



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

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Overview of implications

Implications of the new recommendations

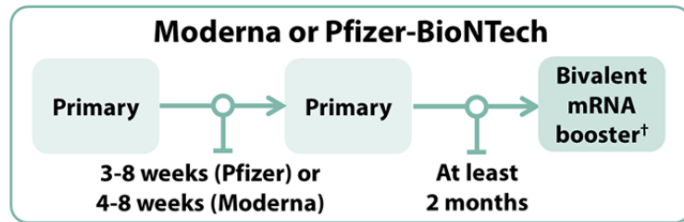
- **Simple and singular for most**
- **Flexible for people at higher risk**
- **Customized recommendations for young children**

Implications of the new recommendations

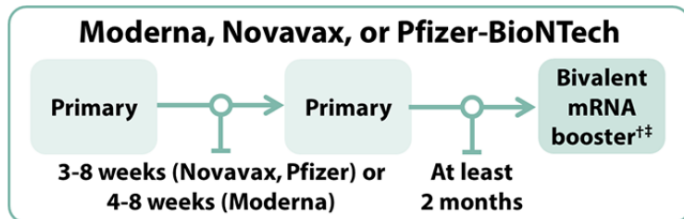
- **Simple and singular for most**
- Flexible for people at higher risk
- Customized recommendations for young children

Previous recommendations for people aged ≥ 6 years without immunocompromise

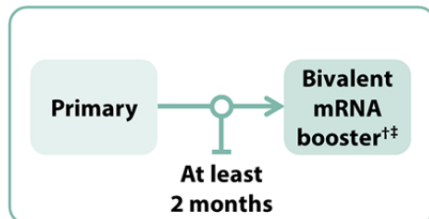
People ages 6 through 11 years



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.

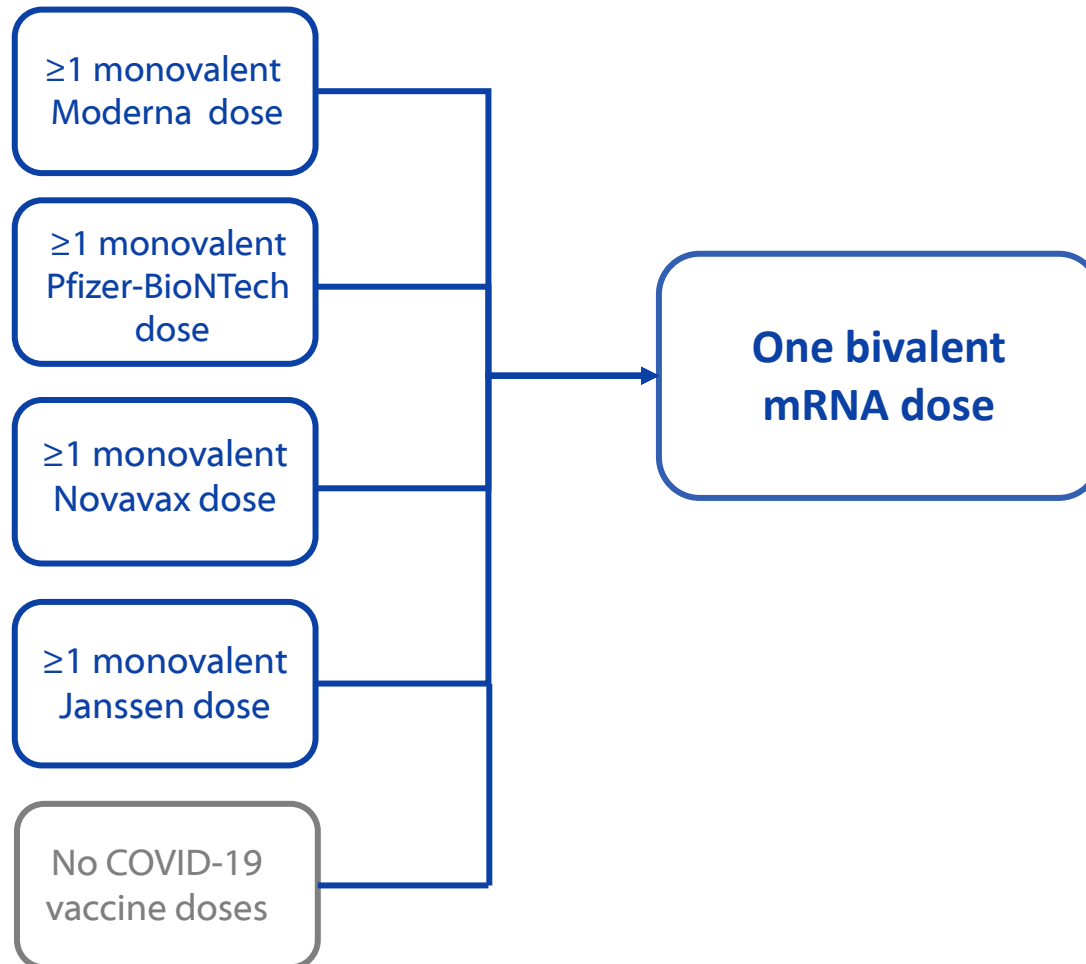
[‡] A monovalent Novavax booster dose may be used in limited situations in people ages 18 years and older who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose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

