



# COVID-19 Vaccine Update

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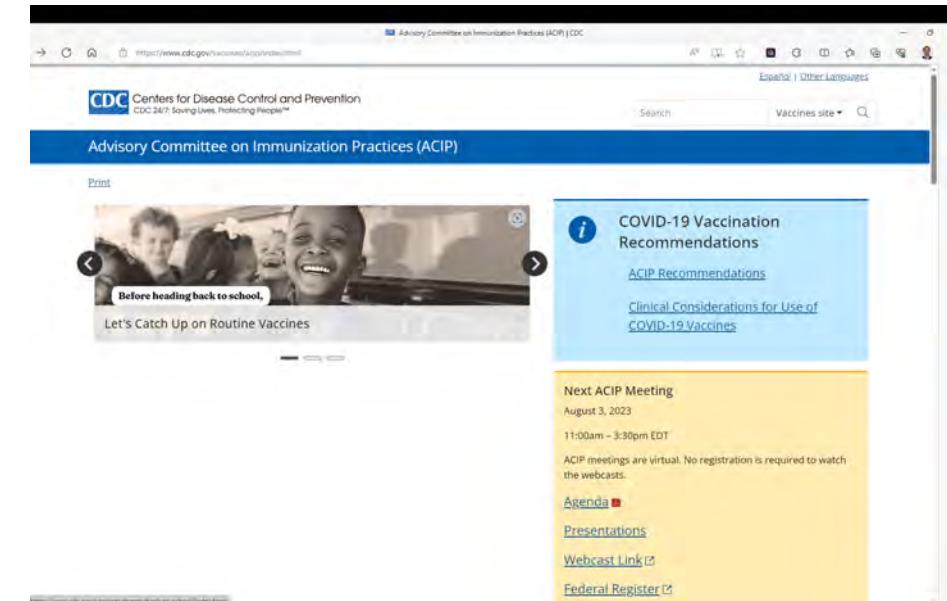
September 21, 2023

# Disclosures

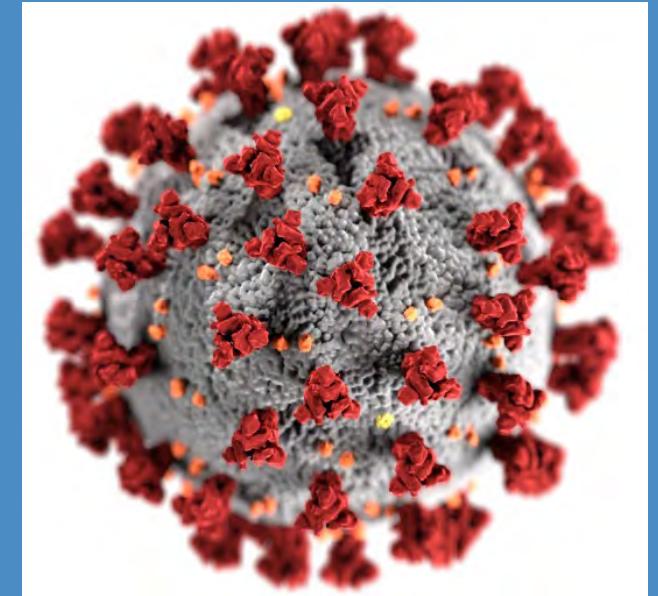
- Andrew Kroger is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation.
- Andrew Kroger will discuss off-label CDC recommendations for COVID-19 vaccines.
- The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

# Disclosures

- The recommendations to be discussed are primarily those of the Advisory Committee on Immunization Practices (ACIP).
  - Composed of 15 experts in clinical medicine and public health
  - Provides guidance on use of vaccines and other biologic products to DHHS, CDC, and the U.S. Public Health Service



Next ACIP Meeting  
September 22, 2023



# COVID-19 Vaccine

# COVID-19 Disease

- Coronavirus (SARS-CoV-2 virus)
- Identified in Wuhan, China (December 2019)
- First U.S. case – January 20, 2020
- On January 30, 2023, the end of the pandemic to occur on May 11, 2023, was declared
- New strain circulating – BA.2.86

