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

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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**
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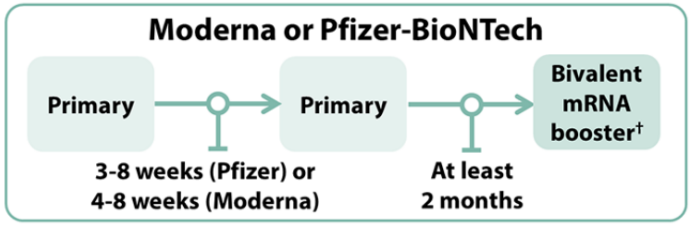
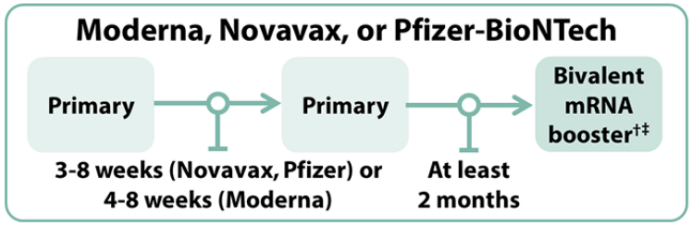
Previous recommendations for people aged ≥6 years without immunocompromise

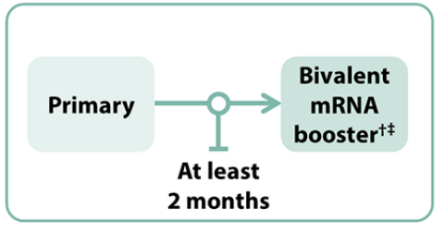
People ages 6 through 11 years



People ages 12 years and older



People ages 18 years and older who previously received Janssen primary series dose§

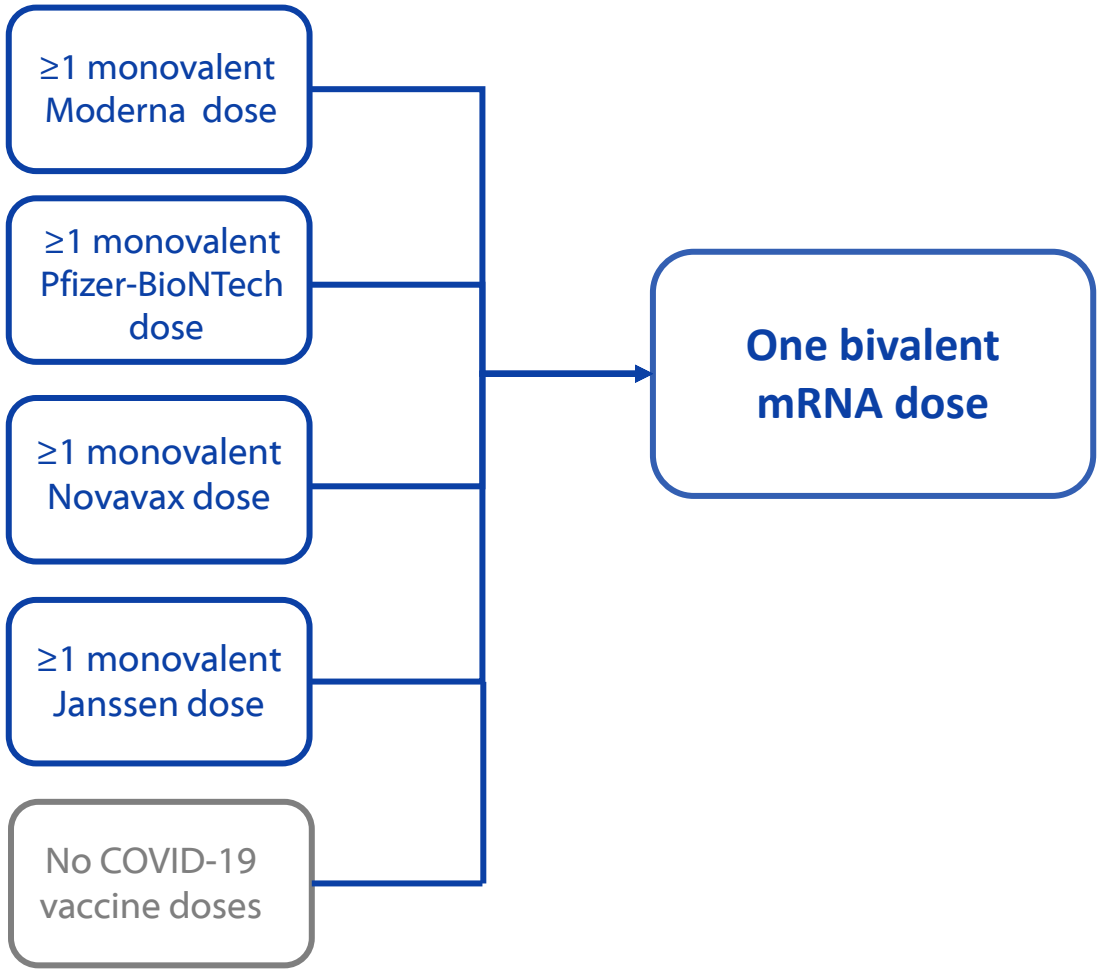


* People ages 6 months–4 years who previously completed a 3-dose monovalent Pfizer-BioNTech primary series are authorized to receive 1 bivalent Pfizer-BioNTech booster dose at least 2 months after completion of the monovalent primary series.
† For people who previously received a monovalent booster dose(s), 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



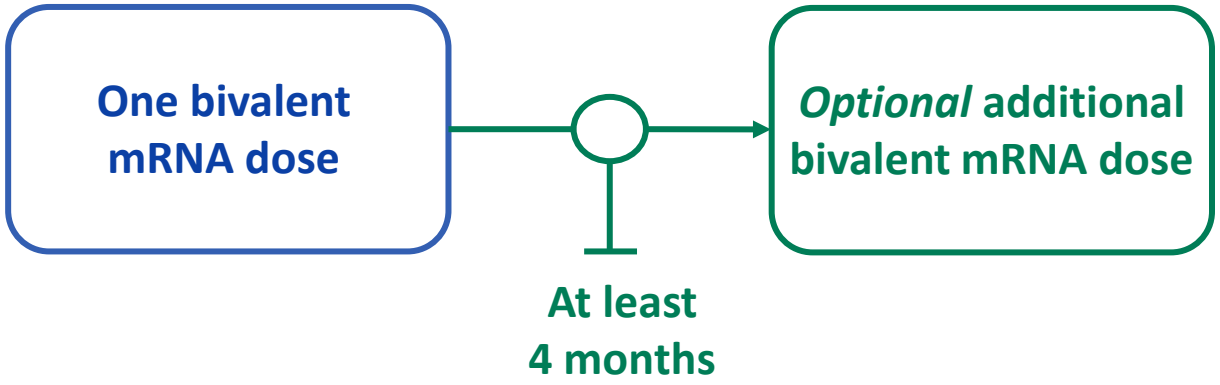
New recommendations for aged ≥6 years without immunocompromise who have already received a bivalent mRNA dose

