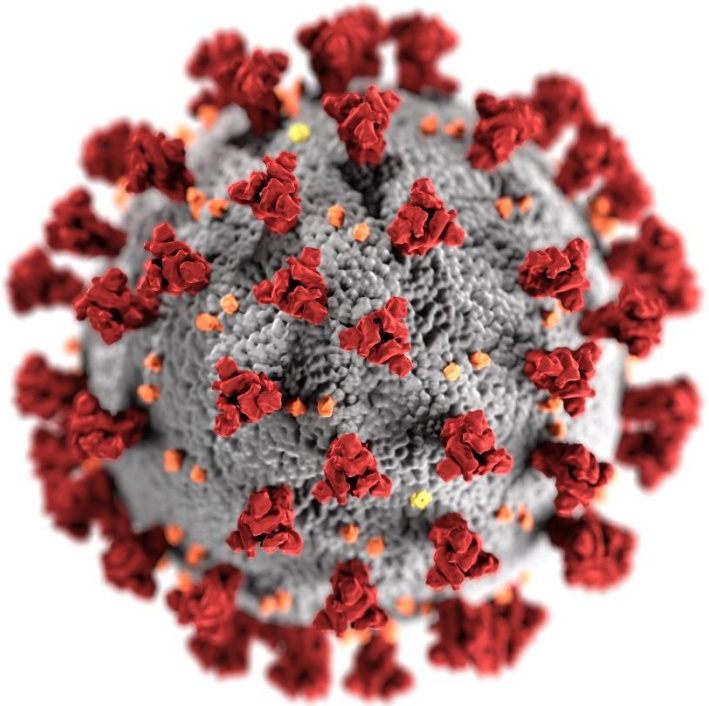
COVID-19 vaccines in Children



Sara Oliver, MD MSPH

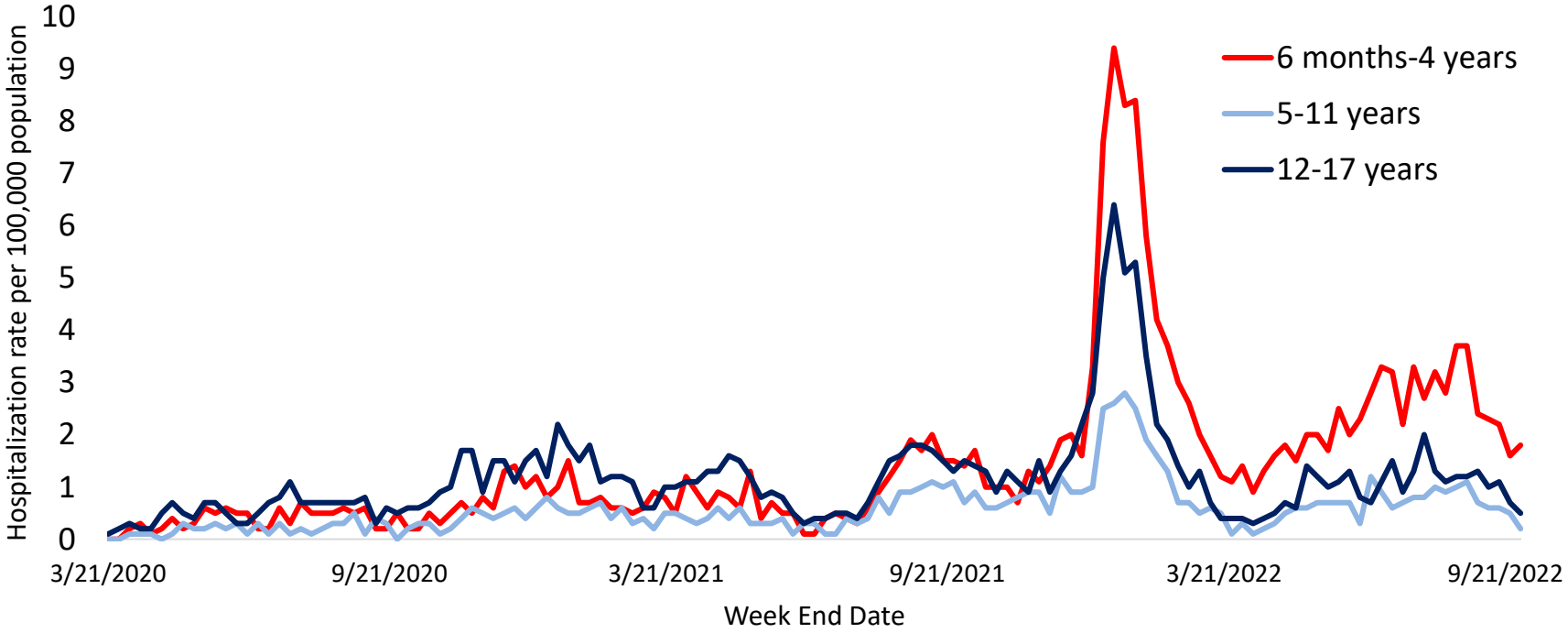
ACIP Meeting

October 19, 2022

cdc.gov/coronavirus

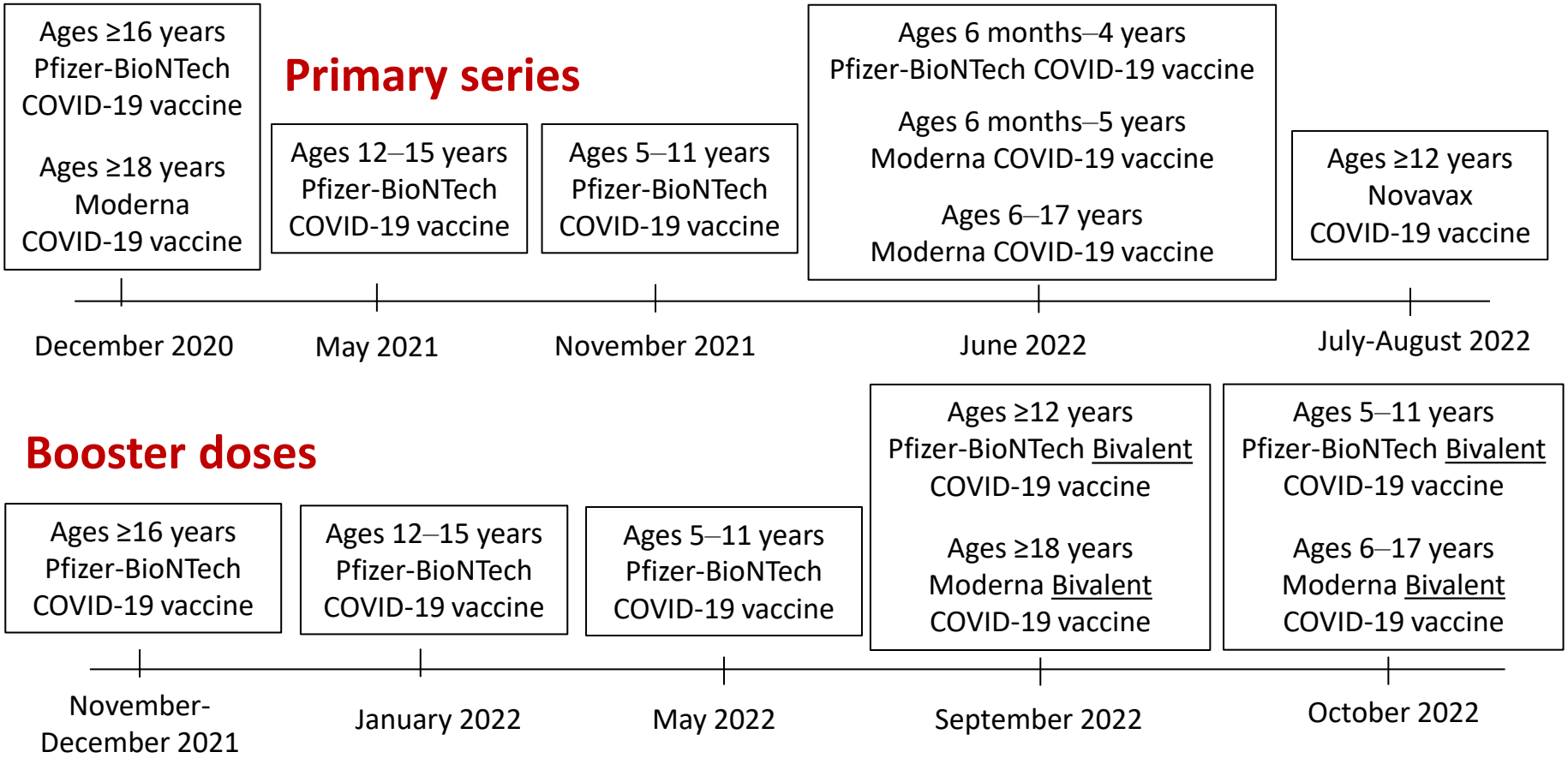
COVID-19-associated hospitalizations among children and adolescents ages 6 months – 17 years, COVID-NET

March 21, 2020 – October 1, 2022



Source: COVID-NET, https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html. Accessed 10/12/2022

Timeline of recommendations for pediatric COVID-19 vaccines



Data to inform pediatric booster recommendations

Monovalent Pfizer-BioNTech COVID-19 vaccine

- Booster dose recommendations for children and adolescents discussed at previous ACIP meetings:
  - Recommendations for adolescents **ages 12–15 years** based on safety data from Israel, waning antibody titers and vaccine effectiveness after a primary series in the setting of Omicron, and during peak of winter Omicron surge[1]
  - Recommendations for children **ages 5–11 years** based on clinical trial as well as post-authorization safety data[2]
    - Booster dose achieved antibody levels higher than after primary series
    - Reactogenicity after a booster dose similar to what was seen after a primary series
    - Rates of myocarditis after primary series in children ages 5–11 years considerably lower than rates in adolescents

