# Updated Recommendations for COVID-19 Vaccine Use

Clinician Outreach and Communication Activity (COCA) Call

Thursday, May 11, 2023

# Free Continuing Education

- Free continuing education is offered for this webinar.
- Instructions on how to earn continuing education will be provided at the end of the call.

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- In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships, in any amount, with ineligible companies over the previous 24 months as well as any use of unlabeled product(s) or products under investigational use.

- CDC, our planners, and presenters wish to disclose they have no financial relationship(s) with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

- Content will not include any discussion of the unlabeled use of a product or a product under investigational use.

- CDC did not accept financial or in-kind support from ineligible companies for this continuing education activity.

# Objectives

At the conclusion of today's session, the participant will be able to accomplish the following:

1. Describe current recommended vaccine doses for people ages 6 years and older.
2. Cite where to find in-depth tables for COVID-19 vaccines indicated for children ages 6 months through 5 years.
3. Discuss the difference in recommendations for use of COVID-19 vaccines between those with and without immunocompromise.
4. Name two populations who can receive an optional additional dose of the updated COVID-19 vaccines.

# To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.

# Today's Presenters

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COVID-19 Response
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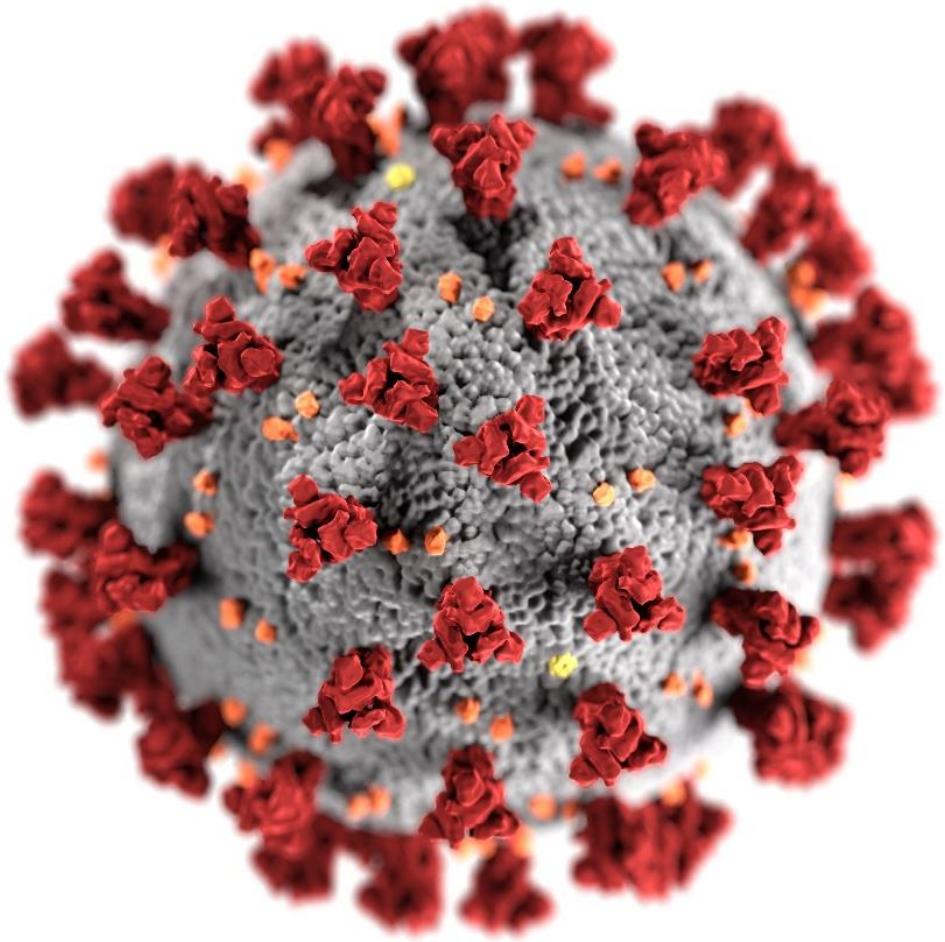
# COVID-19 Vaccines:
## Policy Updates



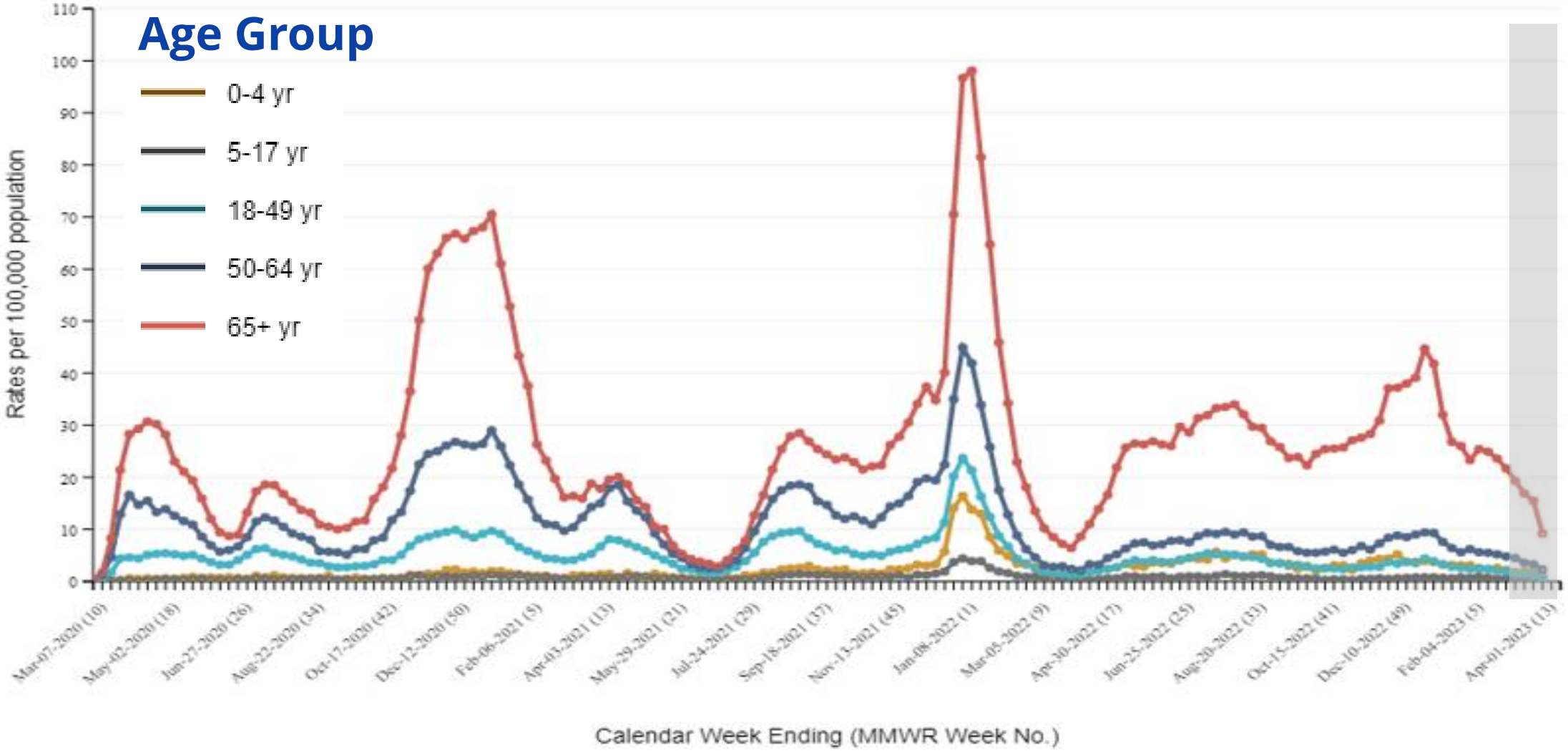
**Sara Oliver, MD, MSPH**

COCA Call

May 11, 2023

**cdc.gov/coronavirus**

# Weekly population-based rates of COVID-19-associated hospitalizations by age group— COVID-NET, March 2020–April 2023




*Gray boxes indicate potential reporting delays. Interpretation of trends should be excluded from these weeks.*

https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network Accessed April 13, 2023

# Updates to COVID-19 vaccine policy

**Steps toward simple recommendations**:

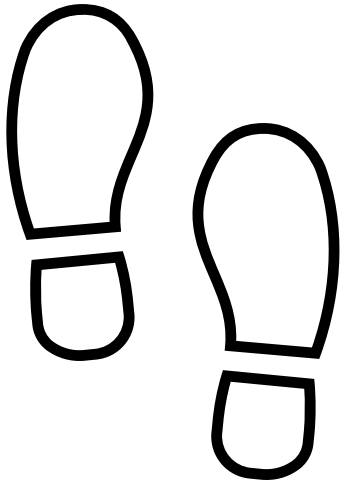
- Single formulation for mRNA COVID-19 vaccines
- Single (possibly annual) dose for most individuals
- Flexibility for vulnerable populations

COVID-19 vaccines: Where we are now

COVID-19 vaccines: Where we are going

**Goal:**
**Simple recommendations**

# Updates to COVID-19 vaccine policy



**Steps toward simple recommendations**:

- Single formulation for mRNA COVID-19 vaccines
- Single (annual?) dose for most individuals
- Flexibility for vulnerable populations

# Single formulation for mRNA COVID-19 vaccines

## Benefits and Harms: Summary from previous ACIP meetings

- Bivalent COVID-19 vaccines are able to **induce an immune response** when given either as a primary series or a booster dose
  - Immunogenicity data showed that a BA.1 bivalent vaccine given as a primary series induced antibody titers to BA.1 that were 25 times higher than the original monovalent vaccine
  - Percentage of patients reporting solicited local or systemic events was similar to or less than percentages seen after original vaccine, however this may be a result of the larger percent of seropositive participants in the bivalent vaccine group
- Limited data to directly compare COVID-19 outcomes after receipt of a monovalent or bivalent vaccine
  - Most studies show **improvement** in neutralizing antibodies for Omicron variants with a bivalent vaccine
  - Bivalent vaccines **expanded** the immune response and provided increased **diversity** in antibody response
  - While unable to directly compare clinical outcomes for monovalent and bivalent vaccines in the U.S., a study in the UK found ~**10% increase** in VE for COVID-19 infections

# Single formulation for mRNA COVID-19 vaccines

## Updates from FDA authorizations

- FDA removed the authorizations for monovalent mRNA COVID-19 vaccines
  - BLAs are still in place for monovalent products:
    - Comirnaty for ages 12 years and older, with limited doses in circulation
    - Spikevax for ages 18 years and older, but all doses are currently expired
- Bivalent mRNA COVID-19 vaccines are now authorized for **all indications**
- No changes to current language in other COVID-19 vaccine authorizations (Novavax or Janssen COVID-19 vaccines)

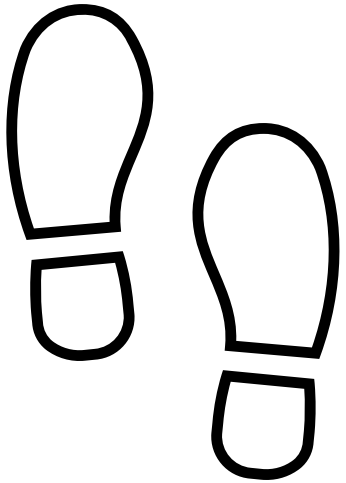
# Single formulation for mRNA COVID-19 vaccines

## Implications for CDC recommendations

- Transition to bivalent COVID-19 vaccines could **simplify** the presentations, reduce administration errors, and allow continued access to vaccines with expiration of monovalent products

Bivalent mRNA COVID-19 vaccines are now recommended for **all indications**

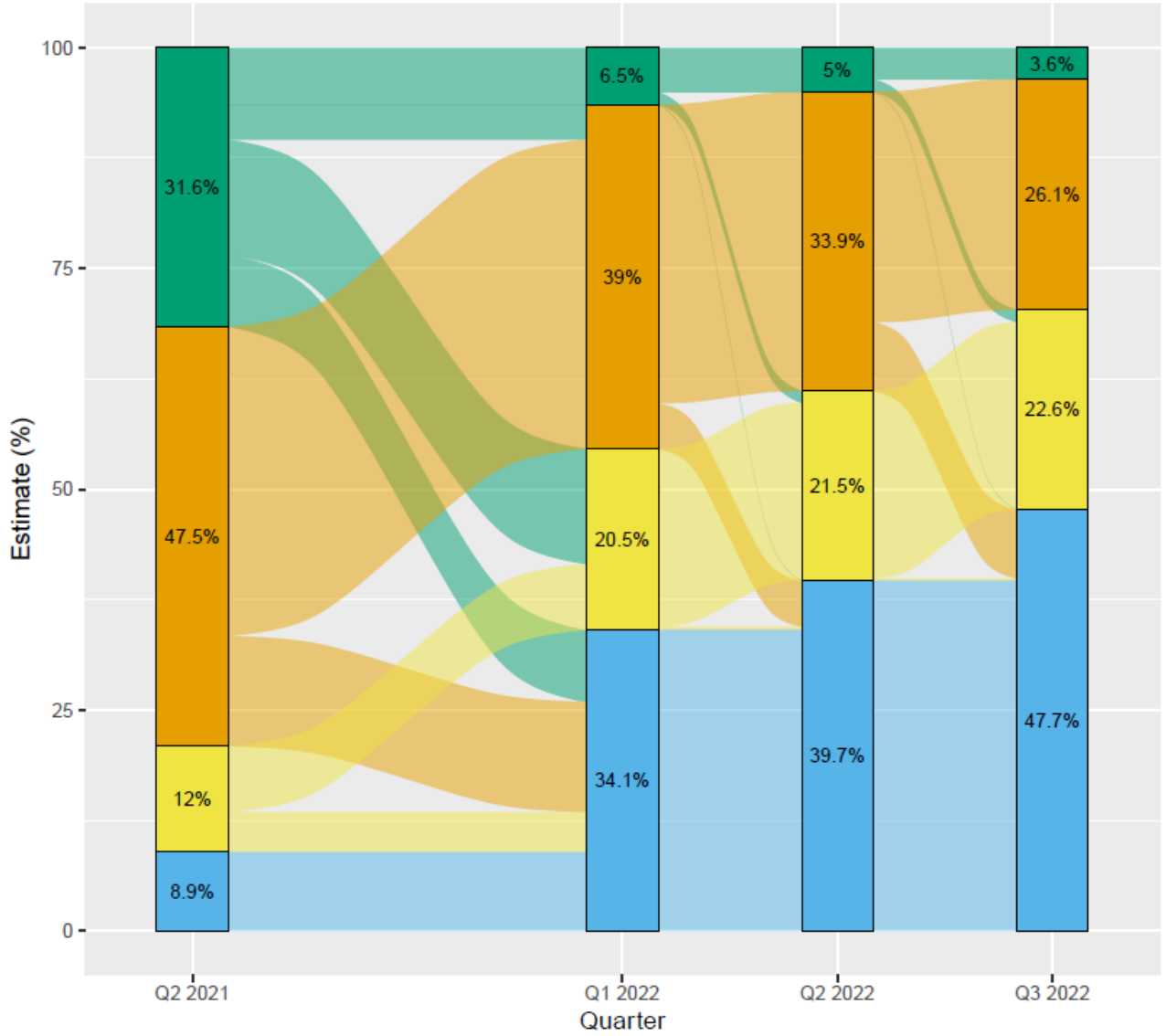
# Updates to COVID-19 vaccine policy



**Steps toward simple recommendations**:

- Single formulation for mRNA COVID-19 vaccines
- Single (annual?) dose for most individuals
- Flexibility for vulnerable populations

# Shifts in vaccine-induced, infection-induced, and hybrid immunity against SARS-CoV-2 among people aged ≥16 years — United States, Quarter 2 2021– Quarter 3 2022




