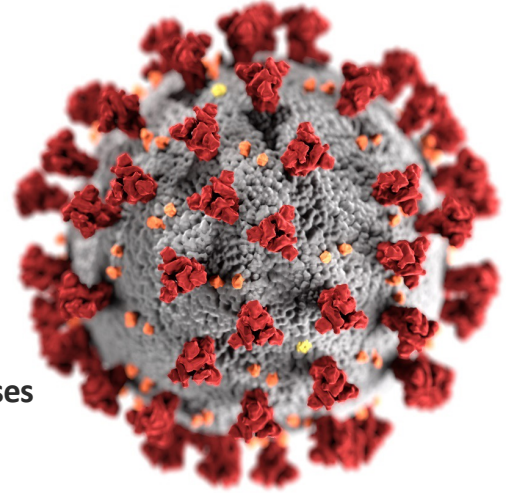


COVID-19 surveillance and vaccine recommendations update

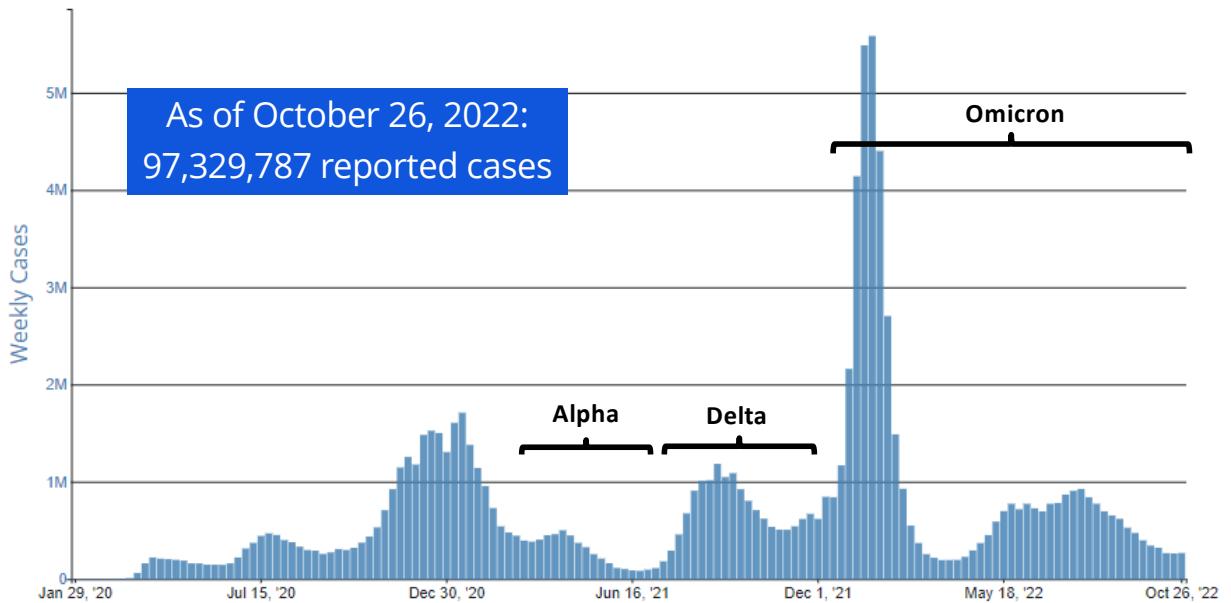
Sara Oliver, MD MSPH
COVID-19 Vaccines ACIP Work Group Lead
National Center for Immunization & Respiratory Diseases
Centers for Disease Control and Prevention



cdc.gov/coronavirus

1

Weekly Trends in Reported COVID-19 Cases, United States

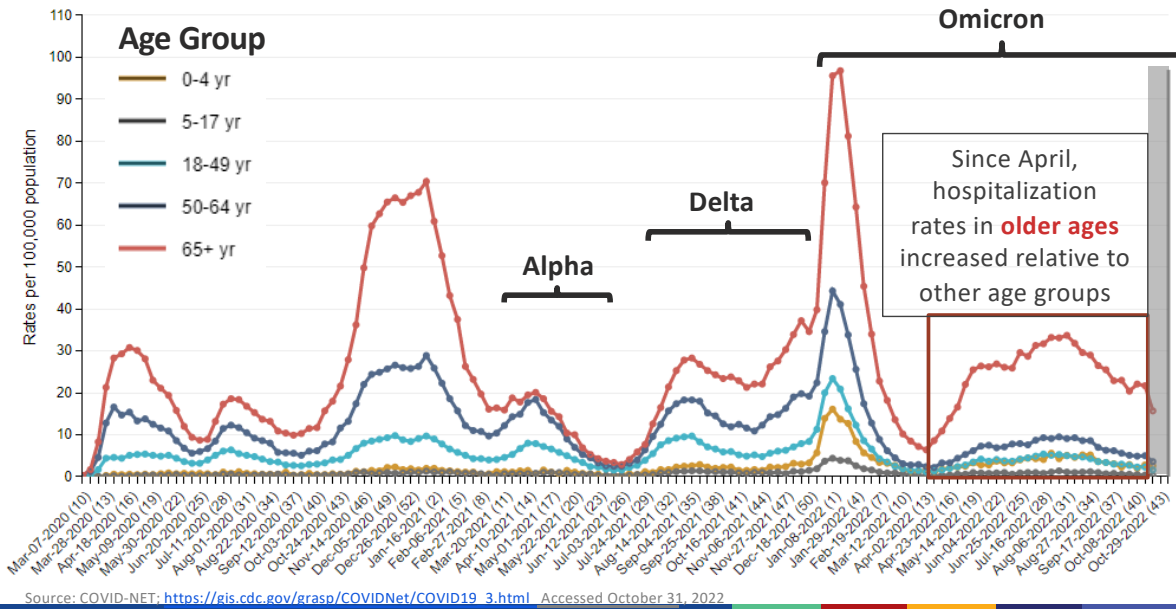


CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#trends_weeklycases_select_00 Accessed October 31, 2022