[1] https://www.cdc.gov/vaccines/acip/meetings/slides-2022-01-05.html; [2] https://www.cdc.gov/vaccines/acip/meetings/slides-2022-05-19.html

Data to inform pediatric booster recommendations

Monovalent Moderna COVID-19 vaccine

- Booster dose studied in **~2600** children and adolescents:
  - 50mcg booster studied in 1349 adolescents 12–17 years
  - 25mcg booster dose studied in 1294 children ages 5–11 years
- 1 Serious Adverse Event (SAE) unrelated to vaccine in a child 5–11 years; no SAEs in adolescents 12–17 years
- Reactogenicity symptoms similar to what was seen for booster doses in other age groups
- Antibody levels after the booster dose were **4–5 times higher** than what was seen after the primary series

Data to inform booster recommendations

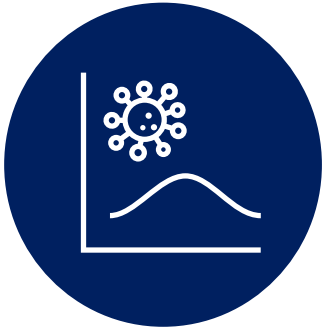
Bivalent mRNA COVID-19 vaccines

- 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 dose[1]

>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

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[1]
- 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[2]
- Interval of **8 weeks** between vaccine doses may further lower myocarditis risk

[1]https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/04-COVID-Kracalic-508.pdf [2]https://www.cdc.gov/mmwr/volumes/71/wr/mm7114e1.htm?s_cid=mm7114e1_w

Benefit-risk assessment of COVID-19 vaccines

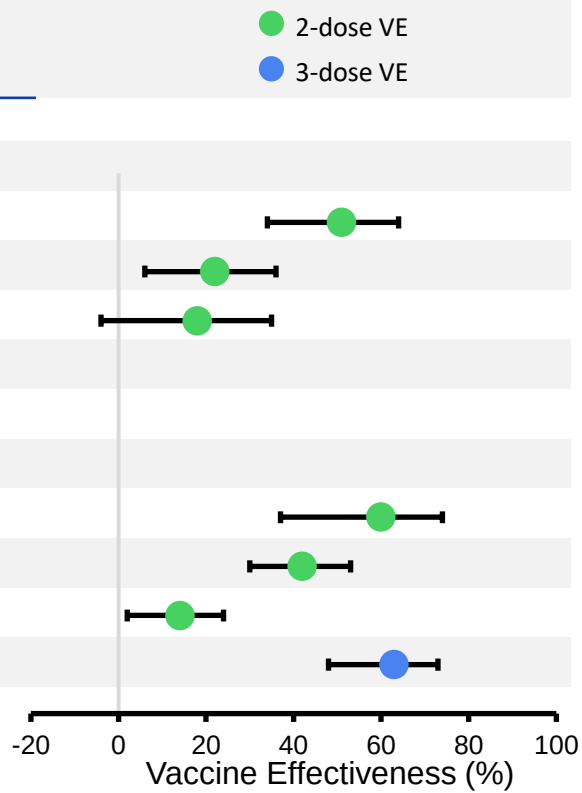
- ACIP has reviewed the balance of benefits and risks **regularly**
  - Primary series for adolescents and young adults: June 23, 2021
  - Primary series for individuals 16-29 years: August 30, 2021
  - Booster doses for individuals ≥18 years: September 23, 2021
  - Booster doses for adolescents 12-15 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 evaluated the benefits and risks of mRNA COVID-19 vaccines, ACIP has determined that the **benefits outweigh the risks**

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

VISION: Pfizer-BioNTech VE for ED/UC visits by number of doses and time since last dose receipt for children and adolescents during Omicron, mid-Dec 2021–mid-Jul 2022

Vaccination status (days since most recent dose)	Total	SARS-CoV-2 positive, N	Adjusted VE (95% CI)
5-11 years			
Unvaccinated	21,009	1,375	Ref
2 doses (14-59)	1,151	72	51 (34-64)
2 doses (60-149)	4,068	179	22 (6-36)
2 doses (≥150)	1,338	109	18 (-4-35)
12-15 years			
Unvaccinated	7,318	1,443	Ref
2 doses (14-59)	219	27	60 (37-74)
2 doses (60-149)	1,082	196	42 (30-53)
2 doses (≥150)	3,308	587	14 (2-24)
3 doses (≥7)	973	43	63 (48-73)



Previously presented to ACIP Sept 1, 2022

CDC, preliminary unpublished data. Individuals with prior infections excluded. ED/UC = Emergency Department/Urgent Care
Adjusted for calendar time, geographic region, age, sex, race, ethnicity, local virus circulation, respiratory or non-respiratory underlying medical conditions, and propensity to be vaccinated
COVID-like illness: included acute respiratory illness (e.g., COVID-19, respiratory failure, or pneumonia) or related signs or symptoms (cough, fever, dyspnea, vomiting, or diarrhea)

mRNA COVID-19 vaccine safety of primary series vaccination in children ages 6 months–5 years