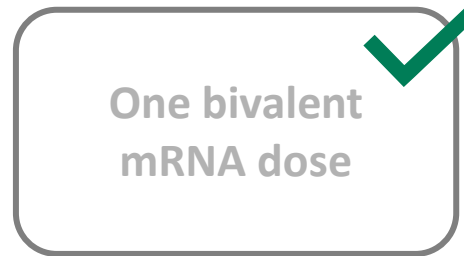
New recommendations for people aged ≥ 6 years without immunocompromise who have not yet received a bivalent mRNA dose

**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

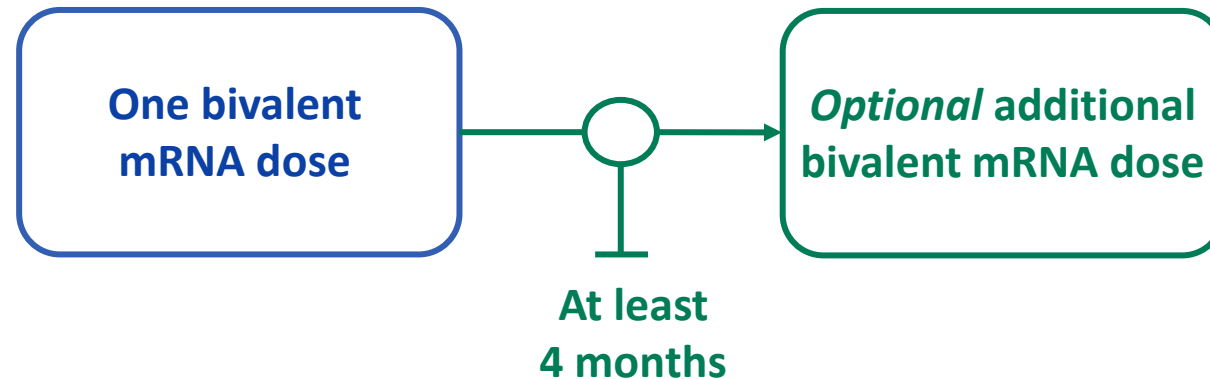


Vaccination is complete.
No doses are indicated at this time.

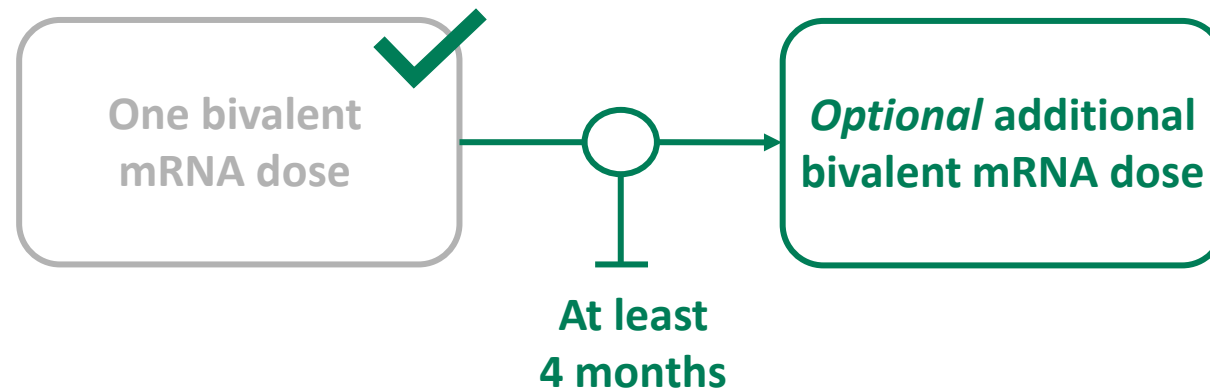
Implications of the new recommendations

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

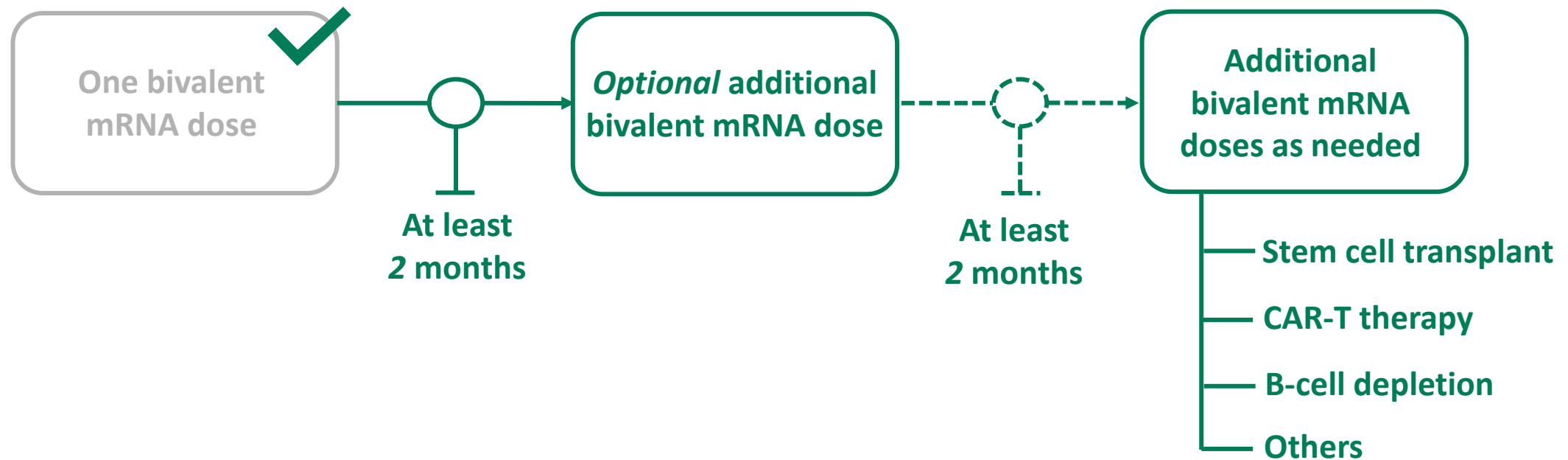
**Flexible for people at higher risk of severe COVID-19:
People aged ≥ 65 years who have not yet received a bivalent mRNA dose**