2

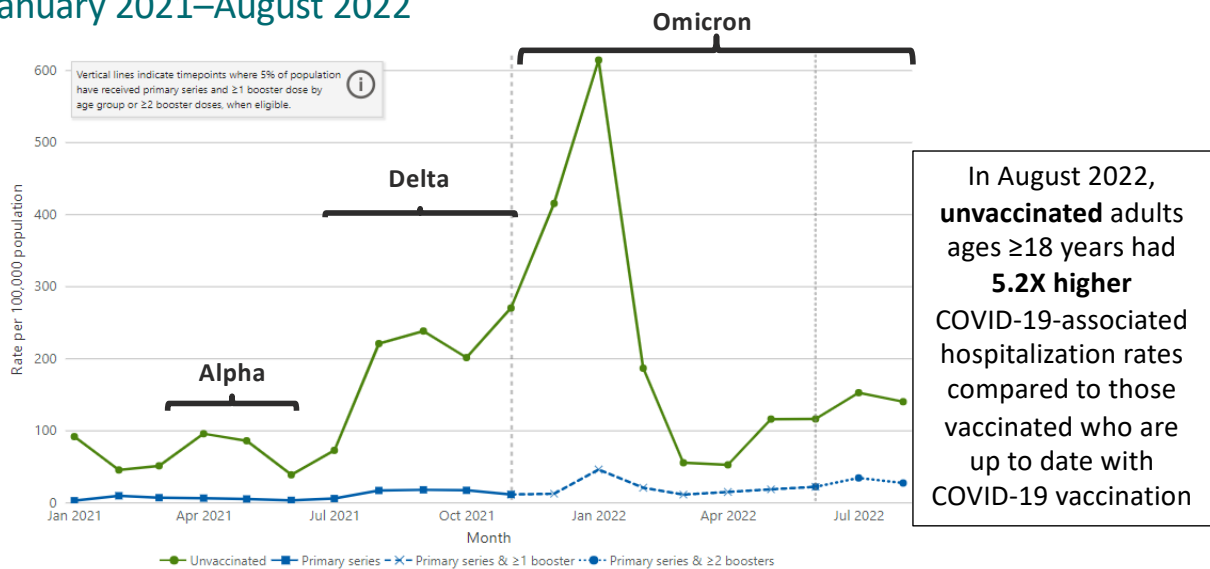
2

Weekly Trends in COVID-19-Associated Hospitalization Rates by Age Group — COVID-NET, March 2020 – October 22, 2022



3

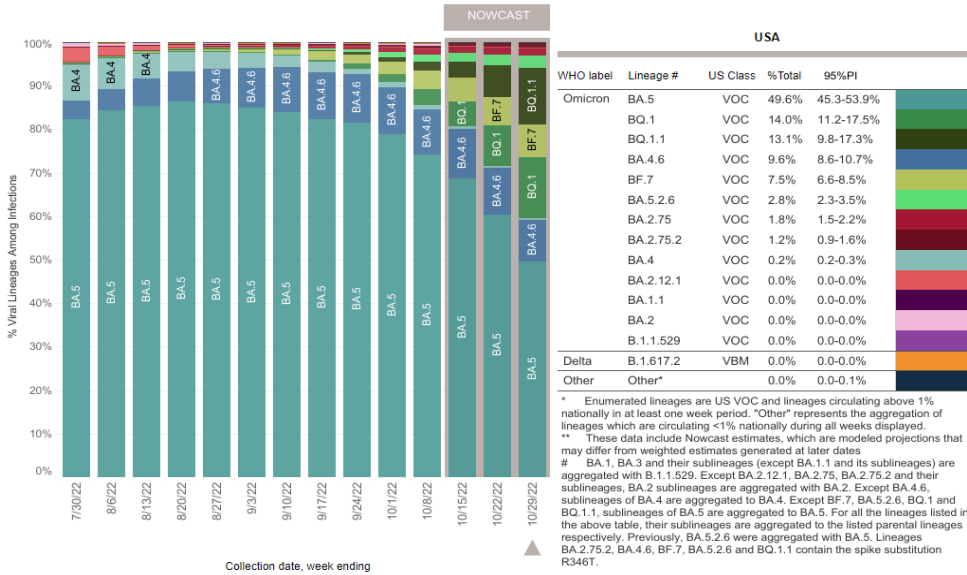
Age-Adjusted Rates of COVID-19-Associated Hospitalization by Vaccination Status and Receipt of Booster Dose in Adults Ages ≥18 Years, January 2021–August 2022



CDC COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination> Accessed October 31, 2022

4

Trends in Weighted Variant Proportion Estimates & Nowcast United States, July 30–October 29, 2022



Over 97% of currently circulating variants represent BA.4 or BA.5 Omicron sub-lineages

CDC COVID Data Tracker: <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> Accessed October 31, 2022

Data to inform booster recommendations Bivalent mRNA COVID-19 vaccines

- At the September 1, 2022 meeting, ACIP discussed **bivalent** mRNA COVID-19 vaccines for all individuals **ages ≥5 years** who were previously recommended to receive a monovalent booster dose¹



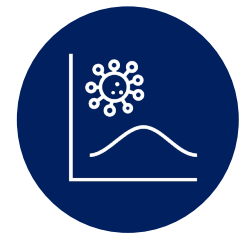
>600 million mRNA doses administered



Clinical data from >1,700 people



Antibody studies and antigenic cartography





Modeling data

¹<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-09-01/08-COVID-Oliver-508.pdf>


Bivalent mRNA Boosters


Monovalent COVID-19 vaccines

50µg  Moderna COVID-19 vaccine
50µg of spike protein from
'ancestral' ('original') SARS-CoV-2

30µg  Pfizer-BioNTech COVID-19 vaccine
30µg of spike protein from
'ancestral' ('original') SARS-CoV-2

Updated (Bivalent) COVID-19 vaccines

50µg  Moderna COVID-19 vaccine
25µg of spike protein from
'ancestral' ('original') SARS-CoV-2
25µg of spike protein from
Omicron (BA.4/BA.5) SARS-CoV-2

30µg  Pfizer-BioNTech COVID-19 vaccine
15µg of spike protein from
'ancestral' ('original') SARS-CoV-2
15µg of spike protein from
Omicron (BA.4/BA.5) SARS-CoV-2

