

COVID-19 Vaccine Updates

**Virginia Department of Health
May 17, 2023**

Speakers & Panelists



Chelsea Sprouse, PharmD, BCACP
Adult Vaccine Coordinator
Office of Epidemiology, Division of Immunization
Virginia Department of Health

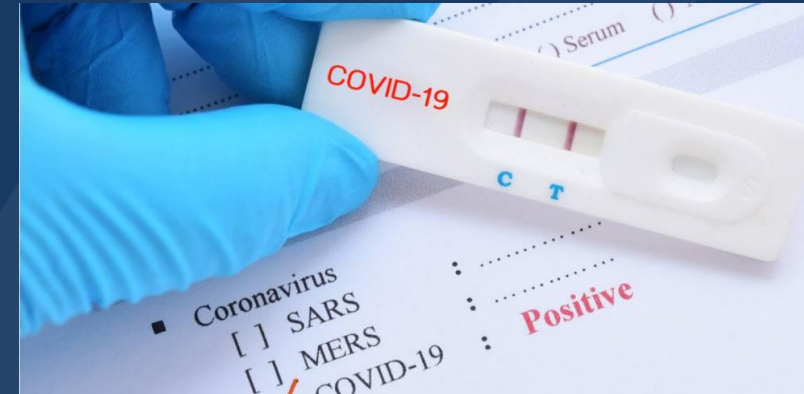


Brooke Rossheim, MD, MPH
Public Health Physician Specialist
Health Information Team
Virginia Department of Health

Epidemiology of COVID-19

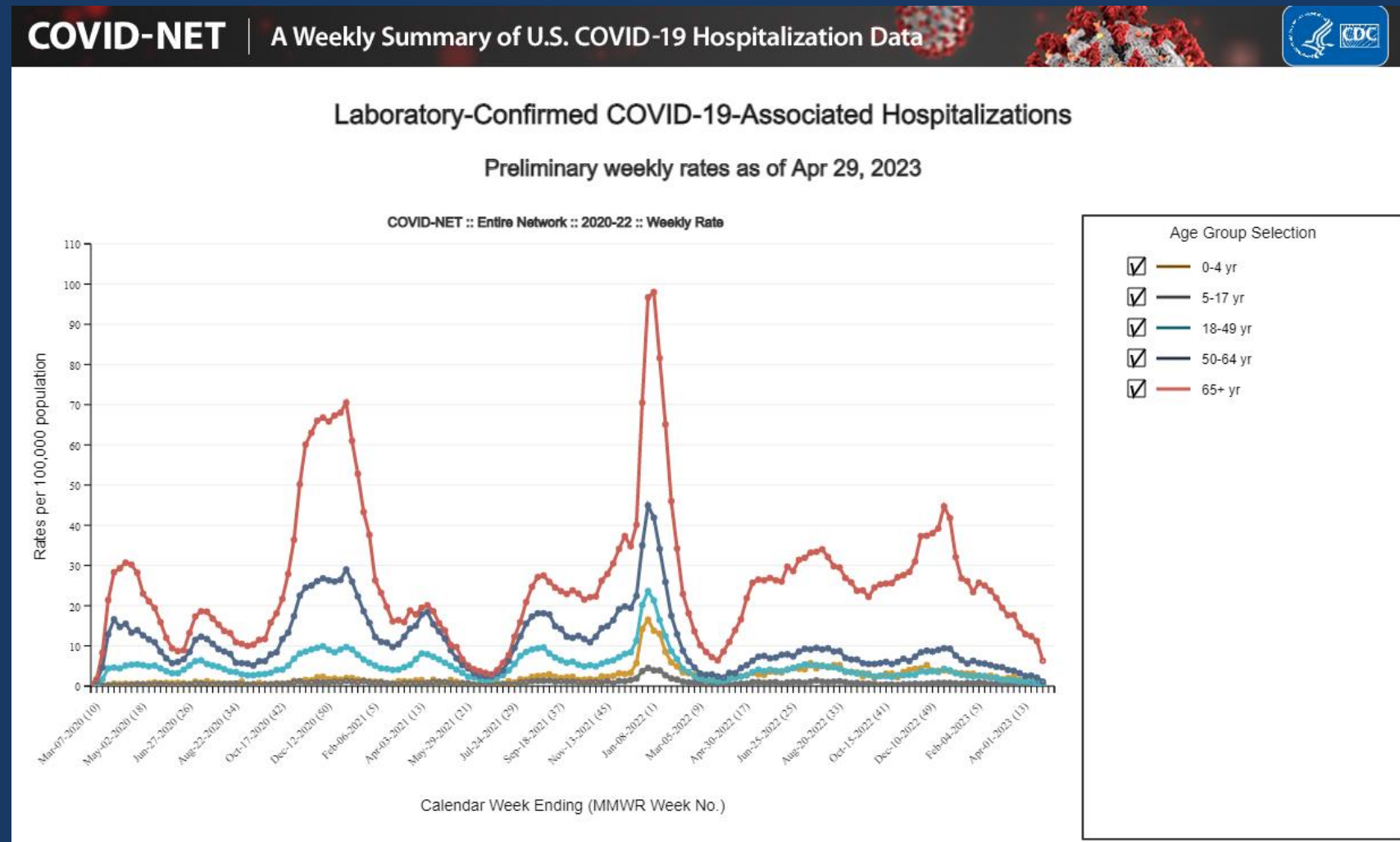
COVID-19 in the U.S.

- As of May 4, 2023, more than 104 million cases of COVID-19 and more than 1.1 million deaths reported in the U.S. since the start of the pandemic.
- Cases, hospitalizations, and deaths have continued to decline.
- Effective vaccines and therapeutics are available.
- Recent end of U.S. federal Public Health Emergency Declaration on May 11, 2023.
- The World Health Organization declared an end to the COVID-19 public health emergency of international concern on May 4, 2023.
- Continued focus on prevention of severe illness and death from COVID-19, especially among people at higher risk.



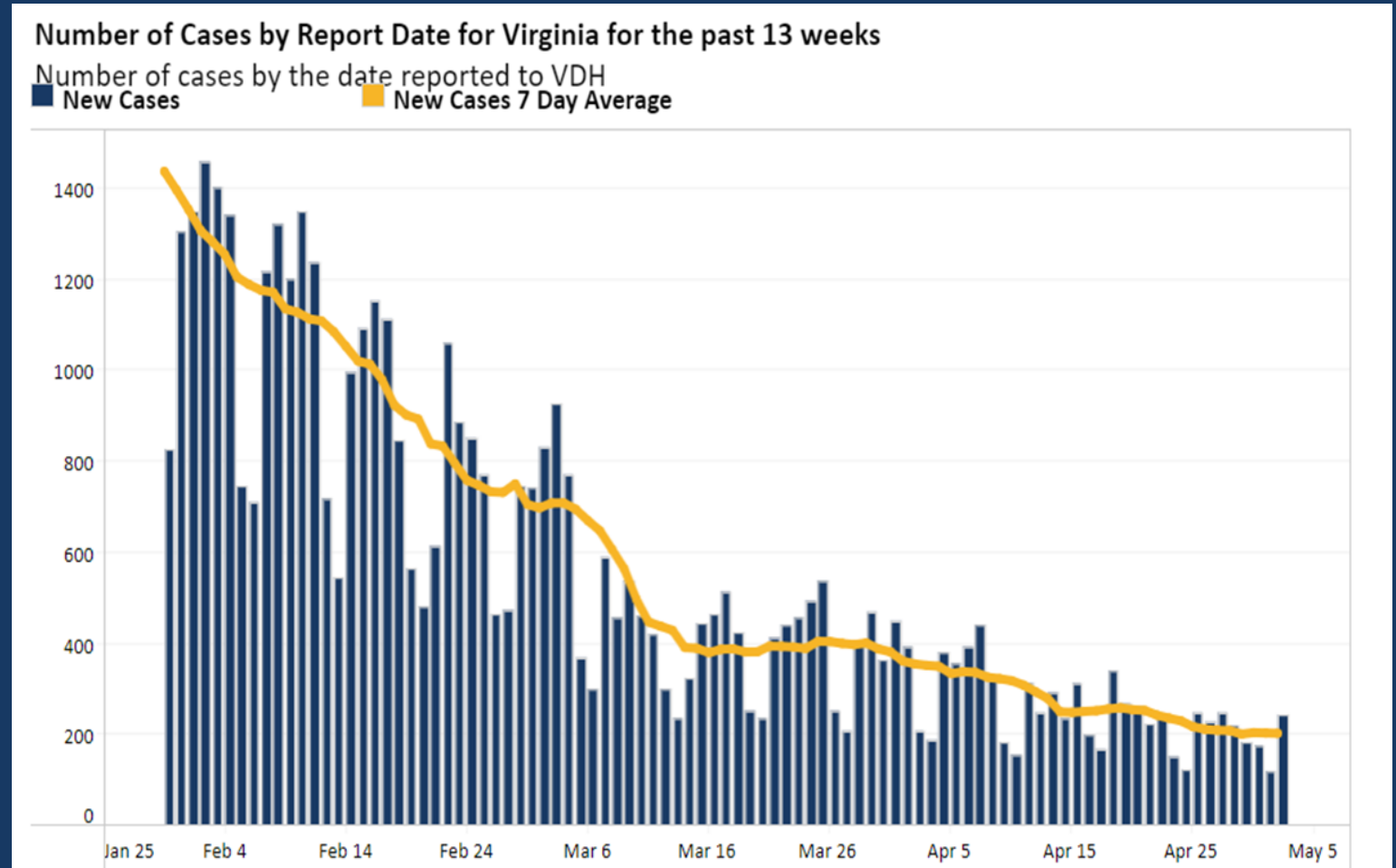
COVID-19 Hospitalization Data in U.S. by Week

