CDC/IDSA COVID-19 Clinician Call

June 25, 2022

Welcome & Introductions

Dana Wollins, DrPH, MGC
Vice President, Clinical Affairs
& Guidelines IDSA

- 89th in a series of calls, initiated in 2020 by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19.
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

COVID-19 Real-Time Learning Network
Brought to you by CDC and IDSA

COVID-19 Summer Update: Where We are Now, Where We are Going

Brendan Jackson, MD, MPH
CDR, U.S. Public Health Service
COVID-19 Response Clinical Team, Late Sequelae Unit
U.S. Centers for Disease Control and Prevention

COVID-19 Vaccination in Children Under 5 Years

Highlights from the June 16-17 VRBPAC Meeting

Archana Chatterjee, MD, PhD
Dean, Chicago Medical School and Vice President for Medical Affairs, Rosalind Franklin University
Member, Vaccines & Related Biological Products Advisory Committee (VRBPAC)

FDA Update

Peter Marks, MD, PhD
Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

ACIP Update

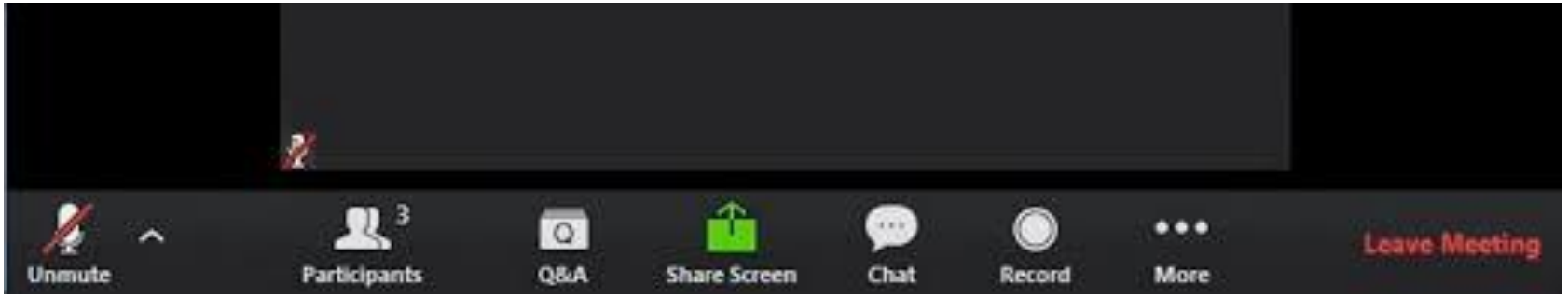
Sara Oliver, MD, MSPH
LCDR, U.S. Public Health Service
Co-Lead, COVID-19 Work Group of the Advisory Committee on Immunization Practices
U.S. Centers for Disease Control and Prevention (ACIP)

Pediatric Vaccine Implementation: Key Considerations for Clinicians

Lisa M. Costello, MD, MPH, FAAP
Assistant Professor and Clerkship Co-director
Division of Pediatric General Medicine
West Virginia University School of Medicine
Immediate Past President, West Virginia Chapter and Member, Committee on State Government Affairs, American Academy of Pediatrics

Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button

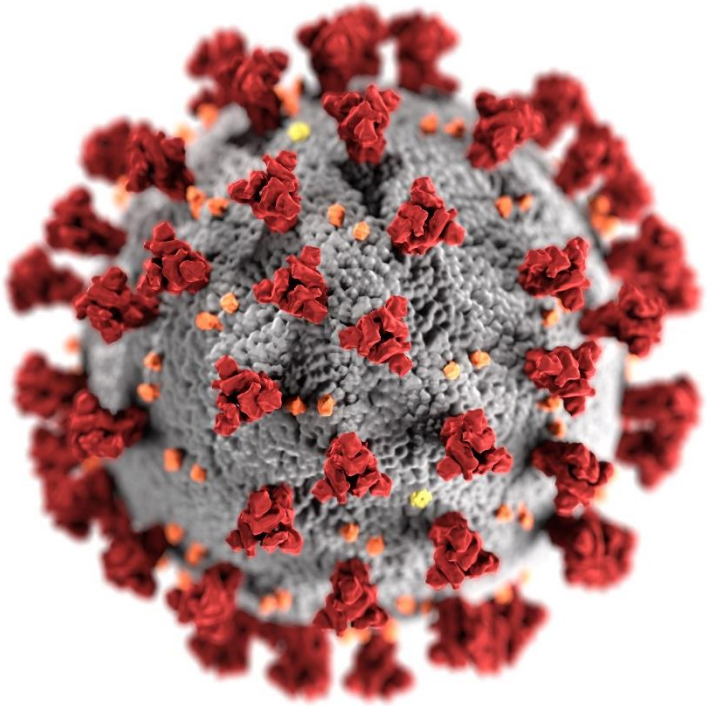


COVID-19 Update

Brendan Jackson, MD, MPH

CDC COVID-19 Response

Where We are Now, Where We are Going



Brendan Jackson, MD ,MPH
Principal Deputy Incident Manager
CDC COVID-19 Response

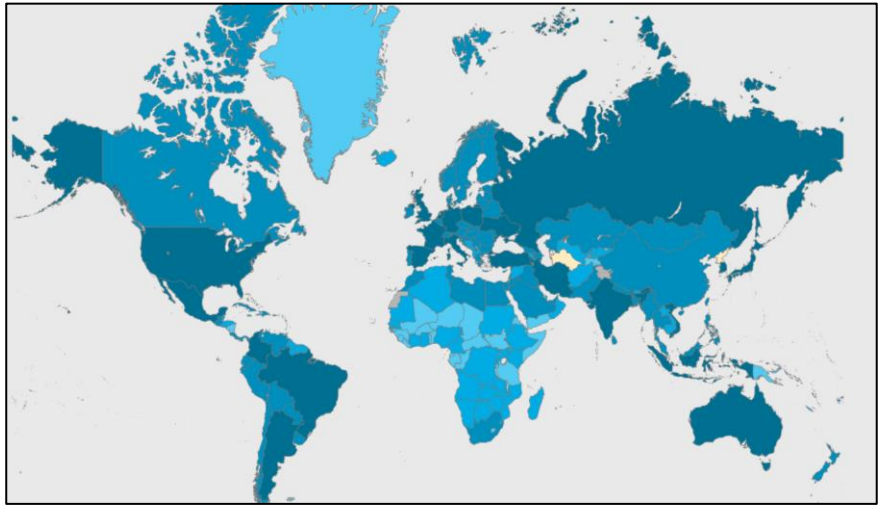
June 25, 2022

cdc.gov/coronavirus

COVID-19 Pandemic Situation Update

COVID-19 Surveillance Summary: Cases

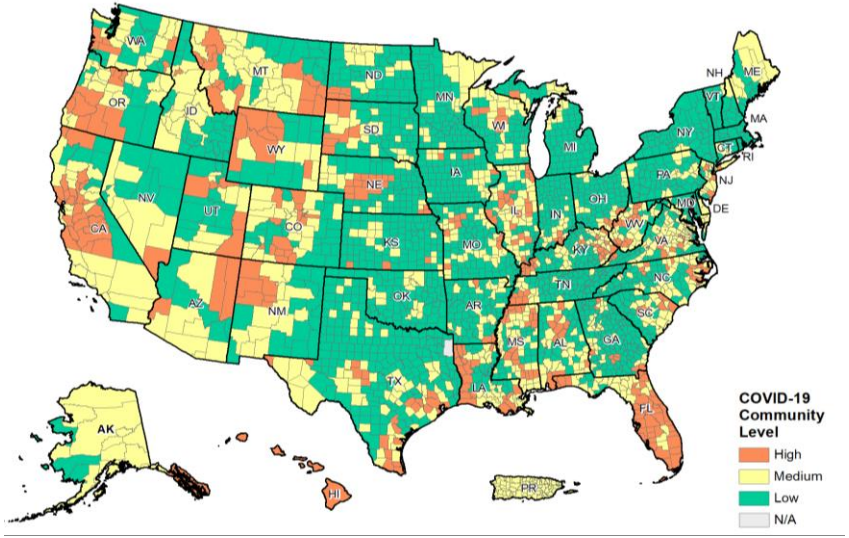
- 539,119,771 cumulative confirmed cases globally
- 6,322,311 cumulative deaths



Data as of June 23, 2022
Source: WHO Coronavirus (COVID-19) Dashboard

COVID-19 Community Levels (CCLs)

COVID-19 Community Levels in the United States by County as of June 23, 2022

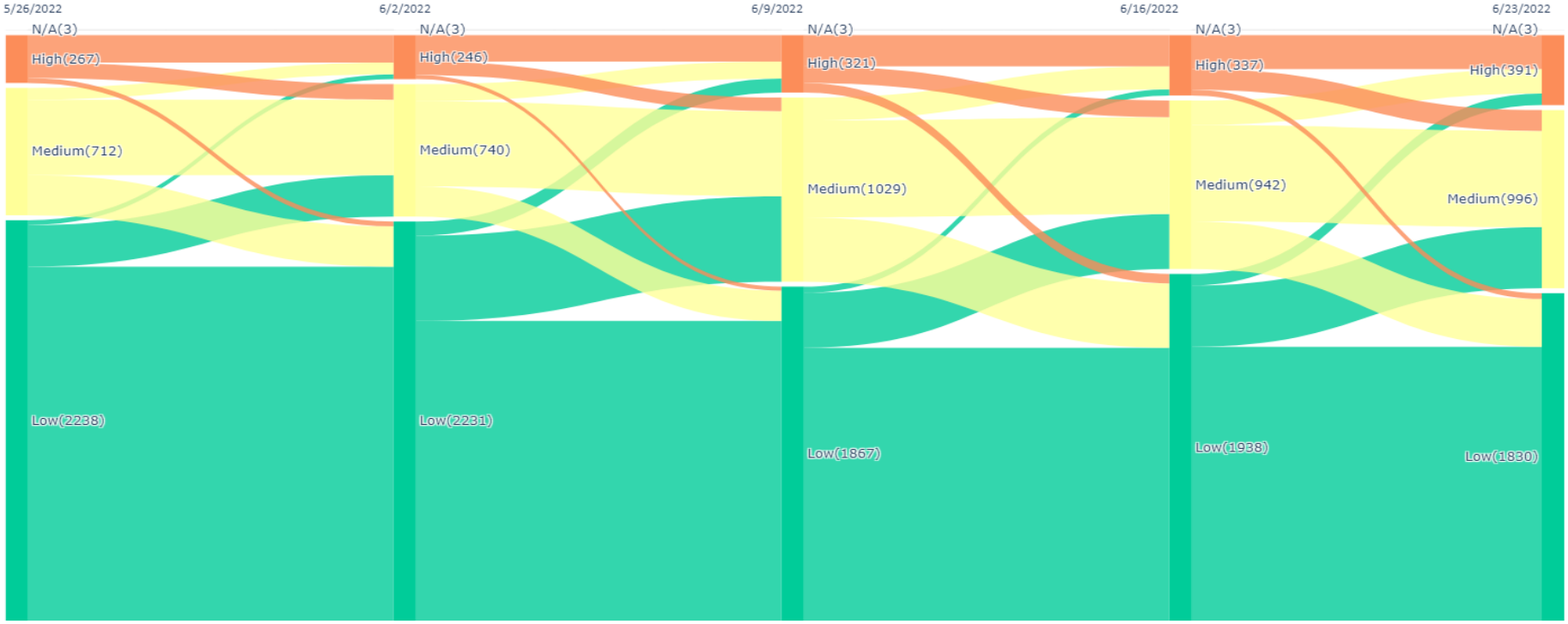


	Total	% of Counties	% Change in Counties	% of Pop.
High	392	12.17%	1.96%	22.56%
Medium	997	30.95%	1.58%	35.78%
Low	1,832	56.88%	-3.54%	41.63%

Time Period: COVID-19 Community Levels were calculated on Thu Jun 23 2022. New COVID-19 cases per 100,000 population (7-day total) are calculated using data from Thu Jun 16 2022 - Wed Jun 22 2022. New COVID-19 admissions per 100,000 population (7-day total) and Percent of inpatient beds occupied by COVID-19 patients (7-day average) are calculated using data from Wed Jun 15 2022 - Tue Jun 21 2022.