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

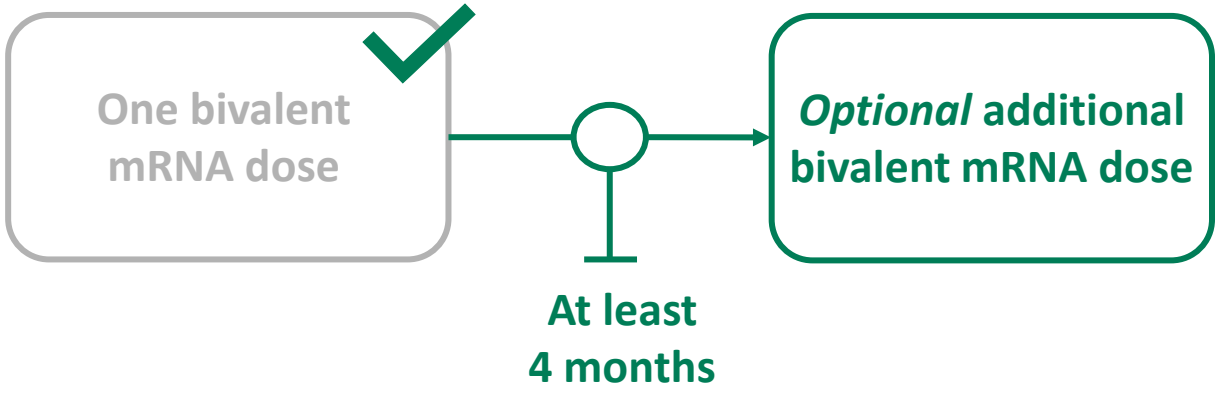
Implications of the new recommendations

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

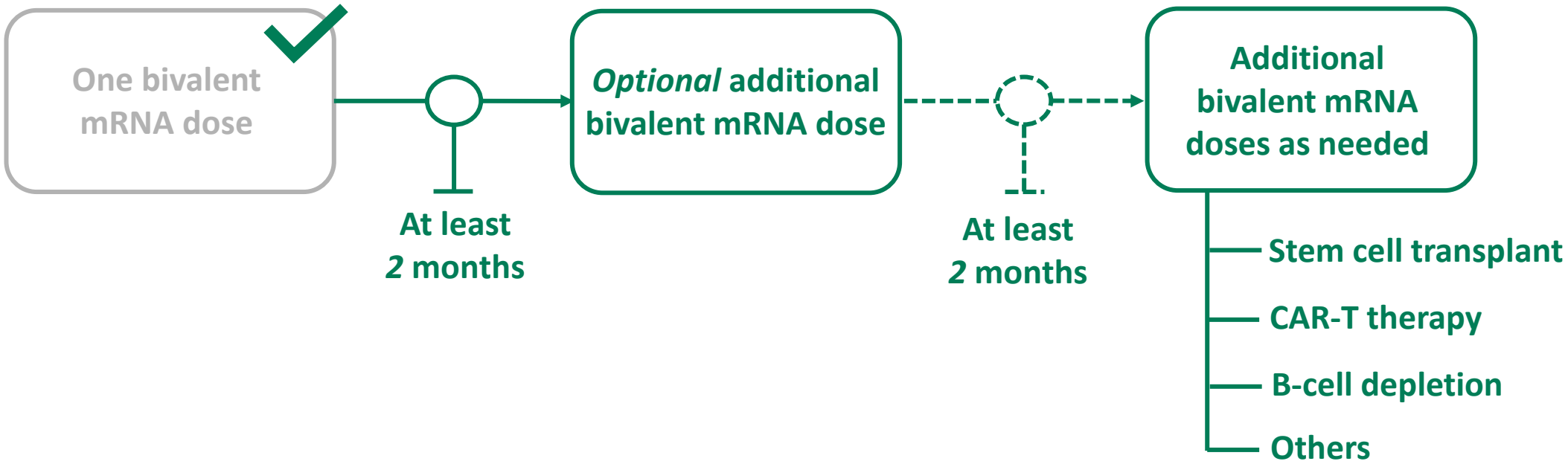
Flexible for people at higher risk of severe COVID-19: People aged ≥65 years who have not yet received a bivalent mRNA dose



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**

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:

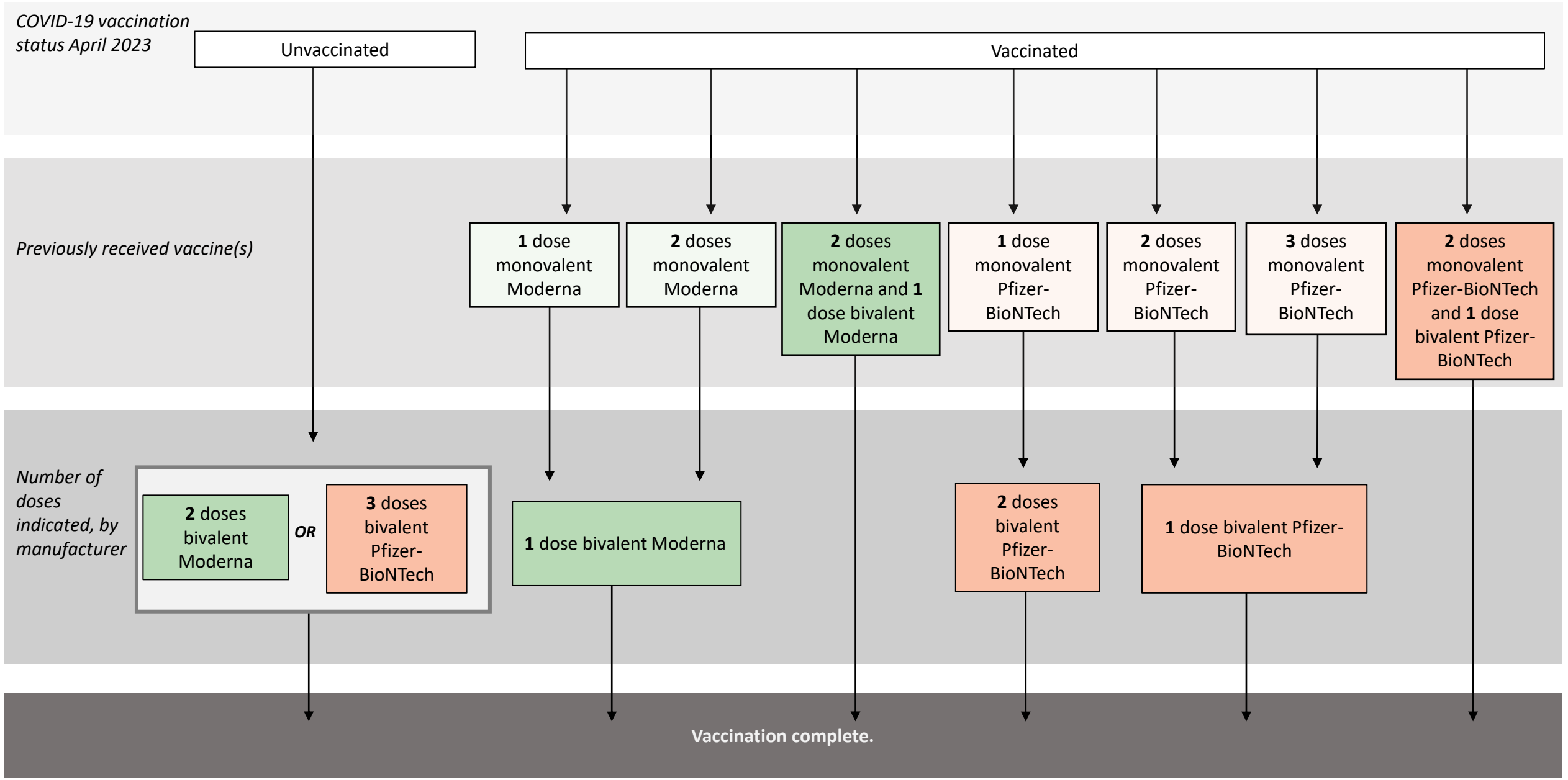
- **2** or **3 monovalent** primary series doses +
- **1 bivalent** primary series dose

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

COVID-19 vaccination algorithm for people without immunocompromise, ages 6 months–4 years, mRNA vaccines April 2023*



*To see product-specific doses and intervals of administration, see Table 1 and 2 forthcoming in Interim Clinical Considerations, forthcoming.

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:

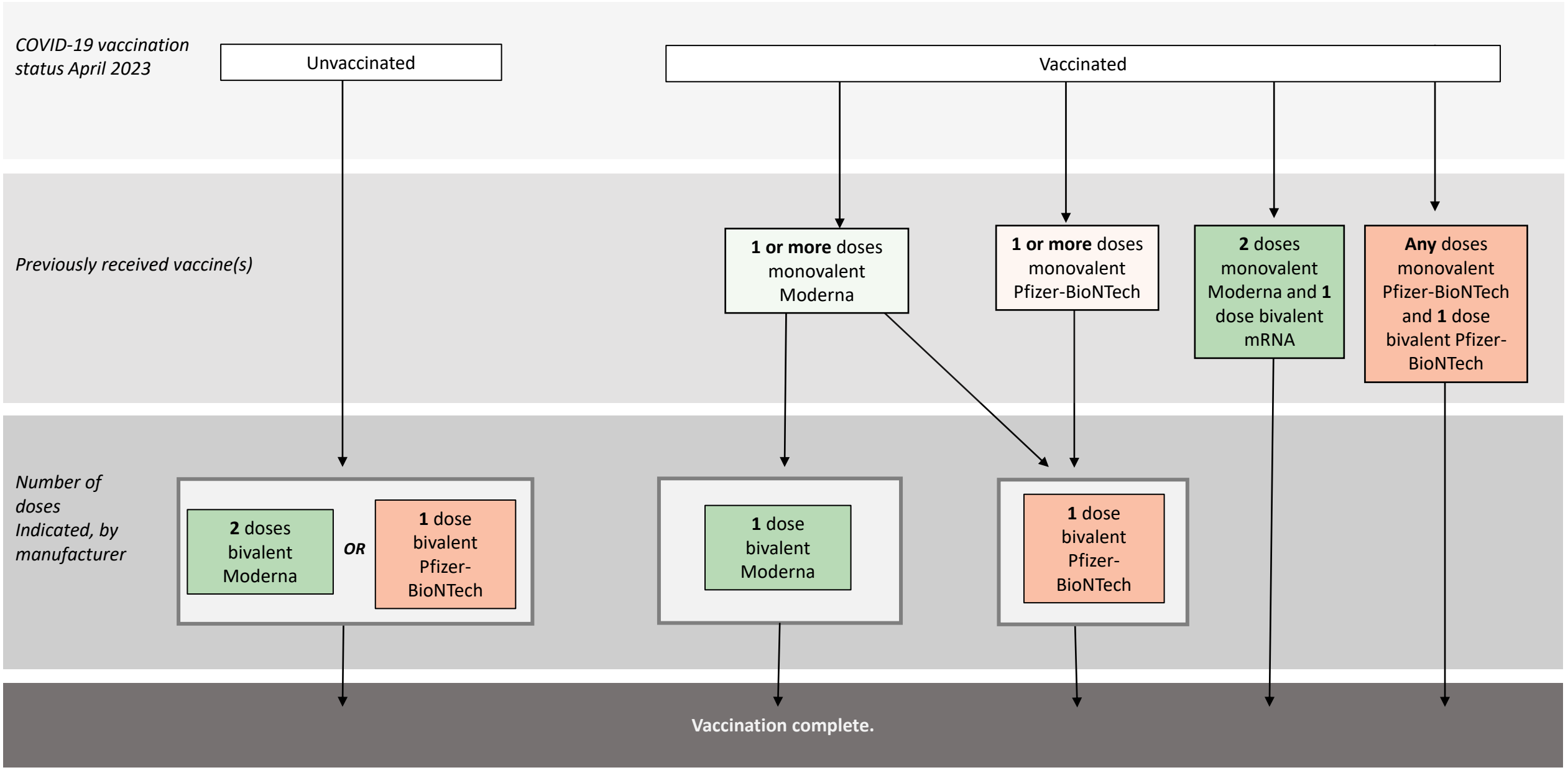
Customized so that **Moderna** recipients receive:

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

And **Pfizer** recipients receive:

- At least **1 bivalent** dose

COVID-19 vaccination algorithm for people without immunocompromise, age 5 years, mRNA vaccines April 2023*



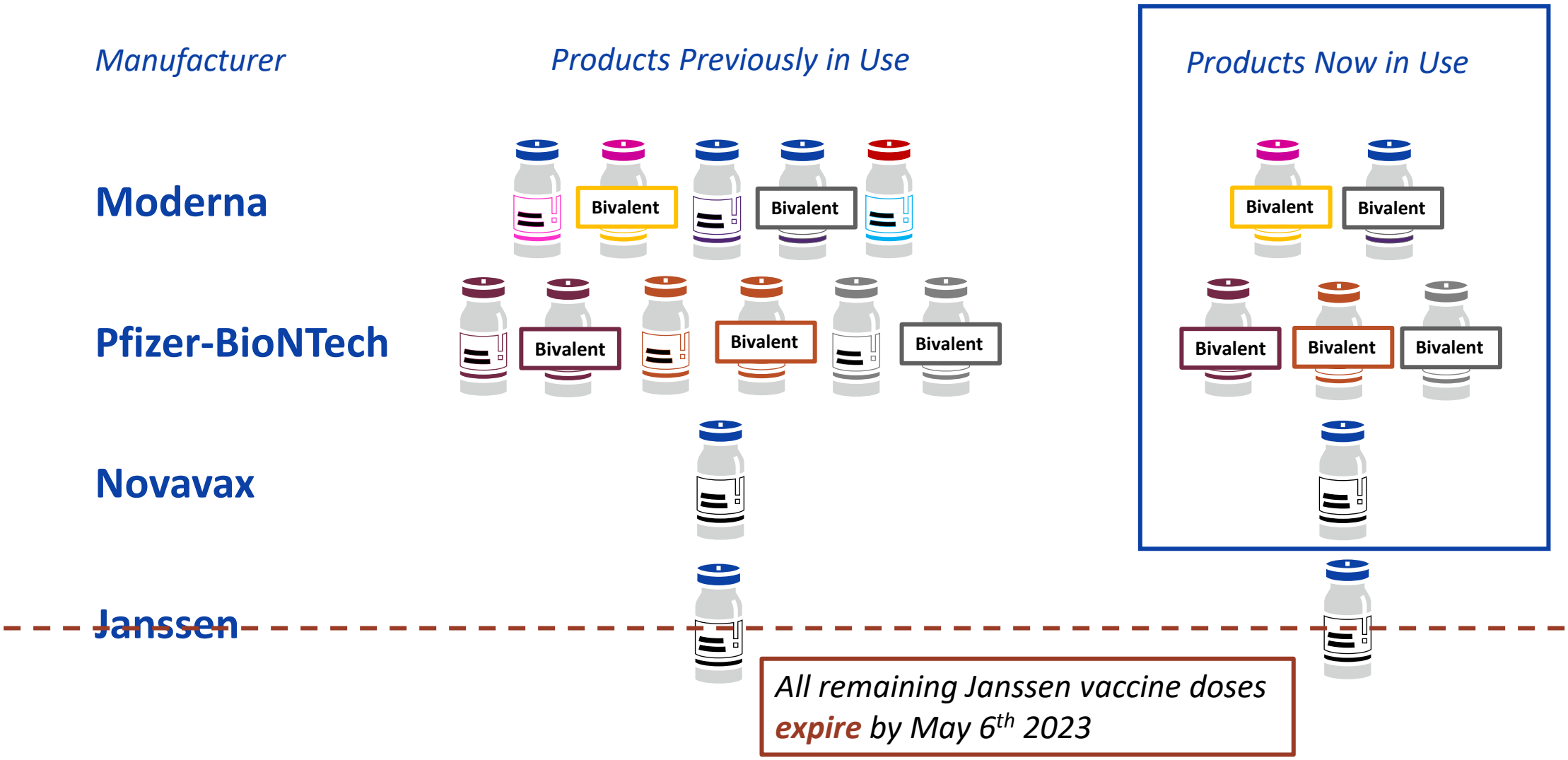
*To see product-specific doses and intervals of administration, see reference Table 1 in Interim Clinical Considerations, forthcoming

Stay Up to Date with COVID-19 Vaccines

- Adults and children aged 6 years and older are up to date with COVID-19 vaccines if they got a bivalent (updated) COVID-19 vaccine.
- Children 6 months through 5 years of age who received the Pfizer-BioNTech COVID-19 vaccine are up to date if:
  - They are 6 months to 4 years of age and got at least 3 COVID-19 vaccine doses, including at least one bivalent (updated) COVID-19 vaccine dose.
  - They are 5 years of age and got at least 1 bivalent (updated) COVID-19 vaccine dose.
- Children 6 months through 5 years of age who got the Moderna COVID-19 vaccine are up to date if they got at least two Moderna COVID-19 vaccine doses, including at least one bivalent (updated) COVID-19 vaccine dose.
- You may be eligible for additional COVID-19 vaccine doses if:
  - You are 65 years of age and older and got your first bivalent (updated) COVID-19 vaccine booster 4 or more months ago.
  - You are moderately or severely immunocompromised and received a bivalent (updated) COVID-19 vaccine booster 2 or more months ago.
- If you are unable or choose not to get a recommended bivalent mRNA vaccine, you will be up to date if you got the Novavax COVID-19 vaccine doses approved for your age group.