- Hospitalization rates highest in people aged 65 years and older
- Hospitalization rates continue to decrease in all age groups



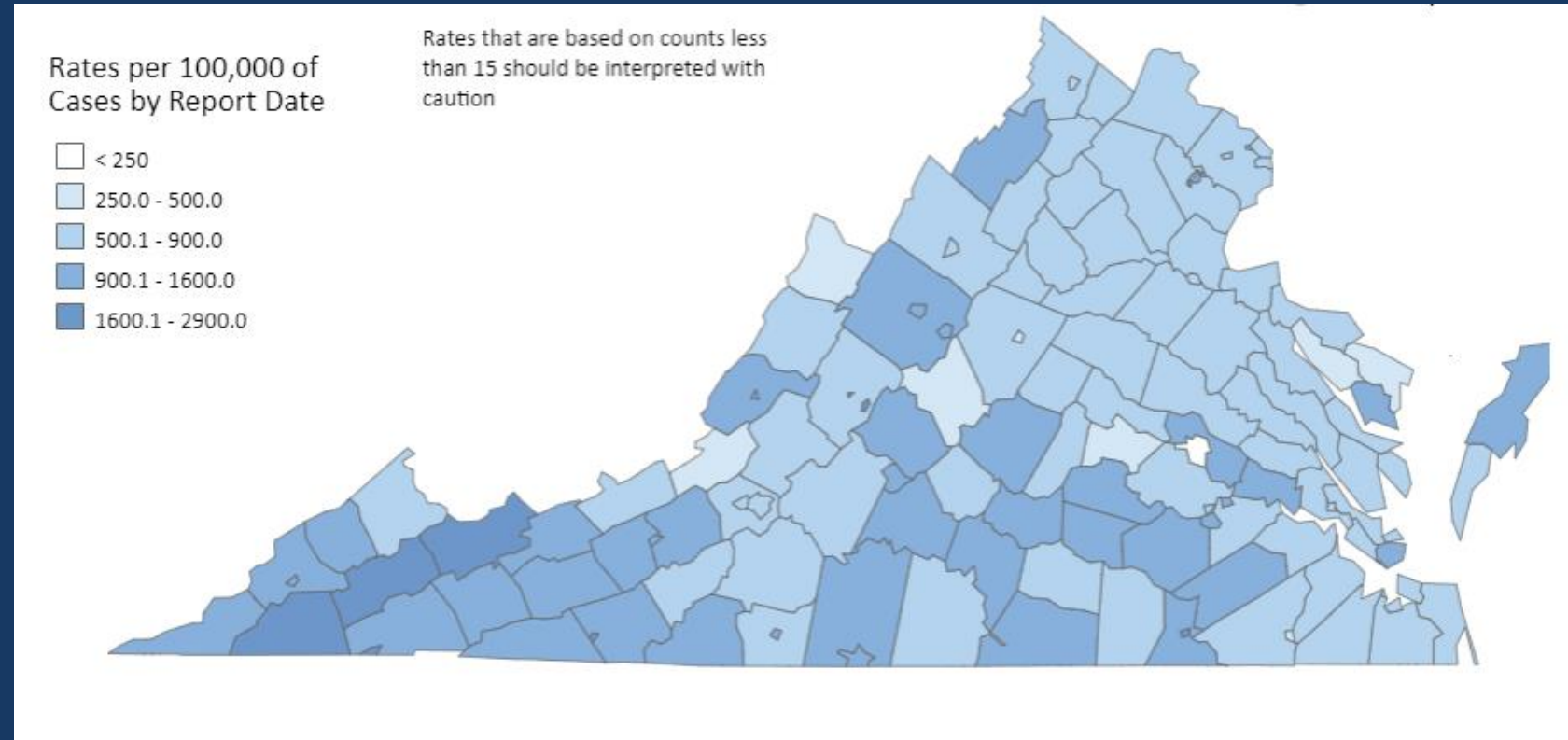
COVID-19 Cases in Virginia

- Cases trending downward in Virginia
- 7-day average approximately 200 cases



COVID-19 Case Rates by Virginia District

- Data are available by district
- In general, seeing low case rates



COVID-19 in Virginia

All Health Districts
Cases* over the Past 13 Weeks

42,530

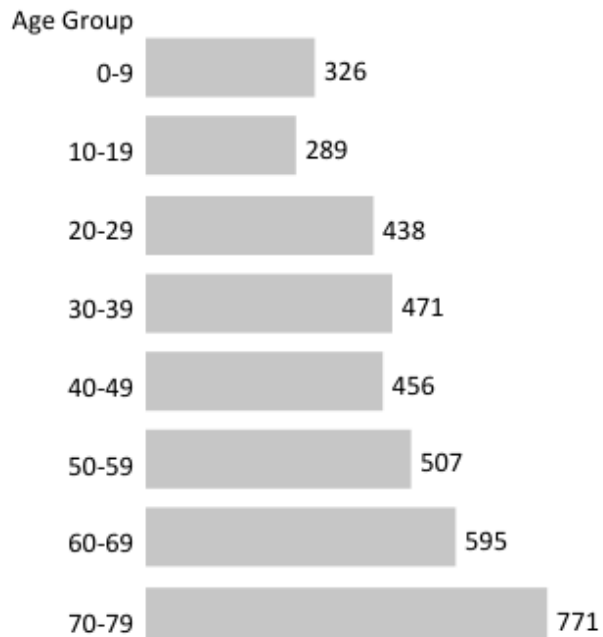
All Health Districts Hospital
Admissions** over the Past 13
Weeks

1,076

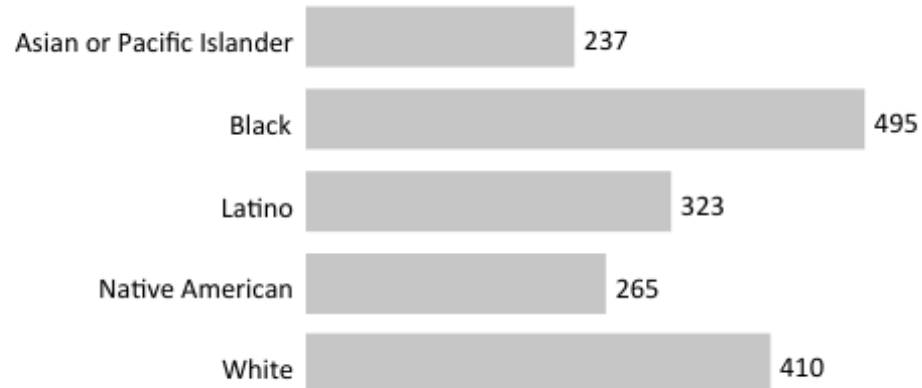
All Health Districts
Deaths over the Past 13 Weeks