No infection or vaccination

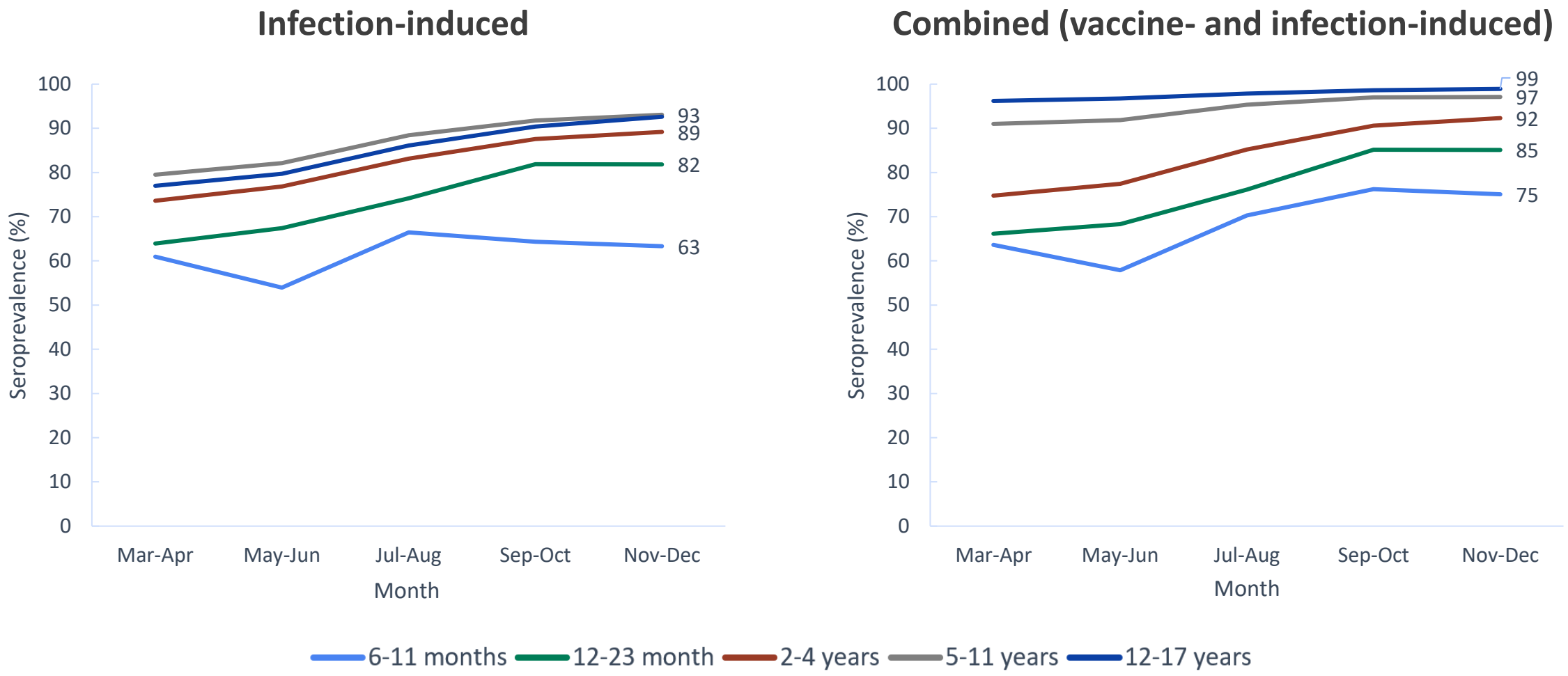
Vaccine only-induced antibodies

Infection only-induced antibodies

Both infection and vaccination-induced antibodies (hybrid immunity)

Source: CDC (unpublished)

# Pediatric infection-induced and combined (vaccine- and infection-induced) Seroprevalence from U.S. commercial laboratories — March–December 2022




Source: https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence and unpublished data (CDC)

# Single (possibly annual) COVID-19 vaccine dose

## Summary from February ACIP meeting

- For most older children, adolescents, and adults, future doses will be additional 'boost' after prior infection, prior vaccination, or both
- Time since last COVID-19 vaccine dose may both increase the incremental benefits of a COVID-19 vaccine, and decrease the risk of myocarditis
- Vaccine protection likely declines over time
- Winter months and immune escape variants have impacted COVID-19 epidemiology
- A simplified, annual recommendation could help reduce vaccine and message fatigue
- A plan for a **fall booster dose** could provide added protection, at a time when many would be ~1 year from last dose
  - Future epidemiology and SARS-CoV-2 virus evolution could help determine the need for continued annual boosters

# Single (possibly annual) COVID-19 vaccine dose

## Updates from FDA authorizations

- FDA authorized a single age-appropriate mRNA COVID-19 vaccine dose for most individuals
- FDA authorized one, two, or three doses of a bivalent mRNA COVID-19 vaccine for children 6 months – 4 or 5 years
- Number of doses depend on **age**, as well as **number** and **type** of prior COVID-19 vaccine doses received

# Single (possibly annual) COVID-19 vaccine dose

## Implications for CDC recommendations

- A COVID-19 vaccine framework for a single dose could be easy for COVID-19 vaccine providers to implement, and for the public to understand
- The current recommendations for a single dose may evolve over time, and could move to an annual recommendation

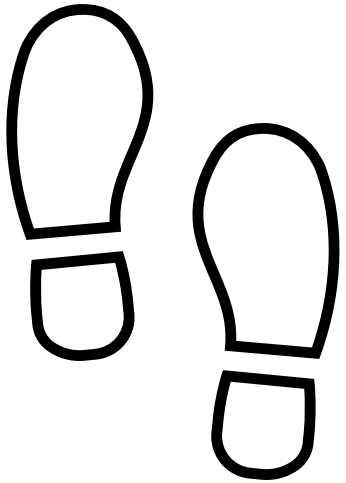
A **single bivalent dose** is now recommended for everyone ages 6 years and older

- For most people, this is not a change: if someone has not received a bivalent vaccine dose yet, they are recommended to receive one, regardless of their previous vaccine history

Children 6 months through 5 years receive **at least two** COVID-19 vaccine doses, including **at least one bivalent** COVID-19 vaccine

- Table and detailed guidance published in **Interim Clinical Considerations**

# Updates to COVID-19 vaccine policy



**Steps toward simple recommendations**:

- Single formulation for mRNA COVID-19 vaccines
- Single (annual?) dose for most individuals
- Flexibility for vulnerable populations

# **COVID-19 vaccines and older adults** (adults ages ≥65 years)

## Summary from February ACIP meeting

- Older adults have higher rates of hospitalization than younger adults
- Among older adults, vaccination rates with a bivalent COVID-19 vaccine dose **remain low**
  - It is important for older adults to be **up to date** on current recommendations, including receiving a bivalent booster
- ACIP discussed that data were insufficient to support a routine recommendation for older adults to receive a COVID-19 vaccine doses every 6 months, but acknowledged this population may continue to be more vulnerable to severe COVID-19 and likely needs **flexibility** with COVID-19 vaccine recommendations

# Flexibility for vulnerable populations

## Implications for CDC recommendations

- The bivalent COVID-19 vaccine continues to provide protection against severe COVID-19 disease, and rates of hospitalization or death among older adults who have received a bivalent booster continue to be low
- However, some older adults may benefit from an additional updated COVID-19 vaccine dose prior to possible future recommendations for updated vaccines this fall

Adults ages 65 years and older may now **choose to receive** another updated COVID-19 vaccine dose

# Flexibility for vulnerable populations

## Implications for CDC recommendations

- For people who are immunocompromised, additional doses have been recommended previously and current updates continue to allow additional protection to a vulnerable population
- Updates also allow **flexibility** to adjust to individual's specific circumstances, including timing of immunosuppression as well as the possible need for re-vaccination after particular events (e.g. stem cell transplant)

People who are immunocompromised may now **choose to receive** another updated COVID-19 vaccine dose -and-

Have the **flexibility** to receive **additional doses** based on their clinical circumstances

# Updates to COVID-19 vaccine policy

**Steps toward simple recommendations**:

- Single formulation for mRNA COVID-19 vaccines
- Single (possibly annual) dose for most individuals
- Flexibility for vulnerable populations

**Future additional steps may be possible** :

- Simplifications for all COVID-19 vaccines
- Possible updated vaccines this fall
- Continue to evaluate data-driven ways to simplify pediatric program
- Flexibility and simple guidance

**Goal:**
**Simple recommendations**

# Updates to COVID-19 vaccine policy

## Steps toward simple recommendations

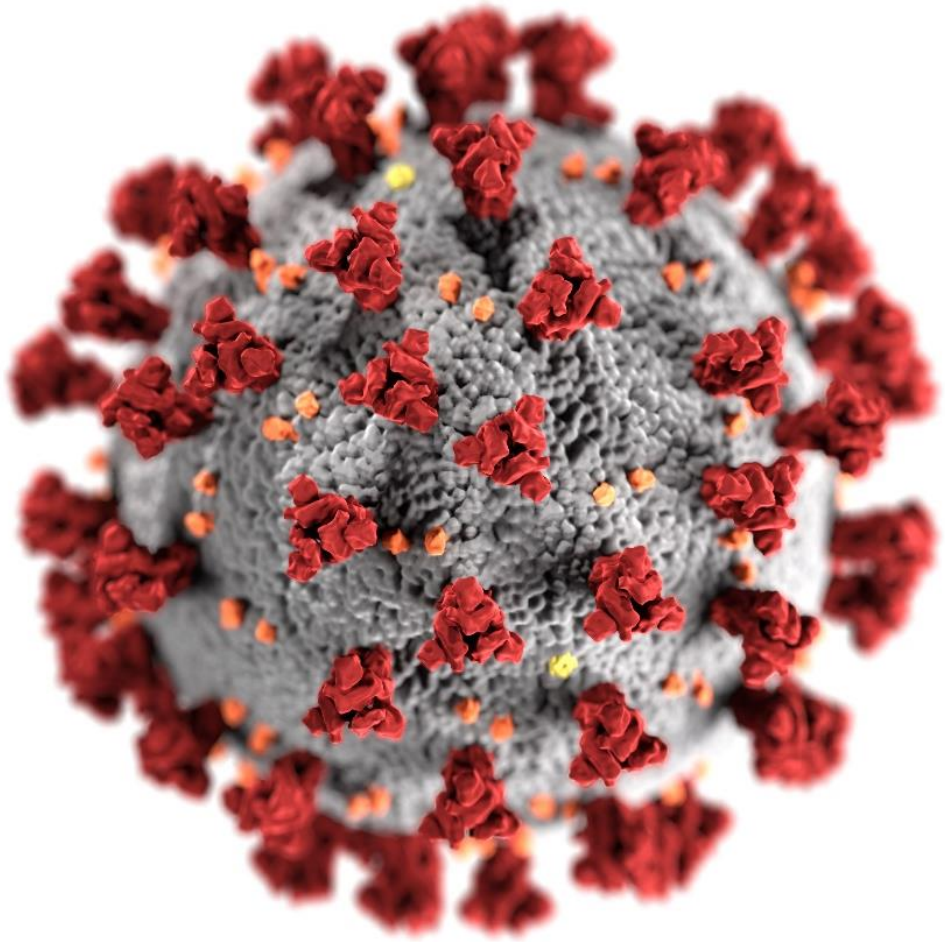
- Continue to **review data** and **evaluate COVID-19 vaccine program** in context of evolving epidemiology
- Early COVID-19 vaccine recommendations made in light of a highly susceptible, immune naive population, with limited treatment options
- Increases in population-level immunity through both vaccine and infection, SARS-CoV-2 virus evolution, availability of anti-viral treatments, and review of COVID-19 epidemiology and hospitalization rates can lead to **evidence-based updates** in vaccine policy
- **Work is ongoing** to review additional data, continue efforts for simplification

# Updates to Interim Clinical Considerations for Use of COVID-19 Vaccines

**Evelyn Twentyman, MD, MPH**

COCA Call

May 11, 2023



**cdc.gov/coronavirus**

# Overview of implications

# Implications of the new recommendations

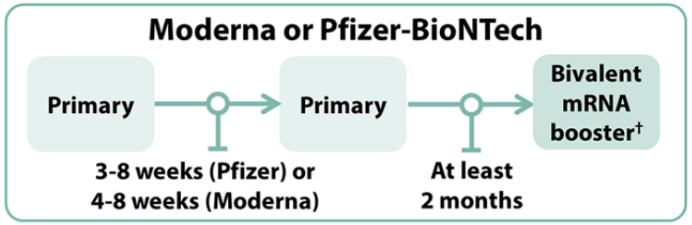
- Simple and singular for most
- Flexible for people at higher risk
- Customized recommendations for young children

# Implications of the new recommendations

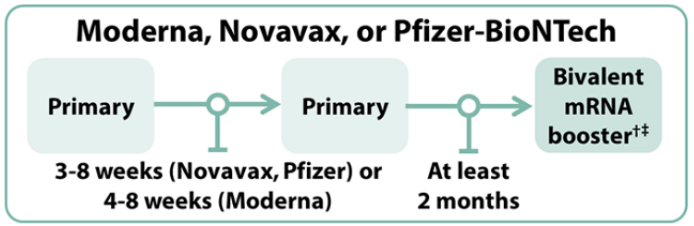
- **Simple and singular for most**
- Flexible for people at higher risk
- Customized recommendations for young children

# Previous recommendations for people aged ≥6 years without immunocompromise

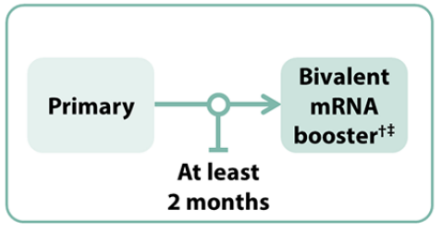
## People ages 6 through 11 years




## 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.

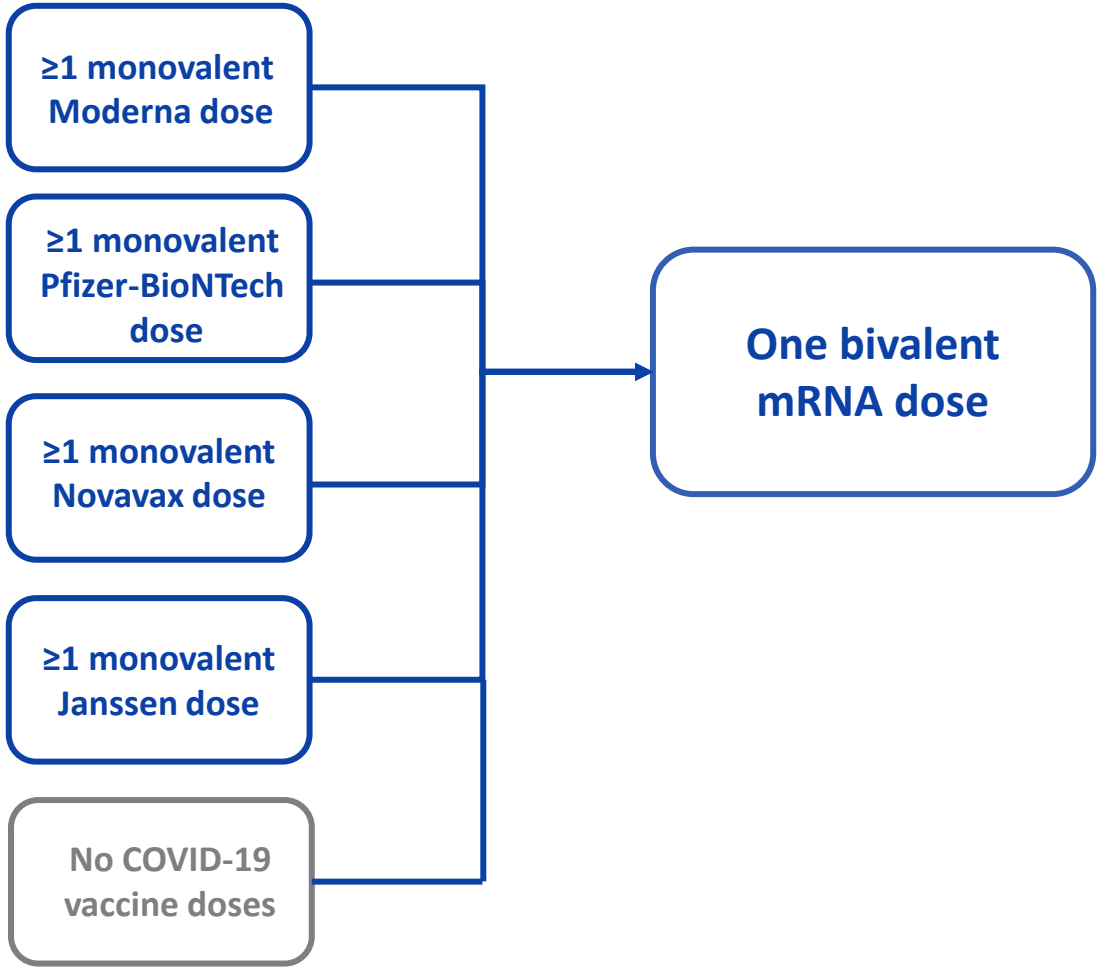
‡ A monovalent Novavax booster dose may be used in limited situations in people ages 18 years and older who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose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