# COVID-19 Vaccine: 2023-2024/1vCOV-mRNA

- Strain XBB.1.5
- Two formulations
  - Comirnaty (Pfizer-BioNTech)
  - Spikevax (Moderna)
- mRNA vaccines
  - Vaccine recipient generates the antigen
- FDA approved/licensed for persons 12 years old and older
- CDC: Effective against COVID-19 hospitalization and long COVID-19
- CDC recommended for all persons 6 months old and older

# COVID-19 Vaccine: Recommendations (5 Years Old and Older)

- One dose of vaccine (Comirnaty or Spikevax) generally recommended regardless of previous history of COVID-19 vaccine doses
- Off-label recommendation for persons 5 years old through 11 years old (emergency use authorization per FDA)
- Note that additional doses may be recommended for 5 year olds that began a series before the 5<sup>th</sup> birthday and are currently 5 years old

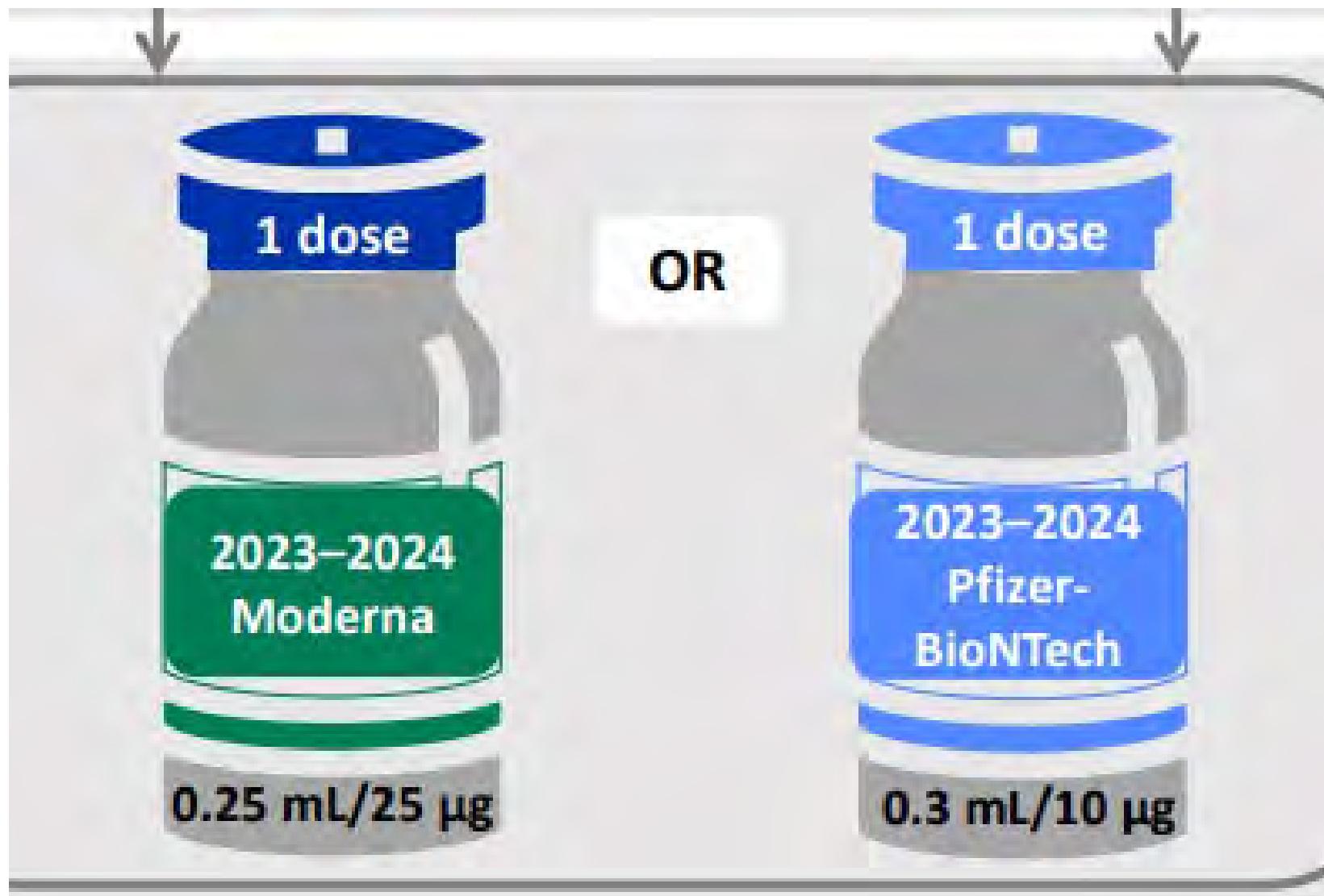
# COVID-19 Vaccine: Recommendations (Aging from 4 to 5 Years) – Immunocompetent