58

Case Rate per 100,000 by Age Group -
35 Selected Districts - Past 13 Weeks

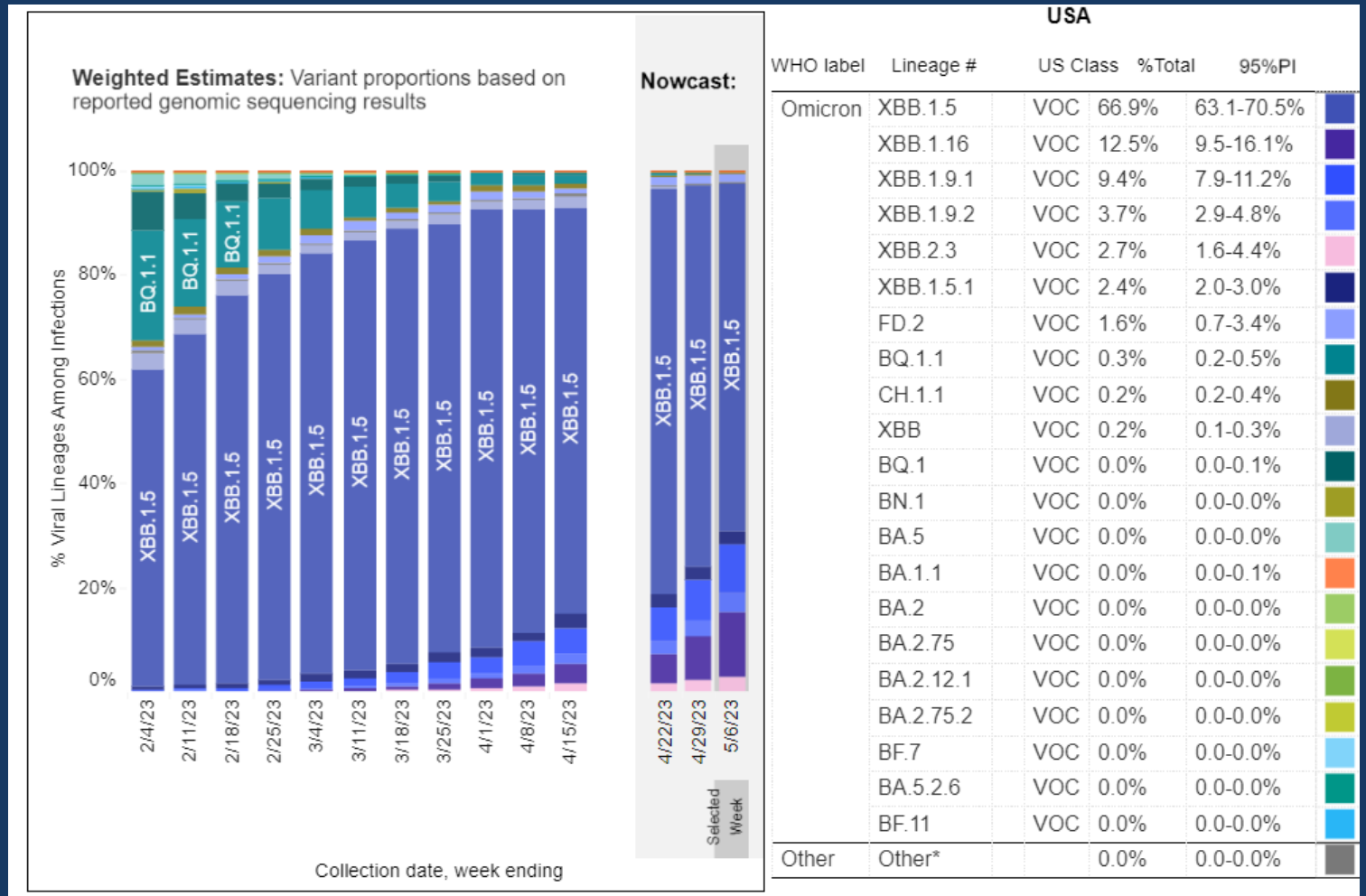


Case Rate per 100,000 by Race and Ethnicity^ -
35 Selected Districts - Past 13 Weeks



CDC Nowcast Estimates for Week Ending May 26, 2023

- XBB.1.5 continues to be the predominant variant but estimated prevalence decreasing
- Estimated prevalence of XBB.1.9.1, XBB.1.5.1, XBB.1.16 increasing



COVID-19 Vaccines: Overview and Updates

COVID-19 Vaccines Currently Available

Three COVID-19 vaccines are approved or authorized in the United States: **Pfizer, Moderna, and Novavax**

Pfizer-BioNTech and Moderna: mRNA vaccines

- As of April 18, 2023, only the **bivalent mRNA vaccines** are authorized for use in all age groups (6 months and older).
- All monovalent mRNA vaccines should be disposed of, as they are no longer authorized for use.
- Bivalent COVID-19 vaccines contain mRNA that encodes the spike proteins of the original (ancestral) strain of the SARS-CoV-2 virus **AND** the Omicron BA.4/BA.5 SARS-CoV-2 virus.

Option for those who are unable or choose not to get an mRNA vaccine:

- **Novavax: protein subunit vaccine**
 - Authorized as a primary series for those 12 years of age and older, and as a first booster dose for those 18 years of age and older.
 - Monovalent vaccine based on the original (ancestral strain) of SARS-CoV-2.

Johnson & Johnson's Janssen (J&J/Janssen): as of May 6, 2023 all doses have expired in the U.S.

- Vaccine providers should dispose of expired vaccine and report wastage in VTrckS.
- All administration of J&J should be discontinued.

Simplification of Updated Guidance

Number of mRNA COVID-19 vaccine products

Moderna: 5 products



Moderna: 2 products



Pfizer-BioNTech: 6 products



Pfizer-BioNTech: 3 products



**Previously:
11 TOTAL Products!**

**Moving forward:
5 Products**

Guidelines for people who are NOT moderately or severely immunocompromised

- **Children 6 months through 4 years of age** are recommended to receive 2 or 3 bivalent vaccine doses depending on vaccine manufacturer.
- **Children 5 years of age** are recommended to receive 1 or 2 bivalent vaccine doses depending on vaccine manufacturer.
- **People 6 years or older** who are unvaccinated or who have only received monovalent vaccines doses are recommended to receive 1 bivalent vaccine dose.
- **People 65 years or older** may choose to receive 1 additional bivalent vaccine dose at least 4 months after their last bivalent dose.



Guidelines for people who are NOT moderately or severely immunocompromised

COVID-19 Vaccination Status	Children aged 6 months to 5 years	People aged 6 years or older
Has not yet received any dose	Recommended to get at least 1 bivalent vaccine dose. The number of doses depends on age and vaccine manufacturer anticipated to use.	Recommended to get 1 bivalent vaccine dose.
Has received at least 1 vaccine dose	Recommended to get at least 1 bivalent vaccine dose. The number of doses depends on age, vaccine manufacturer, and vaccine history.	Recommended to get 1 bivalent vaccine dose at least 8 weeks after last monovalent dose . If already received a bivalent vaccine dose, then an additional bivalent vaccine dose is not recommended. [†]

[†] Individuals **65 and older** may receive an additional bivalent vaccine at least **4 months** after their first bivalent dose.

Guidelines for people who ARE moderately or severely immunocompromised

- **People 6 months or older** are recommended to receive up to 3 bivalent vaccine doses, depending on vaccination history and age.
- **People 6 months or older who already received monovalent dose(s)** are recommended to receive 1 or 2 bivalent vaccine doses, depending on vaccination history and age.
- **People 6 months or older who already received a bivalent dose** are recommended to receive 1 or more additional bivalent vaccine doses.
- Additional bivalent doses may be administered at least 2 months after the previous bivalent dose and is based on informed clinical judgment of a healthcare provider, patient preference and individual risk factors. Further additional doses may be administered in 2 month increments, at the discretion of a healthcare provider.



Vaccination for those who are moderately to severely immunocompromised is particularly important as medication to prevent them from getting COVID-19 (EVUSHELD) is no longer effective against currently circulating variants.

Guidelines for people who ARE moderately or severely immunocompromised

People aged 6 months or older	People aged 6 months or older who received only a monovalent dose(s)	People aged 6 months or older who received a bivalent dose(s)
Recommended to receive up to 3 bivalent vaccine doses.	Recommended to get 1 or 2 bivalent vaccine doses.	Recommended to get 1 or more additional bivalent vaccine doses [†] .
[†] Additional bivalent doses may be administered at least 2 months after the previous bivalent dose and is based on informed clinical judgment of a healthcare provider, patient preference and individual risk factors. Further additional doses may be administered in 2 month increments, at the discretion of a healthcare provider.		

Is My Patient Up To Date With COVID-19 Vaccination?

Everyone aged 6 years and older

- Considered up to date after receiving 1 bivalent Pfizer-BioNTech or Moderna COVID-19 vaccine.

Children aged 6 months—5 years who got the **Pfizer-BioNTech COVID-19 vaccine**

- Aged 6 months—4 years: considered up to date after receiving 3 COVID-19 vaccine doses, including at least 1 bivalent dose.
- Aged 5 years: considered up to date after receiving at least 1 bivalent vaccine dose.

Children aged 6 months—5 years who got the **Moderna COVID-19 vaccine**

- Considered up to date after receiving 2 Moderna COVID-19 vaccine doses, including at least 1 bivalent vaccine dose.

People who are unable or choose not to get a recommended mRNA vaccine

- Considered up to date after receiving all age-appropriate Novavax vaccine doses.

Future of Bivalent Vaccines

- On June 15, 2023, FDA's advisory committee will meet to determine composition of the fall COVID-19 vaccine to target current circulating variants, similar to flu vaccine campaigns.
- CDC and FDA will also discuss a possible annual vaccine schedule.
- CDC indicated that receiving a bivalent dose now should not impact eligibility for a fall vaccine dose.



Clinical Pearls of Vaccination



Coadministration with other vaccines

- COVID-19 vaccines may be administered on the same day as other vaccines.
- Persons, particularly adolescent or young adult males, may consider waiting 4 weeks after orthopoxvirus (mpox) vaccination (either JYNNEOS or ACAM2000) before receiving a COVID-19 vaccine because of the observed risk for myocarditis and/or pericarditis after ACAM2000 and the unknown risk after JYNNEOS vaccination.

History of prior SARS-CoV-2 Infection

- COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection.
- Patient dependent - level and length of protection after infection varies, and immunity decreases with time.