Bivalent vaccines have the
same total antigen amount
as monovalent vaccines

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-09-01/08-COVID-Oliver-508.pdf>

7

7

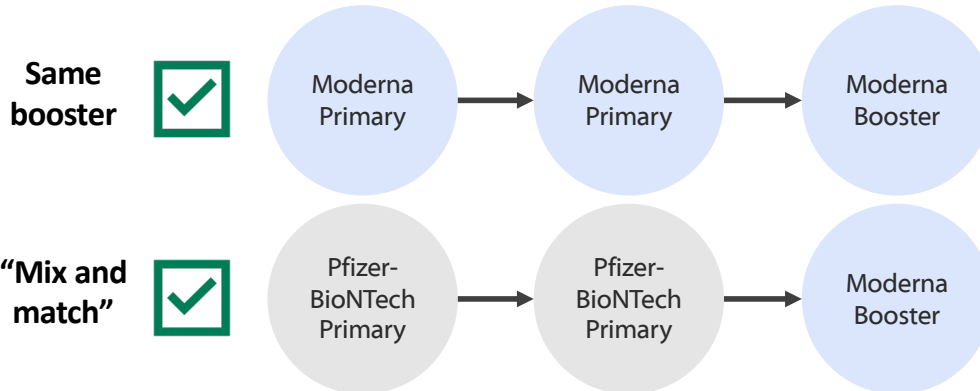
COVID-19 vaccine recommendations

- People **ages 6 months and older** are recommended to receive a **primary series** of any age-appropriate FDA-approved or FDA-authorized monovalent COVID-19 vaccine
- People **ages 5 years and older** are recommended to receive **1 bivalent mRNA booster dose** after completion of any FDA-approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s)
- **Monovalent** mRNA vaccines are **no longer authorized** as booster doses

8

Booster Recommendations: Bivalent Booster, Continued

- **Homologous** (the same) and **heterologous** (“mix and match”) boosters are allowed*; no preference



*Only Pfizer-BioNTech bivalent booster is authorized for people age 5 years. Both Pfizer-BioNTech and Moderna bivalent boosters are authorized for people ages 6 years and older.

9

Booster Recommendations: Monovalent Booster in Limited Situations

- A **monovalent Novavax booster dose** (instead of a bivalent mRNA booster dose) may be used in limited situations in people **ages 18 years and older** who completed any FDA-approved or FDA-authorized monovalent primary series, **have not received a previous booster dose(s)** and are:
 - Unable to receive an mRNA vaccine (i.e., an mRNA is contraindicated or not available)
 - Unwilling to receive an mRNA vaccine and would otherwise remain unvaccinated

10

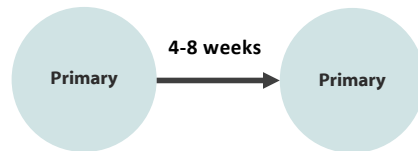
COVID-19 Vaccination Schedule for People Who Are NOT Moderately or Severely Immunocompromised

11

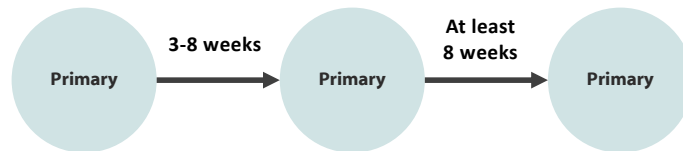


Pediatric Schedule: Ages 6 months–4 Years

**Ages 6 months–
4 years**
(Primary Series:
Moderna)



**Ages 6 months–
4 years**
(Primary Series:
Pfizer-BioNTech)

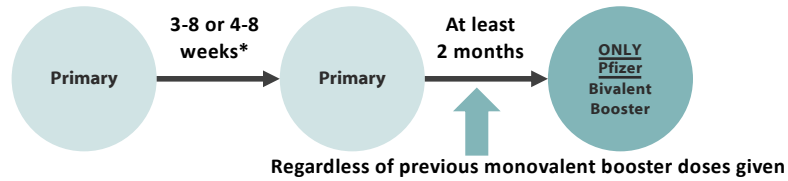


12

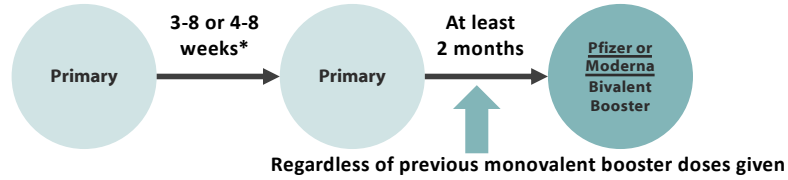


Pediatric Schedule: Ages 5–11 Years

Ages 5 years
(Primary Series:
Moderna or
Pfizer-BioNTech)



Ages 6–11 years
(Primary Series:
Moderna or
Pfizer-BioNTech)



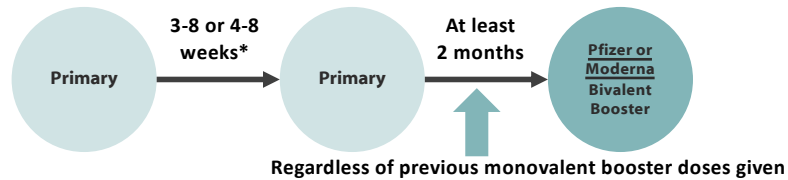
*3-8 week interval for Pfizer-BioNTech; 4-8 week interval for Moderna

13



Pediatric Schedule: Ages 12-17 Years

Ages 12–17 years
(Primary Series:
Moderna,
Novavax, or
Pfizer-BioNTech)