History at Age 4 years	Recommended Doses at Age 5 years
One Moderna bivalent	One Spikevax
One Pfizer bivalent	Two Comirnaty
One Moderna monovalent, one Moderna bivalent	One Spikevax
One Moderna monovalent, one Pfizer bivalent	One Comirnaty
Two Moderna monovalent, one Moderna bivalent	One Spikevax
Two Moderna monovalent, one Pfizer bivalent	One Comirnaty

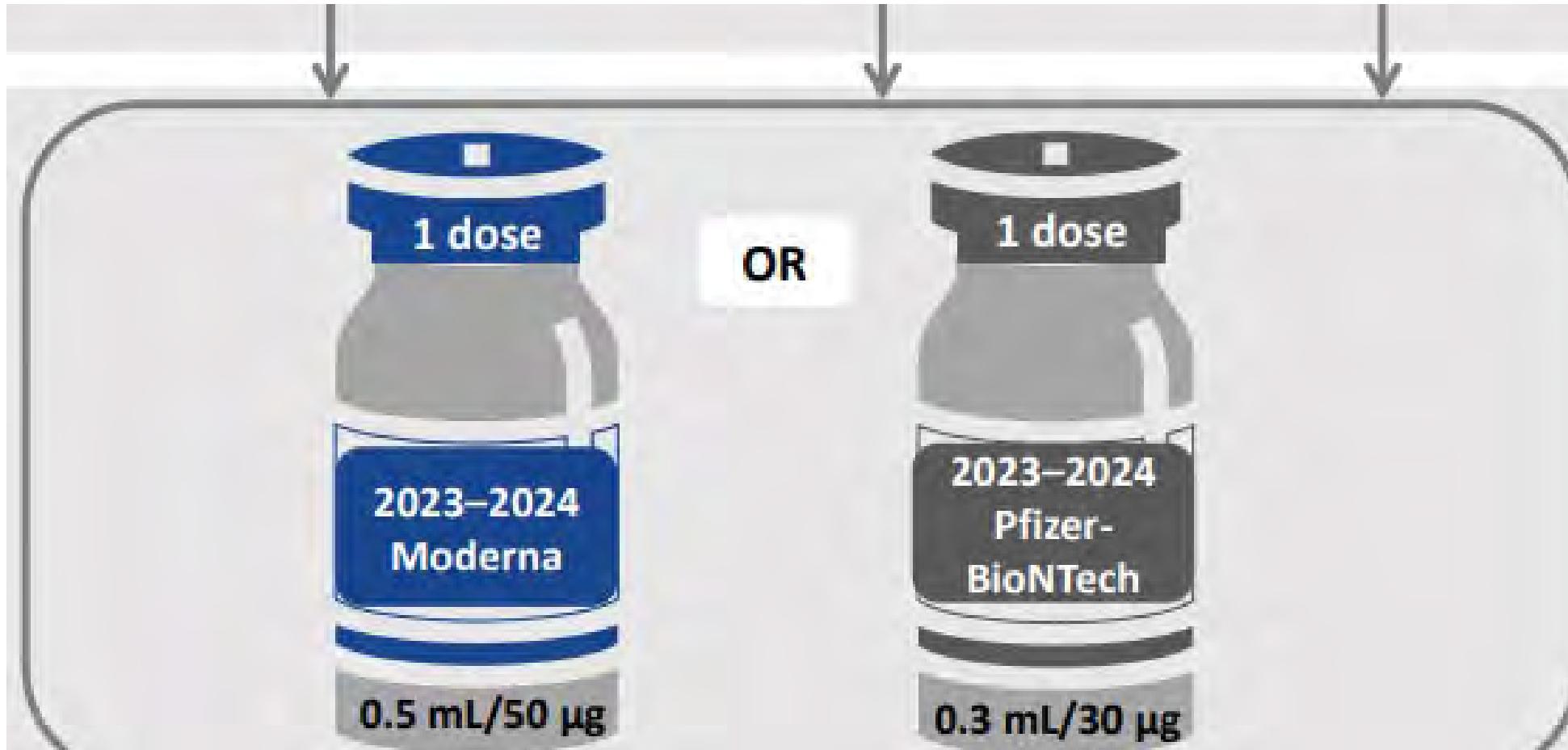
# COVID-19 Vaccine: Recommendations (Aging from 4 to 5 Years) – Immunocompetent