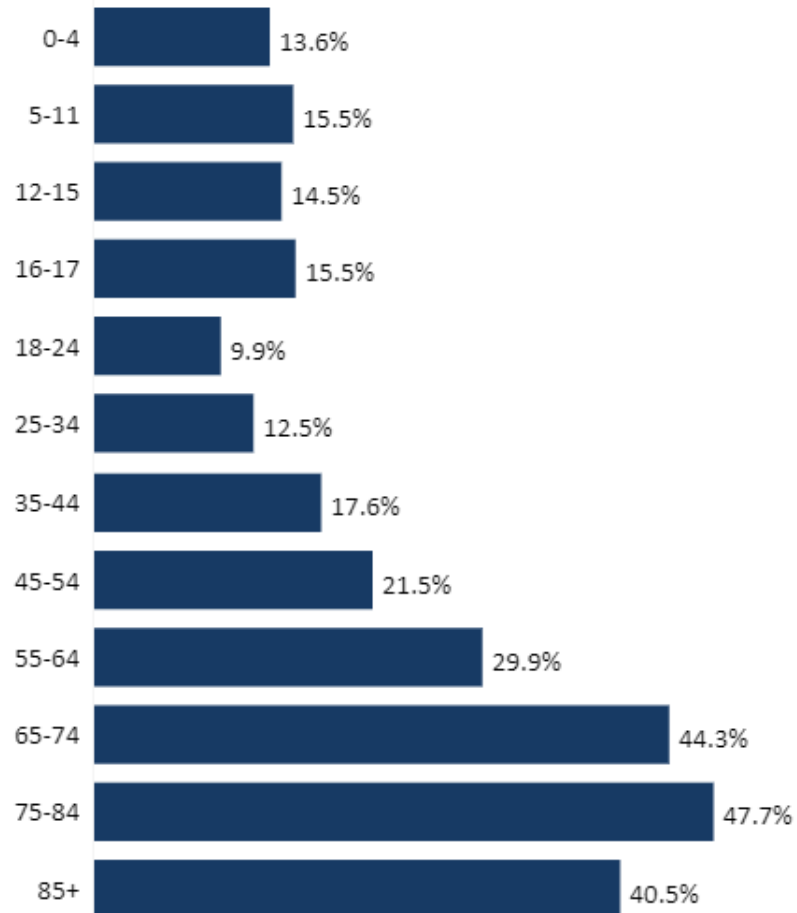
Current or recent infection with SARS-CoV-2

- Defer vaccination until person recovers from acute illness and criteria have been met for them to discontinue isolation.
- People who recently had SARS-CoV-2 infection may consider delaying their next COVID-19 dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

Vaccine Uptake

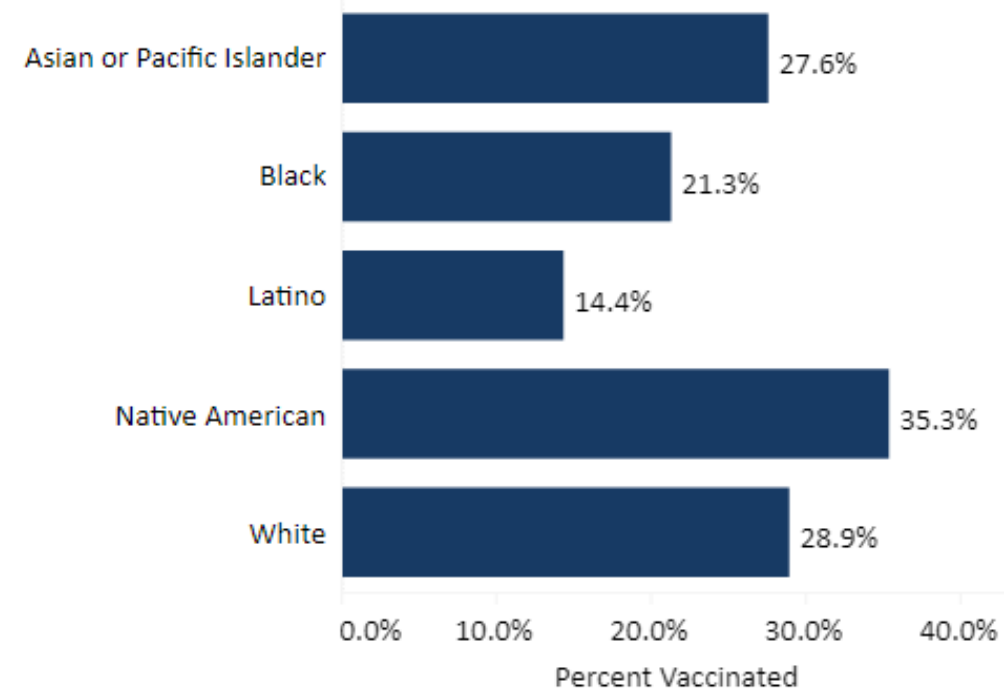
COVID-19 Bivalent Vaccination Rates in Virginia

Percent of the Population Vaccinated with Bivalent Booster - By Age Group



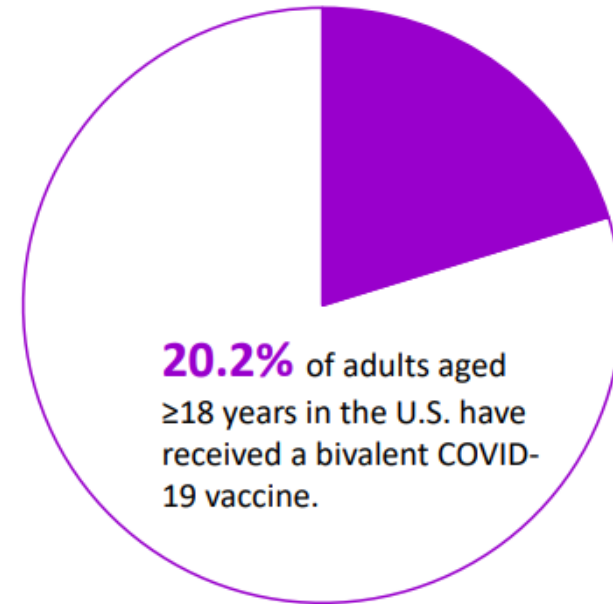
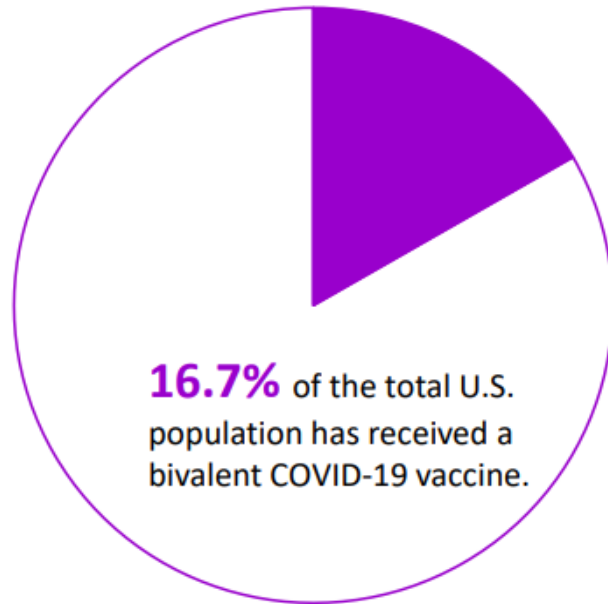
Data as of 5/9/2023

Percent of the Eligible Population Vaccinated with Bivalent Booster - By Race and Ethnicity*



Bivalent COVID-19 Vaccine Uptake in the U.S.

Bivalent COVID-19 vaccine coverage is **low**.

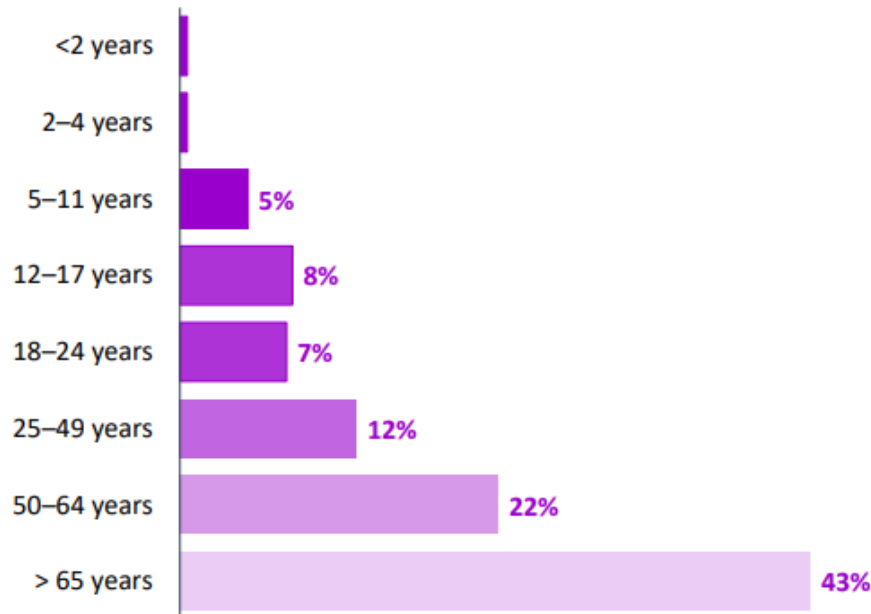


COVID-19 Data Tracker, last updated April 13, 2023, [CDC COVID Data Tracker: Vaccinations in the US](https://www.cdc.gov/covid/data-tracker/vaccinations-in-the-us)

Bivalent COVID-19 Vaccine Uptake in the U.S.

Bivalent COVID-19 vaccine coverage generally **decreases** with **decreasing** age.

Bivalent COVID-19 Vaccination Coverage by Age

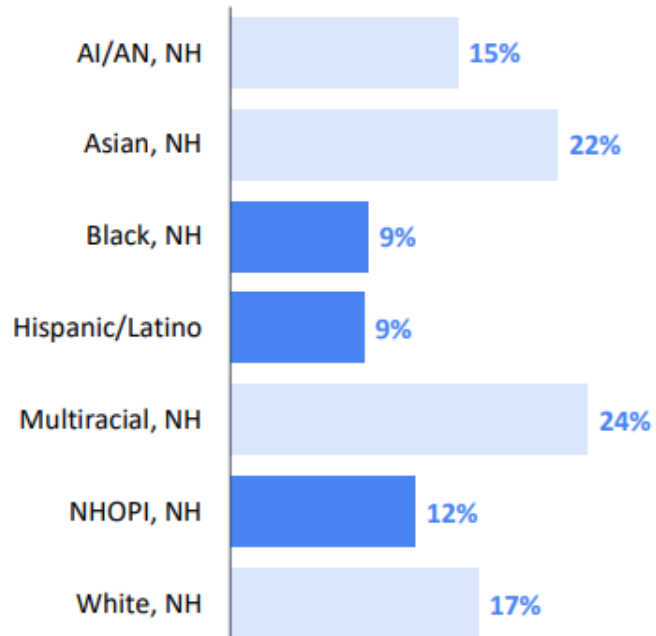


COVID-19 Data Tracker, last updated April 13, 2023, <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends>

Bivalent COVID-19 Vaccine Uptake in the U.S.