*3-8 week interval for Novavax or Pfizer-BioNTech; 4-8 week interval for Moderna

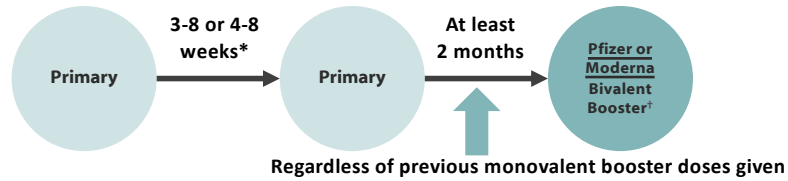
14



Adult Schedule: Ages 18 Years and Older

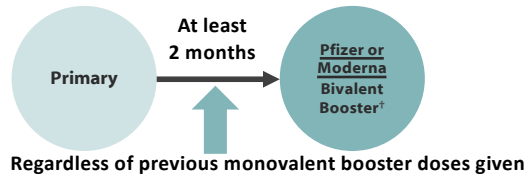
Ages 18 years and older

(Primary Series: Moderna, Novavax, or Pfizer-BioNTech)



Ages 18 years and older

(Primary Series: Janssen)



*3-8 week interval for Novavax and Pfizer-BioNTech; 4-8 week interval for Moderna

† A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in limited situations in people ages 18 years and older who are unable to receive an mRNA vaccine (i.e., contraindicated) or unwilling to receive an mRNA vaccine and would otherwise remain unvaccinated

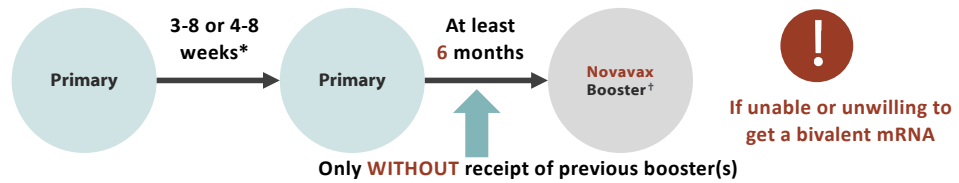
15



Adult Schedule: Ages 18 Years and Older

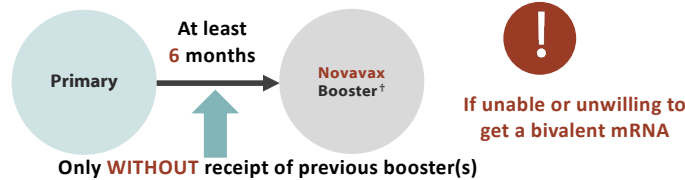
Ages 18 years and older

(Primary Series: Moderna, Novavax, or Pfizer-BioNTech)



Ages 18 years and older

(Primary Series: Janssen)



*3-8 week interval for Novavax and Pfizer-BioNTech; 4-8 week interval for Moderna

† A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in limited situations in people ages 18 years and older who completed any FDA-approved or FDA-authorized monovalent primary series, have not received a previous booster dose(s), and are unable to receive an mRNA vaccine (i.e., contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise remain unvaccinated

16

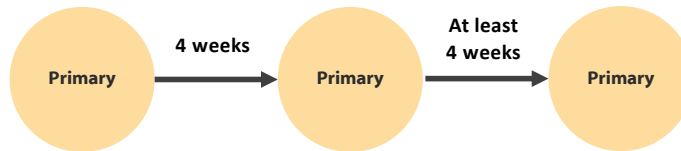
COVID-19 Vaccination Schedule for People Who ARE Moderately or Severely Immunocompromised

17

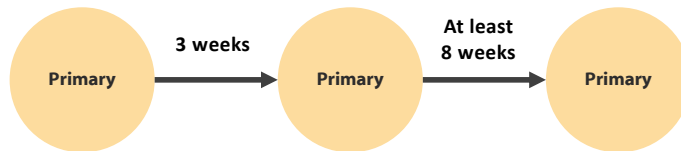


Pediatric Schedule: Ages 6 months–4 Years (Moderately or Severely Immunocompromised)

**Ages 6 months–
4 years**
(Primary Series:
Moderna)



**Ages 6 months–
4 years**
(Primary Series:
Pfizer-BioNTech)



18



Pediatric Schedule: Ages 5–11 Years (Moderately or Severely Immunocompromised)

Ages 5 years
(Primary Series:
Moderna or
Pfizer-BioNTech)



Ages 6–11 years
(Primary Series:
Moderna or
Pfizer-BioNTech)



*3-week interval for Pfizer-BioNTech; 4-week interval for Moderna

19

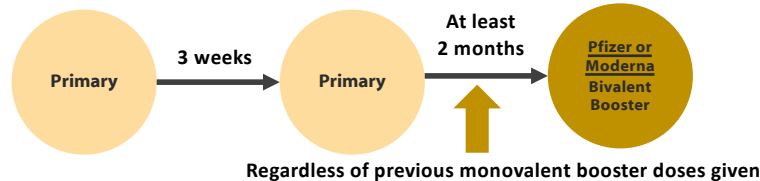


Pediatric Schedule: Ages 12–17 Years (Moderately or Severely Immunocompromised)

Ages 12–17 years
(Primary Series:
Moderna or
Pfizer-BioNTech)