Previously presented to ACIP Sept 1, 2022

- Initial safety findings of both mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) are consistent with those observed in the clinical trials
- Systemic and local reactions are commonly reported adverse events
- Vaccination errors are also being reported to VAERS
- No unexpected safety findings to date
- No evidence of an increased risk for myocarditis following mRNA COVID-19 vaccination in children ages 6 months–5 years

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-09-01/05-COVID-Shimabukuro-508.pdf

VAERS reporting rates of verified myocarditis per 1 million mRNA COVID-19 vaccinations (Pfizer-BioNTech and Moderna combined), days 0–7 post-vaccination*,†

Previously presented to ACIP Sept 1, 2022

	Dose 2 (primary series)		1st booster dose	
Age group	**Male**	**Female**	**Male**	**Female**
5–11 years	2.5	0.7	0.0	0.0
12–15 years	47.1	4.2	12.9	0.7
16–17 years	78.7	7.4	21.6	0.0
18–24 years	39.3	3.9	13.1	0.6
25–29 years	15.3	3.5	4.4	2.2
30–39 years	7.8	1.0	1.9	0.9
40–49 years	3.3	1.6	0.2	0.6
50–64 years	0.7	0.5	0.4	0.1
65+ years	0.3	0.5	0.7	0.2

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-09-01/05-COVID-Shimabukuro-508.pdf

* As of August 18, 2022. Reports verified to meet case definition by provider interview or medical record review.

† An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 risk interval, this estimated background is **0.2 to 2.2 per 1 million person-day 0–7 risk interval** (peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period)

VSD incidence rates of verified myocarditis/pericarditis in the 0–7 days after Pfizer-BioNTech vaccination in people ages 5–39 years, dose 2 and 1st booster*

Previously presented to ACIP Sept 1, 2022

	Dose 2 primary series Pfizer-BioNTech			1st booster dose Pfizer-BioNTech		
	Cases	Dose 2 admin	Incidence rate/ million doses (95% CI)	Cases	1st boosters admin	Incidence rate/ million doses (95% CI)
5-11 years						
Males	3	207,958	14.4 (3.0 – 42.2)	0	50,415	0.0 (0.0 – 59.4)
Females	0	202,596	0.0 (0.0 – 14.8)	0	49,261	0.0 (0.0 – 60.8)
12–15 years						
Males	31	205,955	150.5 (102.3 – 213.6)	5	81,613	61.3 (19.9 – 143.0)
Females	5	204,074	24.5 (8.0 – 57.2)	0	84,114	0.0 (0.0 – 35.6)
16–17 years						
Males	14	102,091	137.1 (75.0 – 230.1)	9	47,874	188.0 (86.0 – 356.9)
Females	1	107,173	9.3 (0.2 – 52.0)	2	55,004	36.4 (4.4 – 131.3)
18–29 years						
Males	27	331,889	81.4 (53.6 – 118.4)	7	166,973	41.9 (16.9 – 86.4)
Females	2	400,321	5.0 (0.6 – 18.0)	1	240,226	4.2 (0.1 – 23.2)
30–39 years						
Males	5	341,527	14.6 (4.8 – 34.2)	3	197,554	15.2 (3.1 – 44.4)
Females	3	410,713	7.3 (1.5 – 21.3)	1	268,412	3.7 (0.1 – 20.8)

*Primary series surveillance for people ages ≥18 years ended May 21, 2022 All other data through August 20, 2022.

VSD vaccine safety datalink

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-09-01/05-COVID-Shimabukuro-508.pdf

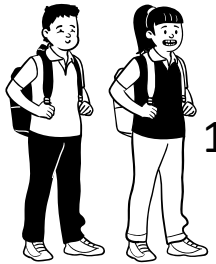
COVID-19 vaccine uptake among children and adolescents