# New recommendations for people aged ≥6 years without immunocompromise who have not yet received a bivalent mRNA dose

One bivalent mRNA dose

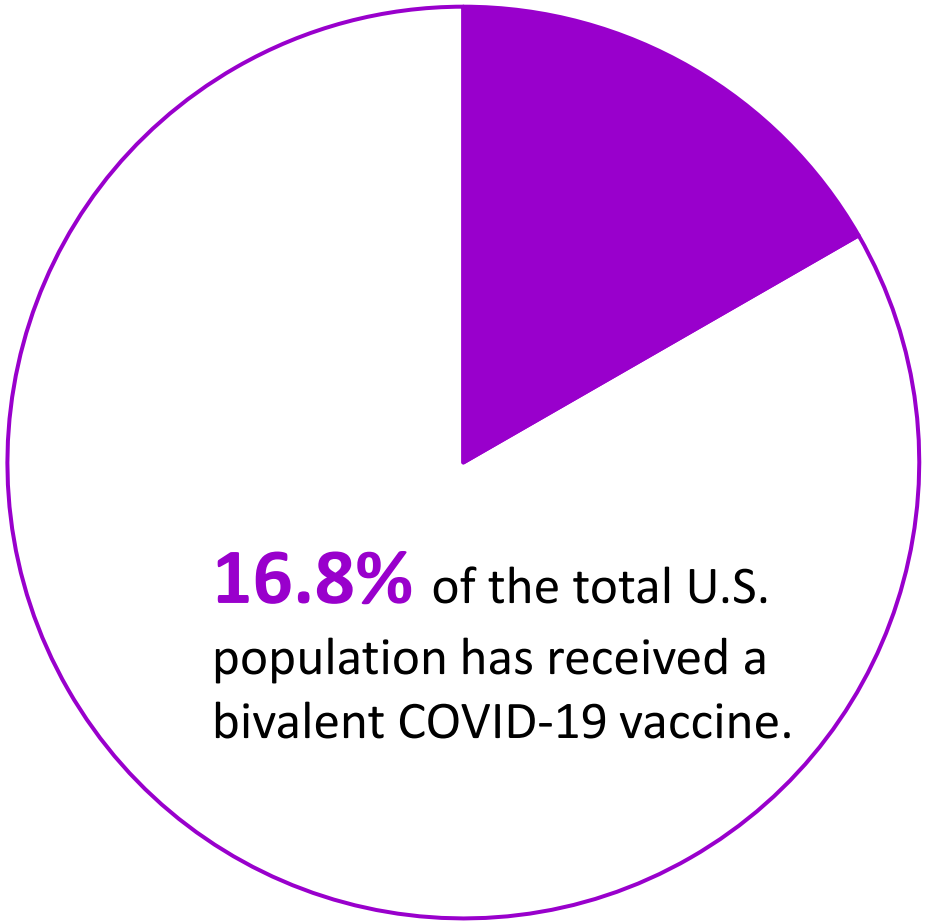
# New recommendations for people aged ≥6 years without immunocompromise who have not yet received a bivalent mRNA dose, regardless of COVID-19 vaccination history

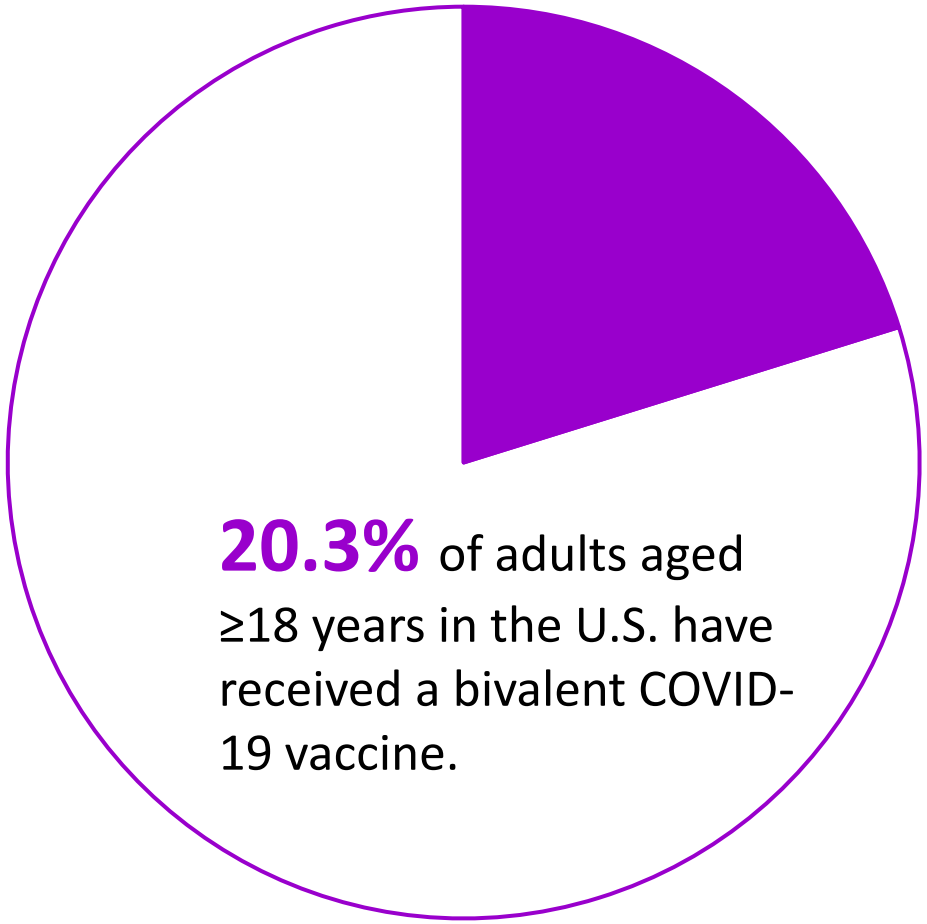


# New recommendations for aged ≥6 years without immunocompromise who have already received a bivalent mRNA dose

Vaccination is complete.
No doses are indicated at this time.

# Bivalent COVID-19 vaccine coverage is low



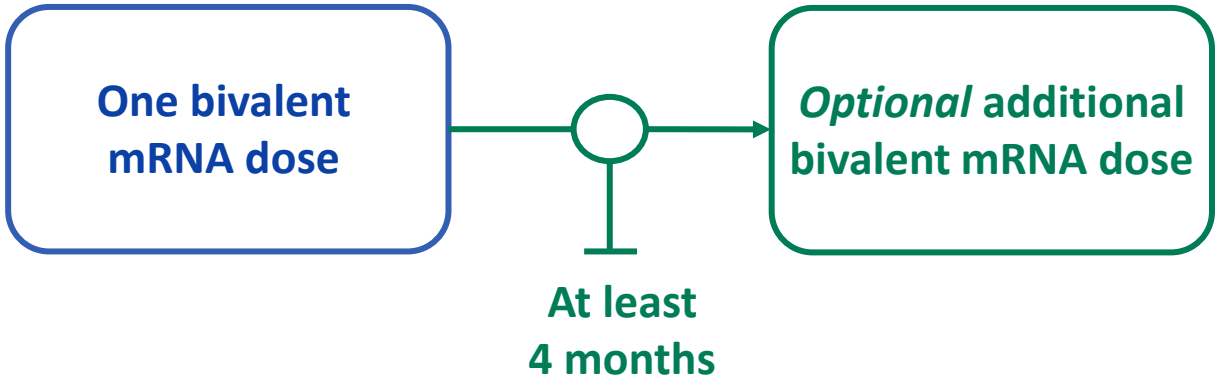




COVID-19 Data Tracker, last updated April 26, 2023, CDC COVID Data Tracker: Vaccinations in the US

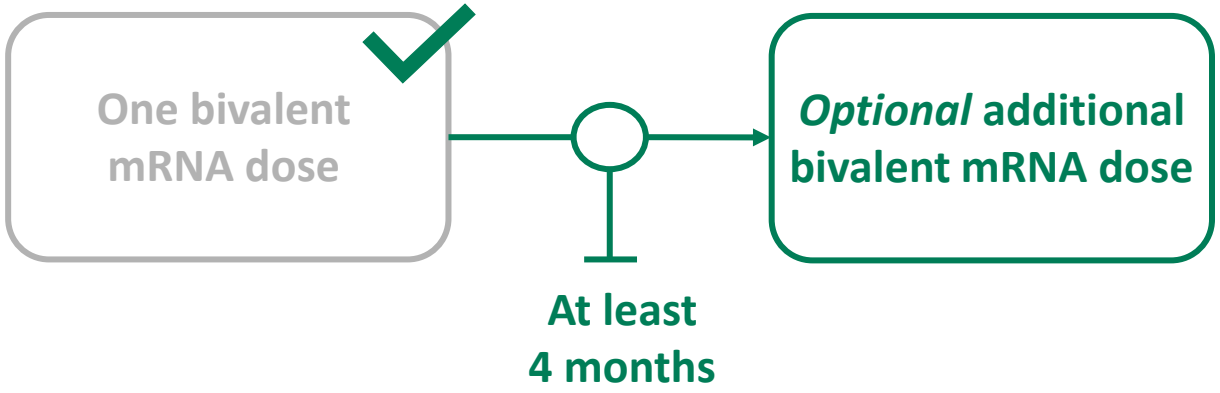
# Implications of the new recommendations

- Simple and singular for most
- **Flexible for people at higher risk**
- Customized recommendations for young children

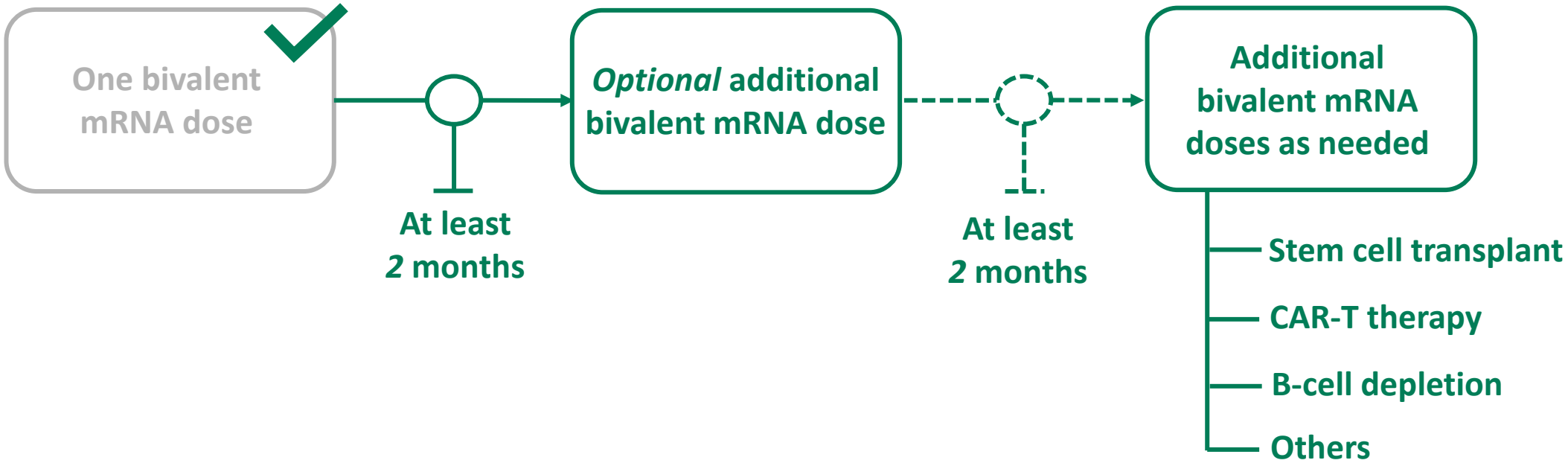
# Flexible for people at higher risk of severe COVID-19: People aged ≥65 years who have not yet received a bivalent mRNA dose



# Flexible for people at higher risk of severe COVID-19: People aged ≥65 years who have already received a bivalent mRNA dose



# New flexibility for people at higher risk of severe COVID-19: People aged ≥6 years *with immunocompromise** who have already received a bivalent mRNA dose




*Including those with imminent immunocompromise (e.g., prior to organ transplant; other causes.)

# Implications of the new recommendations

- Simple and singular for most
- Flexible for people at higher risk
- **Customized recommendations for young children**

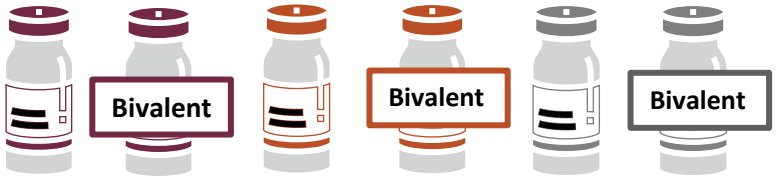
# Implications for vaccine providers

# Fewer COVID-19 Vaccine Products Now in Use

*Manufacturer* | *Products Previously in Use*

**Moderna**

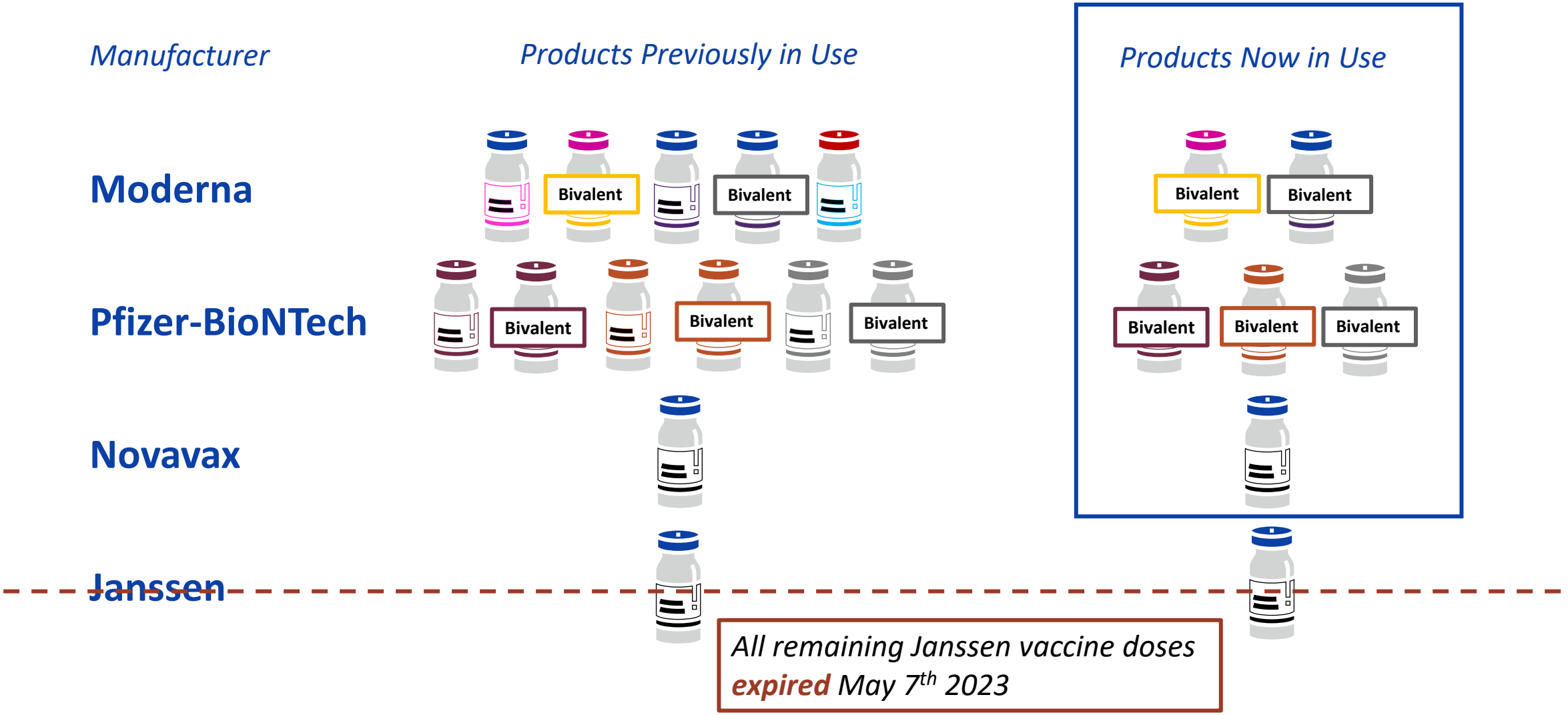
**Pfizer-BioNTech**




**Novavax**

**Janssen**

# Fewer COVID-19 Vaccine Products Now in Use



# COVID-19 Vaccine Products in Use as of May 2023

| *Manufacturer* | *Products Now in Use* |
| --- | --- |
| **Moderna** | Moderna Bivalent 0.2 mL/10 ug; Moderna Bivalent 0.25 mL/25 ug or 0.50 mL/50 ug |
| **Pfizer-BioNTech** | Pfizer-BioNTech Bivalent 0.2 mL/3 ug; Pfizer-BioNTech Bivalent 0.2 mL/10 ug; Pfizer-BioNTech Bivalent 0.3 mL/30 ug |
| **Novavax** | Novavax Monovalent |

# Recommendations for COVID-19 Vaccines by Age and Immunocompromised Status

# Transitioning from the monovalent to the bivalent era for children without immunocompromise aged 6 months – 4 years

**Doses previously recommended:**

**Moderna:**

- **2 monovalent** primary series doses +
- **1 bivalent** booster dose

**Pfizer-BioNTech:**

- **2** or **3 monovalent** primary series doses +
- **1 bivalent** primary series dose