Bivalent COVID-19 vaccine coverage is lower among Black, non-Hispanic, Hispanic/Latino, and Native Hawaiian or Other Pacific Islander.

Bivalent COVID-19 Vaccination Coverage by Race/Ethnicity



COVID-19 Data Tracker, last updated April 14, 2023, <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends>

AI - American Indian; AN - Alaskan Native; NHOPI - Native Hawaiian or Pacific Islander; NH - non-Hispanic

Take Home Messages

- COVID-19 vaccination continues to be a safe and effective method for preventing serious illness, hospitalization, and death.
- Vaccination is a safe and reliable way to build protection.
- Updated CDC recommendations simplify guidance for most people, offer flexibility for those who are immunocompromised, and provide customized recommendation for young children.
- Bivalent vaccine uptake continues to be low, especially in younger populations.
- Patient education around updated COVID-19 vaccine guidance is important to ensure continued protection from the virus, particularly among the most vulnerable populations with highest risk for severe disease.
- Reminder: providers should continue to report side effects, adverse events, and reactions from the COVID-19 vaccine through VAERS: <https://vaers.hhs.gov/>

Resources

CDC:

- [COVID-19 Clinical Considerations](#)
- [Stay Up to Date with COVID-19 Vaccines](#)
- [CDC COCA Call: Updated Recommendations for COVID-19 Vaccine Use](#)
- [ACIP Meeting Notes](#)

VDH:

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

Thank You for Your Attendance and Participation!

Questions?

EXTRA SLIDES

Guidelines for those who received Novavax COVID-19 vaccine

- **People aged 12 years and older** who received 1 or 2 monovalent Novavax COVID-19 primary series dose(s) are recommended to receive 1 bivalent mRNA vaccine dose.
- The monovalent Novavax COVID-19 Vaccine remains authorized for use as a 2-dose primary series and as a booster dose in certain limited situations.
 - A booster dose of Novavax is authorized 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); and 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.
 - The monovalent Novavax booster dose is administered **at least 6 months** after completion of any primary series.

Bivalent Vaccine Effectiveness

- 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 received 2–4 doses of the monovalent COVID-19 vaccine.
- Looking at individuals aged 12 years and older, one study found that the average effectiveness against severe infection resulting in hospitalization or death over a three-month period was 25% for one monovalent booster dose and 62% for one bivalent booster dose.
- Another study found that the bivalent vaccine consistently elicited higher neutralizing responses against BA.5-derived sublineages and the BA.2-derived sublineage than the original monovalent vaccine when administered as a fourth booster dose, regardless of the participants' history of SARS-CoV-2 infection.



Sources: <https://www.cdc.gov/mmwr/volumes/72/wr/mm7205e1.htm>
<https://www.nejm.org/doi/full/10.1056/NEJMc2215471>
<https://www.nejm.org/doi/full/10.1056/NEJMc2214916>

Bivalent Vaccine Effectiveness

- **Bivalent** boosters are helping provide additional protection against emergency department/urgent care encounters and hospitalization, though evidence of waning
- For most people who received **monovalent** doses and are eligible for a **bivalent** booster, more than a year has elapsed since their last monovalent dose. Because of waning, they may have limited remaining protection.
- Vaccines provide durable protection against the most critical illness (mechanical ventilation and death)
- CDC will continue ongoing monitoring of VE, including for all outcomes of interest and for all authorized vaccines in the U.S. (Pfizer-BioNTech, Moderna, Janssen, Novavax) with a focus on assessing new policy recommendations and VE in populations at higher risk of severe COVID-19

VE = Vaccine Effectiveness

23

CDC found that the **bivalent COVID-19 vaccine** provides **added protection against symptomatic infection with Omicron XBB/XBB.1.5-related variants** for at least the first 3 months after vaccination in people who had received 2–4 doses of the monovalent COVID-19 vaccine.

Slide Courtesy of: ACIP April 19, 2023 Presentation Slides | Immunization Practices |
CDC: COVID-19 Vaccine Effectiveness Updates

Source: <https://www.cdc.gov/mmwr/volumes/72/wr/mm7205e1.htm>

Safety Considerations

Contraindications

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- A known diagnosed allergy to a component of the COVID-19 vaccine

Precautions

- History of anaphylaxis after any other vaccine or injectable therapy
- History of multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)
- History of an immediate (within 4 hours of exposure) non-severe allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine
- Allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the other types of COVID-19 vaccines.
- Moderate or severe acute illness, with or without fever
- History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine



Side Effects

- Side effects after a COVID-19 vaccination tend to be **mild, temporary, and like those experienced after routine vaccinations**. They can vary across different age groups.
- Early safety findings from v-safe and the Vaccine Adverse Event Reporting System (VAERS) for bivalent booster vaccination in children aged 5–11 years are similar to those described for monovalent booster vaccination. Most VAERS reports represented vaccine errors rather than adverse events. **Neither myocarditis nor death were reported after bivalent booster vaccination.**

AGE GROUP

6 MONTHS–3 YEARS

Common side effects can include:

- Pain on the leg or arm where the shot was given
- Swollen lymph nodes
- Irritability or crying
- Sleepiness
- Loss of appetite

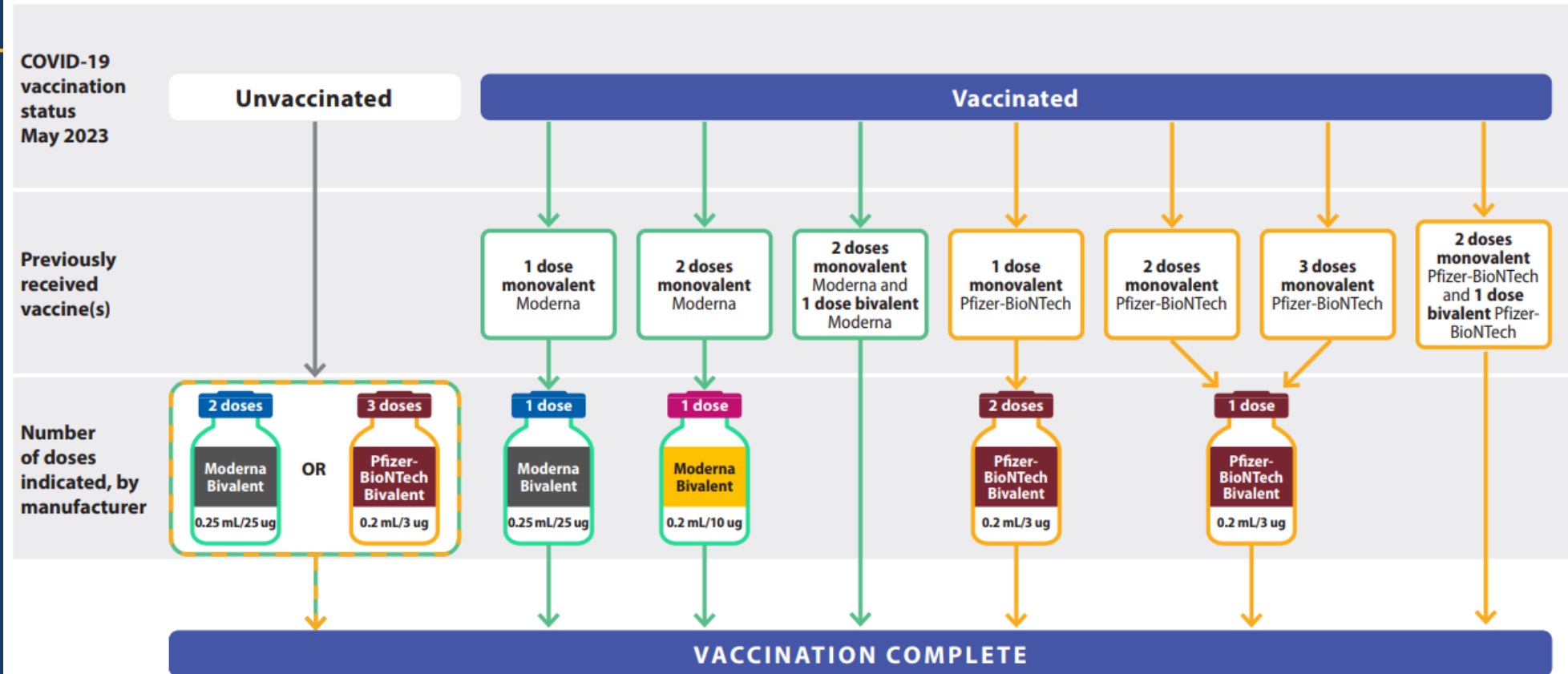
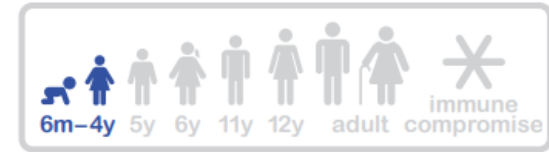
AGE GROUP

4–17 YEARS

Side effects are more common **after the second dose** and can include:

- Pain, swelling, and redness on the arm where the shot was given
- Tiredness
- Headache
- Muscle or joint pain
- Chills
- Swollen lymph nodes

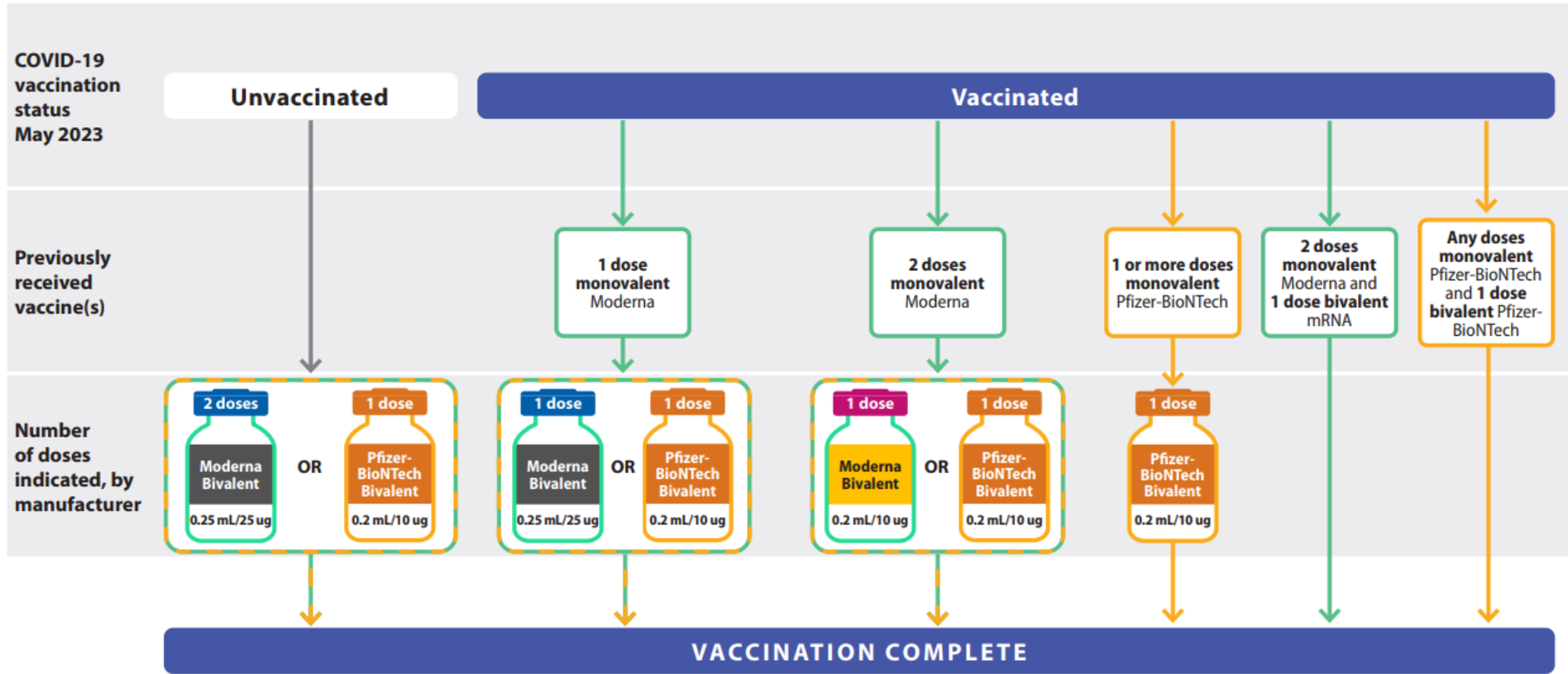
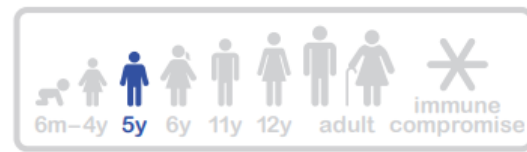
Recommended COVID-19 vaccines for **people without immunocompromise, aged 6 months–4 years**, mRNA vaccines, *with vial icons and dosages, May 2023*[†]



*For administration intervals, see [Table 1](#) in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

[†]Children who receive the Pfizer-BioNTech COVID-19 Vaccine and transition from age 4 years to 5 years during the 3-dose vaccination series must complete the series they start (i.e., receive the 0.2 mL/3 ug dosage supplied in vials with a maroon cap and label with a maroon border for all 3 doses).

Recommended COVID-19 vaccines for **people without immunocompromise, aged 5 years, mRNA vaccines, with vial icons and dosages, May 2023**[†]

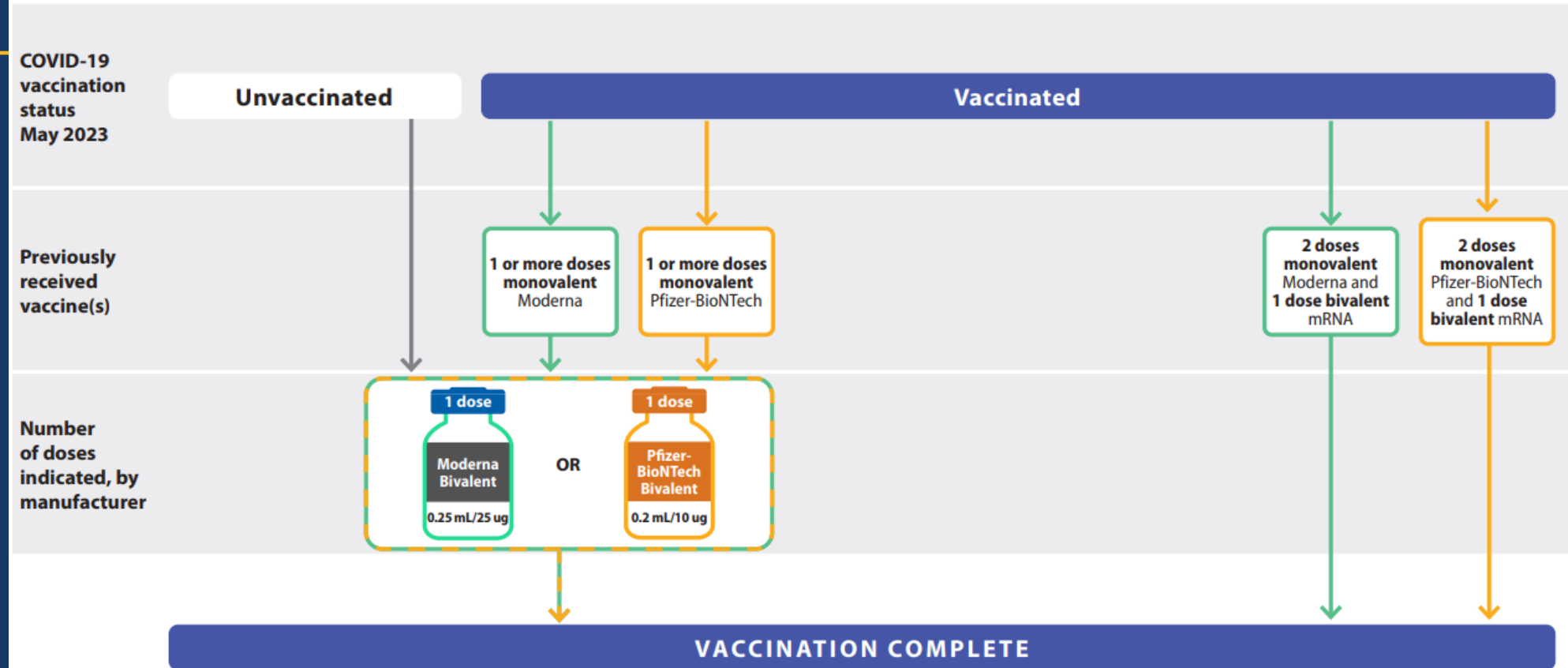
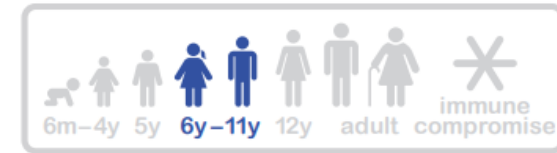


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Children who transition from age 5 years to 6 years during the Moderna vaccination series should receive 2 doses of Moderna COVID-19 Vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border).