Through October 12, 2022

Children 6 months–4 years of age

1.4 million first doses administered

6.9% of children in this age group



Children 5–11 years of age

11.1 million first doses administered

38.6% of children in this age group

1.4 million booster doses administered

15.6% of children in this age group with a primary series

Adolescents 12–17 years of age

18.0 million first doses administered

71.1% of adolescents

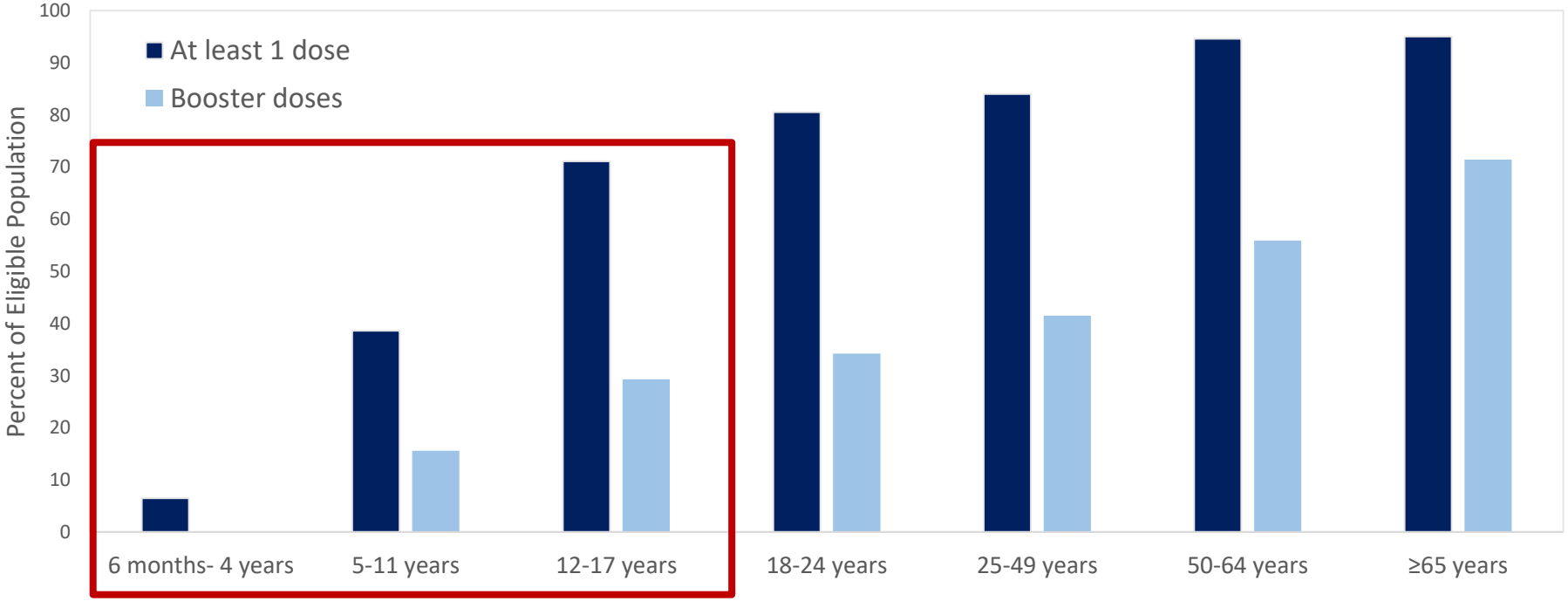
4.5 million booster doses administered

29.3% of adolescents with a primary series

Source: CDC COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends Accessed 10/18/2022

COVID-19 vaccine uptake among children and adolescents

December 2020 – October 2022



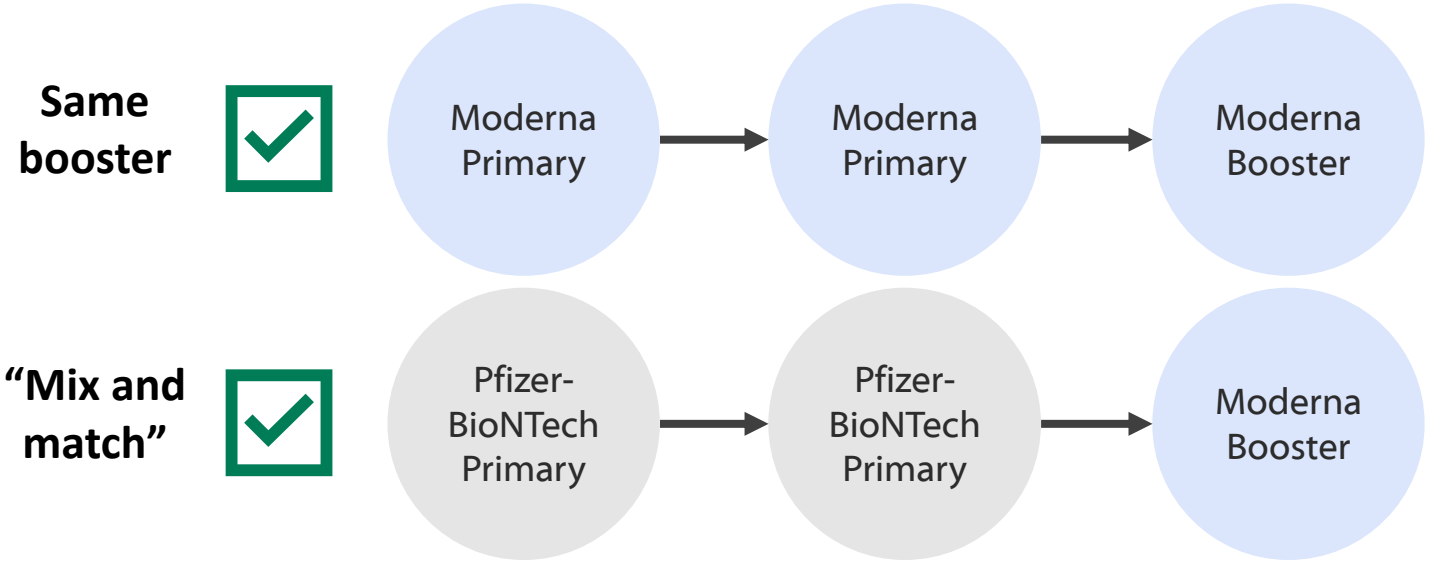
Source: CDC COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends Accessed 10/18/2022