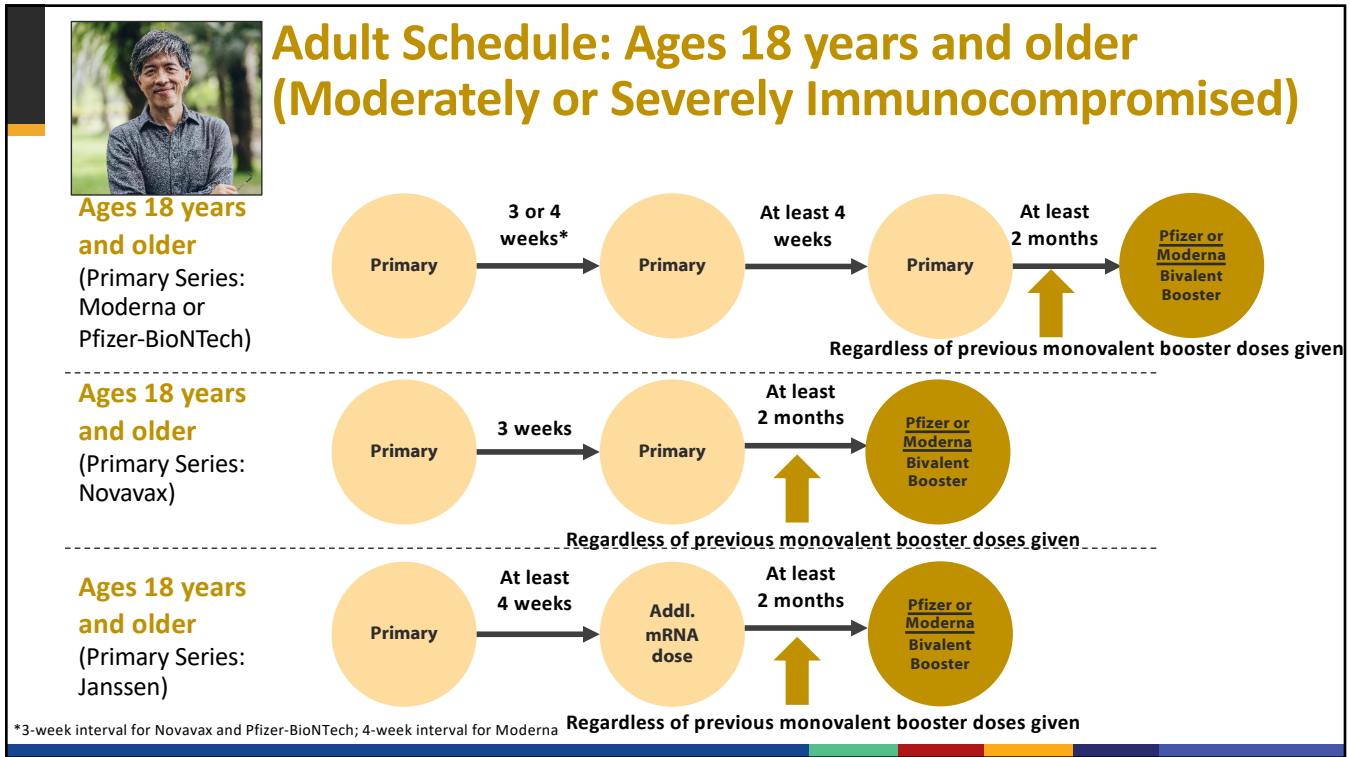


Ages 12–17 years
(Primary Series:
Novavax)

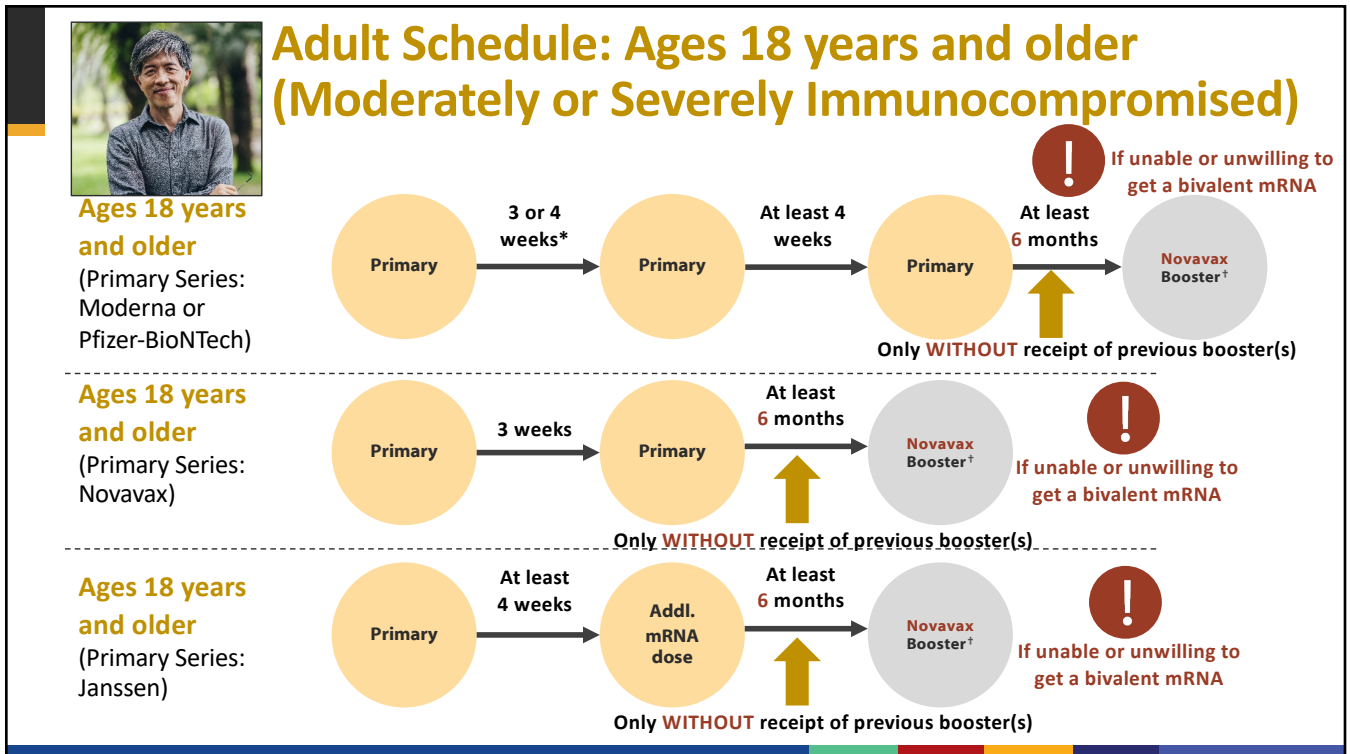


*3 week interval for Novavax or Pfizer-BioNTech; 4 week interval for Moderna

20







21



22

COVID-19 Vaccines: Moderna

Product	 Product for ages 6 months–5 years	 Product for ages 6–11 years	 Product for ages 6 years and older	 Product for ages 12 years and older
Authorized dose type	Primary	Primary	Booster	Primary
Vial cap color	Dark blue	Dark blue	Dark Blue	Red
Label border color	Magenta	Purple	Gray	Light blue
Composition	Monovalent	Monovalent	Bivalent	Monovalent
Dose (mRNA concentration)	25 mcg	50 mcg	6–11 years: 25 mcg 12 years+: 50 mcg	100 mcg
Injection volume	0.25 mL	0.5 mL	6–11 years: 0.25 mL 12 years+: 0.5 mL	0.5 mL
Dilution required	No	No	No	No
Beyond-Use Date	12 hours	12 hours	12 hours	12 hours
Storage	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days