History at Age 4 years	Recommended Doses at Age 5 years
One Pfizer monovalent, one Pfizer bivalent	One Comirnaty
Two Pfizer monovalent, one Pfizer bivalent	One Comirnaty
Three Pfizer monovalent, one Pfizer bivalent	One Comirnaty

# COVID-19 Vaccine: Formulation for 5 through 11 years



# COVID-19 Vaccine: Formulation for 12 Years and Older



# COVID-19 Vaccine in Persons 6 months through 4 Years

- Similar to vaccination in persons 5 years through 11 years
- OFF-LABEL

**Proposed recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 6 months–4 years\***

**COVID-19 vaccination status as of September 2023**

Previously received COVID-19 vaccine(s)

**Unvaccinated**

**Vaccinated**

1 dose any Moderna

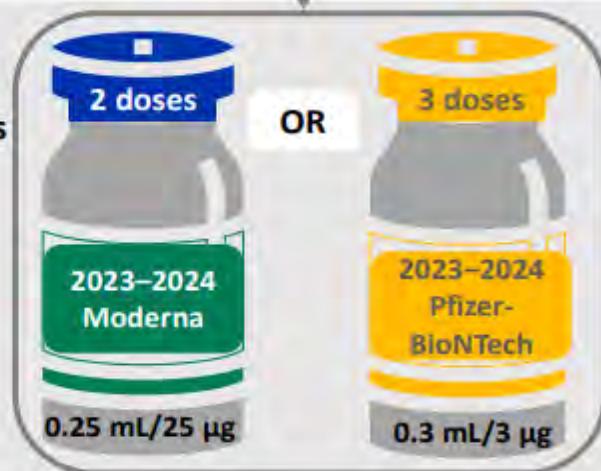
2 or more doses any Moderna

1 dose any Pfizer-BioNTech

2 doses any Pfizer-BioNTech

3 or more doses any Pfizer-BioNTech

Recommendations for 2023–2024 vaccine, by manufacturer