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

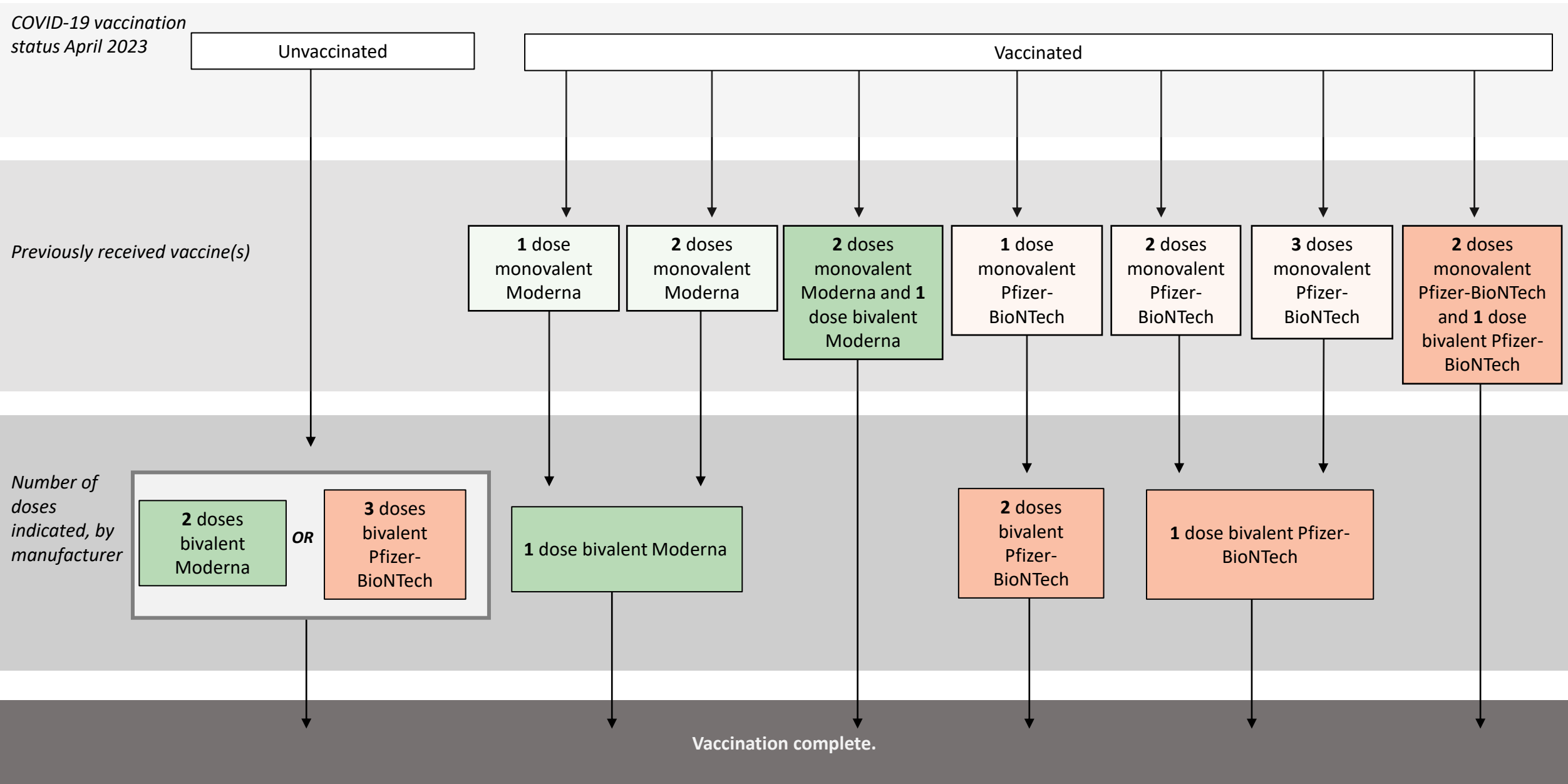
Doses now recommended:

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*

COVID-19 vaccination status April 2023

Unvaccinated

Vaccinated

Previously received vaccine(s)

1 or more doses monovalent Moderna

1 or more doses monovalent Pfizer-BioNTech

2 doses monovalent Moderna and 1 dose bivalent mRNA

Any doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech

Number of doses Indicated, by manufacturer

2 doses bivalent Moderna **OR** 1 dose bivalent Pfizer-BioNTech

1 dose bivalent Moderna

1 dose bivalent Pfizer-BioNTech

Vaccination complete.