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

Booster Recommendations: Bivalent Booster, Continued

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

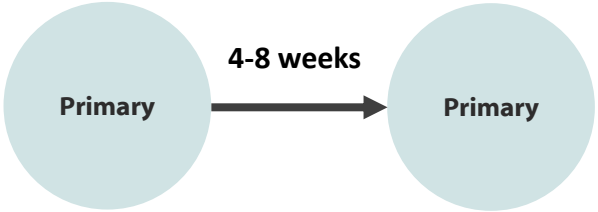


*Only Pfizer-BioNTech bivalent booster is authorized for people age 5 years. Both Pfizer-BioNTech and Moderna bivalent boosters are authorized for people ages 6 years and older.

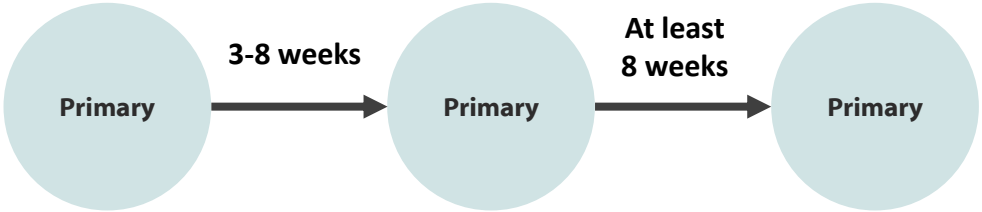
COVID-19 Vaccination Schedule for Children and Adolescents Who Are NOT Moderately or Severely Immunocompromised

Pediatric Schedule: Ages 6 months–4 Years

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

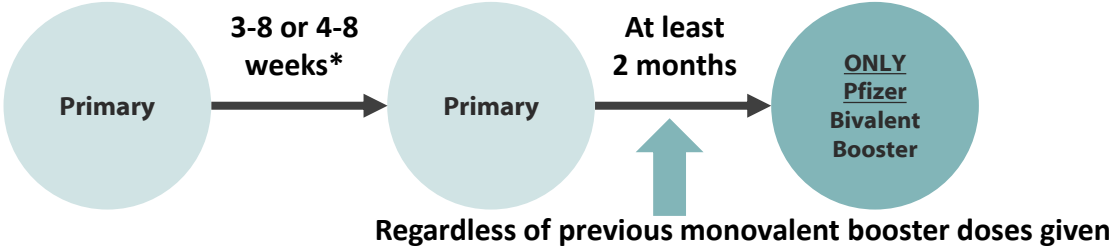


Ages 6 months–4 years
(Primary Series: Pfizer-BioNTech)

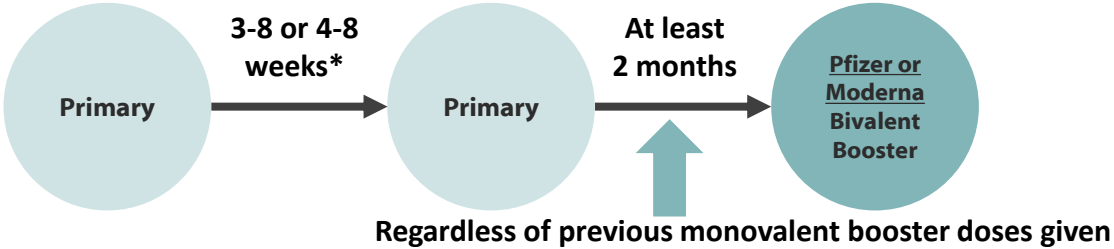


Pediatric Schedule: Ages 5–11 Years

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



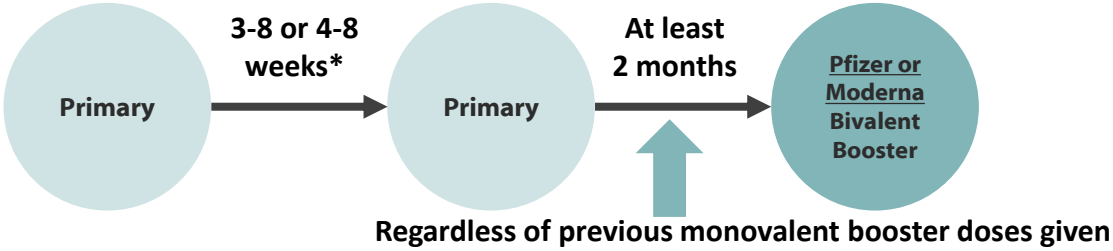
Ages 6–11 years
(Primary Series: Moderna or Pfizer-BioNTech)