# Transitioning from the monovalent to the bivalent era for children without immunocompromise aged 6 months – 4 years

**Doses previously recommended:**

**Moderna:**

- **2 monovalent** primary series doses +
- **1 bivalent** booster dose

**Pfizer-BioNTech:**

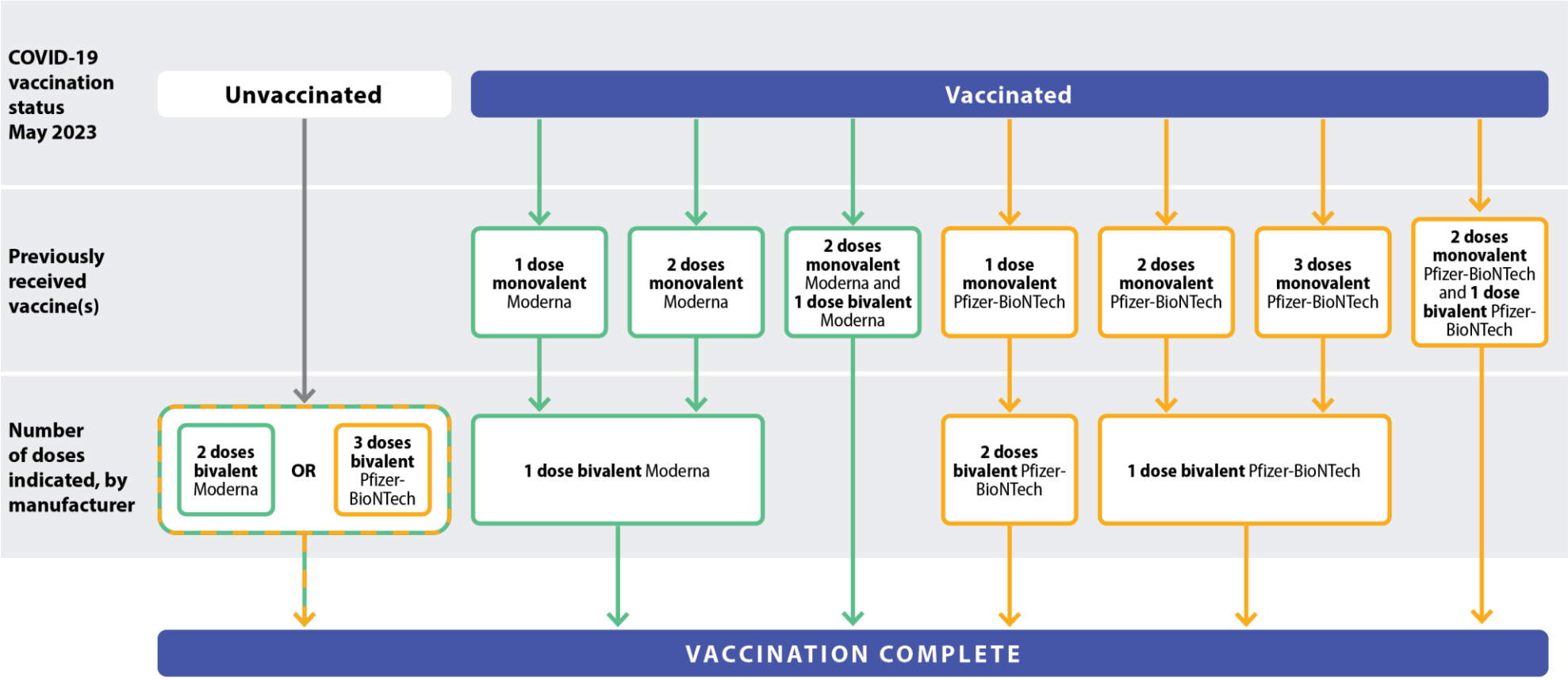
- **2** or **3 monovalent** primary series doses +
- **1 bivalent** primary series dose

**Doses now recommended:**

**Customized** by COVID-19 vaccination history such that all children receive:

- At least 2 vaccine doses in total *including*
- At least **1 bivalent** dose

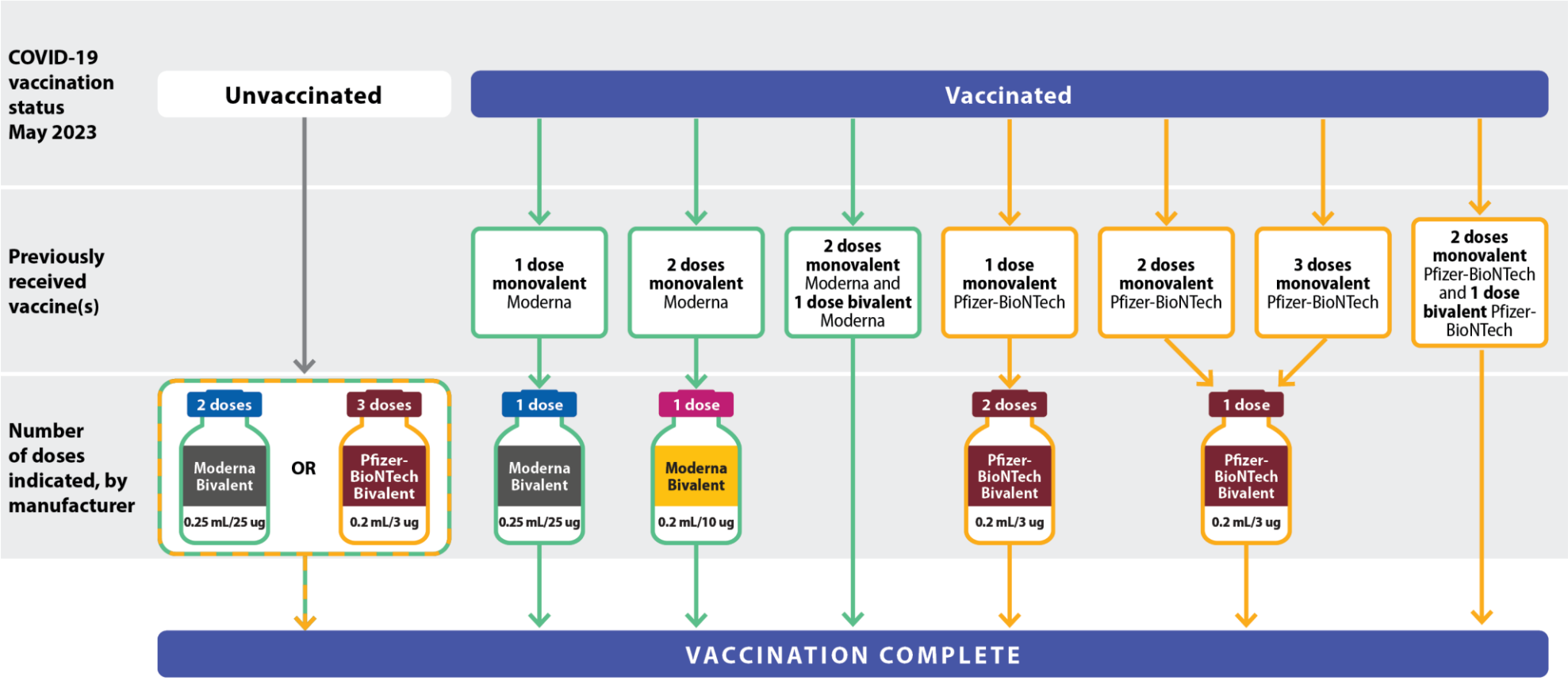
# Recommended COVID-19 vaccines for **people without immunocompromise, aged 6 months–4 years**, mRNA vaccines, May 2023*




*For product- and vaccination history-specific dosages and administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Key**

# 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).

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

# Transitioning from the monovalent to the bivalent era for children without immunocompromise aged 5 years

**Doses previously recommended:**

**Moderna:**

- **2 monovalent** primary series doses +
- **1 bivalent** booster dose

**Pfizer:**

- **2** or **3 monovalent** primary series doses +
- **1 bivalent** primary series dose

# Transitioning from the monovalent to the bivalent era for children without immunocompromise aged 5 years

**Doses previously recommended:**

**Moderna:**

- **2 monovalent** primary series doses +
- **1 bivalent** booster dose

**Pfizer:**

- **2** or **3 monovalent** primary series doses +
- **1 bivalent** primary series dose

**Doses now recommended:**

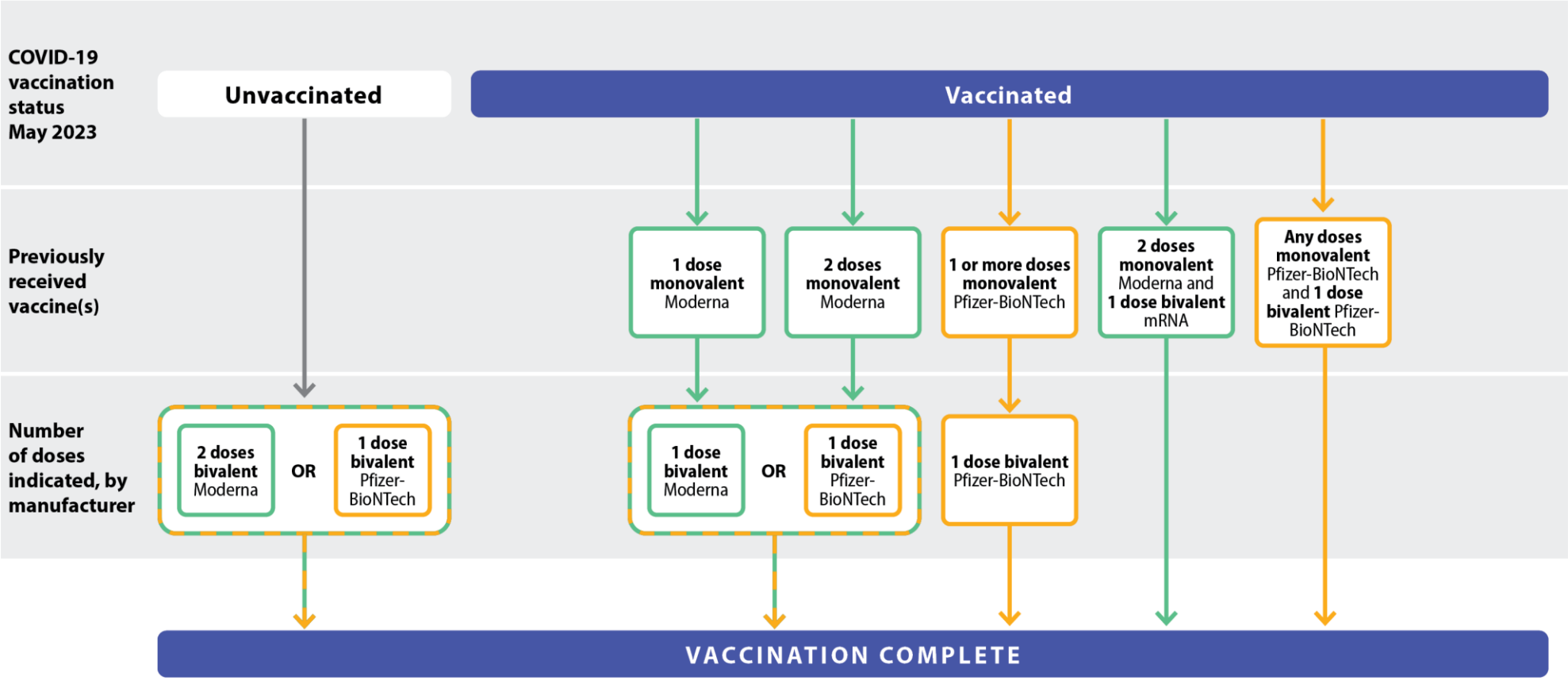
**Customized** so that **Moderna** recipients receive:

- At least 2 vaccine doses in total *including*
- At least **1 bivalent** dose

And **Pfizer-BioNTech** recipients receive:

- At least **1 bivalent** dose

# Recommended COVID-19 vaccines for **people without immunocompromise, aged 5 years,** mRNA vaccines, May 2023*

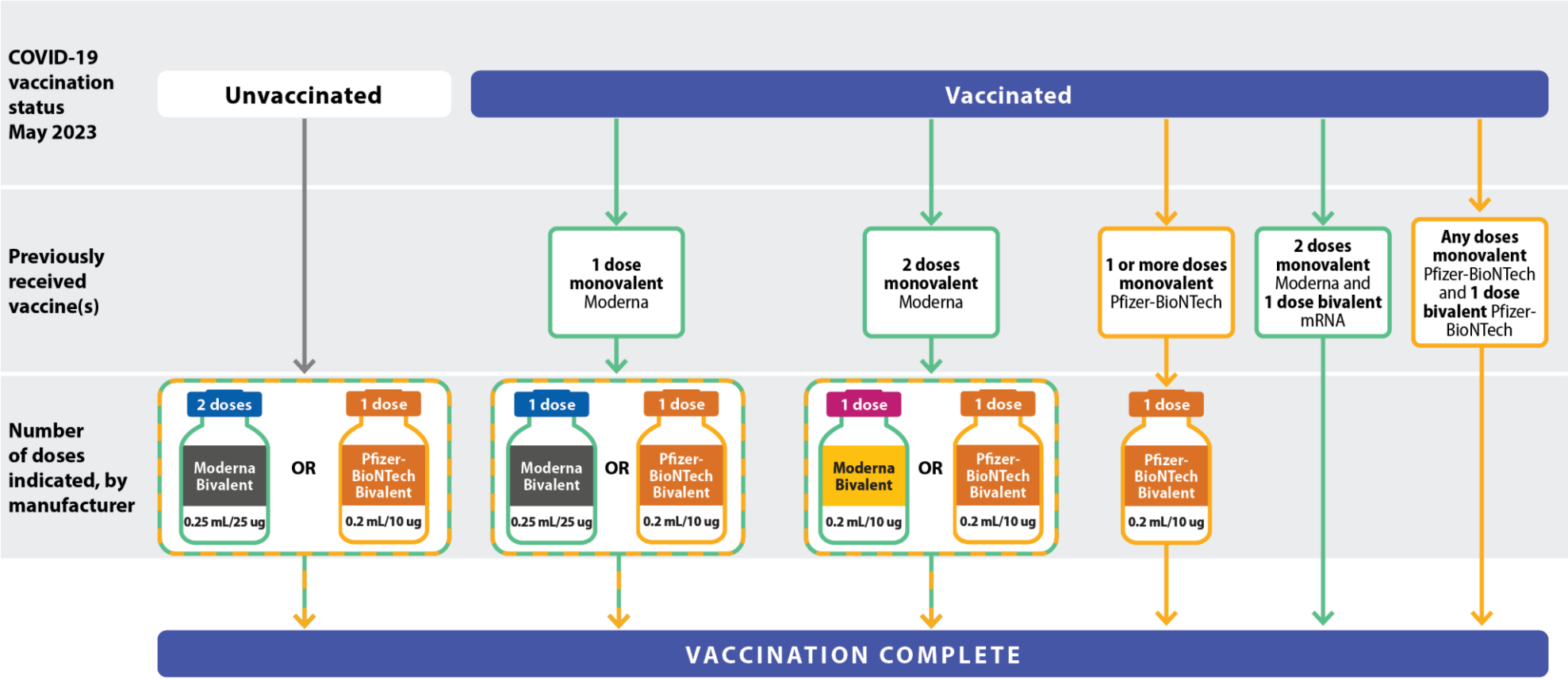



*For product- and vaccination history-specific dosages and administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

# Recommended COVID-19 vaccines for **people without immunocompromise, aged 5 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 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).

