

# Respiratory Vaccines Update

## Webinar 2

September 14<sup>th</sup>, 2023

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Allie Staton, PharmD

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- **You must attend this webinar as it is being presented.**
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- **You must complete the Evaluation Survey following this webinar.**
  - A link to the Evaluation Survey will be posted in the chat at the end of the presentation.
  - **DEADLINE: Midnight on Friday, September 15<sup>th</sup>.**
    - **No late evaluations will be accepted.** Please complete the survey ASAP.
  - The survey link will also be sent out tomorrow afternoon in a follow-up email.
- **Certificates of Completion for attending this course will be available after you complete the Evaluation Survey.**
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  - You will have to write your name on the Certificate.
  - A link to the Certificates of Completion will also be sent out tomorrow afternoon in a follow-up email.

# Webinar

- If you have a question during or after the webinar, please post your question in the chat.
  - We will do our best to answer all questions before the end of the webinar.
- If you have a question after the webinar, please email Allie Staton.
  - [allie@immunizear.org](mailto:allie@immunizear.org)

# Objectives

- Interpret current guidelines for respiratory vaccines.
- Recommend appropriate respiratory vaccines to patients and community members.
- Discuss current respiratory vaccine guidelines and recommendations.



# Topics

- Review updated COVID-19 vaccine products
- Review updated COVID-19 vaccine recommendations
- Discuss commonly asked questions

# COVID-19 Vaccine Products

# COVID-19 Vaccine Commercialization

- You no longer get COVID-19 vaccines for free from the government.
- You *should* be able to order COVID-19 vaccines however you normally order other vaccines.
- Pfizer and Moderna also offer direct ordering.

# Bridge Access Program

## CDC vaccine programs for people who are uninsured

- CDC will provide access to COVID-19 vaccines for uninsured individuals once COVID-19 vaccines become commercially available<sup>1</sup>
- Uninsured children will be able to receive COVID-19 vaccines through the existing Vaccines for Children (VFC) program<sup>1</sup>
  - The VFC program offers vaccines at no low or no cost to eligible children through a national network of participating health care providers<sup>2</sup>
- Adults who are uninsured or underinsured will be able to receive no-cost COVID-19 vaccines through the temporary Bridge Access Program for COVID-19 Vaccines. This program consists of two components:
  - Public health infrastructure: through state immunization programs, State and local health departments and HRSA-supported health centers will provide no-cost COVID-19 vaccines to adults who are uninsured or underinsured
  - Participating retail pharmacies: CVS, Walgreens, and eTrueNorth will continue to provide no-cost COVID-19 vaccines to adults who are uninsured or underinsured<sup>3</sup>

1. CDC. HHS Commercialization Transition Guide: Sunsetting the US Government COVID-19 Vaccine Distribution Program. <https://www.cdc.gov/vaccines/covid-19/downloads/HHS-Commercialization-Transition-Guide-508.pdf> Accessed August 4, 2023

2. CDC. VFC Information for Parents. <https://www.cdc.gov/vaccines/programs/vfc/parents/index.html> Accessed August 30, 2023

3. CDC. Bridge Access Program for COVID-19 Vaccines. <https://www.cdc.gov/vaccines/programs/bridge/index.html> Accessed September 7, 2023

# COVID-19 Vaccine Products

**Bivalent COVID-19 vaccine products are no longer authorized for use.**

- Doses should be discarded immediately.
  - Discard as hazardous waste.
- Proper documentation in WebIZ should be recorded ASAP.
  - Use reason “Wasted – other”

# Updated COVID-19 Vaccines

## COVID-19 vaccine nomenclature

- Updated COVID-19 vaccine referred to as the “2023–2024 COVID-19 vaccine” in this presentation
- Following ACIP meeting, both “updated COVID-19 vaccine” and “2023–2024 COVID-19 vaccine” will be used to refer to the monovalent XBB.1.5 containing vaccines



# COVID-19 Vaccine Products

Pfizer	Moderna	Novavax
mRNA	mRNA	Protein Subunit
6 months and older	6 months and older	12 years and older
<p><b><u>Products</u></b></p> <p><b>2023 – 2024 season</b></p> <ul style="list-style-type: none"> <li>• 6 months thru 4 years</li> <li>• 5 years thru 11 years</li> <li>• 12 years and older</li> </ul>	<p><b><u>Products</u></b></p> <p><b>2023 – 2024 season</b></p> <ul style="list-style-type: none"> <li>• 6 months thru 11 years</li> <li>• 12 years and older</li> </ul>	<p><b><u>Products</u></b></p> <p><b>2023 – 2024 season</b></p> <ul style="list-style-type: none"> <li>• <i>Pending FDA approval</i></li> </ul>