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

Pediatric Schedule: Ages 12-17 Years

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



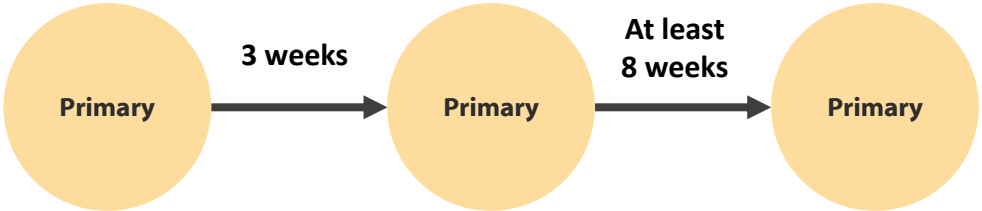
*3-8 week interval for Pfizer-BioNTech; 4-8 week interval for Moderna

COVID-19 Vaccination Schedule for Children and Adolescents Who ARE Moderately or Severely Immunocompromised

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

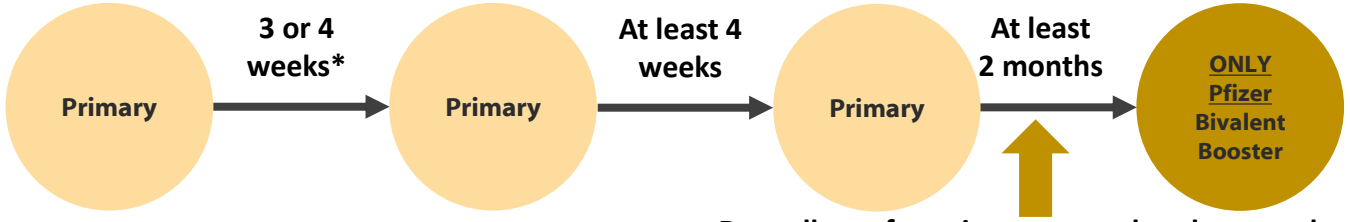
Ages 6 months–4 years
(Primary Series: Moderna)

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

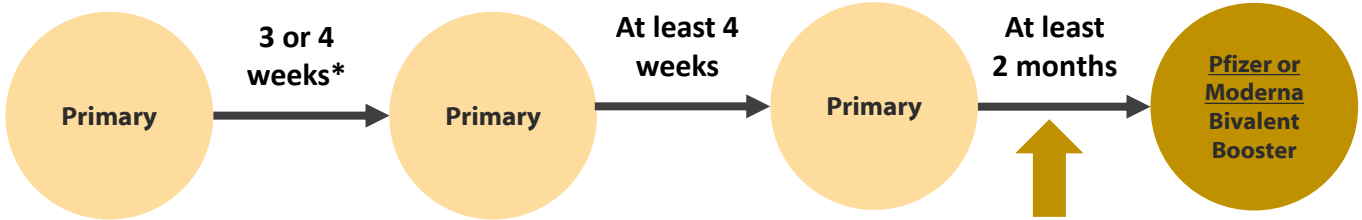


Pediatric Schedule: Ages 5–11 Years (Moderately or Severely Immunocompromised)

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



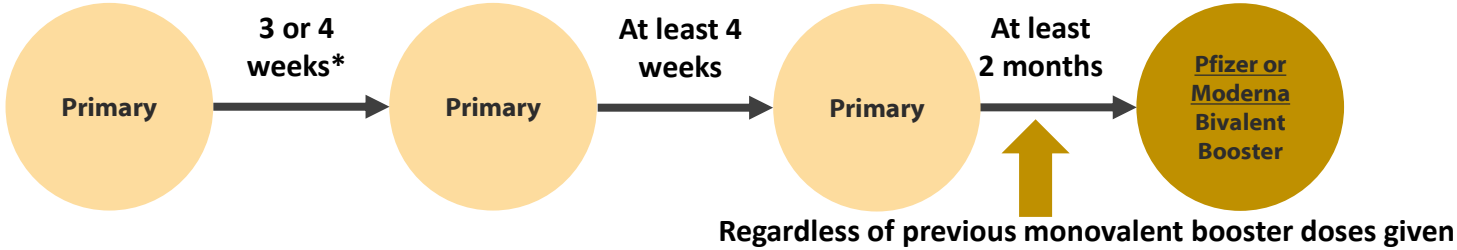
Ages 6–11 years
(Primary Series: Moderna or Pfizer-BioNTech)



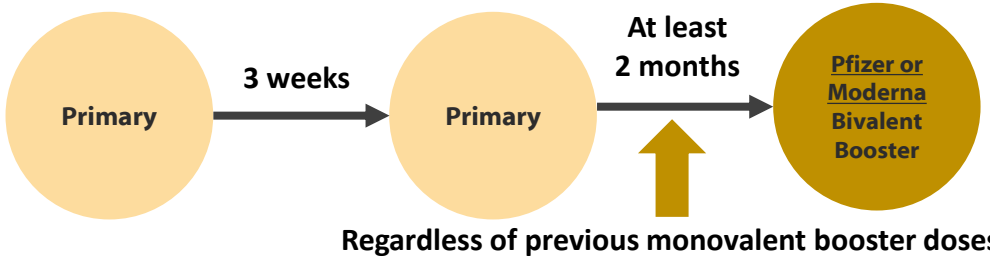
*3-week interval for Pfizer-BioNTech; 4-week interval for Moderna