23

Moderna Labels

Monovalent label
Primary series only
Ages 6–11 years








Despite label, do NOT use for booster doses

Bivalent label
Booster dose only
Ages 6 years and older



24

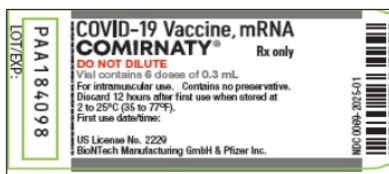
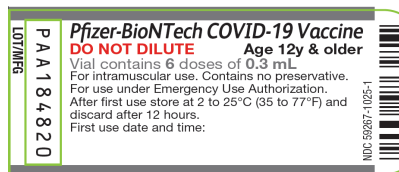
COVID-19 Vaccines: Pfizer-BioNTech

Product	 Product for ages 6 months–4 years	 Product for ages 5–11 years (monovalent)	 Product for ages 5–11 years (bivalent)	 Product for ages 12 years and older (monovalent)	 Product for ages 12 years and older (bivalent)
Authorized dose type	Primary	Primary	Booster	Primary	Booster
Vial cap color/label border color	Maroon	Orange	Orange	Gray	Gray
Composition	Monovalent	Monovalent	Bivalent	Monovalent	Bivalent
Dose (mRNA concentration)	3 mcg	10 mcg	10 mcg	30 mcg	30 mcg
Injection volume	0.2 mL	0.2 mL	0.2 mL	0.3 mL	0.3 mL
Dilution required	Yes—2.2 mL	Yes—1.3 mL	Yes—1.3 mL	No	No
Beyond-Use Date	12 hours after dilution	12 hours after dilution	12 hours after dilution	12 hours after puncture	12 hours after puncture
Storage	Ultra-cold freezer until expiration; Refrigerator (2°C–8°C) up to 10 weeks	Ultra-cold freezer until expiration; Refrigerator (2°C–8°C) up to 10 weeks	Ultra-cold freezer until expiration; Refrigerator (2°C–8°C) up to 10 weeks	Ultra-cold freezer until expiration; Refrigerator (2°C–8°C) up to 10 weeks	Ultra-cold freezer until expiration; Refrigerator (2°C–8°C) up to 10 weeks

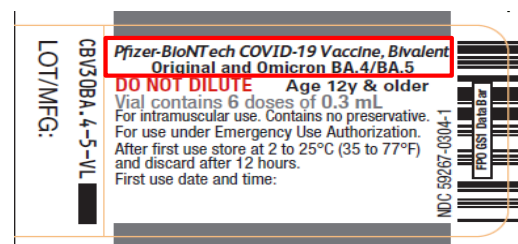
25

Pfizer-BioNTech Labels

Monovalent label
Primary series only
Ages 12 years and older



Bivalent label
Booster dose only
Ages 12 years and older



26

Vaccine Administration Errors: Monovalent mRNA Vaccine Given As Booster Dose

- The dose generally does not need to be repeated.
- However, providers may administer 1 bivalent booster dose as a repeat dose based on clinical judgement and patient preference.
- The repeat dose should be administered at least 2 months after the monovalent booster dose.

27

Vaccine Administration Errors: Pfizer-BioNTech Bivalent Vaccine Given As Primary Dose

- Do not repeat the dose. The bivalent dose can be counted as a primary series dose.
- Continue with the recommended vaccination schedule (i.e., complete the primary series, then administer a bivalent booster dose at least 2 months after completion of the primary series)

28

Vaccine Administration Errors: Moderna Bivalent Vaccine Given As Primary Dose

- Repeat 1 monovalent dose immediately (no minimum interval) because this is a lower-than-authorized dose for the primary series.
 - However, some experts suggest delaying the repeat dose for 8 weeks after the invalid dose.
- Continue with the recommended vaccination schedule (i.e., complete the primary series, then administer a bivalent booster dose at least 2 months after completion of the primary series)

29

COVID-19 Vaccination Clinical and Professional Resources: Your One-Stop-Shop

- <https://www.cdc.gov/vaccines/covid-19/index.html>

The image shows a screenshot of the CDC website page titled "COVID-19 Vaccination Clinical & Professional Resources". The page features a header with "Vaccines & Immunizations" and "cdc". Below the header is a main banner with an illustration of a healthcare provider and patients, and a "STOP COVID-19" sign. A "What's New" section lists recent updates, including the interim immunization schedule for 6 months of age and older, equity in childhood COVID-19 vaccination, and resources for children and teens. Below this are four main resource categories: "Interim Clinical Considerations", "Provider Requirements and Support", "Talking with Vaccine Recipients", and "COVID-19 Tracking and Reporting Systems".

Find vaccine-specific job aids

Read the most updated clinical guidance

Find a variety of tools to help you educate vaccine recipients

Stay up to date with requirements

30

Interim Clinical Considerations for Use of COVID-19 Vaccines

- <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

Check out other resources

Download job aids

The screenshot shows the CDC website page for 'Use of COVID-19 Vaccines in the United States'. The page includes a sidebar with navigation options like 'Product Info by U.S. Vaccine', 'Interim Clinical Considerations', 'FAQs for the Interim Clinical Considerations', 'Managing Anaphylaxis', 'Myocarditis and Pericarditis Considerations', 'Lab Tests After Serious Allergic Reactions', and 'Clinical Care'. The main content area features a 'Summary of recent changes (last updated August 22, 2022):' with bullet points: 'Guidance for primary series vaccination using Novavax COVID-19 Vaccine in adolescents ages 12-17 years' and 'Reorganization of Janssen COVID-19 Vaccine guidance into an appendix'. Below this is a 'Reference Materials' section with links to documents like 'Summary Document for Interim Clinical Considerations' and 'Interim COVID-19 Immunization Schedule'. A 'Get Email Updates' button is also visible.