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

# Transitioning from the monovalent to the bivalent era for individuals aged 6 years and older without immunocompromise

**Doses previously recommended:**

**Moderna and Pfizer-BioNTech:**

- **2 monovalent** primary series doses +
- **1 bivalent** booster dose

**Novavax (ages 12 and older):**

- **2 monovalent** primary series doses +
- **1 bivalent** mRNA booster dose

**Janssen (ages 18 and older):**

- **1 monovalent** primary series doses +

**1 bivalent** mRNA booster dose

# Transitioning from the monovalent to the bivalent era for individuals aged 6 years and older without immunocompromise

**Doses previously recommended:**

**Moderna and Pfizer-BioNTech:**
- **2 monovalent** primary series doses +
- **1 bivalent** booster dose

**Novavax (ages 12 and older):**
- **2 monovalent** primary series doses +
- **1 bivalent** mRNA booster dose

**Janssen (ages 18 and older):**
- **1 monovalent** primary series doses +

**1 bivalent** mRNA booster dose

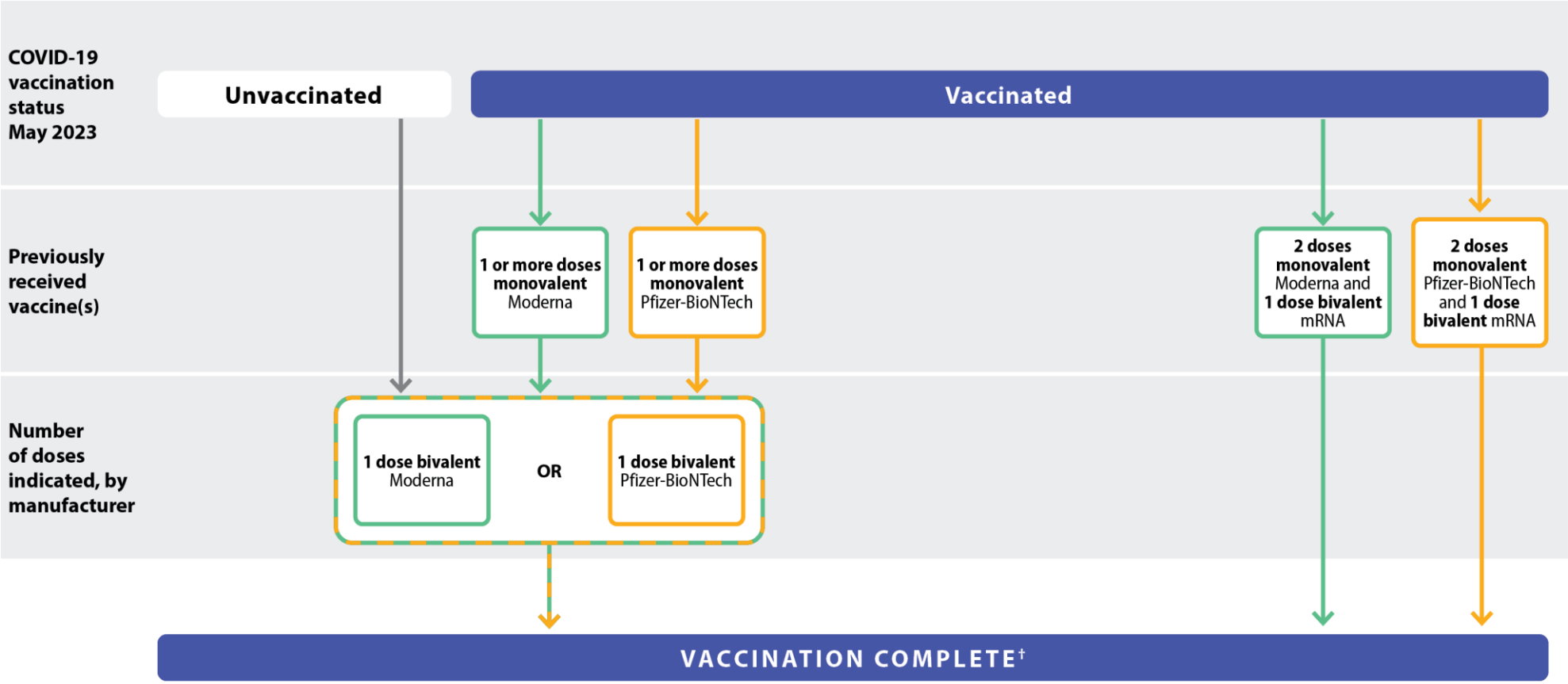
**Doses now recommended:**

**Moderna:**
- At least **1 bivalent** dose

**Pfizer-BioNTech:**
- At least **1 bivalent** dose

**People aged 65 years and older:**
- Option to receive 1 additional bivalent mRNA dose at least 4 months after the first dose of a bivalent mRNA vaccine

# Recommended COVID-19 vaccines for **people without immunocompromise, aged 6 years and older,** mRNA vaccines, May 2023*



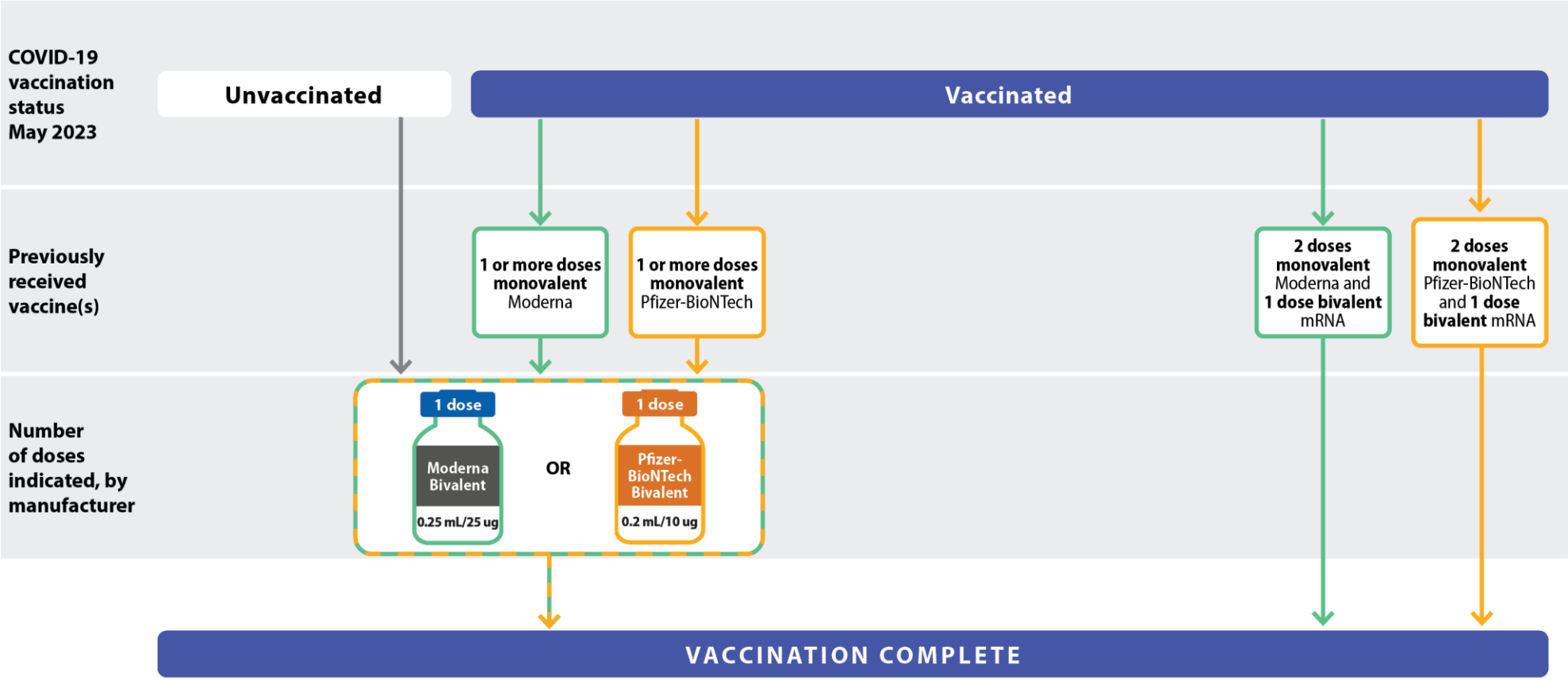

*For product-specific dosages and administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

†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.

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

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

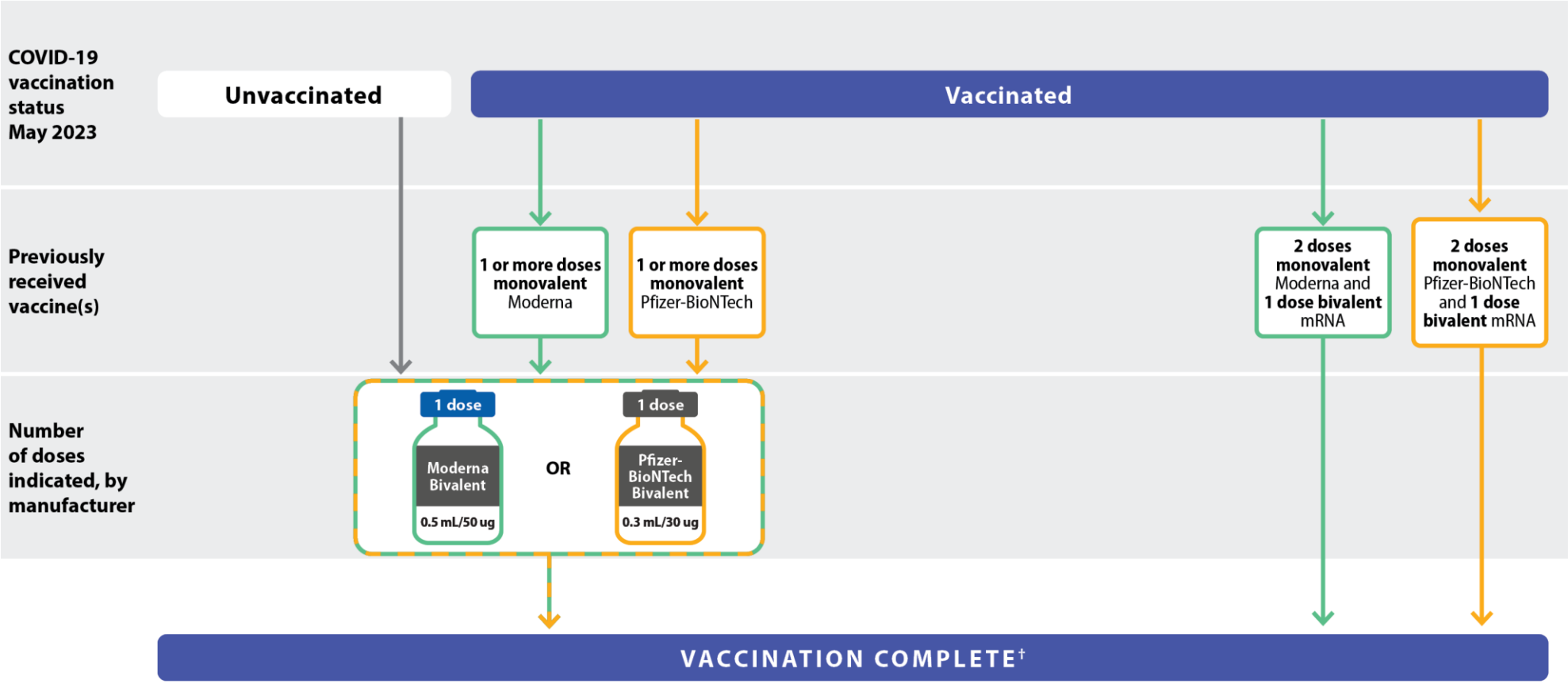



*For administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

# Recommended COVID-19 vaccines for **people without immunocompromise, aged 12 years and older,** 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.

†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.

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

# Transitioning from the monovalent to the bivalent era for people *with moderate to severe immunocompromise* aged 6 months and older

**Doses previously recommended:**

- **monovalent** primary series doses +
- **1 bivalent** booster dose and
- **additional bivalent doses**

# Transitioning from the monovalent to the bivalent era for people *with moderate to severe immunocompromise* aged 6 months and older

**Doses previously recommended:**

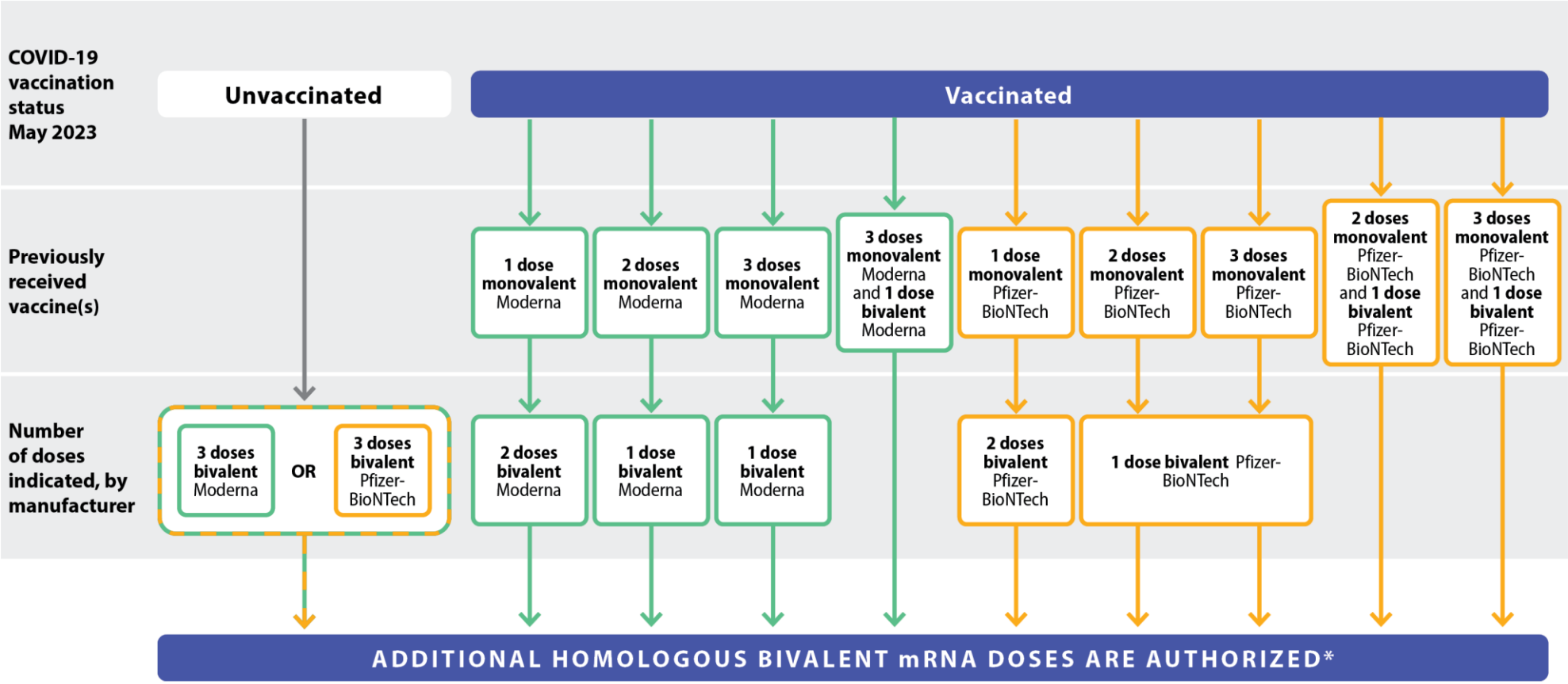
- **monovalent** primary series doses +
- **1 bivalent** booster dose and
- **additional bivalent doses**

**Doses now recommended:**

**Customized** by COVID-19 vaccination history such that immunocompromised people receive:

- **At least 3 vaccine doses in total** *including*
- **At least 1 bivalent dose**
  - **Plus an optional additional bivalent dose**
  - **Plus additional bivalent doses as needed**

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

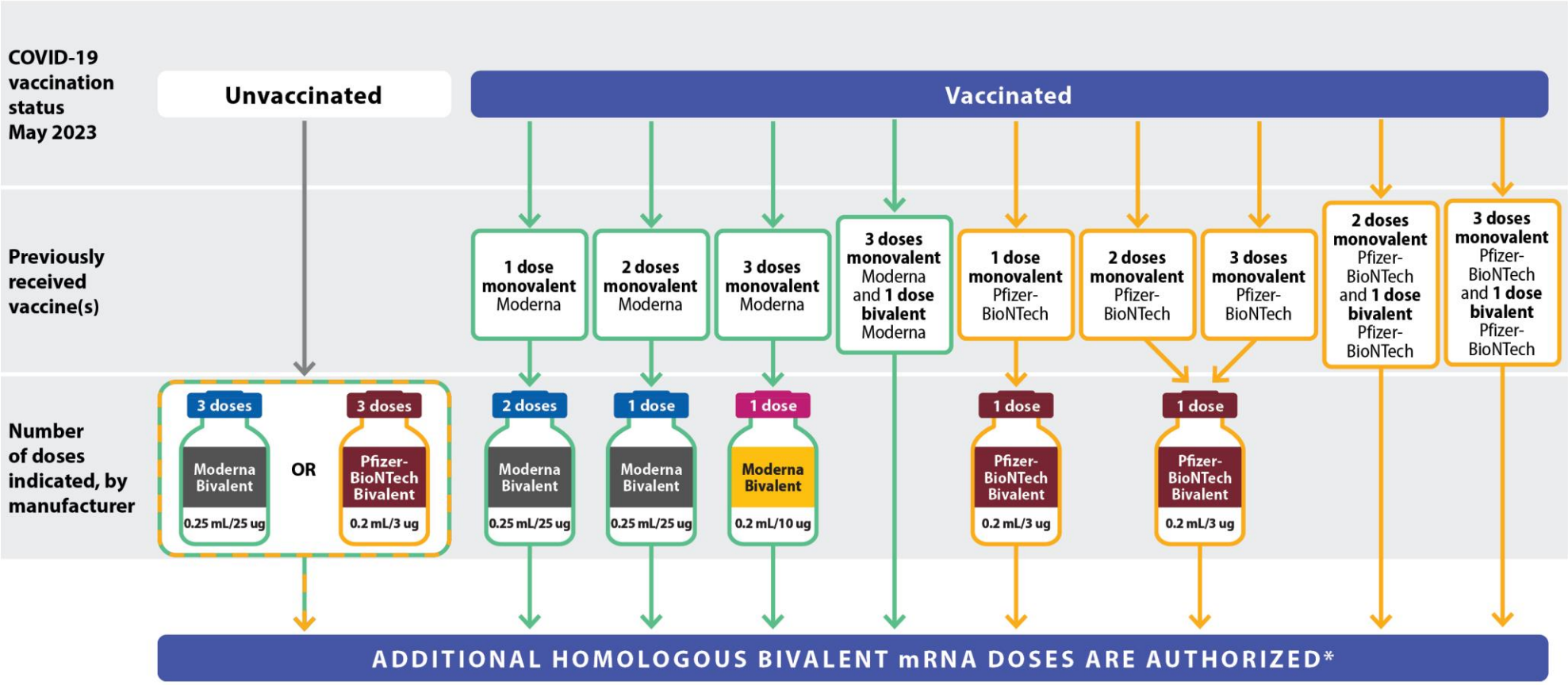



*For product- and vaccination history-specific dosages, administration intervals, and additional dose information, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