## Pfizer Monovalent COVID-19 Vaccines 2023 – 2024 Season

	Pfizer Monovalent <i>Yellow Cap</i>	Pfizer Monovalent <i>Blue Cap</i>	Pfizer <i>Gray Cap</i> <i>(Comirnity)</i>	Pfizer <i>Prefilled Syringe</i> <i>(Comirnity)</i>
<b>Age Group</b>	6 months thru 4 years	5 years thru 11 years	12 years and older	12 years and older
<b>Vial Cap and Label color</b>	Cap: Yellow Label Border: Yellow	Cap: Blue Label Border: Blue	Cap: Gray Label Border: Gray	NA
<b>Dilution?</b>	YES <b>(1.1 mL)</b>	NO	NO	NO
<b>Dose Volume</b>	<b>0.3 mL</b>	<b>0.3 mL</b>	0.3 mL	0.3 mL
<b>Doses per Vial</b>	<b>3</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>Mix? Shake?</b>	Mix by inverting vial gently, 10 times. Do not shake.	Mix by inverting vial gently, 10 times. Do not shake.	Mix by inverting vial gently, 10 times. Do not shake.	Do not mix. Do not shake.
<b>Expiration</b>	UCF: Good until exp date Freezer: NA Fridge: 10 weeks after UCF Room Temp: 12 hours After Puncture: 12 hours	UCF: Good until exp date Freezer: NA Fridge: 10 weeks after UCF Room Temp: 12 hours After Puncture: 12 hours	UCF: Good until exp date Freezer: NA Fridge: 10 weeks after UCF Room Temp: 12 hours After Puncture: 12 hours	UCF: Good until exp date Freezer: NA Fridge: 10 weeks after UCF Room Temp (after thawed): 4 hours After Needle added: 4 hours



<b>Moderna Monovalent COVID-19 Vaccines 2023 – 2024 Season</b>			
	<b>Moderna Monovalent <i>Green Border</i></b>	<b>Moderna Monovalent <i>Blue Border</i> (Spikevax)</b>	<b>Moderna Monovalent <i>Prefilled Syringe</i> (Spikevax)</b>
<b>Age Group</b>	6 months thru 11 years	12 years and older	12 years and older
<b>Vial Cap and Label color</b>	Cap: Blue Label Border: Green	Cap: Blue Label Border: Blue	NA
<b>Dilution?</b>	NO	NO	NO
<b>Dose Volume</b>	<b>0.25 mL</b>	0.5 mL	0.5 mL
<b>Doses per Vial</b>	1	1	1
<b>Mix? Shake?</b>	Swirl gently. Do not shake.	Swirl gently. Do not shake.	Swirl gently. Do not shake.
<b>Expiration</b>	UCF: NA Freezer: Good until exp date Fridge: 30 days after freezer Room Temp: 24 hours (total)	UCF: NA Freezer: Good until exp date Fridge: 30 days after freezer Room Temp: 24 hours (total)	UCF: NA Freezer: Good until exp date Fridge: 30 days after freezer Room Temp: 24 hours (total)

# COVID-19 Vaccine Products

## Current recommendations for Novavax COVID-19 vaccine

- The **original Novavax COVID-19** vaccine remains authorized for use as a 2-dose primary series
- The **original Novavax COVID-19** vaccine can be given as booster dose in limited situations to
  - People ages 18 years and older who previously completed primary vaccination using any FDA-approved or FDA-authorized COVID-19 vaccine
  - Have not received any previous booster dose(s)
  - Are unable (i.e., mRNA vaccine contraindicated or vaccine not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose
- Authorizations or approvals for **2023 – 2024 Novavax COVID-19 vaccine** will be determined by FDA with CDC recommendations to follow