Source: CDC COVID Data Tracker (County View)

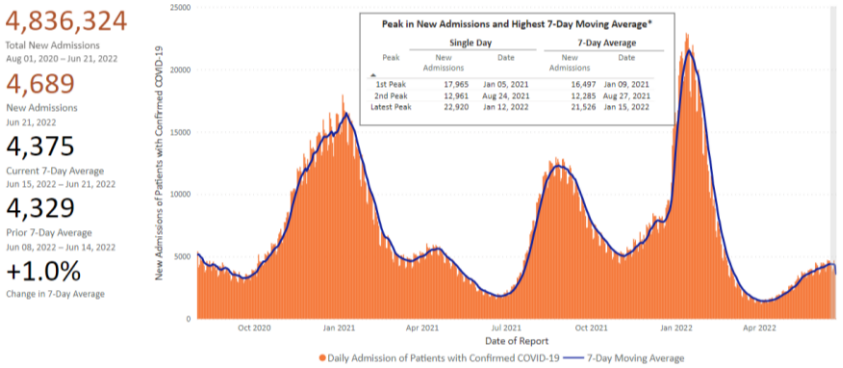
CCL Trajectory Analysis (5/26/2022 – 6/23/2022)



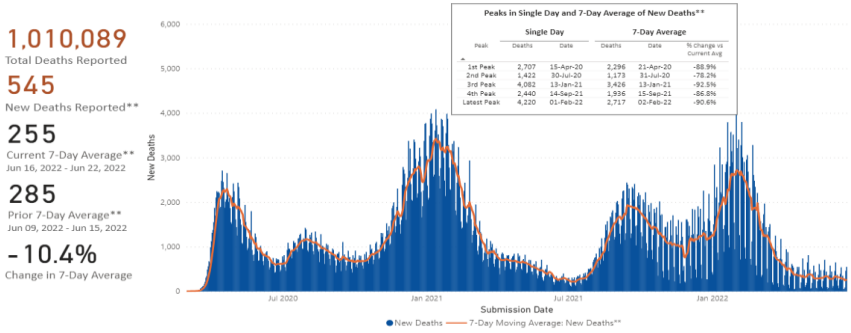
COVID-19 Surveillance Summary: Hospitalizations and Deaths

- As of June 21, 2022
  - 7-day average of daily new hospitalizations **increased 1.0%** compared with previous week
- As of June 22, 2022
  - 7-day average of daily death counts **decreased 10.4%** compared with previous week

New Admissions of Patients with Confirmed COVID-19, United States
August 2020 – June 2022



Daily Change in COVID-19 Death Counts, United States
March 2020 – June 2022
January 22, 2020* - June 22, 2022



*Graph displays data starting on Mar 01, 2020. The totals include deaths reported since Jan 22, 2020
** The histogram, total of new deaths in the last 24 hours, and 7-day averages do not include historical deaths reported retroactively. Historical deaths are still reflected in the cumulative national total. Of 21,715 historical deaths reported retroactively, none were reported on Jun 22, 2022; none in the current week; and none in the prior week.

COVID-19 Surveillance Summary: Cases

- As of June 22, 2022
  - 7-day average of daily case counts **decreased 5.6%** compared with previous week
- How has home testing affected surveillance?

Daily Change in COVID-19 Case Counts, United States
March 2020 –June 2022

January 22, 2020* - June 22, 2022

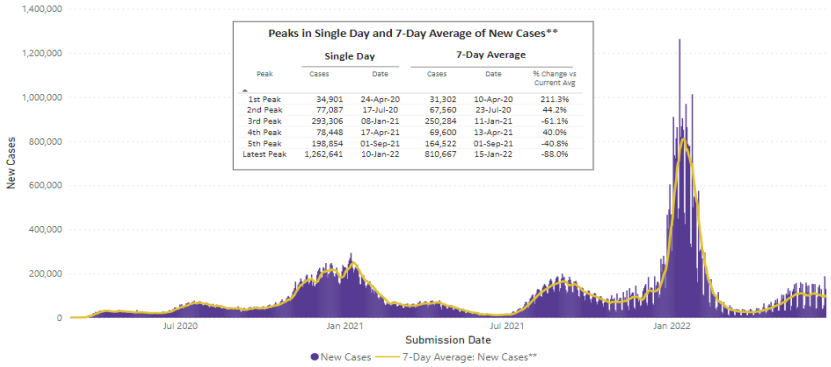
86,512,787
Total Cases Reported

130,274
New Cases Reported**

97,430
Current 7-Day Average**
Jun 16, 2022 - Jun 22, 2022

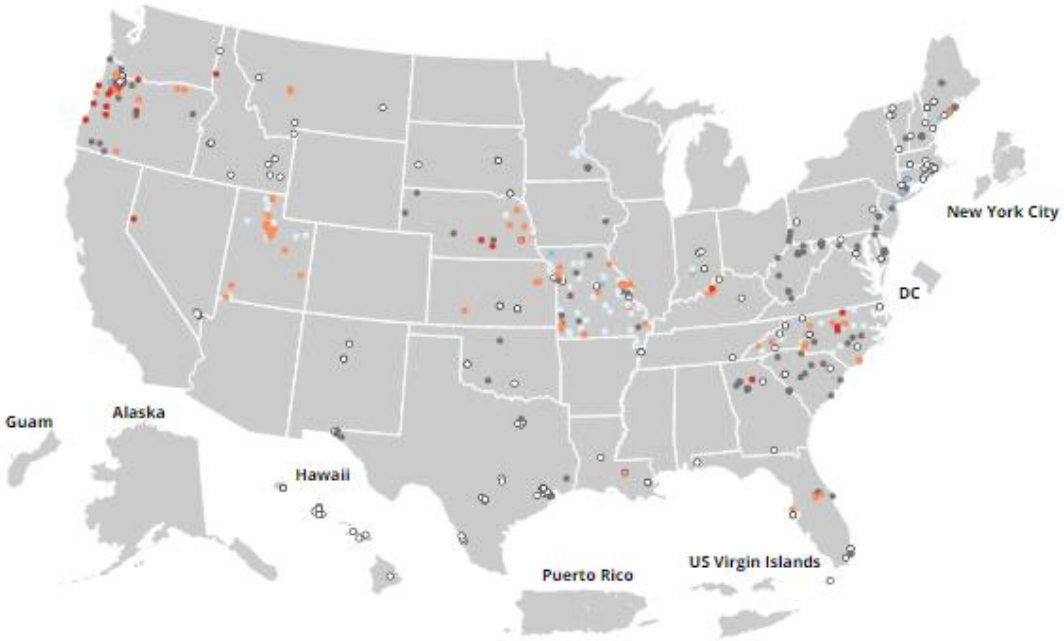
103,175
Prior 7-Day Average**
Jun 09, 2022 - Jun 15, 2022

-5.6%
Change in 7-Day Average



*Graph displays data for Mar 01, 2020, to date. The totals include cases reported since Jan 22, 2020.
** The histogram, total of new cases in the last 24 hours, and 7-day averages do not include historical cases retroactively that are not yet attributed to the correct date of report.
Of 533,666 historical cases reported retroactively, none were reported on Jun 22, 2022; 3 in the current week; and none in the prior week.