# 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*

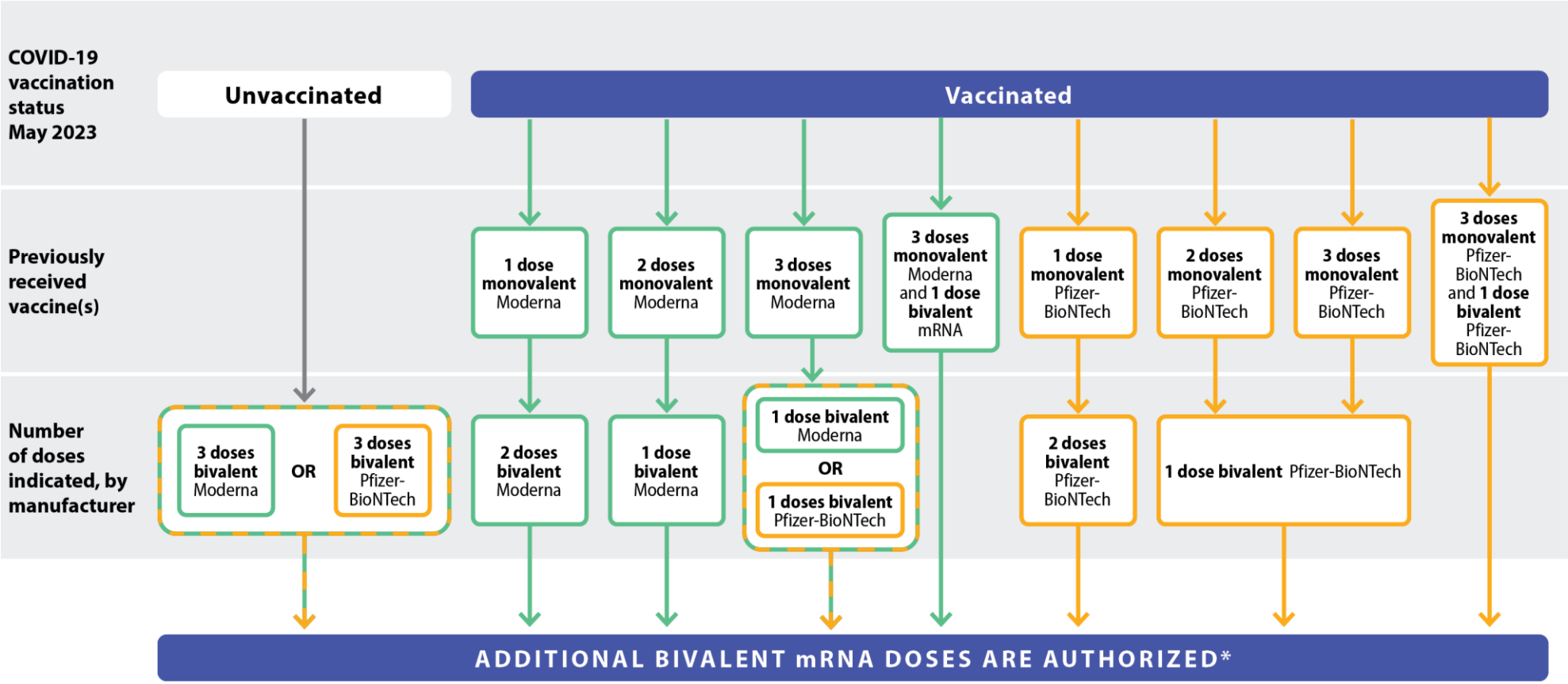



*For product- and vaccination history-specific dosages, administration intervals, and additional dose information, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Key**

| Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech |
|---|---|---|

# Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 5 years,** mRNA vaccines, May 2023*

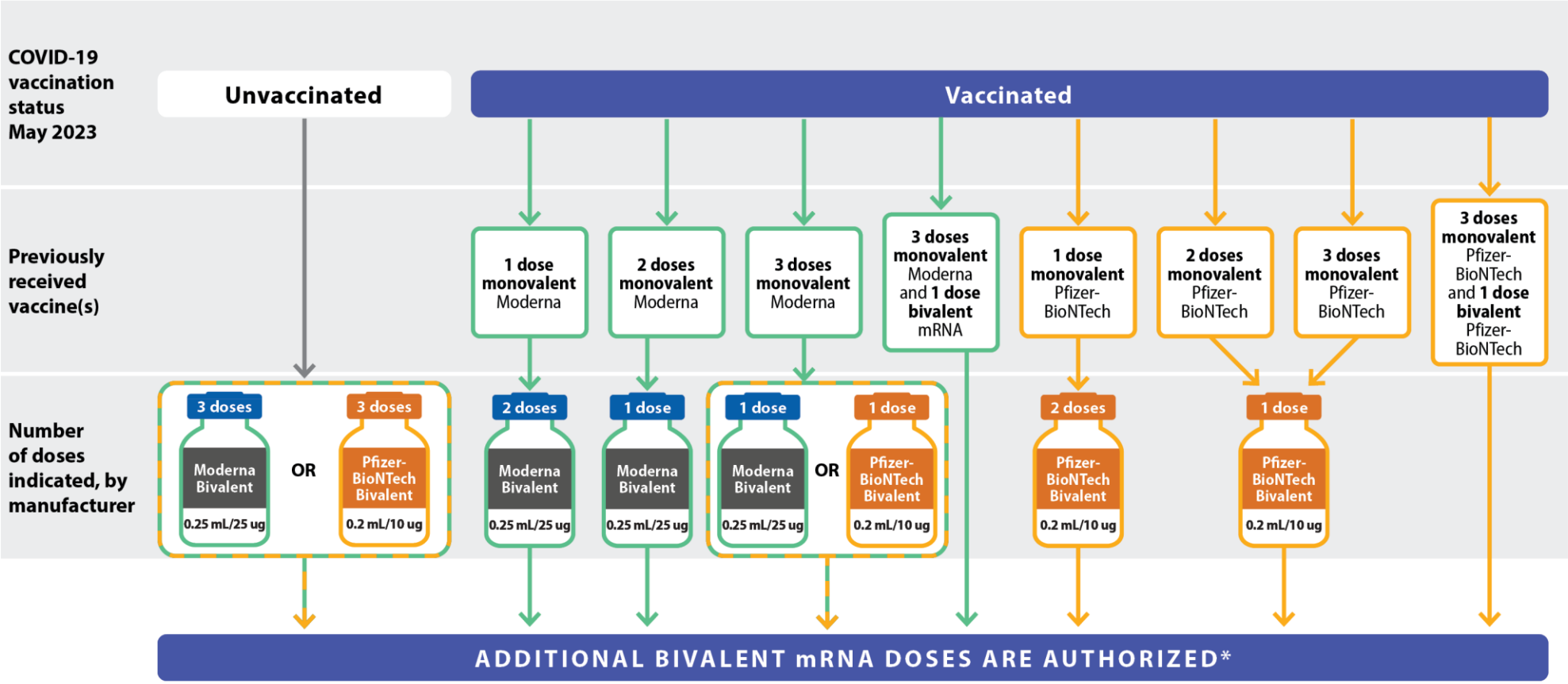



*For product- and vaccination-history-specific dosages, administration intervals, additional dose information, and options for heterologous dosing, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

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

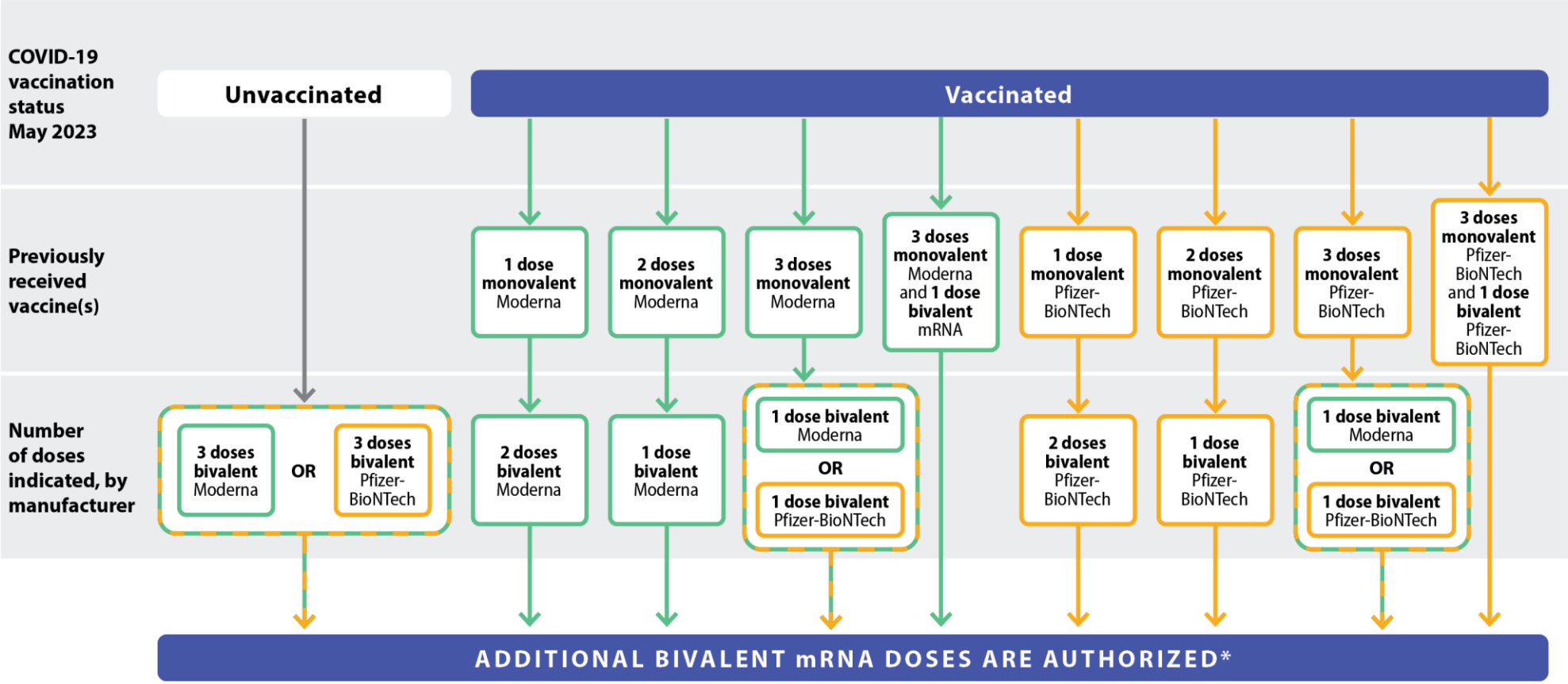



*For administration intervals, additional dose information, and options for heterologous dosing, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

# Recommended COVID-19 vaccines for **people who ARE moderately or severely immunocompromised, aged 6 years and older,** mRNA vaccines, May 2023*

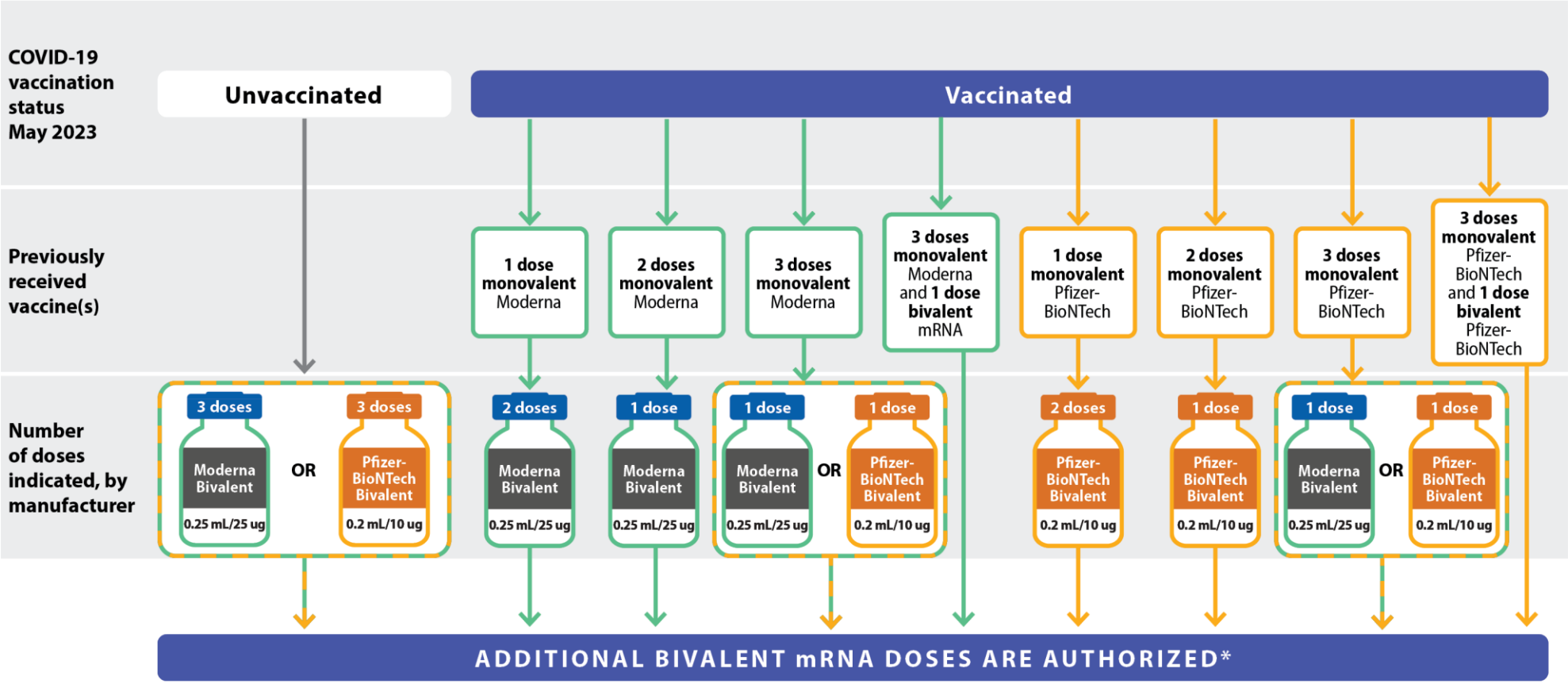



*For product-specific dosages, administration intervals, additional dose information, and options for heterologous dosing, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

# 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*

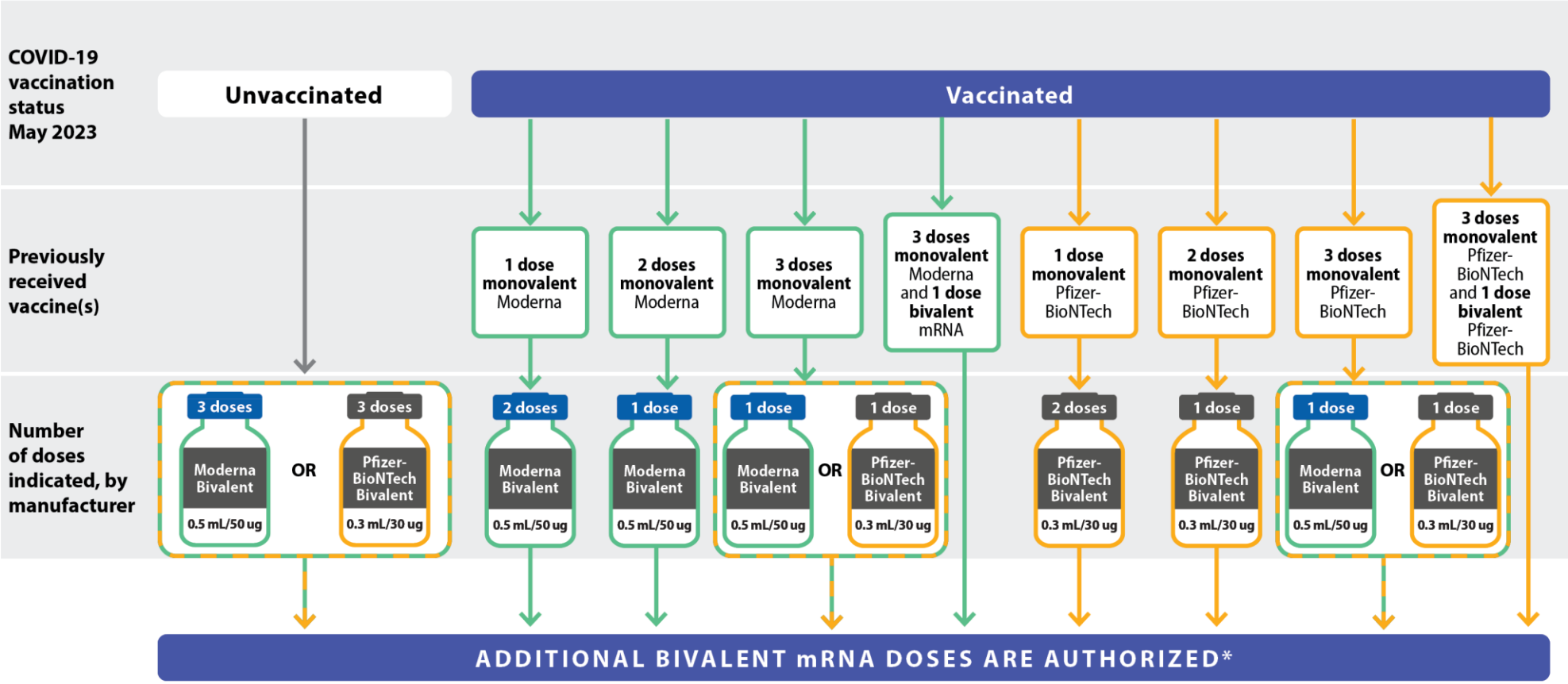



*For product-specific dosages, administration intervals, additional dose information, and options for heterologous dosing, see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