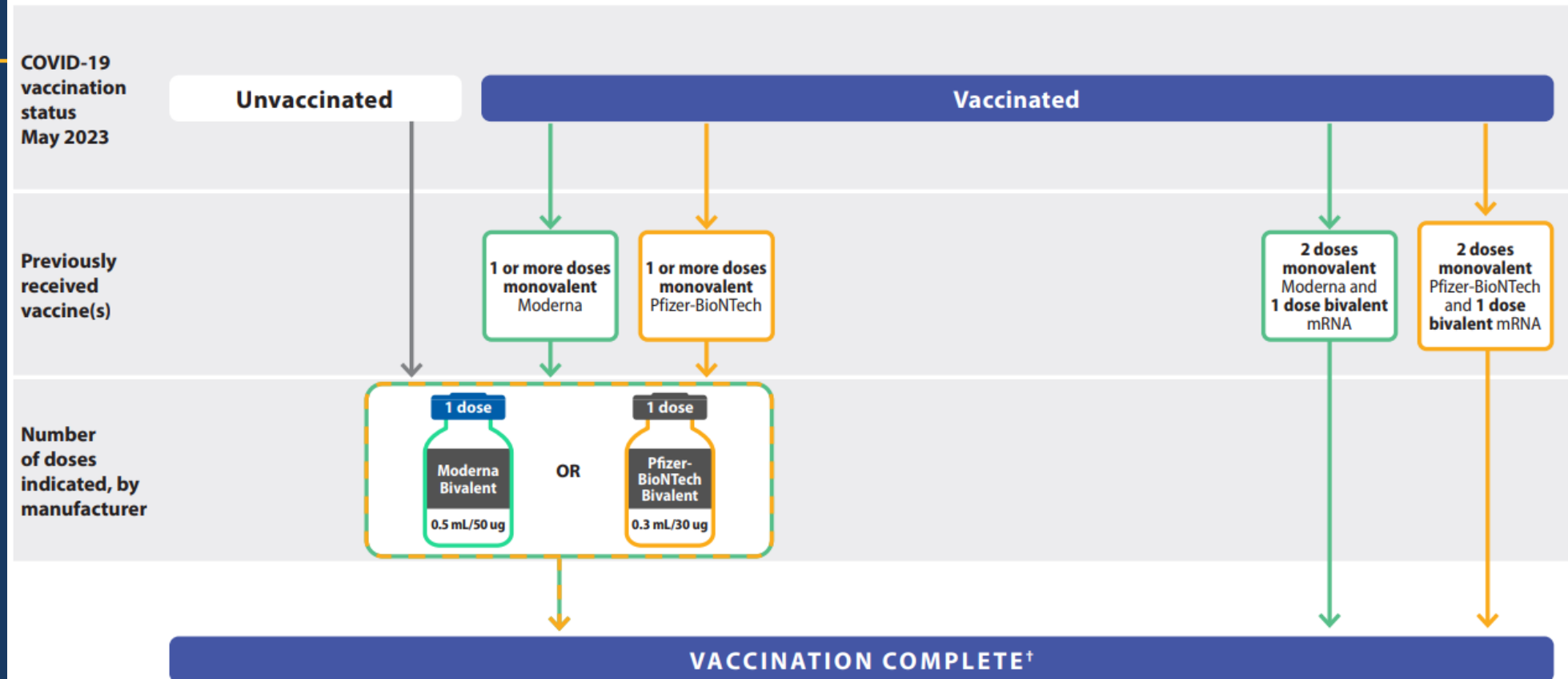
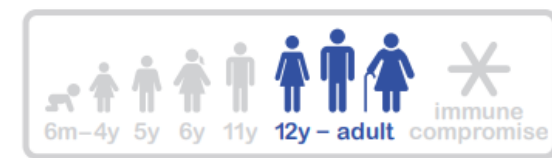
Recommended COVID-19 vaccines for **people without immunocompromise, aged 6–11 years**, mRNA vaccines, *with vial icons and dosages, May 2023*^{*†}



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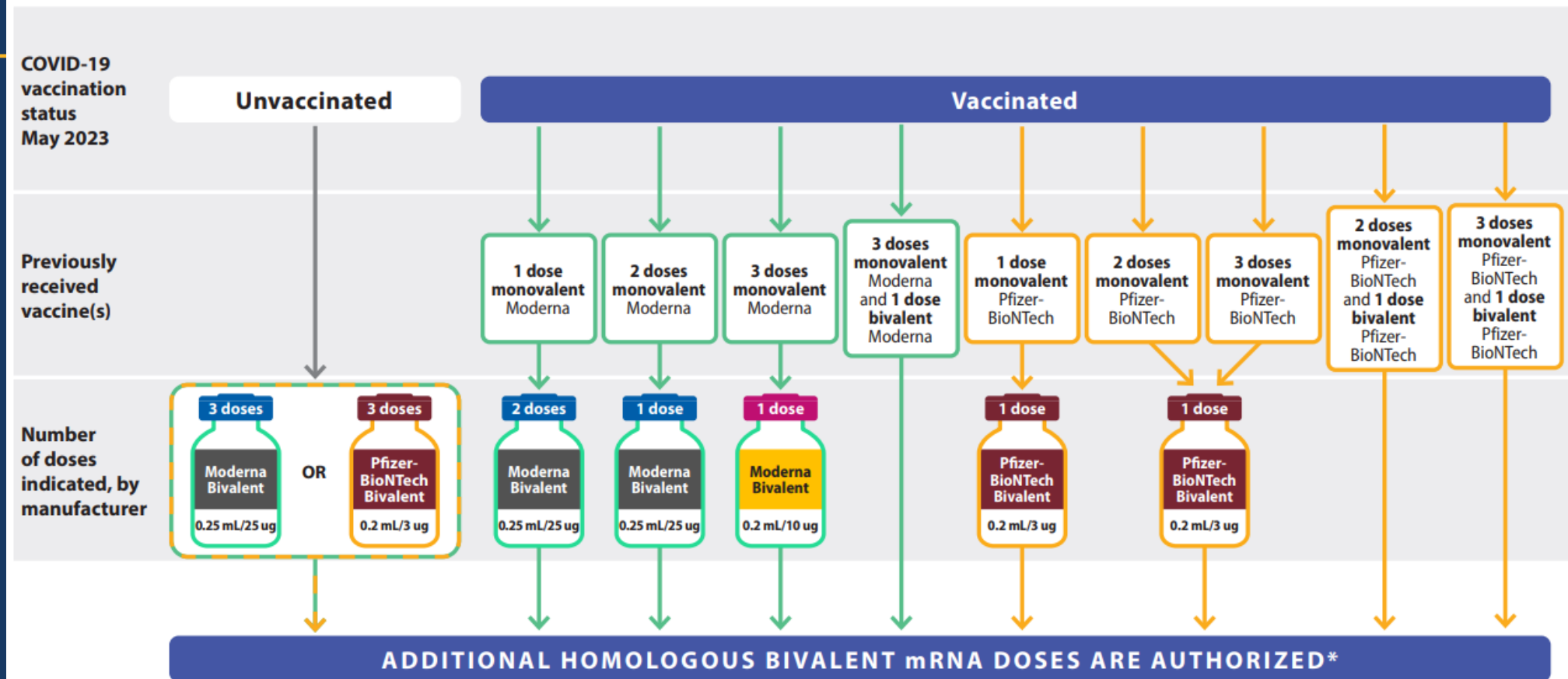
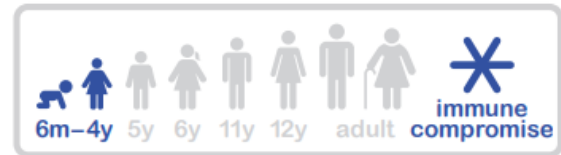
Recommended COVID-19 vaccines for **people without immunocompromise, aged 12 years and older**, mRNA vaccines, with vial icons and dosages, May 2023*†



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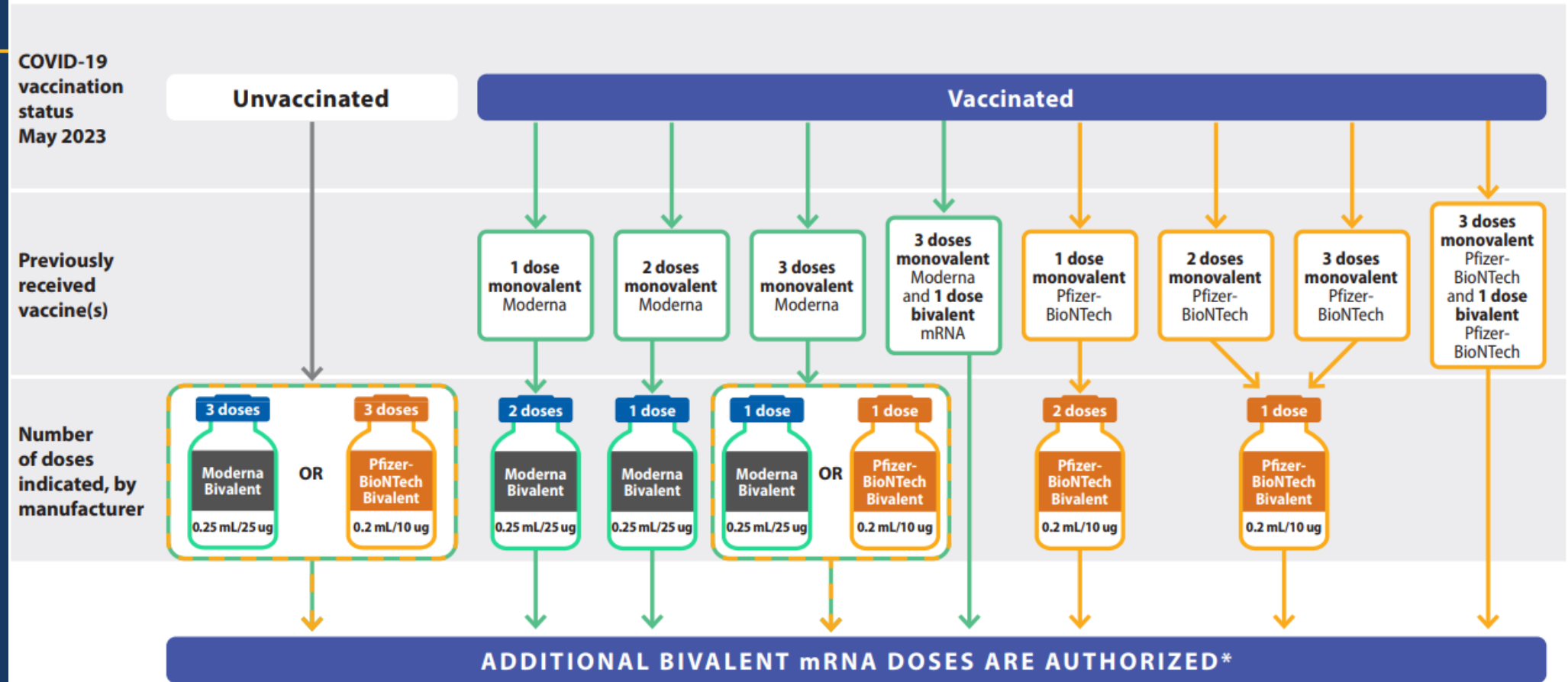
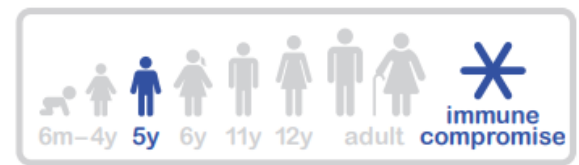
†People ages 65 years and older have the option to receive 1 additional bivalent mRNA dose at least 4 months after the first dose of a bivalent mRNA vaccine; see [Table 1](#) in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 6 months–4 years**, mRNA vaccines, *with vial icons and dosages, May 2023**