COVID-19 Wastewater Surveillance



Current SARS-CoV-2 virus levels by site, United States

Current virus levels category	Num. sites	% sites	Category change in last 7 days
New Site	275	33	1%
0% to 19%	15	2	– 6%
20% to 39%	71	9	18%
40% to 59%	174	21	– 14%
60% to 79%	232	28	1%
80% to 100%	63	8	– 30%

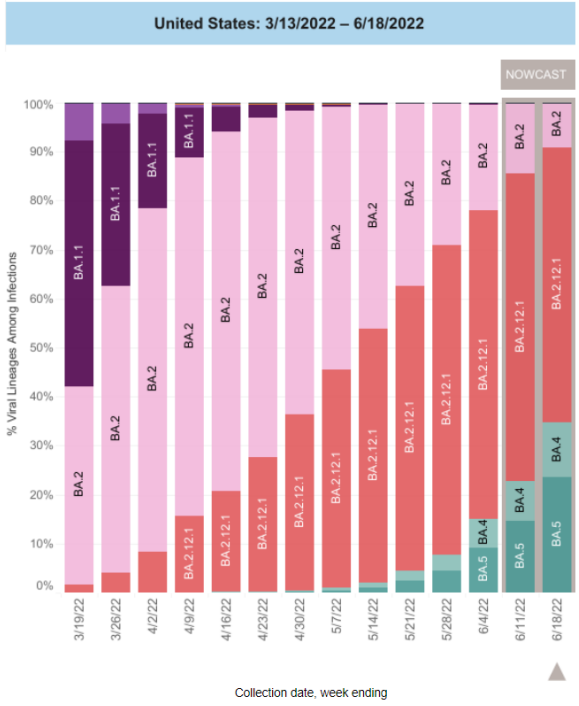
Total sites with current data: 830

Total number of wastewater sampling sites: 1033

Source: [CDC COVID Data Tracker: Wastewater Surveillance]

COVID-19 Variants

- Estimated percentage of COVID-19 variants circulating in the United States as of June 18, 2022
  - Omicron BA.2.12.1: 56.0% of cases
  - Omicron BA.5: 23.5%
  - Omicron BA.4: 11.4%
  - Omicron BA.2: 9.1%



United States: 6/12/2022 – 6/18/2022 NOWCAST

USA

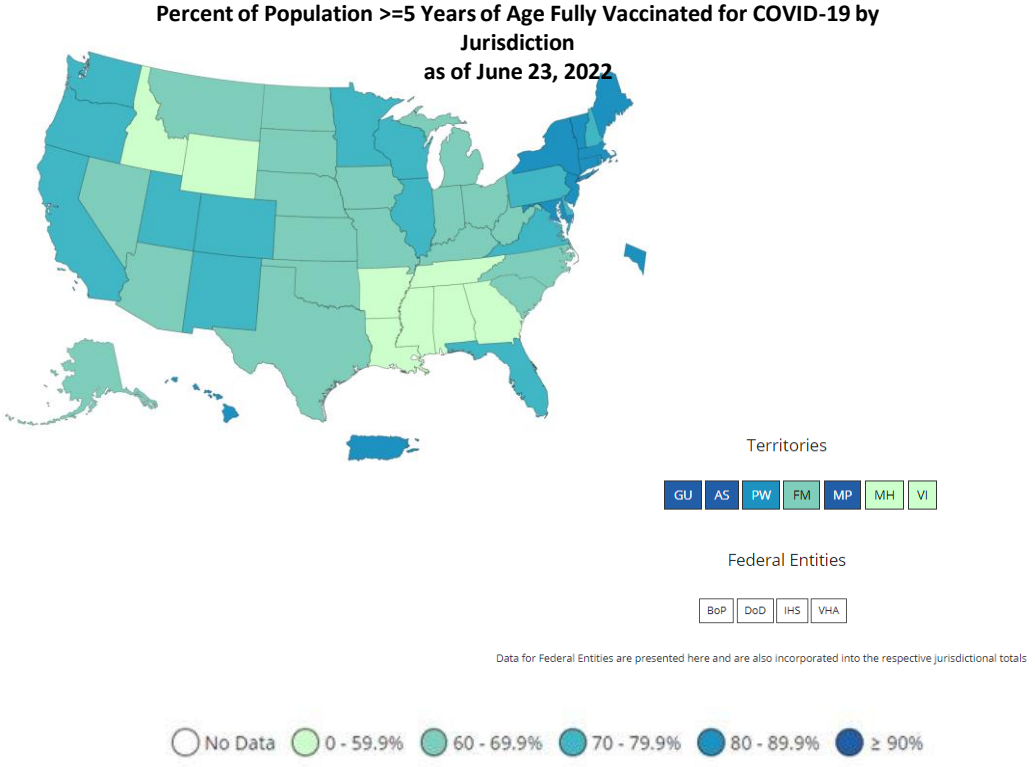
WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.2.12.1	VOC	56.0%	51.4-60.5%
	BA.5	VOC	23.5%	20.3-27.0%
	BA.4	VOC	11.4%	8.8-14.5%
	BA.2	VOC	9.1%	7.9-10.5%
	BA.1.1	VOC	0.0%	0.0-0.0%
	B.1.1.529	VOC	0.0%	0.0-0.0%
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.0%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# AY.1-AY.133 and their sublineages are aggregated with B.1.617.2. BA.1, BA.3 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. For regional data, BA.1.1 and its sublineages are also aggregated with B.1.1.529, as they currently cannot be reliably called in each region. Except BA.2.12.1, BA.2 sublineages are aggregated with BA.2. BA.5.1 is aggregated with BA.5.