Implications for vaccine providers

Fewer COVID-19 Vaccine Products in Use



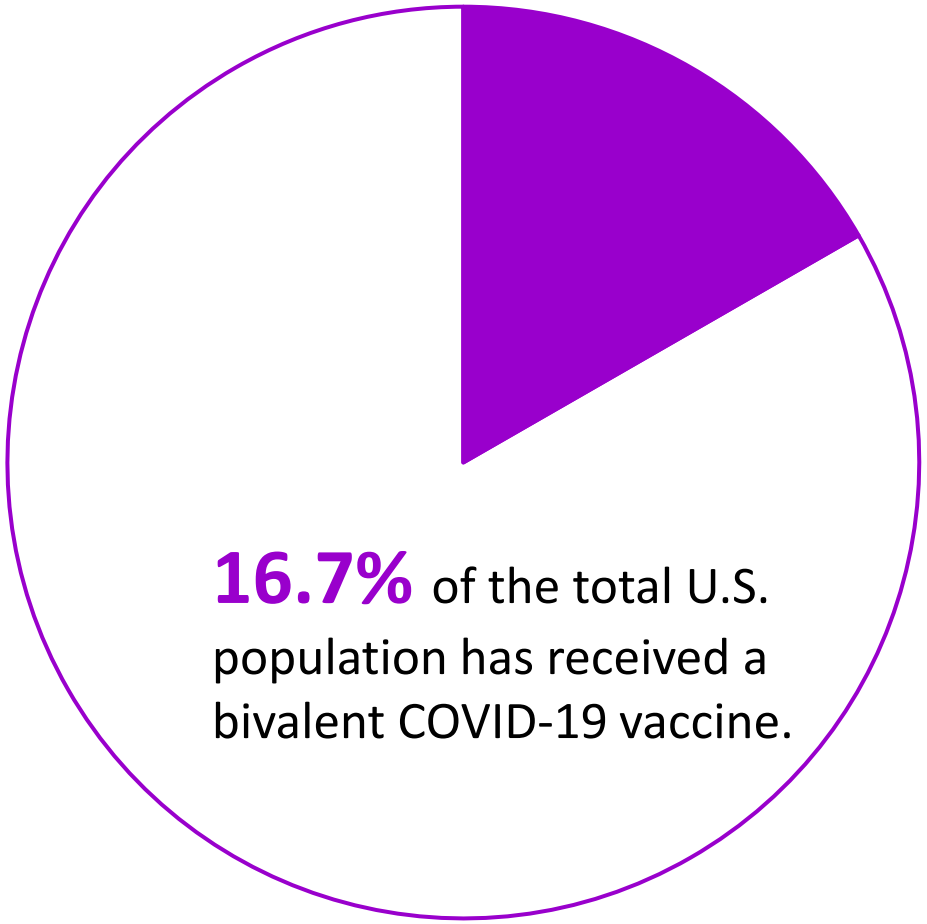
Additional help for providers is on the way

- **CDC's Interim Clinical Considerations for Use of Authorized COVID-19 Vaccines will be updated with comprehensive tables of vaccine doses and dosages indicated**
  - For each age group
  - By history of COVID-19 vaccines received, for children ages 6 months through 5 years
- **Revision of clinical guidance materials is underway**
- **COCA Call to be held May 11th, 2023***

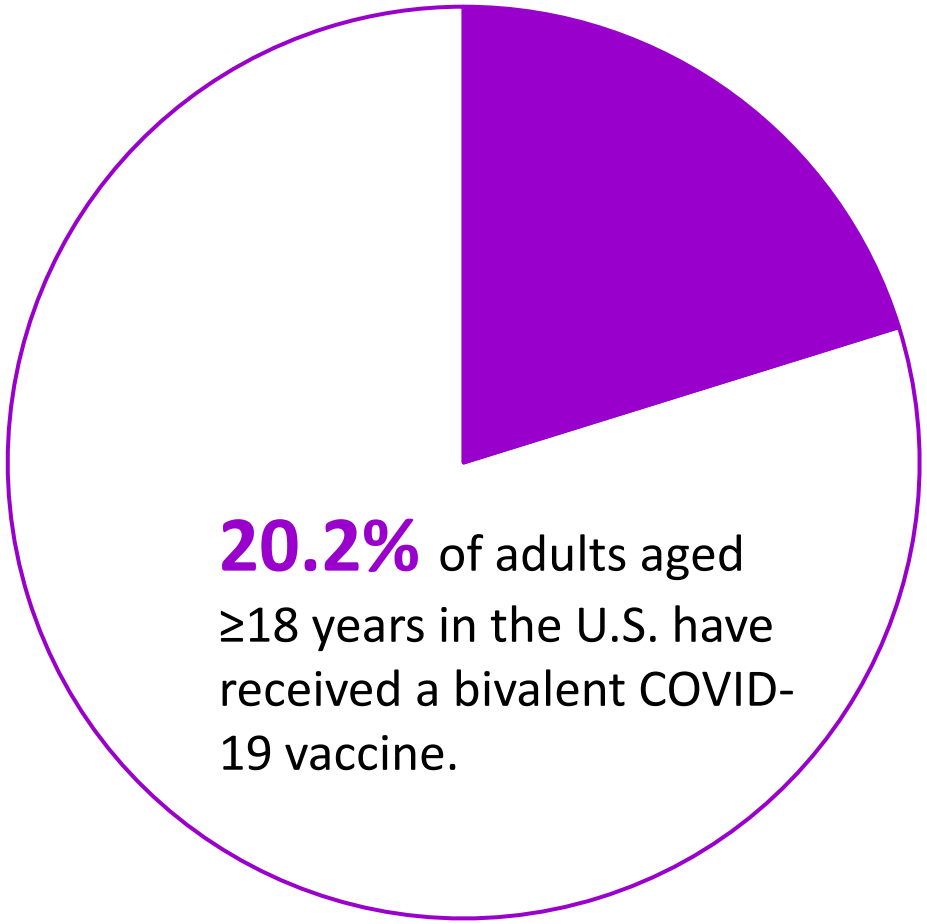
*Please visit https://emergency.cdc.gov/coca/ for complete details

Implications for public health

Bivalent COVID-19 vaccine coverage is low.



16.7% of the total U.S. population has received a bivalent COVID-19 vaccine.