Learn when guidance was last updated

Sign up for email updates

31

US COVID-19 Vaccine Product Information

- <https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>

The screenshot shows the CDC website page for 'U.S. COVID-19 Vaccine Product Information'. The page features a sidebar with navigation options like 'Product Info by U.S. Vaccine', 'Interim Clinical Considerations', 'Clinical Care', 'Provider Requirements and Support', 'Training and Education', 'Vaccine Recipient Education', and 'Health Departments'. The main content area includes a 'U.S. COVID-19 Vaccine Product Information' header, a 'Find a suite of information and materials that are needed for each specific COVID-19 vaccine that cover administration, storage and handling, safety, and reporting.' section, and a grid of product-specific links for 'Janssen/J&J', 'Pfizer-BioNTech', 'Moderna', and 'Novavax'. Below the grid are sections for 'Interim COVID-19 Immunization Schedule for Ages 6 months and older' and 'Prevaccination Screening Checklist' with a 'Select Language' dropdown.

32

Example Product Page

- Tools and resources
 - Storage and handling summary
 - Storage labels
 - Beyond-use date labels
 - Temperature logs
 - Vaccine expiration tracker
 - Schedule
 - Preparation and administration summary
 - Prevaccination checklist
 - Standing orders
 - And more!

33

Example: COVID-19 Vaccines Preparation Summaries

Pfizer-BioNTech COVID-19 Vaccines

Vaccine Preparation and Administration Summary

Concentration	Age Indications	Cap/Label Color	Volume	Use For	Dose
Monovalent	6 months through 5 years	Maroon cap/Maroon bordered label	0.2 mL	Primary series dose	0.25 mL
Monovalent	6 through 11 years	Orange cap/Orange bordered label	1.3 mL	Primary series dose	10 µg/0.2 mL
Trivalent	12 years and older	Change cap/Change bordered label	1.3 mL	Booster dose	10 µg/0.2 mL
Monovalent	12 years and older	Grey cap/Grey bordered label	NONE	Primary series dose	30 µg/0.5 mL
Monovalent	12 years and older	Grey cap/Grey bordered label	NONE	Booster dose	30 µg/0.5 mL

Schedule

Use the [Interim Schedule by Months of Age and Date](#) to determine if a dose is needed or schedule dates.

Preparation and Administration

Remove vaccine from the storage unit.

- Do NOT refrigerate vaccine.
- Do NOT use past date labels for this vaccine to track storage time at refrigerated temperatures.
- Check beyond-use date labels.
- Unopened vial may be stored between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
- Unopened vial may be stored between 8°C and 25°C (46°F and 77°F) for up to 12 hours.
- Once mixed, unopened vial can be stored between 2°C to 25°C (32°F to 77°F) for up to 12 hours.
- NOTE: The beyond-use date (BUD) replaces the manufacturer's expiration date by NDCER systems. Always use the earliest BUD.

Primary series dose

- Use **MONOVALENT** vaccine (Maroon cap and bordered label) Ages 6 months through 5 years
- Use **MONOVALENT** vaccine (Orange cap and bordered label) Ages 6 through 11 years
- Use **MONOVALENT** vaccine (Grey cap and bordered label) Ages 12 and older

Booster dose

- Booster dose is NOT authorized for ages 6 months through 5 years
- Use **BIVALENT** vaccine (Orange cap and bordered label) Ages 6 through 11 years
- Use **BIVALENT** vaccine (Grey cap and bordered label) Ages 12 and older

Check the label to ensure the expiration date or beyond-use date time has not passed.

- Use the expiration date tool at <https://www.cdc.gov/vaccines/imztools/>
- Check beyond-use date labels.
- Unopened vial may be stored between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
- Unopened vial may be stored between 8°C and 25°C (46°F and 77°F) for up to 12 hours.
- Once mixed, unopened vial can be stored between 2°C to 25°C (32°F to 77°F) for up to 12 hours.
- NOTE: The beyond-use date (BUD) replaces the manufacturer's expiration date by NDCER systems. Always use the earliest BUD.

Follow aseptic technique

- Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.
- Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.
- Use a new, sterile needle and syringe for each injection.
- Use vaccine with 0.9% sodium chloride preservative-free diluent. **Do not use** if the diluent is cloudy.
- Use a new vial of diluent for each vial.

Diluent	Primary series dose 6 months – 5 years	Primary series dose 6 months – 11 years	Primary series dose 12 years and older
0.9% sodium chloride, preservative-free diluent	2.2 mL	1.3 mL	1.3 mL

Moderna COVID-19 Vaccines

Vaccine Preparation and Administration Summary

Concentration	Age Indications	Cap/Label Color	Diluent	Use For	Dose
Monovalent	6 months through 5 years	Blue vial cap/Purple bordered label	NONE	Primary series dose	0.5 mL
Monovalent	6 through 11 years	Blue vial cap/Purple bordered label	NONE	Primary series dose	0.5 mL
Monovalent	12 years and older	Blue vial cap/Purple bordered label	NONE	Primary series dose	0.5 mL
Trivalent	6 years and older	Blue vial cap/Purple bordered label	NONE	Booster dose	0.5 mL

Schedule

Use the [Interim Schedule by Months of Age and Date](#) to determine if a dose is needed or schedule dates.

Preparation and Administration

Remove vaccine from the storage unit.

- Do NOT refrigerate vaccine.
- Do NOT use past date labels for this vaccine to track storage time at refrigerated temperatures.
- Check beyond-use date labels.
- Unopened vial may be stored between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
- Unopened vial may be stored between 8°C and 25°C (46°F and 77°F) for up to 12 hours.
- Once mixed, unopened vial can be stored between 2°C to 25°C (32°F to 77°F) for up to 12 hours.
- NOTE: The beyond-use date (BUD) replaces the manufacturer's expiration date by NDCER systems. Always use the earliest BUD.