Source: [CDC COVID Data Tracker: Variant Proportions]

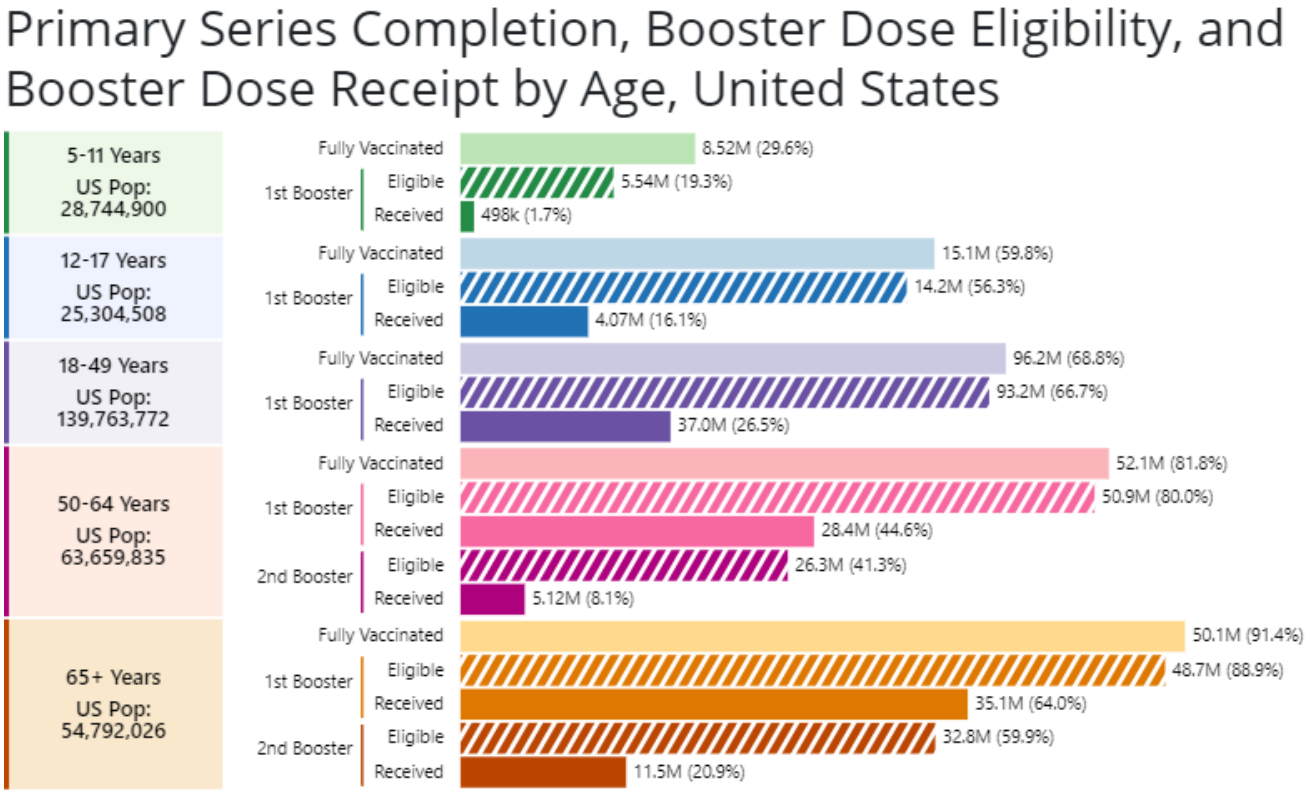
COVID-19 Vaccination: Domestic

- As of June 23, 2022
  - 78.1% of US population has received at least 1 dose
  - 66.9% of US population fully vaccinated
  - 47.3% of fully vaccinated persons have received one additional dose



Source: CDC COVID Data Tracker: Vaccinations in the US

COVID-19 Boosters



Source: CDC COVID Data Tracker: Vaccination Demographics Trends; CDC COVID Data Tracker: Vaccination Demographics

Current Priorities, Future Opportunities

Prioritize Health Equity

- Build on successes, learn from failures, ensure that equity remains a priority at all levels of response
- Ensure health equity consideration from the start in planning scientific studies, programmatic activities, guidance updates, etc.
- Understand and address concerns of people with disabilities, strengthen ties to advocacy organizations
- Assist with equitable access to testing and therapeutics

Protect the Vulnerable

- Communicate effective strategies to help protect yourself and others against COVID-19
- Communicate treatment availability for those at higher risk of severe disease
- Sustain use of COVID-19 vaccines to protect the health of individuals and communities

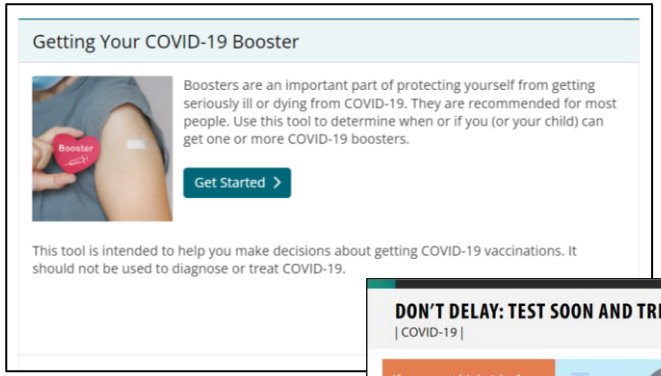


Image Sources: COVID-19 Vaccine Boosters | CDC; DON'T DELAY: TEST SOON AND TREAT EARLY (cdc.gov)

Incorporate COVID-19 into Routine Public Health Practice

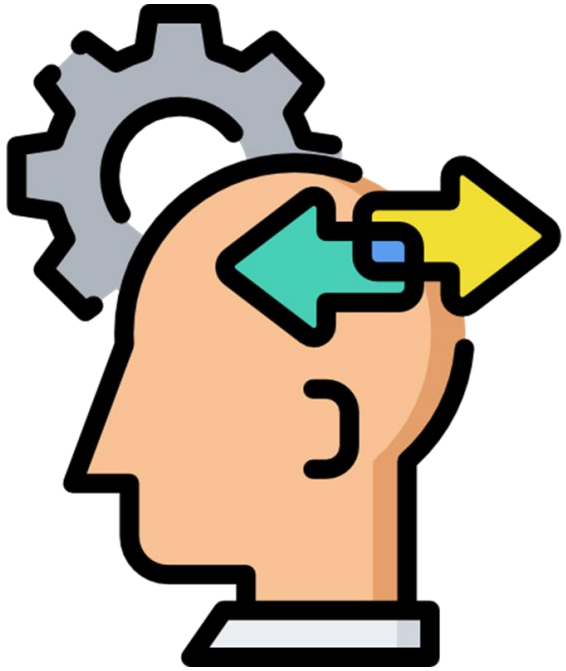
- Planning for sustainability and incorporation of COVID-19 into routine public health practice
- CDC continues to fund and support development of public health emergency response capabilities in health departments

Data Modernization

- Expectations for timely and complete data and analysis have changed from public, media, policy makers, public health practitioners
- Data Modernization Initiative (DMI): Expanding the revolution in data science, analysis, and visualization for public health