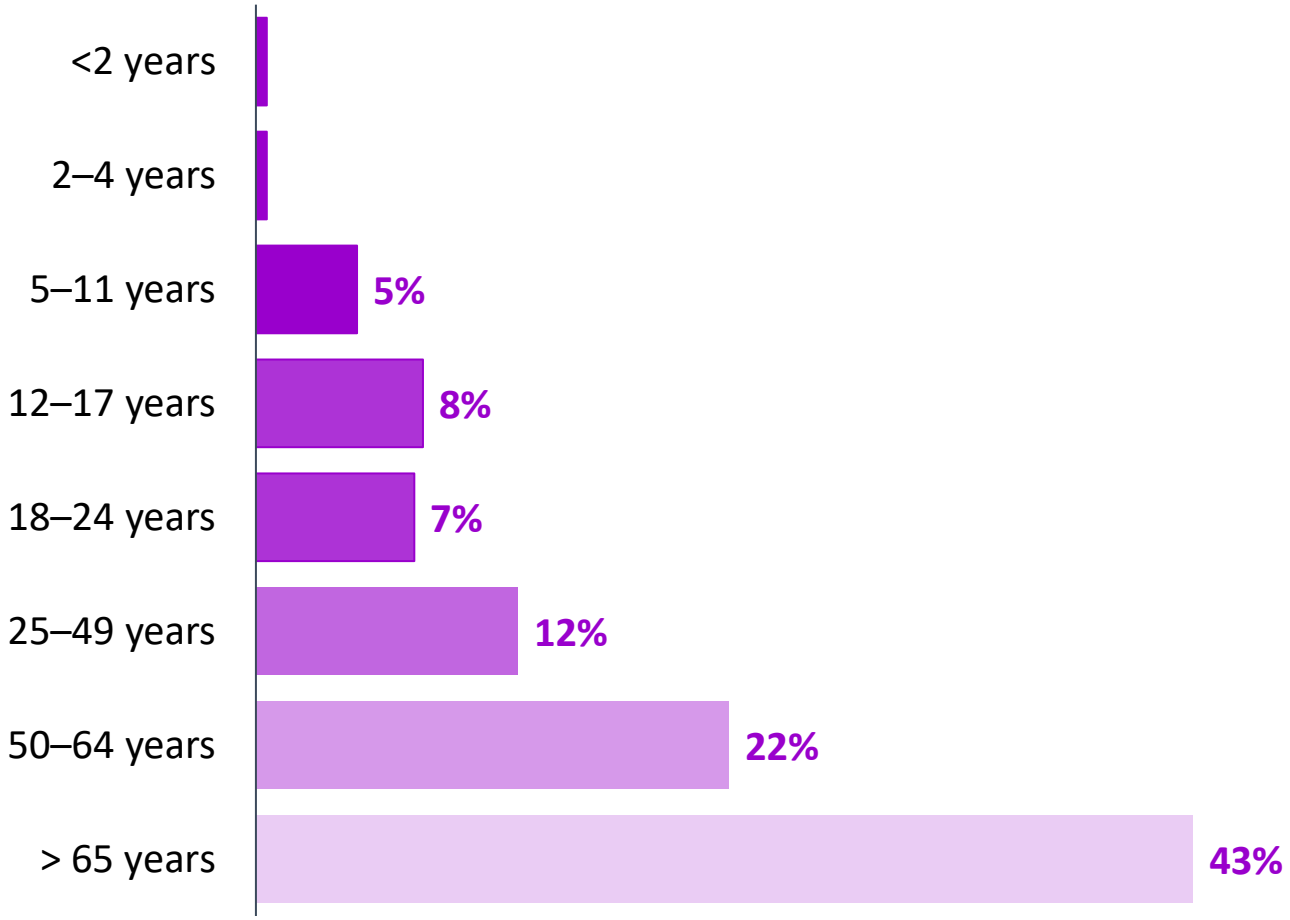


20.2% of adults aged ≥18 years in the U.S. have received a bivalent COVID-19 vaccine.

COVID-19 Data Tracker, last updated April 13, 2023, CDC COVID Data Tracker: Vaccinations in the US

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

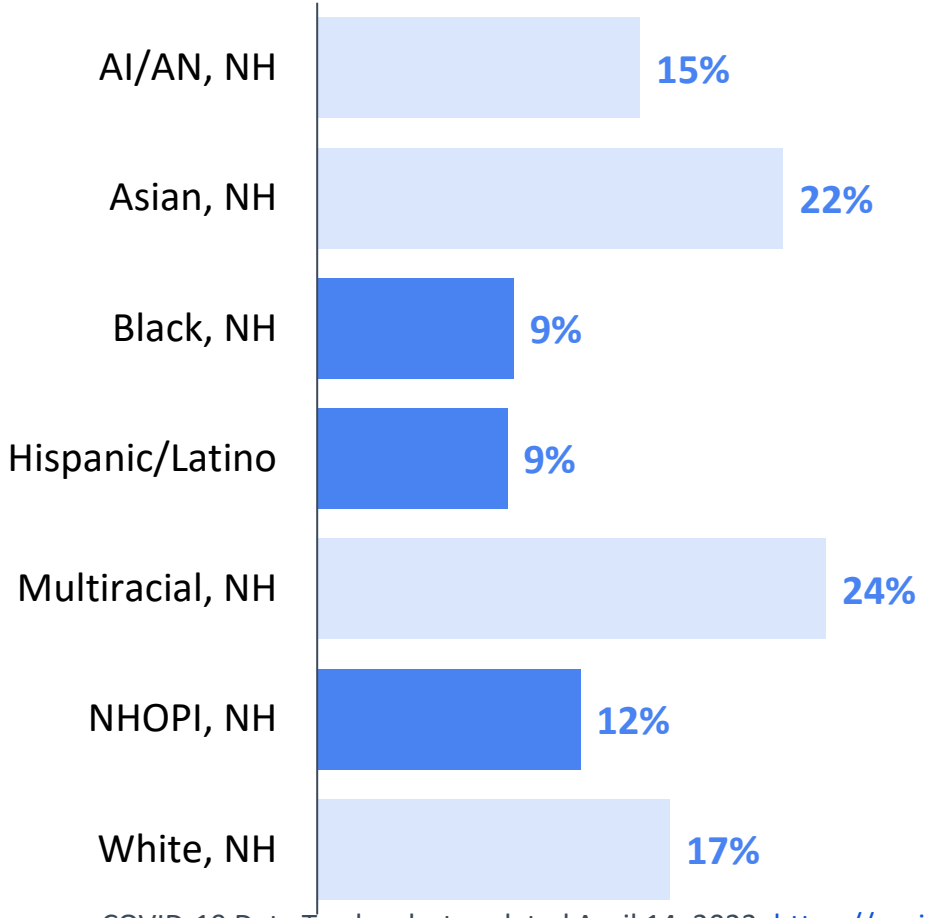
Bivalent COVID-19 Vaccination Coverage by Age



