including all primary series doses and boosters, for maximum protection against COVID-19.



# Overview of Bivalent Boosters

	Moderna Bivalent Booster	Pfizer-BioNTech Bivalent Booster
<b>Eligibility</b>	ages <b>18</b> and older	ages <b>12</b> and older
<b>Series</b>	Single booster dose	Single booster dose
<b>Interval</b>	Single booster dose administered at least <b>2 months</b> after: <ul style="list-style-type: none"><li>● completion of primary series OR</li><li>● receipt of most recent monovalent booster dose</li></ul>	
<b>Vial Color</b>	Dark blue vial cap with gray label border	Gray vial cap with gray label border
<b>Dose Volume</b>	0.5 mL	0.3 mL

# Bivalent Boosters: Clinical Trial Data

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- The FDA evaluated immunogenicity and safety data from a clinical study of a bivalent booster dose that contained a component of the original strain of SARS-CoV-2 and a component of omicron lineage BA.1.
  - There are subtle differences in mutations between BA.1 and BA.4/BA.5 spike protein sequences, thus do not anticipate differences in safety or immunogenicity of vaccines
  - While BA.4/BA.5 are two different omicron sub-lineages, the Spike protein (focus of the vaccines) is identical
- Two study arms in the trial
  - One group: 2-dose primary series + monovalent booster + monovalent booster
  - Second group: 2-dose primary series + monovalent booster + bivalent booster
- Recipients of the bivalent booster doses showed an **increased immune response**
- Safety profile: similar to that of monovalent COVID-19 vaccines

# Bivalent Boosters: Clinical Information

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## Monovalent vs. Bivalent Boosters

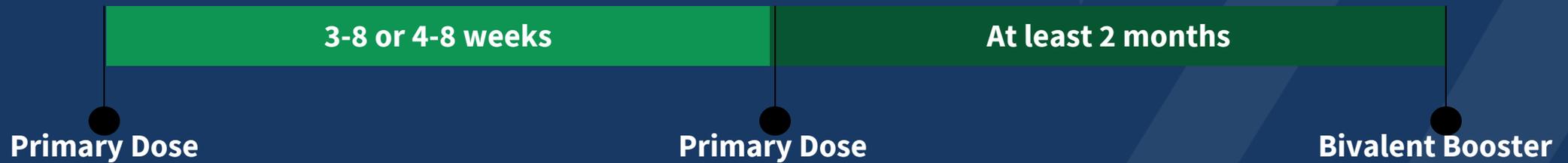
- The bivalent booster recommendation replaces previous monovalent booster recommendations for people ages 12 years and older.
- **This means that everyone who is eligible for a booster dose (5 years and older) will now only be eligible for ONE booster dose.**
  - People ages 5 through 11 years (who received Pfizer-BioNTech primary series): 1 monovalent booster dose
  - People ages 12 years and older (who received Pfizer-BioNTech, Moderna, or Novavax primary series): 1 bivalent booster dose

## **Timing** with current or recent SARS-CoV-2 infection:

- Defer any COVID-19 vaccination at least until recovery from acute illness (if symptoms were present) and criteria to discontinue isolation have been met.
- Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination
  - People who recently had infection may consider delaying any COVID-19 vaccination, including bivalent booster vaccination, by 3 months from symptom onset or positive test (if infection was asymptomatic)

# COVID-19 Vaccination Schedule: Non-Immunocompromised

## Moderna, Novavax, or Pfizer-BioNTech Primary Series



## Janssen Primary Series Dose



# COVID-19 Vaccination Schedule: Moderately or Severely Immunocompromised

## Moderna or Pfizer-BioNTech Primary Series



## NovaVax Primary Series



## Janssen Primary Series Dose



Source: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#recommendations>



# COVID-19 Vaccination Schedule: Fall Booster “Reset”

- Recommendations are simplified
- Change from dose counting to one bivalent booster for all eligible persons
- If eligible, a bivalent should not be denied based on total number of doses
- This strategy will help move towards a “seasonal” booster

Vaccination History	→	Next Dose
Primary Series	At least 2 months	1 bivalent booster dose
Primary Series + 1 booster	At least 2 months	1 bivalent booster dose
Primary Series + 2 booster	At least 2 months	1 bivalent booster dose