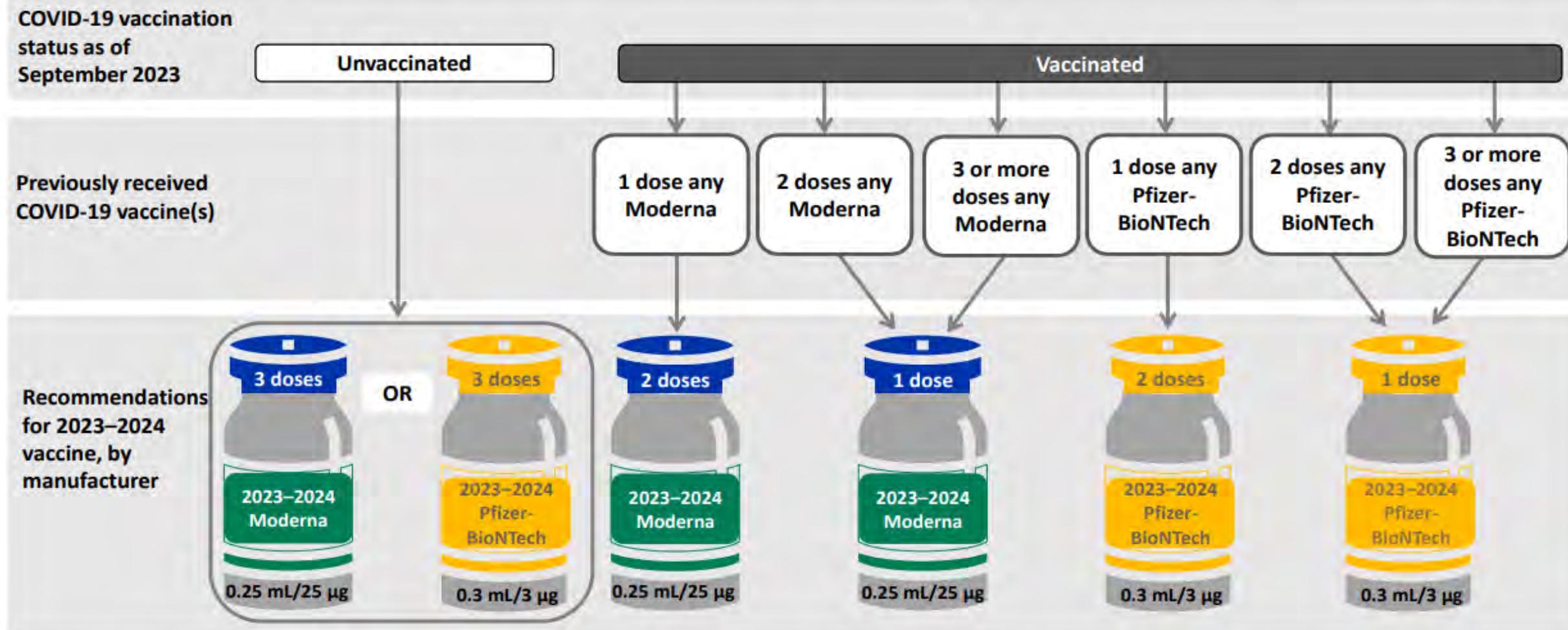


\*For information about administration intervals and people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

# Immunosuppressed Patients

- Can receive additional doses of Comirnaty or Spikevax at two month intervals, per provider's discretion

**Proposed recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 6 months–4 years\***



\*For information about administration intervals, people who transition from age 4 years to age 5 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Proposed recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 5–11 years\***

**COVID-19 vaccination**

**status as of  
September 2023**

**Previously received  
COVID-19 vaccine(s)**

**Unvaccinated**

**Vaccinated**

**1 dose any  
Moderna**

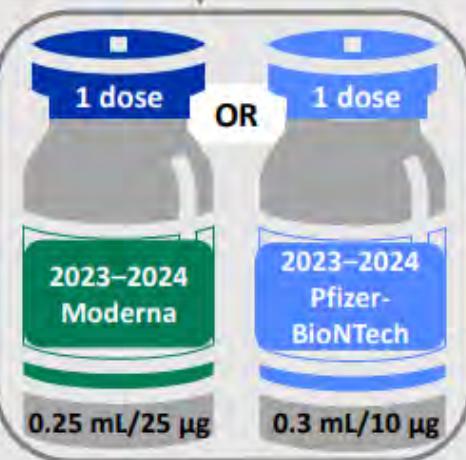
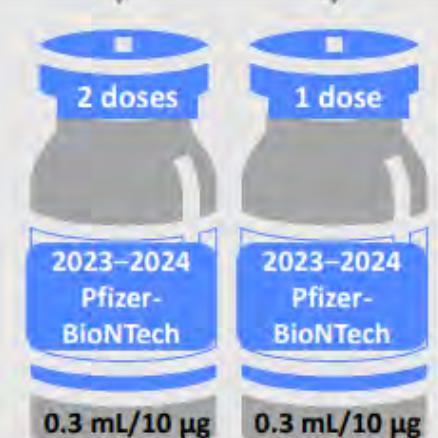
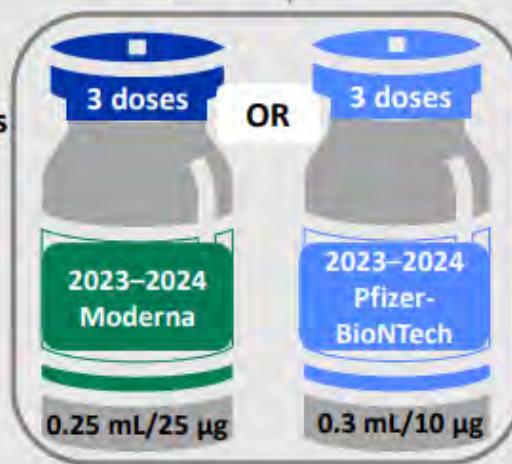
**2 doses any  
Moderna**