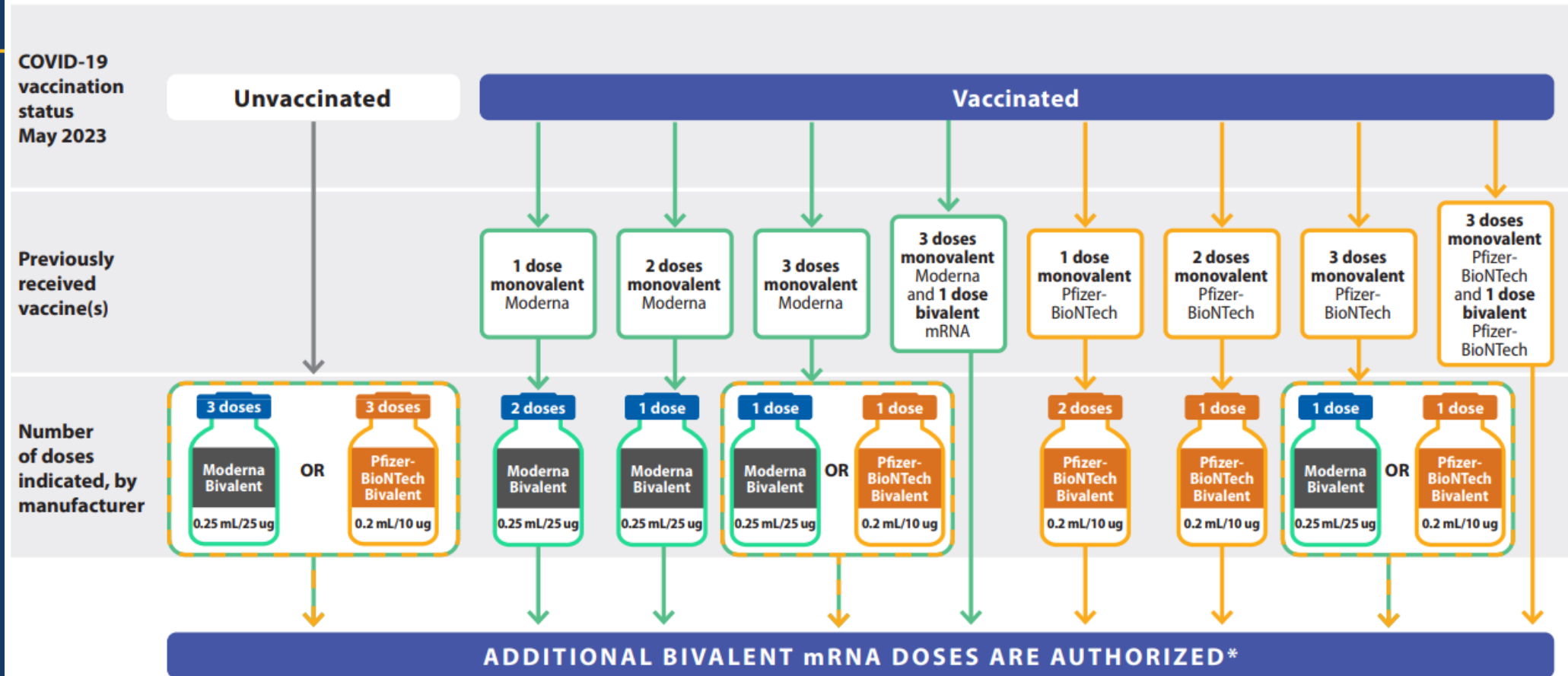
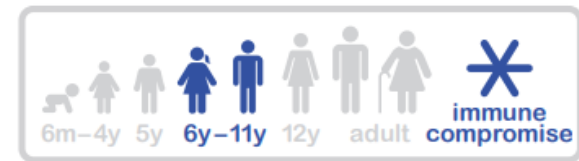
*For product- and vaccination history-specific dosages, administration intervals, and additional dose information, see [Table 2](#) in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 5 years, mRNA vaccines, with vial icons and dosages, May 2023***



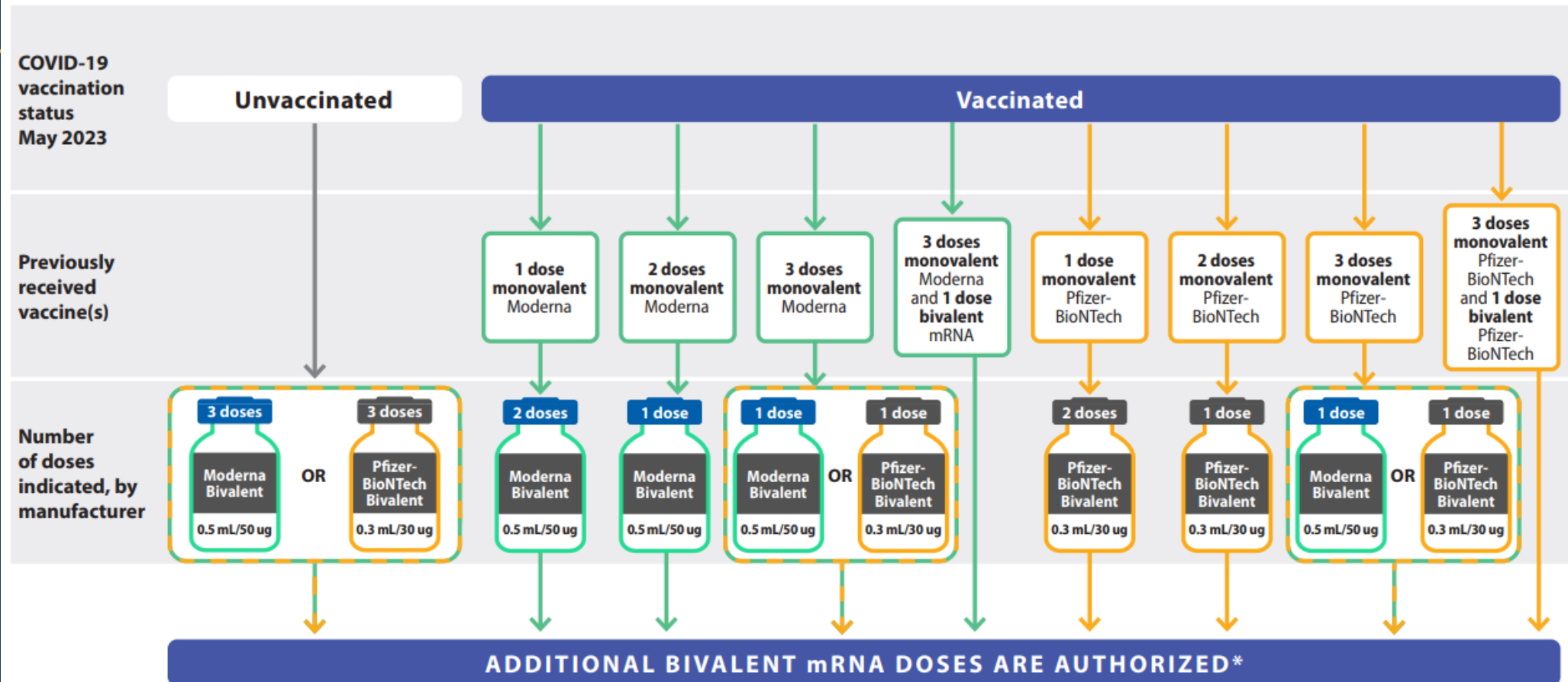
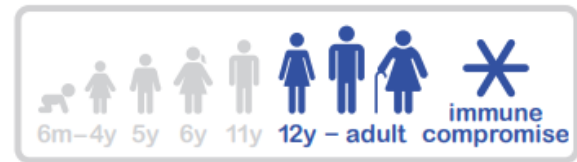
*For administration intervals, additional dose information, and options for heterologous dosing, see [Table 2](#) in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 6–11 years**, mRNA vaccines, with vial icons and dosages, May 2023*



*For product-specific dosages, administration intervals, additional dose information, and options for heterologous dosing, see [Table 2](#) in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 12 years and older, mRNA vaccines, with vial icons and dosages, May 2023***



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