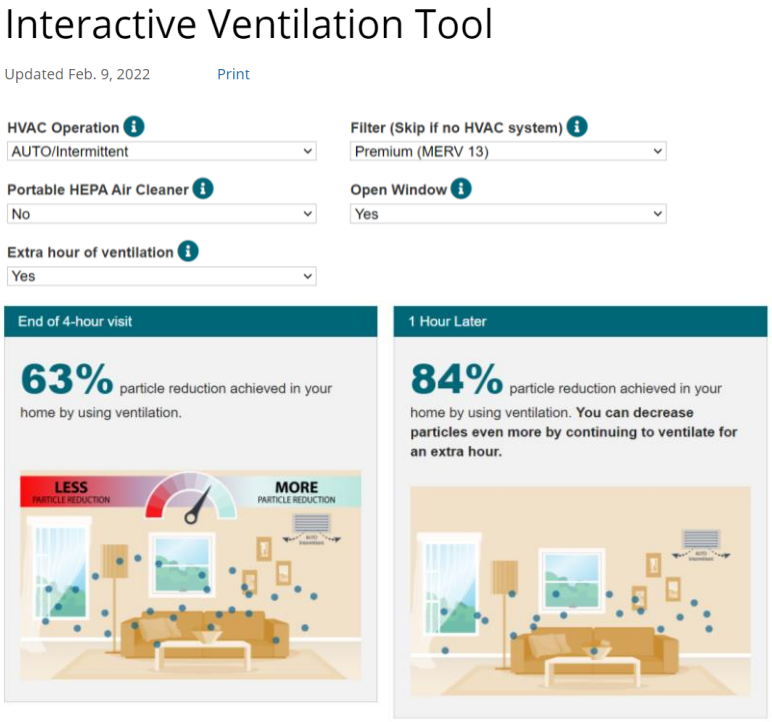
Potential Long-Term Behavior Changes?

- Staying home when sick
- Normalization of option for people to use masks use in daily life
- Home testing for COVID-19 and other illnesses

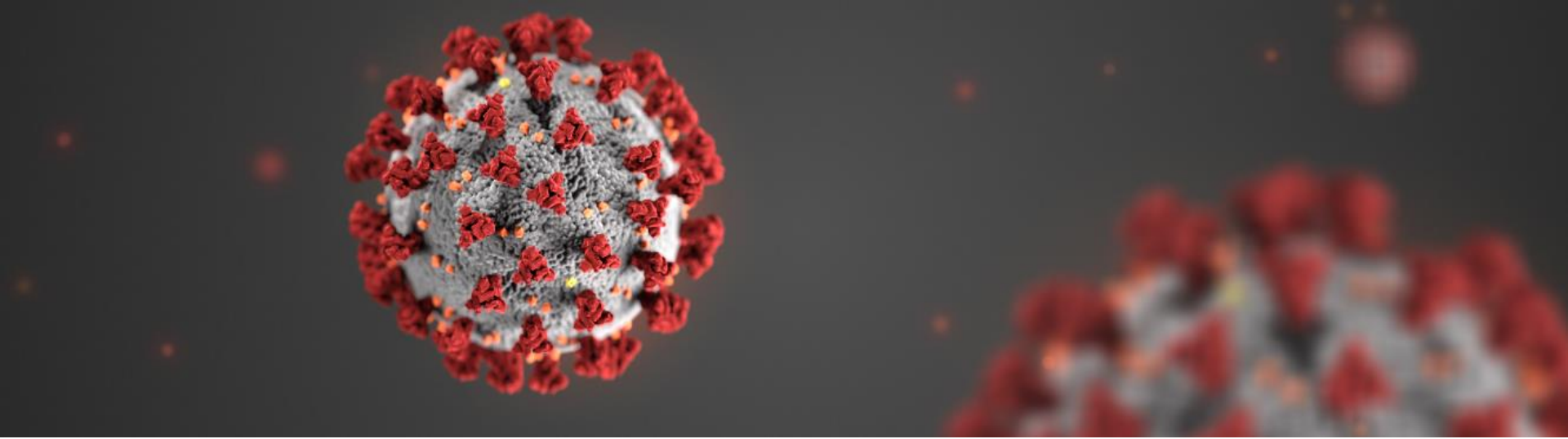


Indoor Air Quality: Next Step in the Sanitary Revolution

- Recognizing and acting on the importance of effective ventilation, filtration, disinfection
- Benefits in reduction of other respiratory infections
- [Interactive Ventilation Tool | CDC]



Source: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/interactive-ventilation-tool.html



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.

Vaccination in Children Under 5 Years: Re-Cap of Recent Decisions and the Data Underlying Them

Perspectives from VRBPAC

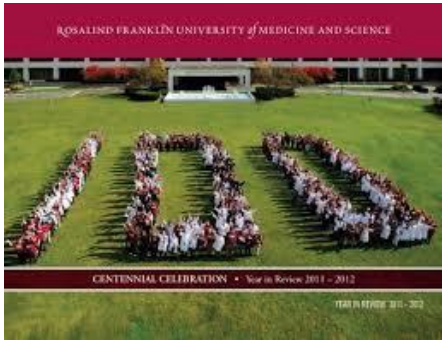
Archana Chatterjee, MD, PhD

CDC/IDSA COVID-19 Clinician Call June 25, 2022: Perspectives from VRBPAC

Archana Chatterjee, MD, PhD

Dean, Chicago Medical School

Vice President for Medical Affairs, Rosalind Franklin University of Medicine and Science



Highlights from VRBPAC Meeting June 14-15, 2022

Day 1

- Focused on Moderna COVID-19 Vaccine: Request for Emergency Use Authorization (EUA) Amendment, Use of a 2-Dose Primary Series in Children and Adolescents 6 years through 17 Years of Age.
- CDC Presentations on:
  - COVID-19 Epidemiology and Disease Burden in Infants, Children and Adolescents
  - mRNA COVID-19 Vaccine Effectiveness
  - mRNA COVID-19 Vaccine Post Authorization Safety Assessment in Pediatric Age Groups

Day 2

- Focused on Moderna COVID-19 Vaccine: Request for EUA Amendment, use of a 2-Dose Primary Series in Infants and Children 6 Months through 5 Years of Age.
- Focused on Pfizer-BioNTech COVID-19 Vaccine: Request for EUA Amendment, Use of a **3**-Dose Primary Series in Infants and Children 6 Months through 4 Years of Age