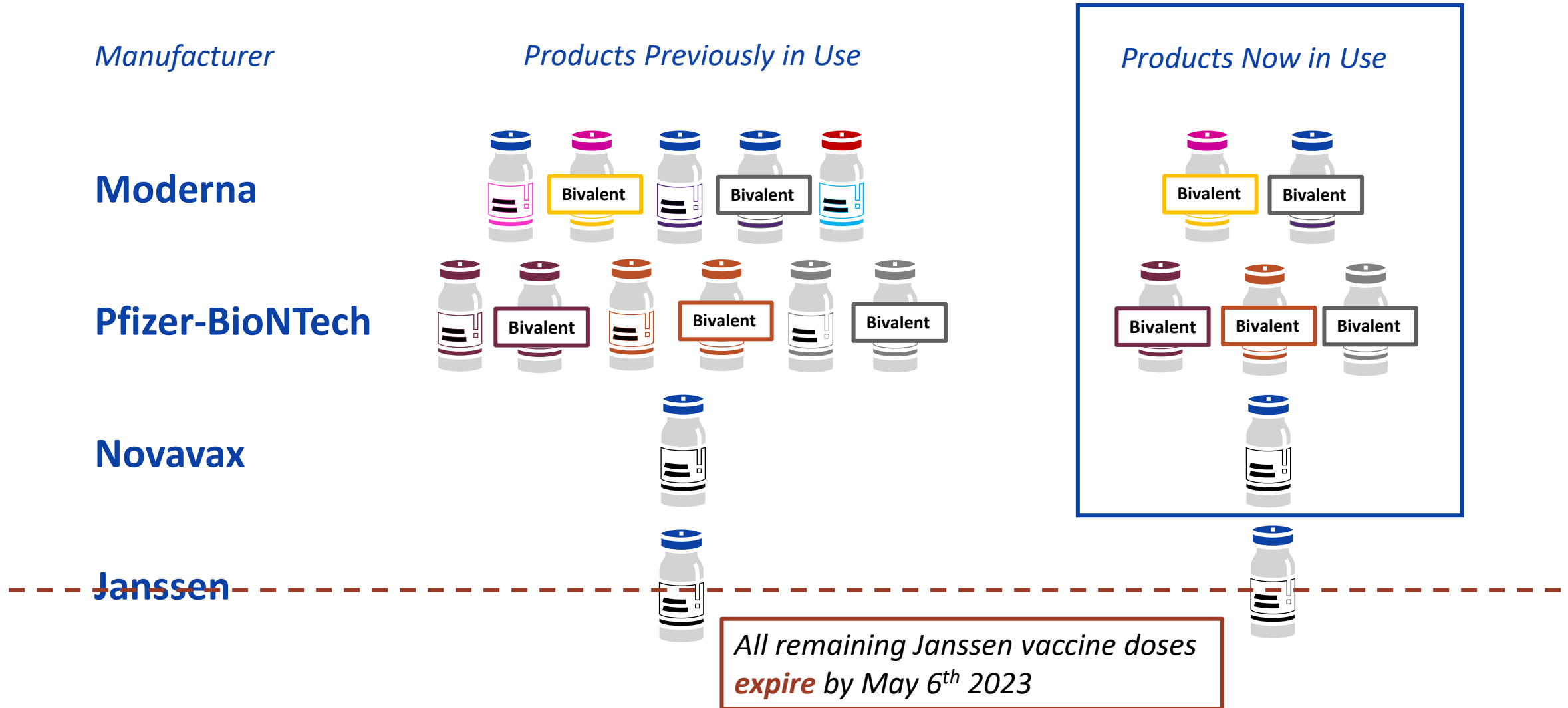
*To see product-specific doses and intervals of administration, see reference Table 1 in Interim Clinical Considerations, forthcoming