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

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

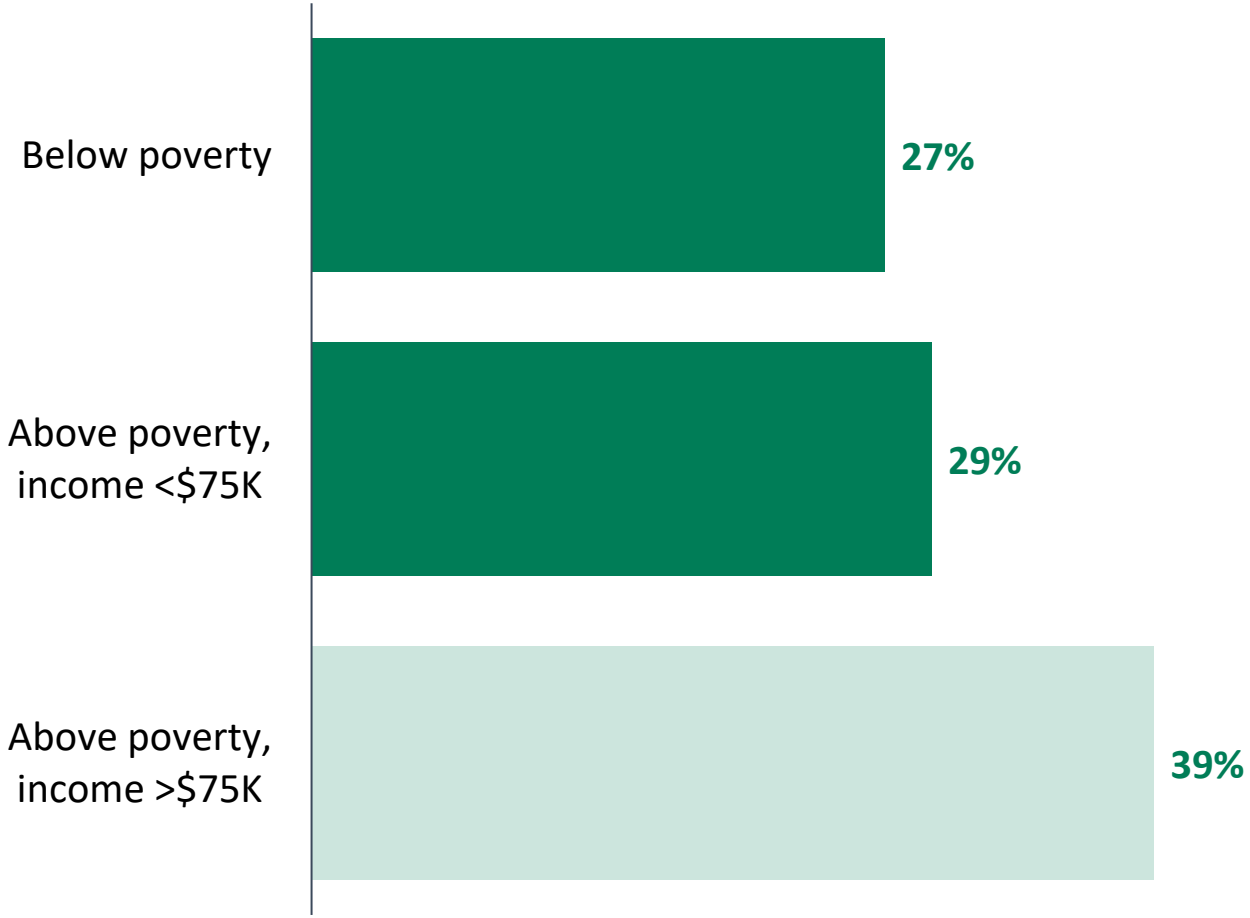
Bivalent COVID-19 Vaccination Coverage by Race/Ethnicity



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

Bivalent COVID-19 vaccine coverage is lower among those with lower income.

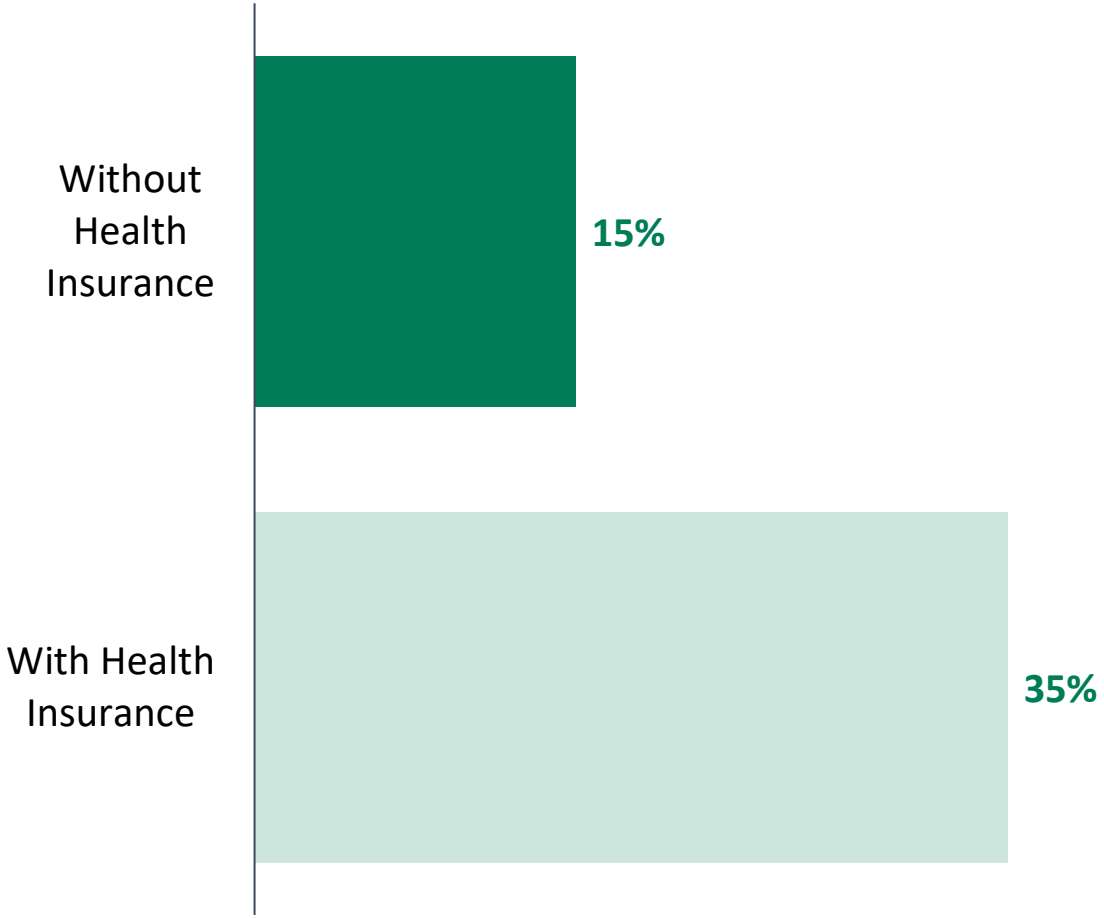
Bivalent COVID-19 vaccine coverage by income among adults aged ≥18 years