Moderna Pediatric Clinical Trials

	6-11 years	12-17 years
Dose/regimen:	50 µg Two doses (0, 28 days)	100 µg Two doses (0, 28 days)
Pediatric Study	P204	P203
mRNA-1273 recipients	3,007	2,486
Immunobridging to 18-25-year-old participants in P301 (GMT and seroresponse)	✓	✓
Descriptive efficacy	✓	✓

Summary of Benefits & Risks (6 through 17 Years)

Known and Potential Benefits	Uncertainties in Benefits	Known and Potential Risks	Uncertainties in Risks
Prevention of symptomatic COVID-19, based on: • Immunobridging analyses met pre-specified success criteria that allow for inference of vaccine effectiveness for individuals 6 -17 years of age • Supportive evidence of vaccine efficacy against symptomatic COVID-19 in descriptive analyses • Expectation of greater effectiveness against more severe COVID-19	• Effectiveness against: emerging SARS-CoV-2 variants, long term effects of COVID-19 disease • Effectiveness in: certain populations at higher risk of severe COVID-19, individuals previously infected with SARS-CoV-2 • Duration of protection	• Local and systemic reactogenicity • Lymphadenopathy • Myocarditis/pericarditis • Anaphylaxis, and other hypersensitivity reactions	• Safety in certain subpopulations • Adverse reactions that are uncommon or that require longer follow-up to be detected

Voting Questions for EUA

1. Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (100 µg each dose) outweigh its risks for use in adolescents 12 through 17 years of age?

2. Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (50 µg each dose) outweigh its risks for use in children 6 through 11 years of age?

Moderna Infants & Children Study

	6-23 months	2-5 years
Dose/regimen:	25 µg Two doses (0, 28 days)	25 µg Two doses (0, 28 days)
Pediatric Study	P204	P204
mRNA-1273 recipients	1,761	3,031
Immunobridging to 18-25-year-old participants in P301 (GMC and seroresponse)	✓	✓
Descriptive efficacy	✓	✓

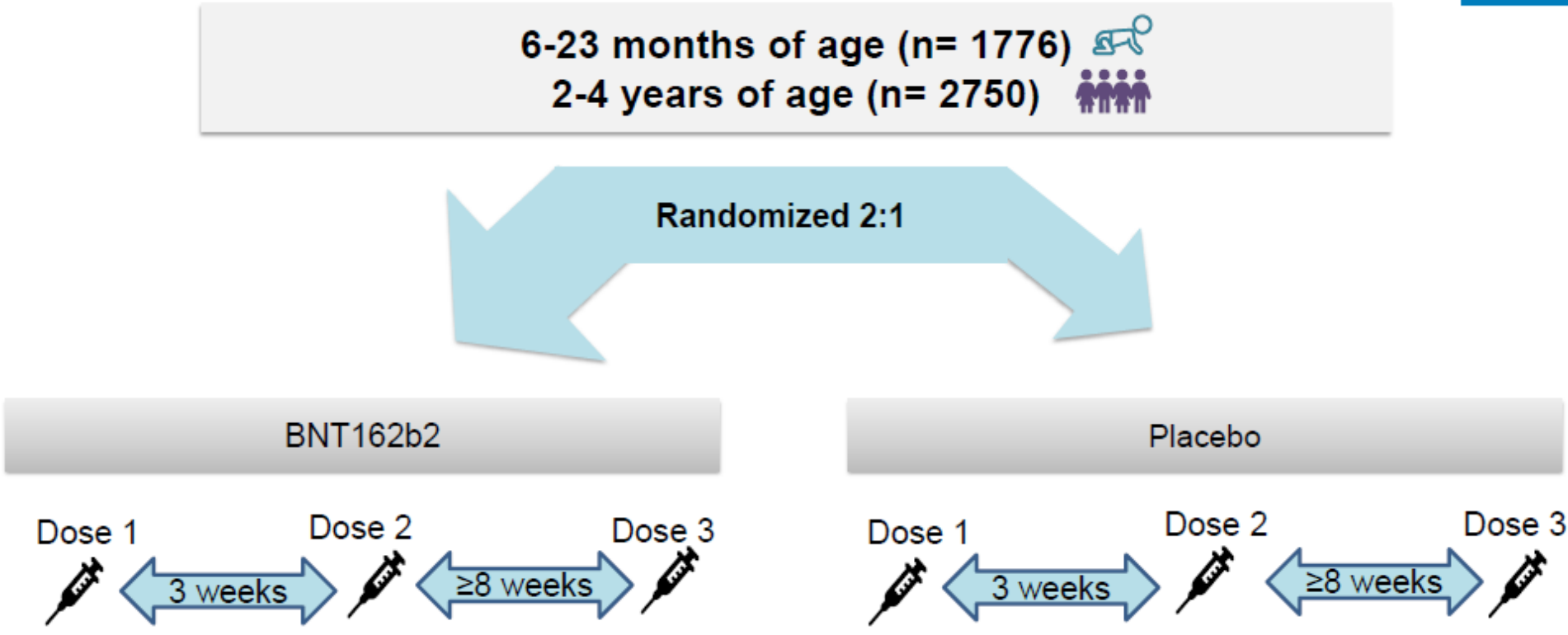
Summary of Benefits and Risks 6 months-5 years

Known and Potential Benefits	Uncertainties in Benefits	Known and Potential Risks	Uncertainties in Risks
Prevention of symptomatic COVID-19, based on: • Immunobridging analyses met pre-specified success criteria that allow for inference of vaccine effectiveness for individuals 6 months- 5 years of age • Supportive evidence of vaccine efficacy against symptomatic COVID-19 in descriptive analyses • Expectation of greater effectiveness against more severe COVID-19	• Effectiveness against: emerging SARS-CoV-2 variants, long term effects of COVID-19 disease • Effectiveness in: certain populations at higher risk of severe COVID-19, individuals previously infected with SARS-CoV-2 • Duration of protection	• Local and systemic reactogenicity • Lymphadenopathy • Myocarditis/pericarditis • Anaphylaxis and other hypersensitivity reactions	• Safety in certain subpopulations • Adverse reactions that are uncommon or that require longer follow-up to be detected