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



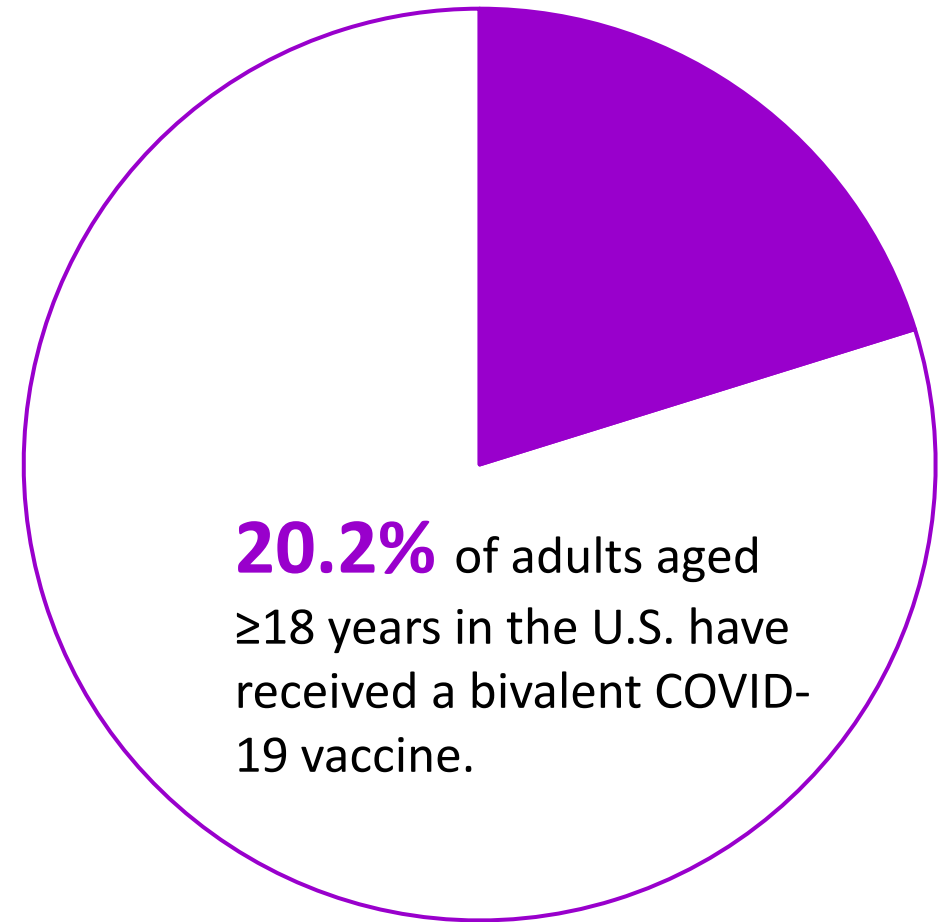
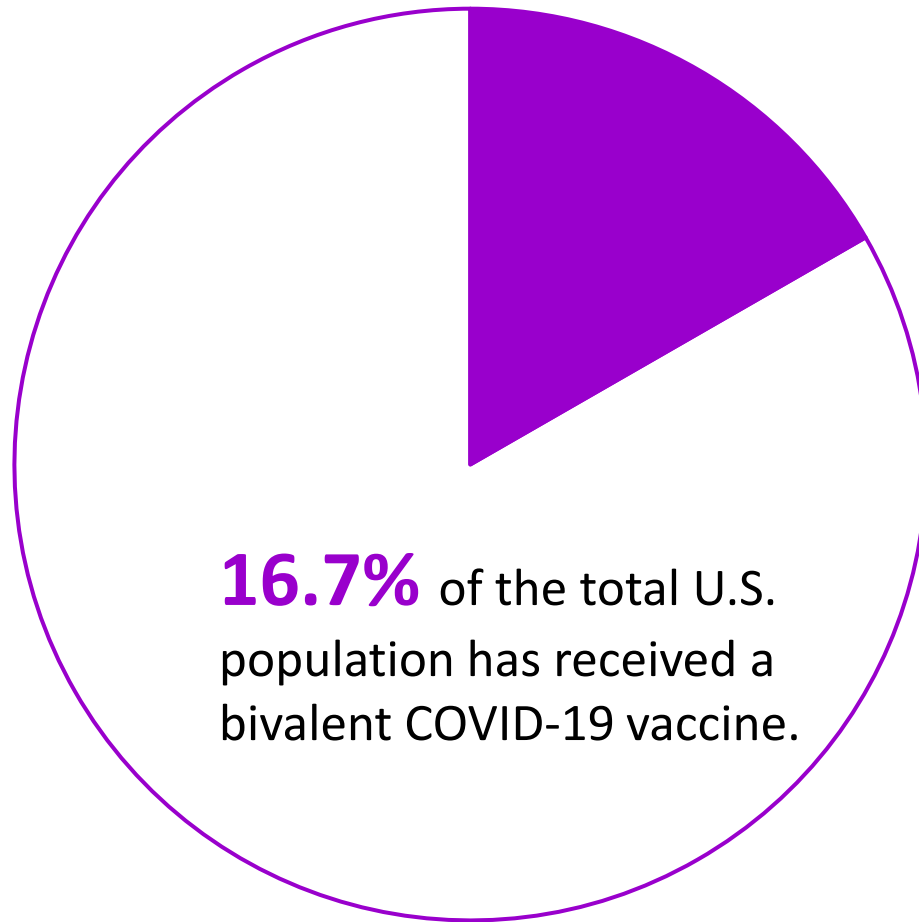
Additional help for providers is on the way