**1 dose any  
Pfizer-  
BioNTech**

**2 doses any  
Pfizer-  
BioNTech**

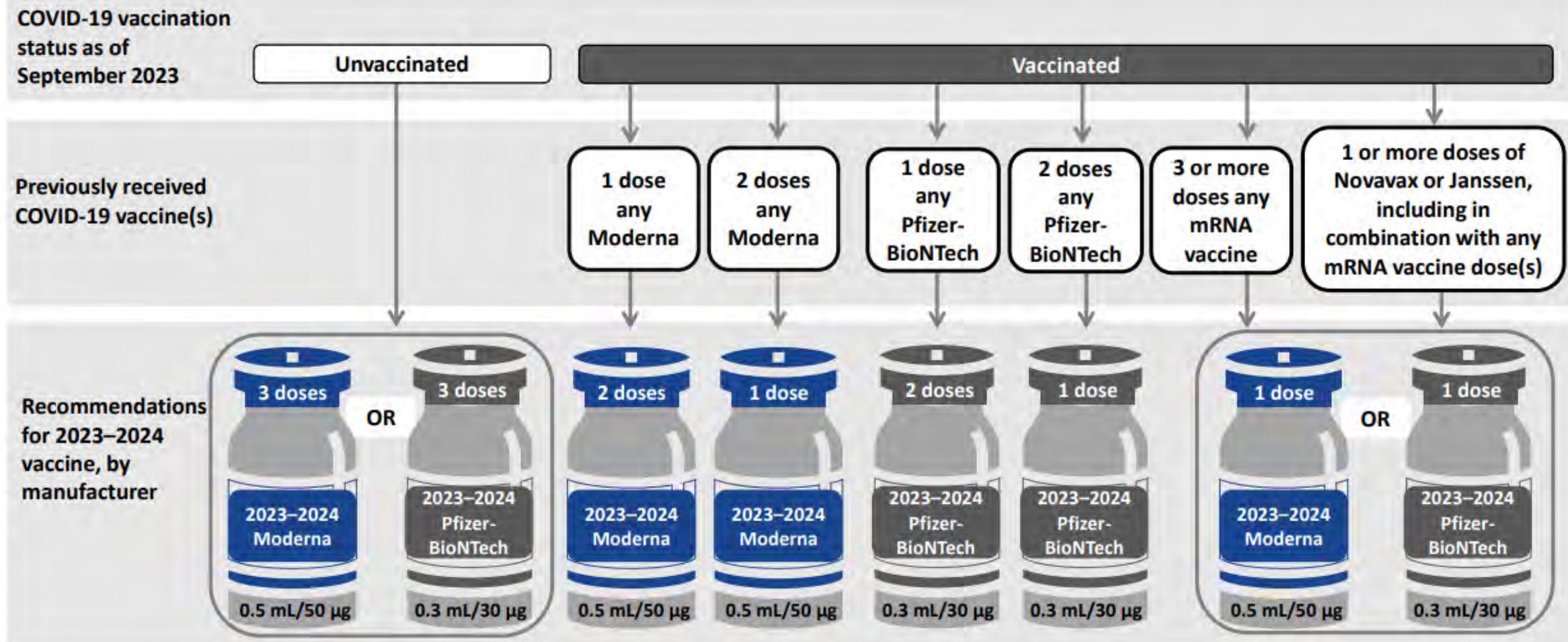
**3 or more doses  
any mRNA  
vaccine**