# Bivalent Booster: Storage & Handling

	Moderna Bivalent	Pfizer-BioNTech Bivalent
Storage and Handling	<ul style="list-style-type: none"> <li>● NO ULTRA-COLD FREEZER STORAGE</li> <li>● Freezer storage (-25°C to -15°C) until expiry</li> <li>● Refrigerate (2°C to 8°C) up to 30 days without puncturing                             <ul style="list-style-type: none"> <li>○ Do not refreeze once thawed</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>● Ultra-cold freezer storage (-90°C to -60°C) until expiry (12 months from manufacture date)</li> <li>● NO FREEZER STORAGE</li> <li>● Refrigerate (2°C to 8°C) up to 10 weeks without puncturing                             <ul style="list-style-type: none"> <li>○ Do not refreeze once thawed</li> </ul> </li> </ul>
Preparation	<ul style="list-style-type: none"> <li>● Each vial must be thawed prior to administration. DO NOT DILUTE prior to use.</li> <li>● Thaw time in the refrigerator [2°C to 8°C (35°F to 46°F)]: 2 hours</li> <li>● Let vial stand at room temperature for 15 minutes before administering.</li> <li>● Thaw time at room temperature [15°C to 25°C (59°F to 77°F)]: 45 minutes</li> </ul>	<ul style="list-style-type: none"> <li>● Each vial must be thawed prior to administration. DO NOT DILUTE prior to use.</li> <li>● Thaw time in the refrigerator:                             <ul style="list-style-type: none"> <li>○ A carton of 10 single dose vials: up to 2 hours</li> <li>○ A carton of 10 multiple dose vials: up to 6 hours</li> </ul> </li> <li>● If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature for 30 minutes.</li> </ul>
After first puncture	<ul style="list-style-type: none"> <li>● Vials should be discarded 12 hours after the first puncture.</li> <li>● Total storage at room temperature must not exceed 24 hours.</li> </ul>	<ul style="list-style-type: none"> <li>● Vials may be stored at room temperature for a total of 12 hours prior to first puncture.</li> <li>● After first puncture, the multi-dose vial should be held between 2°C to 25°C (35°F to 77°F). Multi-dose vials should be discarded 12 hours after first puncture.</li> </ul>

# Bivalent Booster: Additional Product Information

	Pfizer-BioNTech	Moderna
<b>Ancillary Kits</b>	Ancillary supplies will be provided, including a variety of 1-inch and 1.5-inch needles and syringes. An ancillary opt-out continues to be available for kits not needing diluent.	
<b>Order Quantity*</b>	The minimum order quantity is 300 doses *For those utilizing VaXMaX, ordering will be available on 9/8, with deliveries occurring on 9/16 and 9/19	The minimum order quantity is 100 doses *For those utilizing VaXMaX, ordering will be available on 9/8, with deliveries occurring on 9/16 and 9/19
<b>Training</b>	Visit Pfizer's <a href="#">website</a> for training session links and information	Moderna will be hosting weekly Wednesday webinar sessions. Register here: <a href="#">Moderna Webinar</a>

# Additional Resources

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## CDC Resources:

- [COVID-19 Clinical Considerations](#)
- [Stay Up to Date with COVID-19 Vaccines Including Boosters](#) - *\*Includes booster schedule calculator*
- [COVID-19 Vaccines for Children and Teens](#)
- [Resources to Promote the COVID-19 Vaccine for Children & Teens](#)
- [CDC Fall Vaccination Operational Planning Guide – Information for the Fall Vaccine Campaign, Including Upcoming Bivalent COVID-19 Vaccine Booster Doses](#)

## VDH Resources:

- [COVID-19 Vaccination FAQs](#)
- [COVID-19 Resources for Healthcare Professionals](#)
- [Vaccinate.Virginia.Gov](#)

**Q&A**

# CME Information

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This activity, NovaVax and Bivalent COVID-19 Booster Vaccine Update, has been reviewed and is acceptable for up to 1 live Prescribed credit by the American Academy of Family Physicians. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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The VAFP will report CME credits to the AAFP for all Active and Life Members. Other attendees will be responsible for reporting their own CME.

**To submit your request for CME credits, please use this QR code.**

**If you have questions, please do not hesitate to contact Cheryl Modesto ([cmodesto@vafp.org](mailto:cmodesto@vafp.org))**

**or call 804-968-5200.**