- **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***

Implications for public health

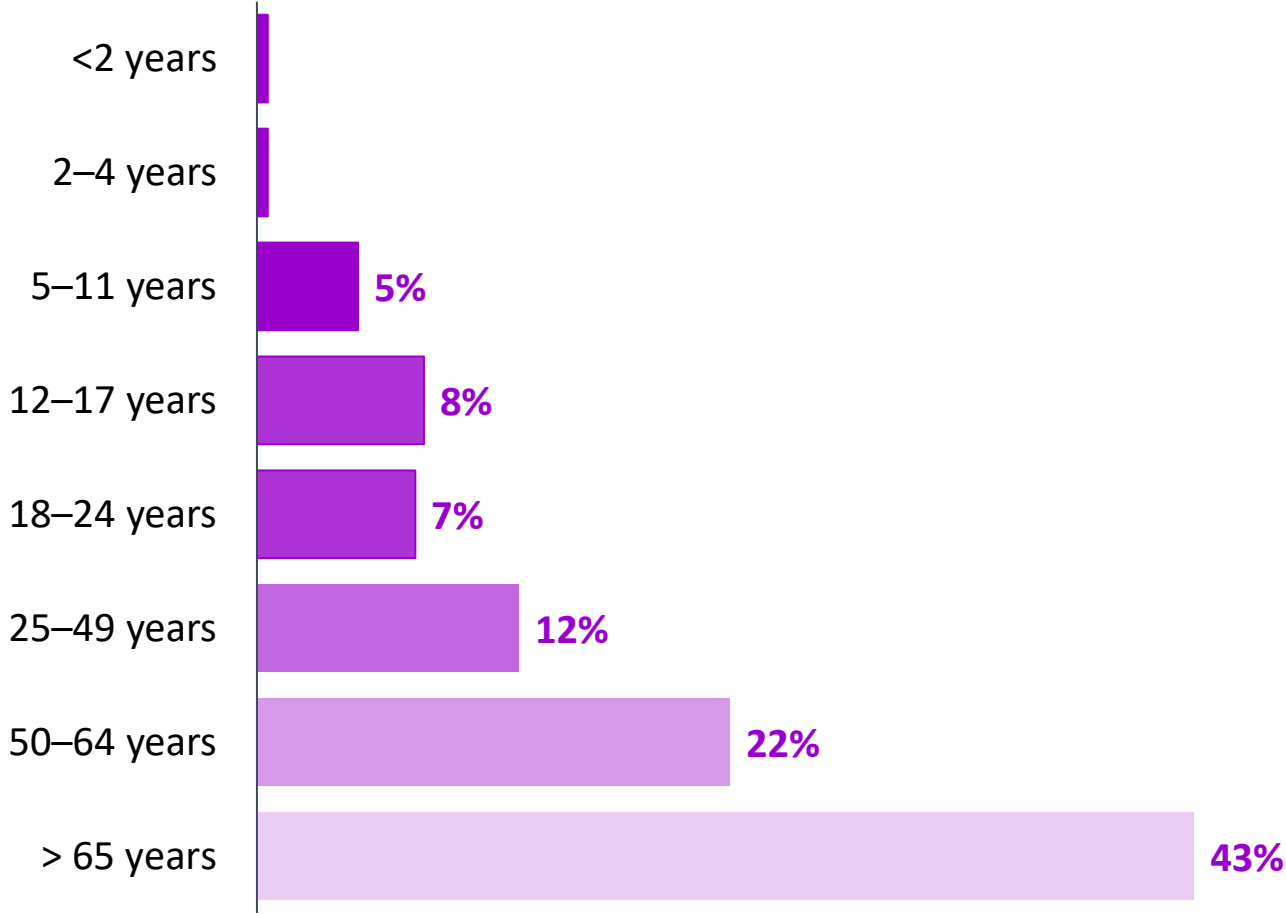
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Bivalent COVID-19 vaccine coverage is low.



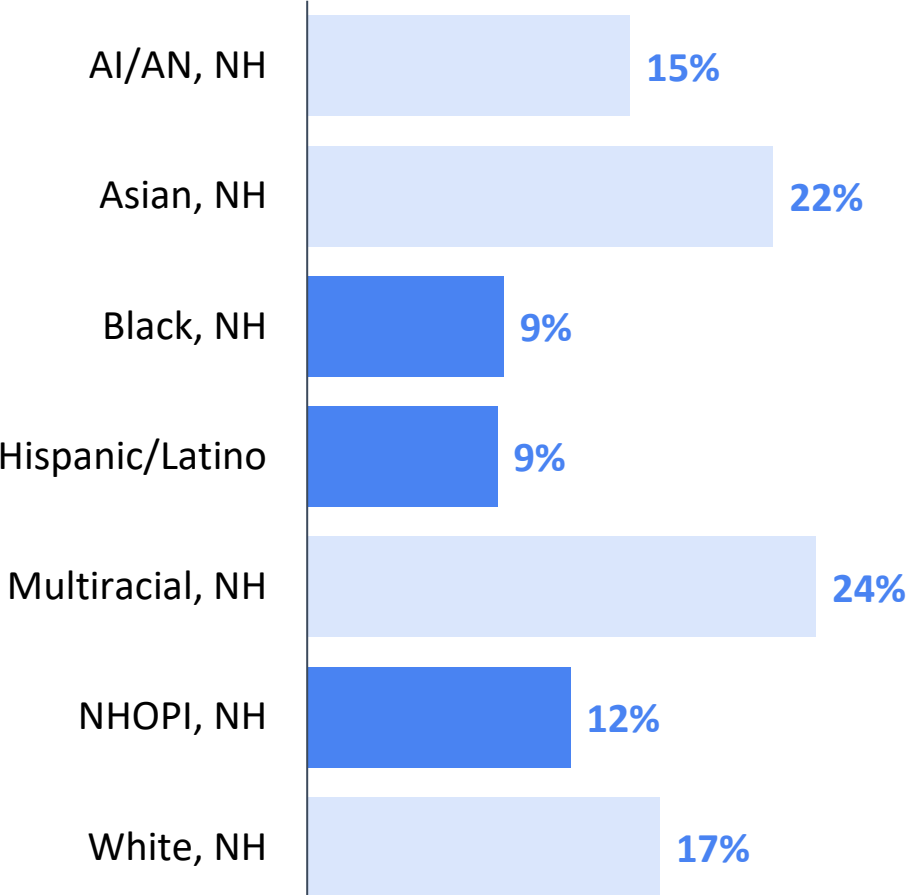
Bivalent COVID-19 vaccine coverage generally decreases with decreasing age.