**Recommendations  
for 2023–2024  
vaccine, by  
manufacturer**



\*For information about administration intervals, people who transition from age 4 years to age 5 years or age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Proposed recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged  $\geq 12$  years\***



\*For information about administration intervals, people who transition from age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

# COVID-19 Vaccine: Recommendations (Aging from 4 to 5 Years) - Immunosuppressed

History at Age 4 Years	Recommended Doses at Age 5 Years
One monovalent Moderna	Two Spikevax
One bivalent Moderna	Two Spikevax
One monovalent Pfizer	Two Comirnaty
One bivalent Pfizer	Two Comirnaty

# COVID-19 Vaccine: Recommendations (Aging from 4 to 5 Years) - Immunosuppressed

History at Age 4 Years	Recommended Doses at Age 5 Years
One monovalent Moderna, one bivalent Moderna	One Spikevax
Two monovalent Moderna, one bivalent Moderna	One Spikevax
Three monovalent Moderna, one bivalent Moderna	One Spikevax
Three monovalent Moderna, one bivalent Pfizer	One Comirnaty
One monovalent Pfizer, one bivalent Pfizer	One Comirnaty
Two monovalent Pfizer, one bivalent Pfizer	One Comirnaty

# COVID-19 Vaccine: Recommendations (Aging from 4 to 5 Years) - Immunosuppressed

History at Age 4 Years	Recommended Doses at Age 5 Years
Three monovalent Pfizer, one bivalent Pfizer	One Comirnaty

# Timing of First Dose

- Person can receive a dose of Comirnaty or Spikevax if it has been two months from their most recent mRNA (Pfizer/Moderna), Novavax, or Janssen dose.

# Contraindications and Precautions

## Contraindications and precautions

CDC considers the conditions listed in Table 3 to be COVID-19 vaccination contraindications and precautions.

**Table 3. Contraindications and precautions to COVID-19 vaccination**

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction* (e.g., anaphylaxis <sup>+</sup> ) after a previous dose or to a component of the COVID-19 vaccine <sup>+</sup>	Contraindication	Do not vaccinate with the same COVID-19 vaccine type. <sup>§</sup> May administer the alternate COVID-19 vaccine type. <sup>§</sup> See <a href="#">Considerations for people with a history of allergies and allergic reactions</a> for additional information.
History of a diagnosed non-severe allergy* to a component of the COVID-19 vaccine <sup>+</sup>	Precaution	May administer the alternate COVID-19 vaccine type. <sup>§</sup> For additional information, see <a href="#">Considerations for people with a history of allergies and allergic reactions</a> .
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type <sup>§</sup>	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	<a href="#">Defer vaccination</a> until the illness has improved.
History of MIS-C or MIS-A	Precaution	See <a href="#">COVID-19 vaccination and MIS-C and MIS-A</a> .
History of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See <a href="#">COVID-19 vaccination and myocarditis and pericarditis</a> .

**Abbreviations:** MIS-C = multisystem inflammatory syndrome in children; MIS-A = multisystem inflammatory syndrome in adults

\*Allergic reactions in Table 3 are defined as follows:

**Severe allergic reactions** include: known or possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria (hives) but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure; angioedema (visible swelling) affecting the airway (i.e., tongue, uvula, or larynx); diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome).

**Non-severe allergic reactions** include but are not limited to: urticaria beyond the injection site; angioedema involving lips, facial skin, or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) is considered a severe allergic reaction.

<sup>+</sup>Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines ([estimated incidence: 5 per million doses of mRNA COVID-19 vaccines administered](#)). For more information on the assessment and potential management of anaphylaxis, see [Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination](#).

<sup>§</sup>See [package inserts](#) and [FDA EUA fact sheets](#) for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG).

<sup>+</sup>The mRNA COVID-19 vaccines (Moderna and Pfizer-BioNTech) are one type of COVID-19 vaccine and Novavax (protein subunit) is another type of COVID-19 vaccine.