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

Bivalent COVID-19 vaccine coverage is lower among those without health insurance.

Bivalent COVID-19 vaccine coverage among adults aged ≥18 years by insurance status



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

Reflections and Next Steps

- 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 is continuing to work toward **additional materials** for vaccine providers, clinicians and the general public 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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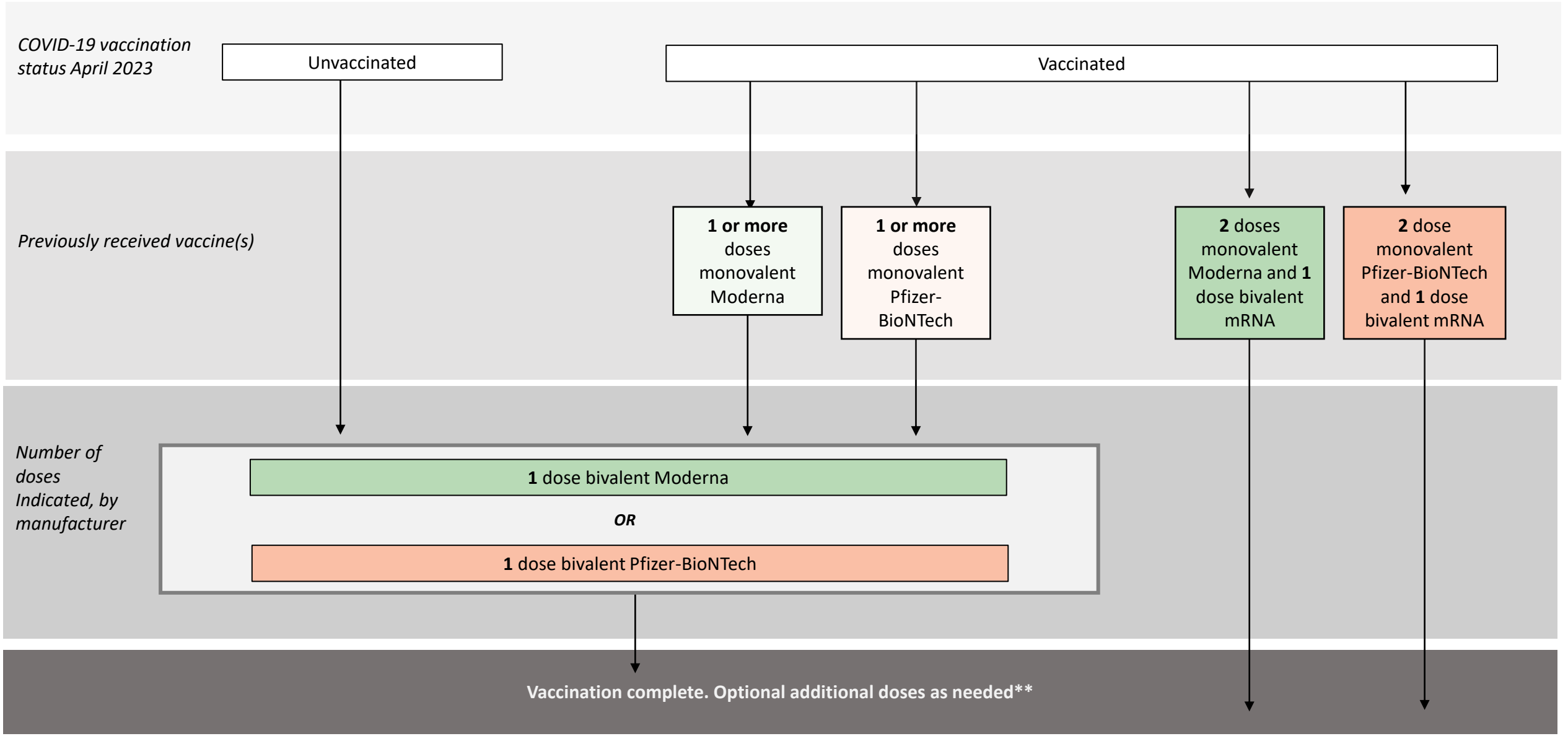
- Coronavirus and other Respiratory Viruses Division
- Immunization Services Division
- National Center for Immunization and Respiratory Diseases

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

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Additional Flowcharts

COVID-19 vaccination algorithm for people who are NOT moderately or severely immunocompromised, age 6 years and older, mRNA vaccines April 2023*



*To see product-specific doses and intervals of administration, see reference Table 1 in Interim Clinical Considerations, forthcoming.

**People ages 65+ have the option to receive 1 additional bivalent mRNA dose at least 4 months after the first dose of a bivalent mRNA vaccine.

Tables

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 ___or___	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
	Pfizer BioNTech	3	0.2 mL/3 ug	Maroon	Dose 1 and Dose 2: 3–8 weeks Dose 2 and dose 3: 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 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 ___*or*___	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
	Pfizer BioNTech	1	0.2 mL/10 ug	Orange	
1 dose monovalent Moderna	Moderna ___*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 ___*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