Bivalent COVID-19 Vaccination Coverage by Age



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

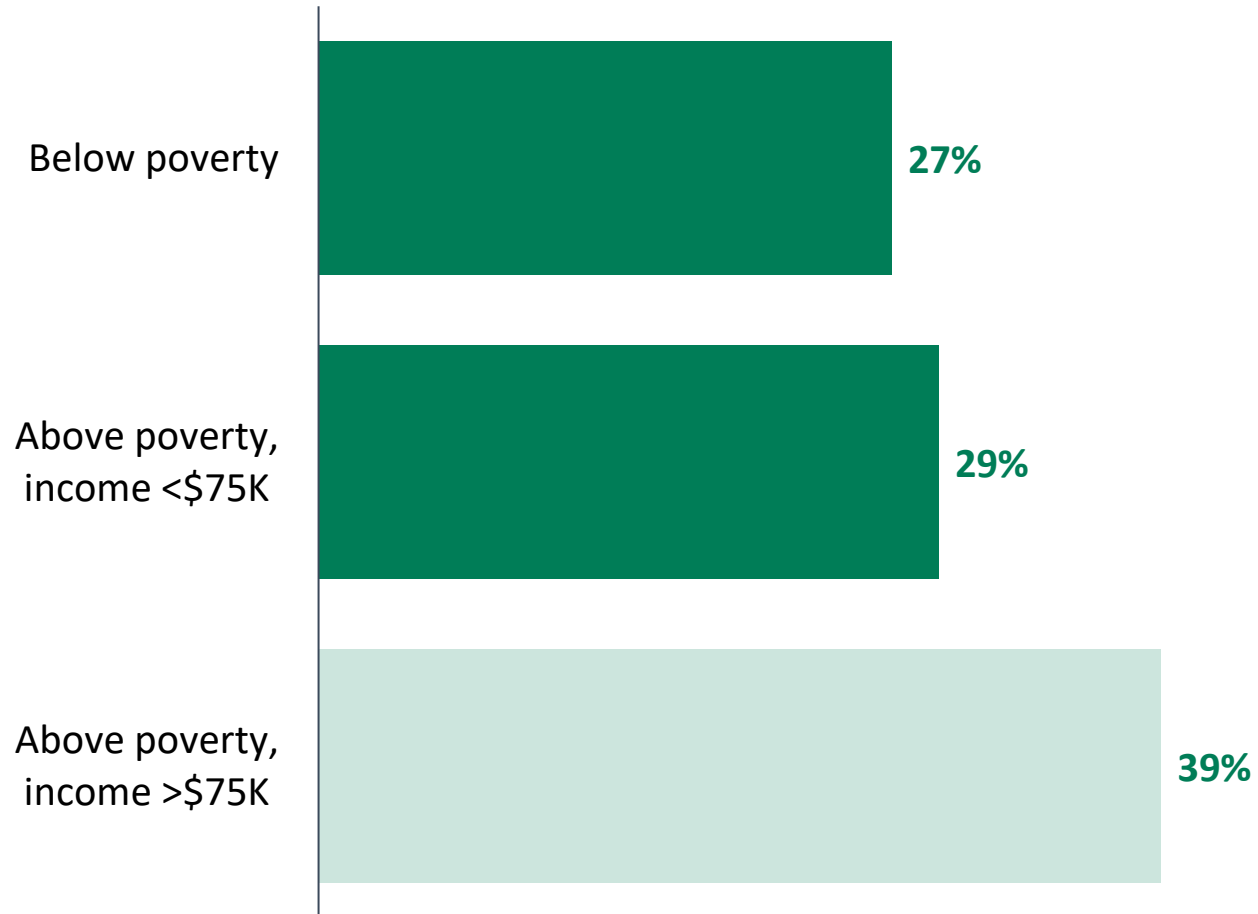
Bivalent COVID-19 Vaccination Coverage by Race/Ethnicity



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

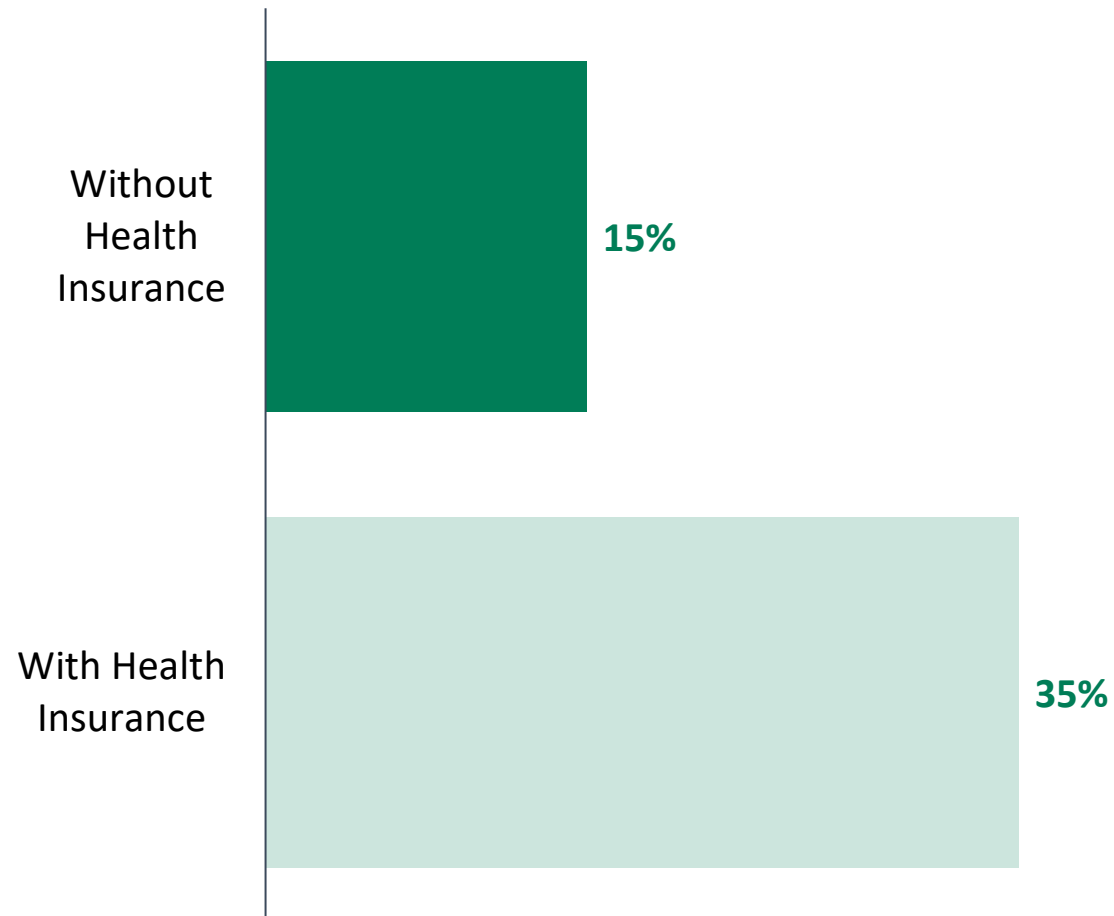
Bivalent COVID-19 vaccine coverage is lower among those with lower income.