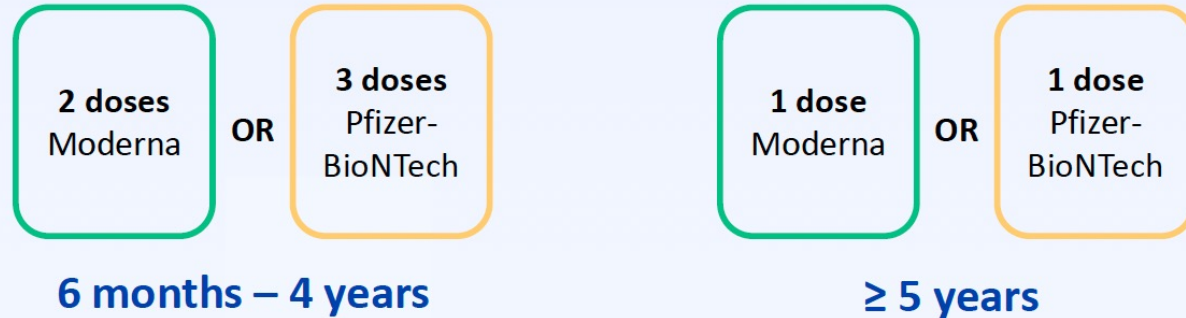
# COVID-19 Vaccine

## Current Recommendations

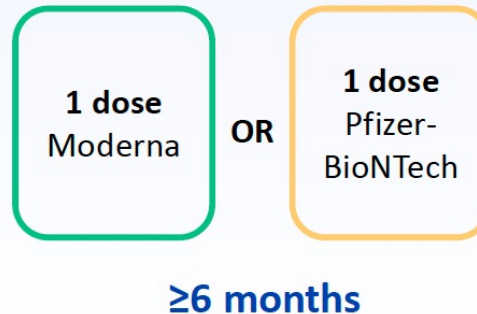
# COVID-19 Vaccine Current Recommendations

## Proposed 2023 – 2024 COVID-19 vaccine recommendations for mRNA COVID-19 vaccines

**Unvaccinated**



**Previously vaccinated**



Note: Those ages 6 months – 4 years who have previously received a single dose of Pfizer-BioNTech would need 2 additional doses. Additional doses are recommended for persons with immunocompromising conditions.

# COVID-19 Vaccine Current Recommendations

## Proposed 2023 – 2024 mRNA COVID-19 vaccine recommendations:

- Everyone ages 5 years and older is recommended to receive 1 dose of a 2023–2024 mRNA COVID-19 vaccine
- Children ages 6 months–4 years should complete a multi-dose initial series (2 doses of Moderna or 3 doses of Pfizer-BioNTech mRNA COVID-19 vaccine) with at least one dose of the 2023–2024 COVID-19 vaccine<sup>1</sup>
- People who are moderately or severely immunocompromised should complete a 3-dose initial series with at least one dose of the 2023–2024 COVID-19 vaccine and may receive 1 or more additional 2023–2024 COVID-19 vaccine doses<sup>2</sup>
- Bivalent mRNA COVID-19 vaccines are no longer recommended in the United States

1. Children ages 6 months – 4 years that previously received a single dose of Pfizer-BioNTech vaccine should receive 2 doses of Pfizer-BioNTech vaccine.

2. Additional details in the interim clinical considerations

# COVID-19 Vaccine Current Recommendations

## Proposed recommendations for people aged 5 years and older without immunocompromise

### Doses recommended:

- **1 dose of 2023–2024 COVID-19 vaccine**, regardless of prior vaccination history

- New harmonized age cutoff for recommendations for young children for Moderna and Pfizer-BioNTech COVID-19 vaccines
- Resulting in simplified recommendations for 5-year-olds
- All Moderna doses in ages 6 months – 11 years are now 25 µcg
- 2023–2024 COVID-19 vaccine dose is recommended at least 2 months after receipt of the last COVID-19 vaccine dose

# COVID-19 Vaccine Current Recommendations

## **Proposed recommendations for children aged 6 months – 4 years without immunocompromise**

### **Doses recommended:**

- Initial series of 2 Moderna vaccine doses OR 3 Pfizer-BioNTech vaccine doses
  - **At least 1 dose of 2023–2024 COVID-19 vaccine**
- 
- All doses should be homologous (i.e., from the same manufacturer)
  - All Moderna doses in ages 6 months – 11 years are now 25 µcg

# COVID-19 Vaccine Current Recommendations

## Proposed recommendations for people aged $\geq 6$ months who are moderately or severely immunocompromised

### Doses recommended:

- Initial COVID-19 vaccine series\*
- **At least 1 2023–2024 COVID-19 vaccine dose**
- May receive 1 or more additional 2023-2024 mRNA COVID-19 vaccine doses\*\*

\*Series of 3 homologous mRNA COVID-19 vaccine doses at time of initial vaccination. This could also include a history of receipt of 1 or more doses of Novavax or Janssen, including in combination with mRNA vaccine dose(s).