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

**Key**

Moderna | Pfizer-BioNTech | Moderna **OR** Pfizer-BioNTech

# Tables and Doses:
# COVID-19 vaccines for people without immunocompromise

## Table 1. COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised by COVID-19 vaccination history, April 2023: Ages 6 months–4 years

| COVID-19 vaccination history | Bivalent vaccine | Number of bivalent doses indicated | Dosage (mL/ug) | Vaccine vial cap and label colors | Interval between doses |
|---|---|---|---|---|---|
| Unvaccinated | Moderna<br>___or___ | 2 | 0.25 mL/25 ug | Dark blue cap; gray label border | Dose 1 and Dose 2:<br>4–8 weeks |
| | Pfizer BioNTech | 3 | 0.2 mL/3 ug | Maroon | Dose 1 and Dose 2:<br>3–8 weeks<br>Dose 2 and dose 3:<br>At least 8 weeks |
| 1 dose monovalent Moderna | Moderna | 1 | 0.25 mL/25 ug | Dark blue cap; gray label border | 4-8 weeks after monovalent dose |
| 2 doses monovalent Moderna | Moderna | 1 | 0.2 mL/10 ug | Dark pink cap; yellow label border | At least 8 weeks after last monovalent dose |
| 2 doses monovalent Moderna and 1 dose bivalent Moderna | NA; previously received 1 bivalent vaccine dose | NA | NA | NA | NA |
| 1 dose monovalent Pfizer-BioNTech | Pfizer BioNTech | 2 | 0.2 mL/3 ug | Maroon | Dose 1: 3–8 weeks after monovalent dose<br>Dose 1 and Dose 2: At least 8 weeks |
| 2 doses monovalent Pfizer-BioNTech | Pfizer BioNTech | 1 | 0.2 mL/3 ug | Maroon | At least 8 weeks after last monovalent dose |
| 3 doses monovalent Pfizer-BioNTech | Pfizer BioNTech | 1 | 0.2 mL/3 ug | Maroon | At least 8 weeks after last monovalent dose |
| 2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech | NA; previously received 1 bivalent vaccine dose | NA | NA | NA | NA |

## Table 1. COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised by COVID-19 vaccination history, April 2023: Age 5 years

| COVID-19 vaccination history | Bivalent vaccine | Number of bivalent doses indicated | Dosage (mL/ug) | Vaccine vial cap and label colors | Interval between doses |
|---|---|---|---|---|---|
| Unvaccinated | Moderna<br>___*or*___ | 2 | 0.25 mL/25 ug | Dark blue cap; gray label border | Dose 1 and Dose 2:<br>4–8 weeks |
| | Pfizer BioNTech | 1 | 0.2 mL/10 ug | Orange | |
| 1 dose monovalent Moderna | Moderna<br>___*or*___ | 1 | 0.25 mL/25 ug | Dark blue cap; gray label border | 4–8 weeks after monovalent dose |
| | Pfizer BioNTech | 1 | 0.2 mL/10 ug | Orange | At least 8 weeks after monovalent dose |
| 2 doses monovalent Moderna | Moderna<br>___*or*___ | 1 | 0.2 mL/10 ug | Dark pink cap; yellow label border | At least 8 weeks after last monovalent dose |
| | Pfizer BioNTech | 1 | 0.2 mL/10 ug | Orange | At least 8 weeks after last monovalent dose |
| 2 doses monovalent Moderna and 1 dose bivalent mRNA | NA; previously received 1 bivalent vaccine dose | NA | NA | NA | NA |
| 1 or more doses monovalent Pfizer-BioNTech | Pfizer-BioNTech | 1 | 0.2 mL/10 ug | Orange | At least 8 weeks after last monovalent dose |
| 2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech | NA; previously received 1 bivalent vaccine dose | NA | NA | NA | NA |
| Ever received 1 dose bivalent Pfizer-BioNTech (regardless of monovalent vaccine history) | NA; previously received 1 bivalent vaccine dose | NA | NA | NA | NA |

## Table 1. COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised by COVID-19 vaccination history, April 2023: Ages 6–11 years

| COVID-19 vaccination history | Bivalent vaccine | Number of bivalent doses indicated | Dosage (mL/ug) | Vaccine vial cap and label colors | Interval between doses |
|---|---|---|---|---|---|
| **Unvaccinated** | Moderna ____*or*___ | 1 | 0.25 mL/25 ug | Dark blue cap; gray label border | --- |
| | Pfizer BioNTech | 1 | 0.2 mL/10 ug | Orange | --- |
| **1 or more doses monovalent mRNA (no doses bivalent mRNA)** | Moderna ___*or*____ | 1 | 0.25 mL/25 ug | Dark blue cap; gray label border | At least 8 weeks after last monovalent dose |
| | Pfizer BioNTech | 1 | 0.2 mL/10 ug | Orange | At least 8 weeks after last monovalent dose |
| **2 or more doses monovalent mRNA and 1 dose bivalent mRNA** | NA; previously received 1 bivalent vaccine dose | NA | NA | NA | NA |
| **Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)** | NA; previously received 1 bivalent vaccine dose | NA | NA | NA | NA |

## Table 1. COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised by COVID-19 vaccination history, April 2023: Age 12 years and older*

| COVID-19 vaccination history | Bivalent vaccine | Number of bivalent doses indicated | Dosage (mL/ug) | Vaccine vial cap and label colors | Interval between doses |
|---|---|---|---|---|---|
| Unvaccinated | Moderna ___or___ | 1 | 0.50 mL/50 ug | Dark blue cap; gray label border | --- |
| | Pfizer BioNTech | 1 | 0.3 mL/30 ug | Gray | --- |
| 1 or more doses monovalent mRNA (no doses bivalent mRNA) | Moderna ___or___ | 1 | 0.50 mL/50 ug | Dark blue cap; gray label border | At least 8 weeks after last monovalent dose |
| | Pfizer BioNTech | 1 | 0.3 mL/30 ug | Gray | At least 8 weeks after last monovalent dose |
| Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history) | NA; previously received 1 bivalent vaccine dose | NA | NA | NA | NA |

***People ages 65 years and older** have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine. If Moderna is used, administer 0.50 mL/50 ug (blue cap and label with a gray border); if Pfizer-BioNTech is used, administer 0.3 mL/30 ug (gray cap and label with a gray border).

# Tables and Doses:
# COVID-19 vaccines for people with immunocompromise

## Table 2. COVID-19 vaccination schedule for people who are moderately or severely immunocompromised by COVID-19 vaccination history, May 2023: Ages 6 months–4 years

| COVID-19 vaccination history | Bivalent vaccine | Number of bivalent doses indicated | Dosage (mL/ug) | Vaccine vial cap and label colors | Interval between doses |
|---|---|---|---|---|---|
| **Unvaccinated** | Moderna<br>___*or*___<br>Pfizer BioNTech | 3 | 0.25 mL/25 ug | Blue cap; gray label border | Dose 1 and Dose 2:<br>4 weeks<br>Dose 2 and Dose 3: At least 4 weeks |
| | | 3 | 0.2 mL/3 ug | Maroon | Dose 1 and Dose 2:<br>3 weeks<br>Dose 2 and dose 3:<br>At least 8 weeks |
| **1 dose monovalent Moderna** | Moderna | 2 | 0.25 mL/25 ug | Blue cap; gray label border | Dose 1: 4 weeks after monovalent dose<br>Dose 1 and Dose 2:<br>At least 4 weeks |
| **2 doses monovalent Moderna** | Moderna | 1 | 0.25 mL/25 ug | Blue cap; gray label border | At least 4 weeks after last monovalent dose |
| **3 doses monovalent Moderna** | Moderna | 1 | 0.2 mL/10 ug | Dark pink cap; yellow label border | At least 8 weeks after last monovalent dose |
| **3 doses monovalent Moderna and 1 dose bivalent Moderna** | — | See footnote | — | — | — |
| **1 dose monovalent Pfizer-BioNTech** | Pfizer-BioNTech[†] | 2 | 0.2 mL/3 ug | Maroon | Dose 1: 3 weeks after monovalent dose<br>Dose 1 and Dose 2:<br>At least 8 weeks |
| **2 doses monovalent Pfizer-BioNTech** | Pfizer-BioNTech | 1 | 0.2 mL/3 ug | Maroon | At least 8 weeks after last monovalent dose |
| **3 doses monovalent Pfizer-BioNTech** | Pfizer-BioNTech | 1 | 0.2 mL/3 ug | Maroon | At least 8 weeks after last monovalent dose |
| **2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech** | — | See footnote | — | — | — |
| **3 doses of monovalent Pfizer-BioNTech and 1 bivalent Pfizer-BioNTech dose** | — | See footnote | — | — | — |

# Table 2. COVID-19 vaccination schedule for people who are moderately or severely immunocompromised by COVID-19 vaccination history, May 2023: Age 5 years

| COVID-19 vaccination history | Bivalent vaccine | Number of bivalent doses indicated | Dosage (mL/ug) | Vaccine vial cap and label colors | Interval between doses |
|---|---|---|---|---|---|
| **Unvaccinated** | Moderna<br>___*or*___<br>Pfizer BioNTech | 3 | 0.25 mL/25 ug | Blue cap; gray label border | Dose 1 and Dose 2:<br>4 weeks<br>Dose 2 and Dose 3: At least 4 weeks |
| | | 3 | 0.2 mL/10 ug | Orange | Dose 1 and Dose 2:<br>3 weeks<br>Dose 2 and dose 3: At least 4 weeks |
| **1 dose monovalent Moderna** | Moderna | 2 | 0.25 mL/25 ug | Blue cap; gray label border | Dose 1: 4 weeks after monovalent dose<br>Dose 1 and Dose 2:<br>At least 4 weeks |
| **2 doses monovalent Moderna** | Moderna | 1 | 0.25 mL/25 ug | Blue cap; gray label border | At least 4 weeks after last monovalent dose |
| **3 doses monovalent Moderna** | Moderna<br>___*or*___<br>Pfizer BioNTech | 1 | 0.25 mL/25 ug | Blue cap; gray label border | At least 8 weeks after last monovalent dose |
| | | 1 | 0.2 mL/10 ug | Orange | At least 8 weeks after last monovalent dose |
| **3 doses monovalent Moderna and 1 dose bivalent mRNA** | — | See footnote | — | — | — |
| **1 dose monovalent Pfizer-BioNTech** | Pfizer-BioNTech | 2 | 0.2 mL/10 ug | Orange | Dose 1: 3 weeks after monovalent dose<br>Dose 1 and Dose 2:<br>At least 4 weeks |
| **2 doses monovalent Pfizer-BioNTech** | Pfizer-BioNTech | 1 | 0.2 mL/10 ug | Orange | At least 4 weeks after last monovalent dose |
| **3 doses monovalent Pfizer-BioNTech** | Pfizer-BioNTech | 1 | 0.2 mL/10 ug | Orange | At least 8 weeks after last monovalent dose |
| **3 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech** | — | See footnote | — | — | — |

## Table 2. COVID-19 vaccination schedule for people who are moderately or severely immunocompromised by COVID-19 vaccination history, May 2023: Ages 6–11 years

| COVID-19 vaccination history | Bivalent vaccine | Number of bivalent doses indicated | Dosage (mL/ug) | Vaccine vial cap and label colors | Interval between doses |
|---|---|---|---|---|---|
| **Unvaccinated** | Moderna<br>___*or*___<br>Pfizer-BioNTech | 3 | 0.25 mL/25 ug | Blue cap; gray label border | Dose 1 and Dose 2:4 weeks<br>Dose 2 and Dose 3: At least 4 weeks |
| | | 3 | 0.2 mL/10 ug | Orange | Dose 1 and Dose 2:3 weeks<br>Dose 2 and dose 3: At least 4 weeks |
| **1 dose monovalent Moderna** | Moderna | 2 | 0.25 mL/25 ug | Blue cap; gray label border | Dose 1: 4 weeks after monovalent dose<br>Dose 1 and Dose 2: At least 4 weeks |
| **2 doses monovalent Moderna** | Moderna | 1 | 0.25 mL/25 ug | Blue cap; gray label border | At least 4 weeks after last monovalent dose |
| **3 doses monovalent Moderna** | Moderna<br>___*or*___<br>Pfizer-BioNTech | 1 | 0.25 mL/25 ug | Blue cap; gray label border | At least 8 weeks after last monovalent dose |
| | | 1 | 0.2 mL/10 ug | Orange | At least 8 weeks after last monovalent dose |
| **3 doses monovalent Moderna and 1 dose bivalent mRNA** | — | See footnote | — | — | — |
| **1 dose monovalent Pfizer-BioNTech** | Pfizer-BioNTech | 2 | 0.2 mL/10 ug | Orange | Dose 1: 3 weeks after monovalent dose<br>Dose 1 and Dose 2:<br>At least 4 weeks |
| **2 doses monovalent Pfizer-BioNTech** | Pfizer-BioNTech | 1 | 0.2 mL/10 ug | Orange | At least 4 weeks after last monovalent dose |
| **3 doses monovalent Pfizer-BioNTech** | Moderna<br>___*or*___<br>Pfizer-BioNTech | 1 | 0.25 mL/25 ug | Blue cap; gray label border | At least 8 weeks after last monovalent dose |
| | | 1 | 0.2 mL/10 ug | Orange | At least 8 weeks after last monovalent dose |
| **3 doses monovalent Pfizer-BioNTech and 1 dose bivalent mRNA** | — | See footnote | — | — | — |

# Table 2. COVID-19 vaccination schedule for people who are moderately or severely immunocompromised by COVID-19 vaccination history, May 2023: Age 12 years and older*

| COVID-19 vaccination history | Bivalent vaccine | Number of bivalent doses indicated | Dosage (mL/ug) | Vaccine vial cap and label colors | Interval between doses |
|---|---|---|---|---|---|
| Unvaccinated | Moderna[†] ___*or*___ Pfizer BioNTech[‡] | 3 | 0.5 mL/50 ug | Blue cap; gray label border | Dose 1 and Dose 2: 4 weeks<br>Dose 2 and Dose 3: At least 4 weeks |
| | | 3 | 0.3 mL/30 ug | Gray | Dose 1 and Dose 2: 3 weeks<br>Dose 2 and dose 3: At least 4 weeks |
| 1 dose monovalent Moderna | Moderna[†] | 2 | 0.5 mL/50 ug | Blue cap; gray label border | Dose 1: 4 weeks after monovalent dose<br>Dose 1 and Dose 2: At least 4 weeks |
| 2 doses monovalent Moderna | Moderna[†] | 1 | 0.5 mL/50 ug | Blue cap; gray label border | At least 4 weeks after last monovalent dose |
| 3 doses monovalent Moderna | Moderna___*or*___ Pfizer-BioNTech | 1 | 0.5 mL/50 ug | Blue cap; gray label border | At least 8 weeks after last monovalent dose |
| | | 1 | 0.3 mL/30 ug | Gray | At least 8 weeks after last monovalent dose |
| 3 doses monovalent Moderna and 1 dose bivalent mRNA | — | See footnote | — | — | — |
| 1 dose monovalent Pfizer-BioNTech | Pfizer-BioNTech[‡] | 2 | 0.3 mL/30 ug | Gray | Dose 1: 3 weeks after monovalent dose<br>Dose 1 and Dose 2: At least 4 weeks |
| 2 doses monovalent Pfizer-BioNTech | Pfizer-BioNTech[‡] | 1 | 0.3 mL/30 ug | Gray | At least 4 weeks after last monovalent dose |
| 3 doses monovalent Pfizer-BioNTech | Moderna___*or*___ Pfizer-BioNTech | 1 | 0.5 mL/50 ug | Blue cap; gray label border | At least 8 weeks after last monovalent dose |
| | | 1 | 0.3 mL/30 ug | Gray | At least 8 weeks after last monovalent dose |
| 3 doses monovalent Pfizer-BioNTech and 1 dose bivalent mRNA | — | See footnote | — | — | — |