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



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



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

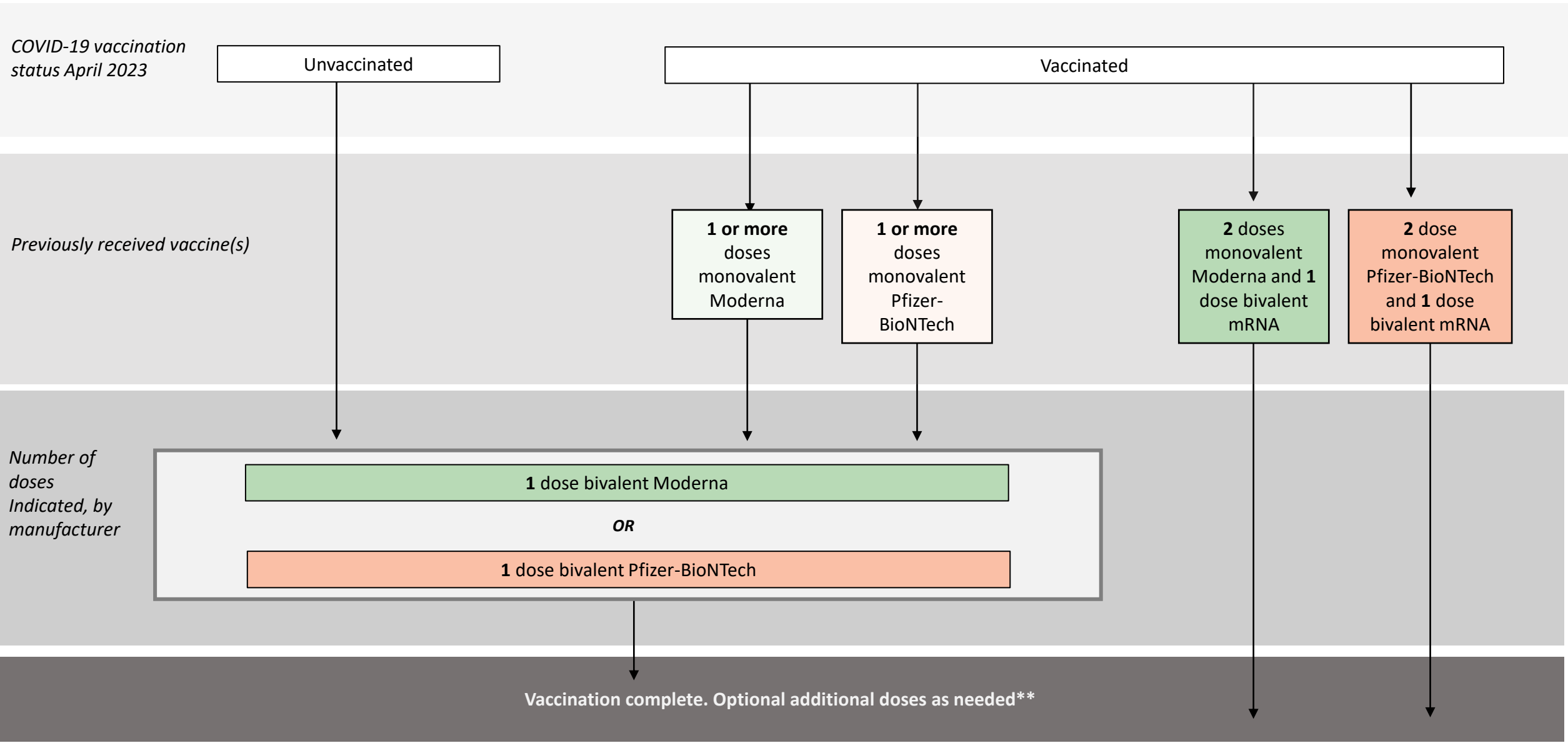
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Additional Flowcharts

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 <u>or</u>	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