Primary series dose

- Use **MONOVALENT** vaccine (Blue cap and purple bordered label) Ages 6 months through 5 years
- Use **MONOVALENT** vaccine (Blue cap and purple bordered label) Ages 6 through 11 years
- Use **MONOVALENT** vaccine (Blue cap and purple bordered label) Ages 12 years and older

Booster dose

- Booster dose is NOT authorized for ages 6 months through 5 years
- Use **BIVALENT** vaccine (Blue cap and purple bordered label) Ages 6 through 11 years
- Use **BIVALENT** vaccine (Blue cap and purple bordered label) Ages 12 and older

Check the label to ensure the expiration date or beyond-use date time has not passed.

- Use the expiration date tool at <https://www.cdc.gov/vaccines/imztools/>
- Check beyond-use date labels.
- Unopened vial may be stored between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
- Unopened vial may be stored between 8°C and 25°C (46°F and 77°F) for up to 12 hours.
- Once mixed, unopened vial can be stored between 2°C to 25°C (32°F to 77°F) for up to 12 hours.
- NOTE: The beyond-use date (BUD) replaces the manufacturer's expiration date by NDCER systems. Always use the earliest BUD.

Follow aseptic technique

- Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.
- Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.
- Use a new, sterile needle and syringe for each injection.
- Use vaccine with 0.9% sodium chloride preservative-free diluent. **Do not use** if the diluent is cloudy.
- Use a new vial of diluent for each vial.

Novavax COVID-19 Vaccine

Vaccine Preparation and Administration Summary

General Information

Vaccine: Novavax COVID-19 vaccine

Do NOT use: 12 years of age and older

Age Indications

For an up-to-date vaccination schedule for primary doses of Novavax COVID-19 vaccine, see <https://www.cdc.gov/vaccines/imztools/012022/covid-19-prevention>.

Preparation and Administration

Remove vaccine from the storage unit.

- Do NOT refrigerate vaccine.
- Do NOT use past date labels for this vaccine to track storage time at refrigerated temperatures.
- Check beyond-use date labels.
- Unopened vial may be stored between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
- Unopened vial may be stored between 8°C and 25°C (46°F and 77°F) for up to 12 hours.
- Once mixed, unopened vial can be stored between 2°C to 25°C (32°F to 77°F) for up to 12 hours.
- NOTE: The beyond-use date (BUD) replaces the manufacturer's expiration date by NDCER systems. Always use the earliest BUD.

Primary series dose

- Use **MONOVALENT** vaccine (Blue cap and purple bordered label) Ages 6 months through 5 years
- Use **MONOVALENT** vaccine (Blue cap and purple bordered label) Ages 6 through 11 years
- Use **MONOVALENT** vaccine (Blue cap and purple bordered label) Ages 12 years and older

Booster dose

- Booster dose is NOT authorized for ages 6 months through 5 years
- Use **BIVALENT** vaccine (Blue cap and purple bordered label) Ages 6 through 11 years
- Use **BIVALENT** vaccine (Blue cap and purple bordered label) Ages 12 and older

Check the label to ensure the expiration date or beyond-use date time has not passed.

- Use the expiration date tool at <https://www.cdc.gov/vaccines/imztools/>
- Check beyond-use date labels.
- Unopened vial may be stored between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
- Unopened vial may be stored between 8°C and 25°C (46°F and 77°F) for up to 12 hours.
- Once mixed, unopened vial can be stored between 2°C to 25°C (32°F to 77°F) for up to 12 hours.
- NOTE: The beyond-use date (BUD) replaces the manufacturer's expiration date by NDCER systems. Always use the earliest BUD.

Follow aseptic technique

- Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.
- Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.
- Use a new, sterile needle and syringe for each injection.
- Use vaccine with 0.9% sodium chloride preservative-free diluent. **Do not use** if the diluent is cloudy.
- Use a new vial of diluent for each vial.

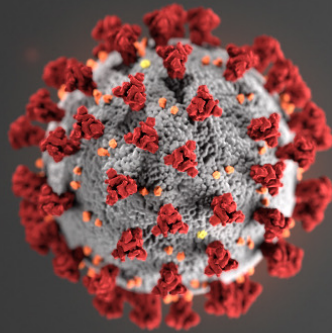
<https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>

34

FDA Resources

- Moderna COVID-19 Vaccines: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines>
- Novavax COVID-19 Vaccine, Adjuvanted: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted>
- Pfizer-BioNTech COVID-19 Vaccines: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines>

35



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.



36

Myocarditis and COVID-19 vaccines

- Risk of **myocarditis/pericarditis** has been identified after COVID-19 vaccines
 - Risk is **rare** and primarily observed in adolescent and young adult males, within the first week after receiving the second dose or booster dose of an mRNA COVID-19 vaccine
- Most individuals with myocarditis/pericarditis have **fully recovered** at follow-up
- The risk of adverse cardiac outcomes were **1.8 – 5.6 times higher** after SARS-CoV-2 infection than after mRNA COVID-19 vaccination among males ages 12 – 17 years
- Interval of **8 weeks** between vaccine doses may further lower myocarditis risk

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/04-COVID-Kracalic-508.pdf> https://www.cdc.gov/mmwr/volumes/71/wr/mm7114e1.htm?s_cid=mm7114e1_w

37

Benefit-risk assessment of COVID-19 vaccines

- ACIP has reviewed the balance of benefits and risks **regularly**
 - Primary series for adolescents and young adults: June 23, 2021
 - Primary series for individuals 16-29 years: August 30, 2021
 - Booster doses for individuals ≥18 years: September 23, 2021
 - Booster doses for adolescents 12-15 years: January 5, 2022
 - Booster doses for children 5-11 years: May 19, 2022
 - Bivalent booster doses for individuals ≥5 years: September 1, 2022
- Each time ACIP has assessed the benefits and risks of mRNA COVID-19 vaccines, ACIP has determined that the **benefits outweigh the risks**

38

Post-authorization monitoring for COVID-19 vaccines

- Since authorization, **22** ACIP meetings focused on COVID-19 vaccines
 - COVID-19 vaccine effectiveness (VE) data presented at **11** ACIP meetings
 - COVID-19 vaccine safety data presented at **21** ACIP meetings
- CDC evaluates VE through multiple observational studies employing various methods and using information collected through different surveillance platforms, electronic health records, or prospective studies
- COVID-19 vaccines continue to undergo the most comprehensive and intense safety monitoring in U.S. history