\*\*Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Further additional doses should be administered at least 2 months after the last 2023-2024 COVID-19 vaccine dose.



# COVID-19 Vaccine Current Recommendations

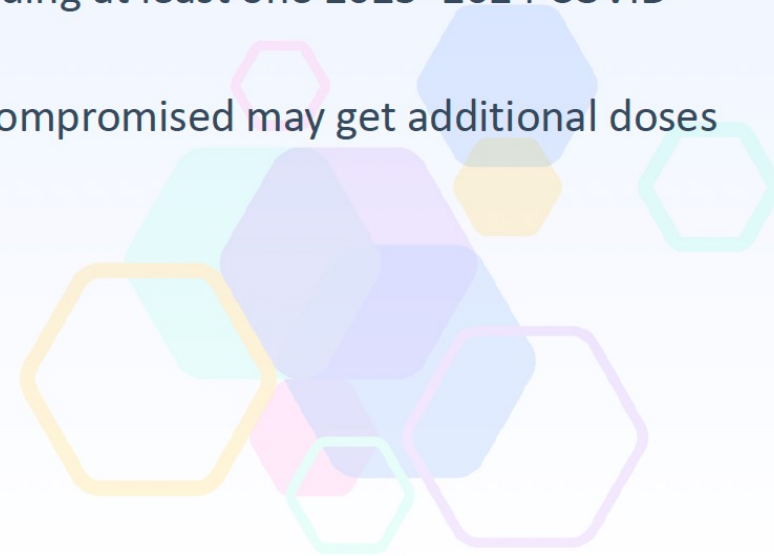
## Key changes from bivalent mRNA recommendations

Bivalent recommendations	Proposed 2023 – 2024 vaccine recommendations	Rationale
Everyone ages <b>6 years</b> and older recommended for a single bivalent dose	Everyone ages <b>5 years</b> and older recommended for a single 2023 – 2024 dose	Eliminates complex recommendations for 5-year-olds
Two Moderna dosages authorized for 6 months – 5 years, depending on vaccination history and immune status	All Moderna doses in ages 6 months – 11 years are now 25 µcg	Reduces the number of COVID-19 vaccine products in use
Optional 2 <sup>nd</sup> bivalent dose for those ages 65 years and older	No additional dose recommendation <b>at this time</b>	Will monitor epidemiology and vaccine effectiveness to determine if additional doses are needed

# COVID-19 Vaccine Current Recommendations

## Proposed 2023 – 2024 COVID-19 Vaccine Up to Date Definition

- Everyone aged 5 years and older are recommended get one 2023–2024 COVID-19 vaccine to be up to date.
- Children aged 6 months–4 years and people who are moderately or severely immunocompromised need multiple doses, including at least one 2023–2024 COVID-19 vaccine dose to be up to date.
- People who are moderately to severely immunocompromised may get additional doses of the 2023–2024 COVID-19 vaccine.



# COVID-19 Vaccines

## Common Questions

# Do we still have to document doses on COVID-19 vaccine record cards?

- Technically, no.
- However, please document if the patient asks.

# Do we still have to document all doses in WebIZ?

- Technically, no.
- However, please continue to document all doses in WebIZ.
- It IS a requirement to document doses in WebIZ if doses are administered through the Bridge Program.
- All doses of every vaccine are required to be documented in WebIZ for patients ages 21 and younger.

Regardless of Arkansas Law...

- Please, please, please document EVERY dose of EVERY vaccine in WebIZ.
- This is absolutely best practice.
- Every single provider who administers vaccines *should* be doing this.

# When will your charts be available?

- Soon!
- I am waiting for CDC Interim Clinical Considerations to be posted.
- I will likely host another CE to review the recommendations more thoroughly.
- Charts will be available here:
  - <https://www.immunizear.org/covid-19-provider-resources>

# Thank you!

Questions?

# Resources

## Pfizer:

- <https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccine>
- <https://www.fda.gov/media/151707/download>

## Moderna:

- <https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/moderna-covid-19-vaccine>
- <https://www.fda.gov/vaccines-blood-biologics/spikevax>

## Other Information:

- <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-09-12.html>, accessed 9/12/23