*People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

# Conclusion

- COVID-19 vaccines continue to be the **most effective tool** we have to prevent serious illness, hospitalization and death from COVID-19
  - Uptake of the updated (bivalent) COVID-19 vaccines is not yet equitable, and remains generally low
- **Simple recommendations** are easier to communicate, which may improve vaccine uptake
- CDC **materials** for vaccine providers, clinicians and the general public are available on the CDC website to make it easy for everyone to get up to date and **stay up to date** with COVID-19 vaccines

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- Aron Hall
- Barbara Mahon
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- Coronavirus and other Respiratory Viruses Division
- Immunization Services Division
- National Center for Immunization and Respiratory Diseases

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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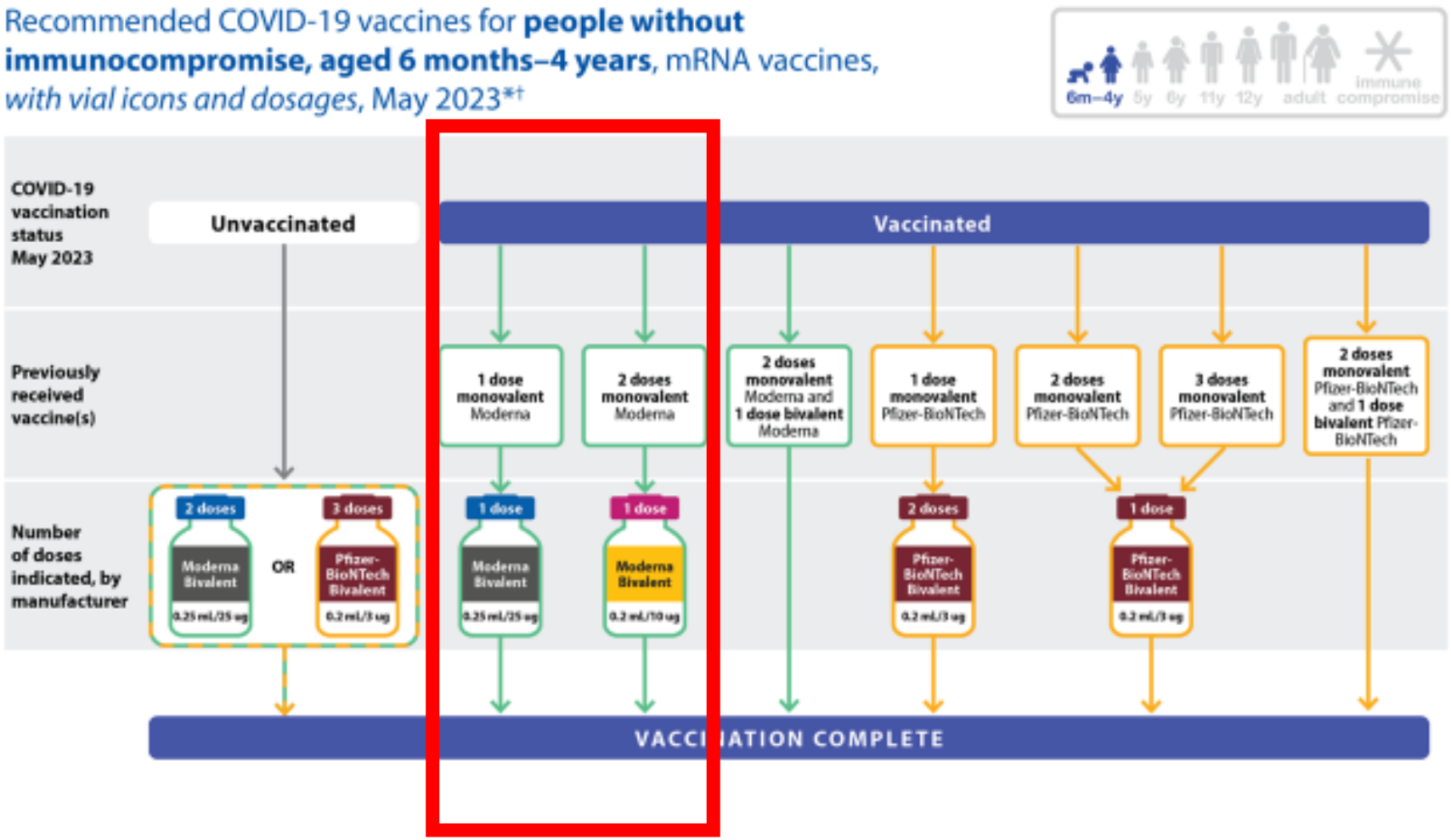
# Frequently Asked Questions

# FAQ #1: Has the vaccine changed?

- **No, these Spring updates are language changes, not vaccine changes**
  - The monovalent vaccines are not longer authorized
  - The bivalent mRNA vaccines are the same as those authorized in Fall 2022.

# FAQ #2: Could you clarify Moderna dosing for young children?

- Receipt of a dose from the blue cap or pink cap Moderna vaccine vial will depend on a child's vaccination history



# FAQ #3: How should vaccination errors be reported?

- Adverse events that occur in a recipient following COVID-19 vaccination, including errors, should be reported to VAERS. Reports may be made by:
  - Writing info@VAERS.org or
  - Calling 1-800-822-7967

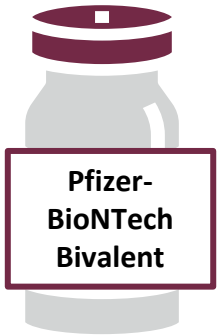
# FAQ #4: Can you clarify the interchangeability guidance for children?

- **CDC recommends children ages 6 months-5 years who are unvaccinated and recommended to receive more than 1 bivalent mRNA dose for initial vaccination receive all doses from the same manufacturer.**
- **FDA authorization allows for administration of a mixed product series for initial vaccination in some children:**
  - Ages 6 months–4 years who are unvaccinated or previously received 1 or more doses of a monovalent mRNA vaccine are authorized to receive only bivalent mRNA vaccine dose(s) from the same vaccine manufacturer.
  - Age 5 years who are unvaccinated or previously received 1 or more doses of monovalent Moderna COVID-19 Vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.
  - Age 5 years who are unvaccinated or previously received 1 or more doses of monovalent Pfizer-BioNTech COVID-19 are authorized to receive only bivalent Pfizer-BioNTech COVID-19 Vaccine.
  - Ages 6 years and older who are unvaccinated or previously received 1 or more doses of any monovalent COVID-19 vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.

# FAQ #5: What should be done for children who transition from a younger to older age group during their initial vaccination doses?

- **Generally, CDC recommends people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination**
- **If a person moves to an older age group between vaccine doses, they should receive the product and dosage for the older age group for all subsequent doses with the following exception:**

  - Children who receive Pfizer-BioNTech and transition from age 4 to 5 years during the 3-dose vaccination series must complete the series they start




0.2 mL/3 ug

  - Children who transition from 5 to 6 years during the Moderna series should receive 2 dose of the Moderna vaccine (0.25 mL/25 mcg dose)

0.25 mL/25 ug

# FAQ #6: Can individuals still self-attest to their immunocompromised status?

## Description of moderate and severe immunocompromising conditions and treatment

Moderate and severe immunocompromising conditions and treatments include **but are not limited to**:

- Active treatment for solid tumor and hematologic malignancies
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
- Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen rec
  transplantation or taking immu
- Moderate or severe primary in
  immunodeficiency, DiGeorge s
- Advanced HIV infection (peopl
  without immune reconstitutio
- Active treatment with high-dos
  administered for 2 or more we
  cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell-depleting agents)

Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

For additional information about the degree of immune suppression associated with different medical conditions and treatments, providers can consult ACIP's general best practices for vaccination of people with altered immunocompetence, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host.

## Self-attestation of immunocompromised status

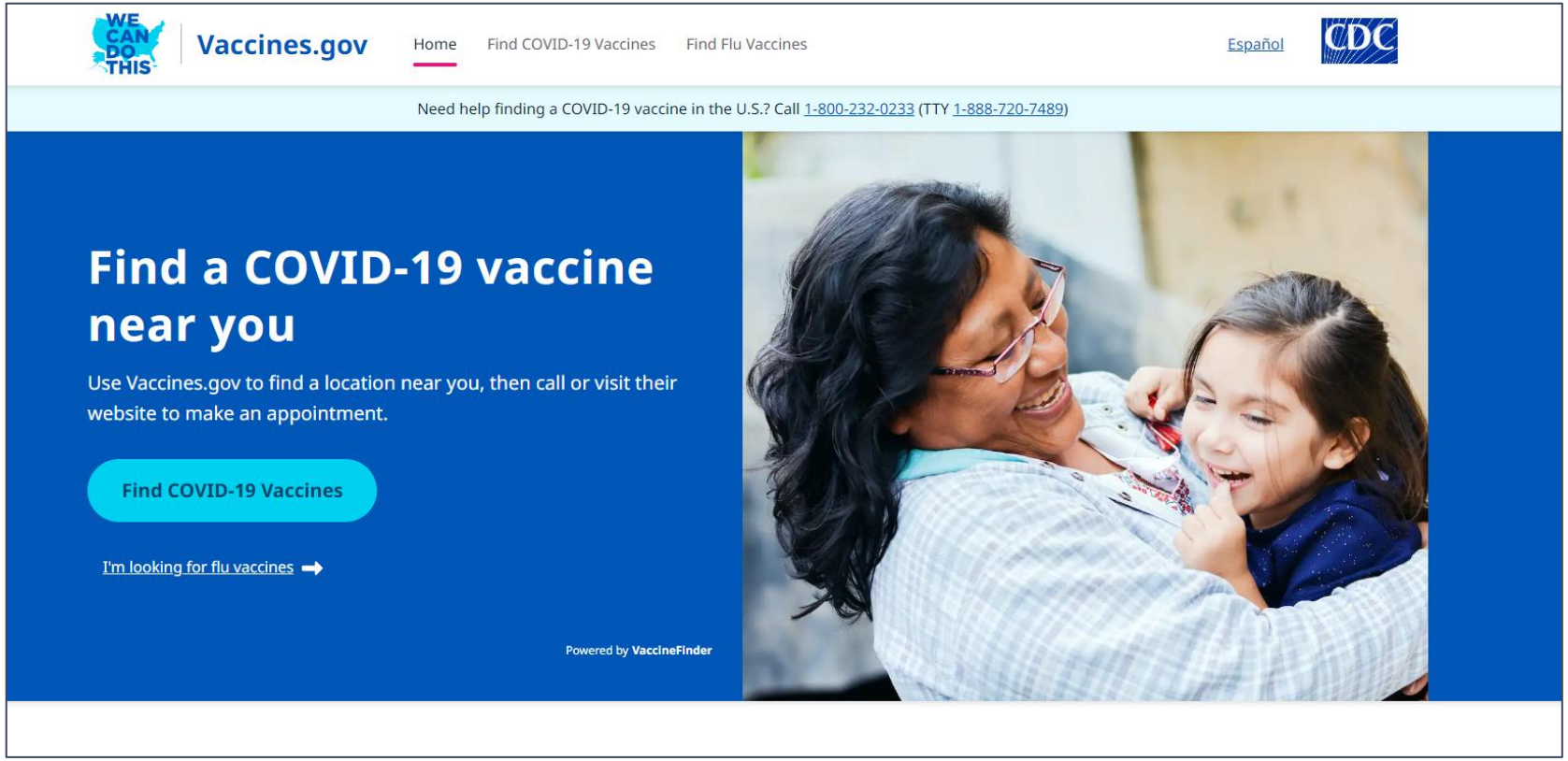
People can self-attest to their moderately or severely immunocompromised status and receive COVID-19 vaccine doses wherever vaccines are offered. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.

# FAQ #7: Should patients get a bivalent now or wait for fall?

- CDC recommends that those who are eligible for a bivalent mRNA vaccination receive one now.
- CDC and interagency partners will continue to collaboratively review all COVID-19 vaccine safety and effectiveness data, as well as all COVID-19 epidemiology, and will discuss these data in preparation for potentially updated recommendations in the fall of 2023.

# FAQ #8: Where can I find a vaccine?

- Information about finding a COVID-19 vaccine near you can be found at vaccines.gov




https://www.vaccines.gov/

# Self-knowledge Check

People who are not immunocompromised are able to get one additional updated (bivalent) COVID-19 vaccine dose if they are aged:

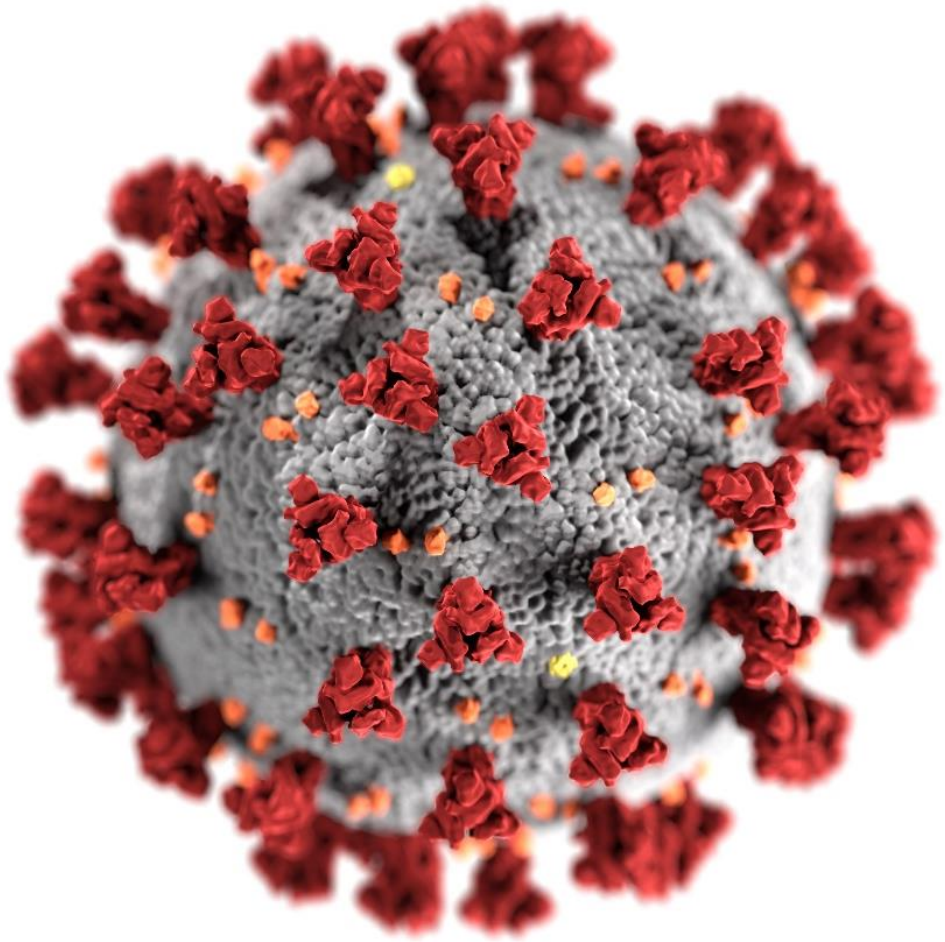
A. 6 months – 4 years
B. 18 – 49 years
C. 50+ years
D. 65+ years

# Self-knowledge Check

The correct answer is: D

People aged 65 years and older are able to receive one additional updated (bivalent) COVID-19 vaccine dose if it has been at least 4 months since their first updated (bivalent) COVID-19 vaccine dose.

# COVID-19 Public Health Emergency Expiration: Updates for Clinicians



**Brendan Jackson, MD, MPH**
CDR, U.S. Public Health Service
Incident Manager, CDC COVID-19 Response
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cdc.gov/coronavirus

# Joining the Q&A Session

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# To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.

# Continuing Education

- All continuing education for COCA Calls is issued online through the CDC Training & Continuing Education Online system at https://tceols.cdc.gov/.

- Those who participate in today's COCA Call and wish to receive continuing education please complete the online evaluation by **Monday, June 12, 2023,** with the course code **WC4520-051123**. The access code is **COCA051123.**

- Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation between **June 13, 2023,** and **June 13, 2025,** and use course code **WD4520-051123.** The access code is **COCA051123.**

- Continuing education certificates can be printed immediately upon completion of your online evaluation. A cumulative transcript of all CDC/ATSDR CEs obtained through the CDC Training & Continuing Education Online System will be maintained for each user.

# Today's COCA Call Will Be Available to View On-Demand

- **When:** A few hours after the live call ends*
- **What:** Video recording
- **Where:** On the COCA Call webpage https://emergency.cdc.gov/coca/calls/2023/callinfo_051123.asp

**A transcript and closed-captioned video will be available shortly after the original video recording posts at the above link.*

# Additional Resources

- Continue to visit emergency.cdc.gov/coca for more details about upcoming COCA Calls.
- Subscribe to receive notifications about upcoming COCA calls and other COCA products and services at emergency.cdc.gov/coca/subscribe.asp.

# Thank you for joining us today!

emergency.cdc.gov/coca