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)



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

Complexity of pediatric mRNA COVID-19 vaccines

Pfizer-BioNTech COVID-19 vaccines	 Ages 6 months–4 years	 Ages 5–11 years (monovalent)	 Ages 5–11 years (bivalent)	 Ages ≥12 years (monovalent)	 Ages ≥12 years (bivalent)
Authorized dose type	Primary	Primary	Booster	Primary	Booster
Vial cap color	Maroon	Orange	Orange	Gray	Gray
Composition	Monovalent	Monovalent	Bivalent	Monovalent	Bivalent
Dose	3 mcg	10 mcg	10 mcg	30 mcg	30 mcg

Moderna COVID-19 vaccines	 Ages 6 months–5 years	 Ages 6–11 years	 Ages ≥6 years	 Ages ≥12 years
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	25 mcg	50 mcg	6–11 years: 25 mcg ≥12 years: 50 mcg	100 mcg

Pediatric COVID-19 vaccines

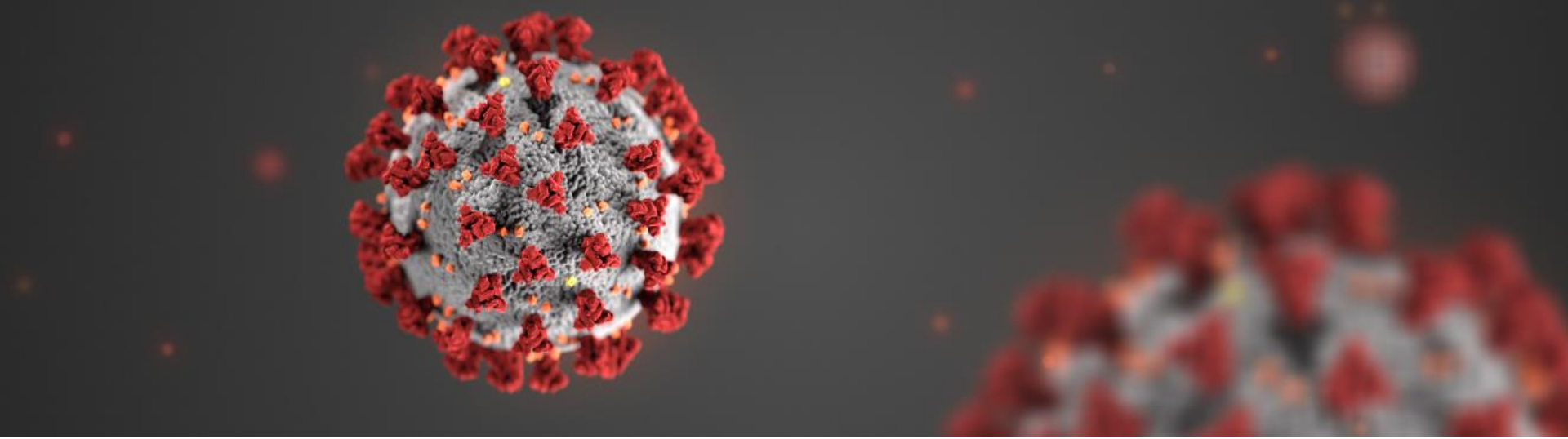
- COVID-19 vaccination is the single **best way** to protect people from serious COVID-19 illness
  - COVID-19 vaccines continue to be effective in reducing the risk of severe disease, hospitalization and death, including against the currently circulating Omicron variants
  - Many children haven't yet initiated COVID-19 vaccine primary series
- The **benefits** of COVID-19 vaccination **outweigh** the known and potential risks, including the very small risk of myocarditis or pericarditis

Pediatric COVID-19 vaccines

- Over **30 million children and adolescents** have received at least one COVID-19 vaccine dose
- Incorporation of COVID-19 vaccines in the immunization schedule and the Vaccines for Children (VFC) program is an important step toward inclusion of COVID-19 vaccines in routine vaccination program
- Details of implementation for the COVID-19 vaccine VFC program will require ongoing work, but ACIP vote allows the process to **begin**
- **Equitable** access to COVID-19 vaccines for **all ages and populations** remains critically important

Acknowledgements

- Coronavirus and Other Respiratory Viruses Division (proposed)
- Immunization Services Division
- Immunization Safety Office
- Vaccine Policy Team
  - Evelyn Twentyman
  - Megan Wallace
  - Monica Godfrey
  - Katherine Fleming-Dutra
  - Hannah Rosenblum
  - Dani Moulia
  - Lauren Roper
  - Tamara Pilishvili
  - Ruth Link-Gelles
  - Elisha Hall
  - Mary Chamberland
  - Susan Goldstein
  - JoEllen Wolicki
  - Lauren Hughes
  - Alex Premkumar
  - Sarah Morales
  - Sierra Scarbrough



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