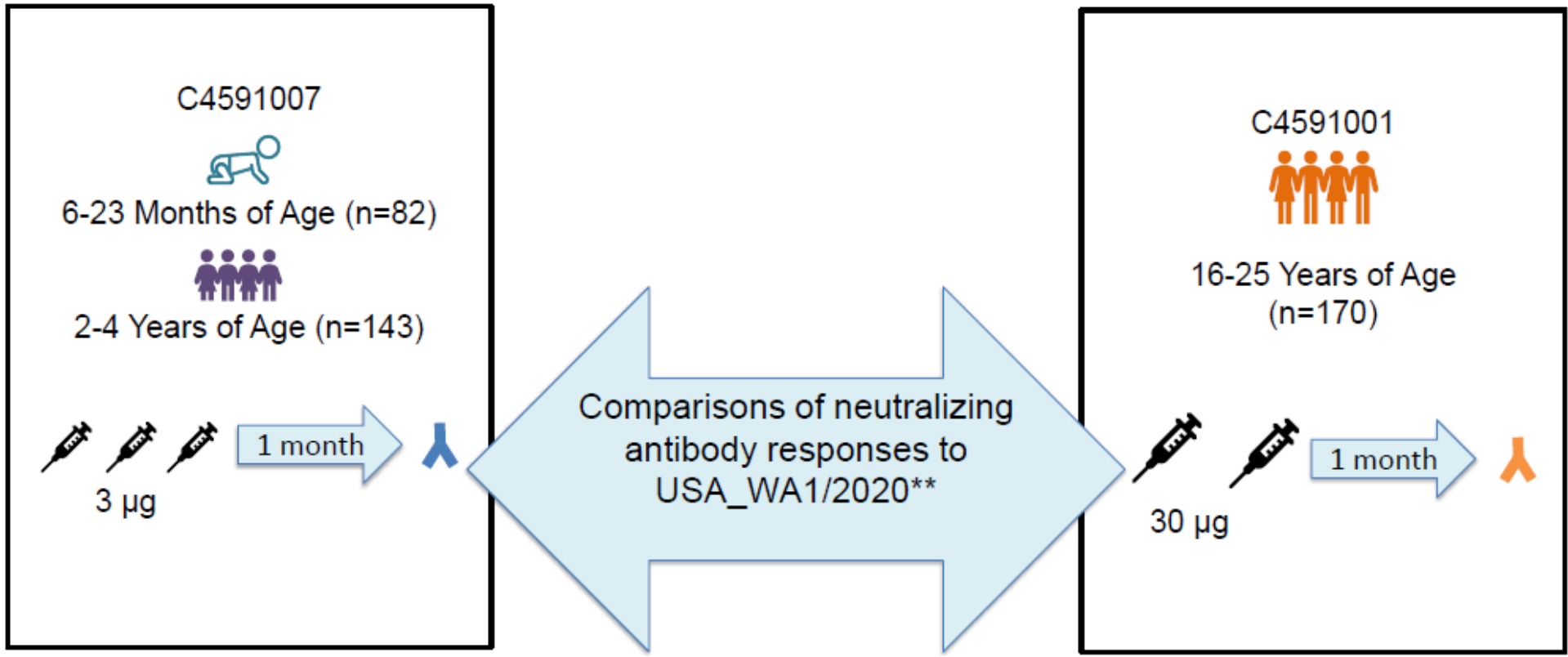
Voting Question for EUA

- Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (25 µg each dose) outweigh its risks for use in children 6 months through 5 years of age?

Pfizer C4591007: Amended Phase 2/3 Study Design



C4591007: Immunobridging Analysis



Summary of Benefits & Risks 6 Months – 4 Years

Known and Potential Benefits	Uncertainties in Benefits	Known and Potential Risks	Uncertainties in Risks
Prevention of symptomatic COVID-19, based on: • Immunobridging analyses met pre-specified success criteria that allow for inference of vaccine effectiveness for individuals 6 months- 4 years of age • Preliminary evidence of vaccine efficacy against COVID-19 in descriptive analyses • Expectation of greater effectiveness against more severe COVID-19	• Effectiveness against: emerging SARS-CoV-2 variants, long term effects of COVID-19 • Effectiveness in: certain populations at higher risk of severe COVID-19, individuals previously infected with SARS-CoV-2 • Duration of protection	• Local and systemic reactogenicity • Myocarditis/pericarditis • Lymphadenopathy • Anaphylaxis and other hypersensitivity reactions	• Safety in certain subpopulations • Adverse reactions that are uncommon or that require longer follow-up to be detected

Voting Question for EUA

- Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine, when administered as a three-dose series (3 mcg each dose), outweigh its risks for use in infants and children 6 months through 4 years of age?

Vaccination in Children Under 5 Years: Re-Cap of Recent Decisions and the Data Underlying Them

FDA Update

Peter Marks, MD, PhD

U.S. FOOD & DRUG ADMINISTRATION

Pediatric COVID-19 Vaccines

Peter Marks, MD, PhD

IDSA/CDC Call

June 25, 2022

COVID-19 Vaccines in Young Children

- Special considerations in children 5 years and younger
  - Determination of appropriate dosage and number of doses
  - Duration and number of children for safety follow-up
  - Benefit-risk considerations
- Trials completed is several thousand children with immunogenicity determined in several hundred
  - Moderna 2-dose regimen
  - Pfizer-BioNTech 3-dose regimen

Moderna 6 mo through 5 yrs

2 dose regimen 25 mcg (1/4 adult dose) days 1, 28

Parameter		6 mo – 2 yrs Vaccine	6 mo – 2 yrs Placebo	2 yrs – 5 yrs Vaccine	2 yrs – 5 yrs Placebo
Safety Dose 2	Local Redness	13.5%	3.8%	8.8%	1.6%
	Fever	14.6%	8.3%	16.9%	6.6%

Parameter	6 mo – 2 yrs	2 yrs – 5 yrs
Immunogenicity (GMTR)	1.3 (95% CI 1.1, 1.5)	1.0 (95% CI 0.98, 1.27)

Parameter	6 mo – 2 yrs	2 yrs – 5 yrs
Effectiveness	31.5% (95% CI -27.7, 62.0)	46.4% (95% CI 19.8, 63.8)

GMTR compared with 18 to 25 yrs.; Efficacy cases n = 37:18, 71:43 with 3:1 randomization

Pfizer-BioNTech 6 mo through 4 yrs

3 dose regimen 3 mcg (1/10 adult dose) days 1, 21, 81

Parameter		6 mo – 2 yrs Vaccine	6 mo – 2 yrs Placebo	2 yrs – 5 yrs Vaccine	2 yrs – 5 yrs Placebo
Safety Dose 3	Local Redness	7.1%	5.3%	10.9%	3.4%
	Fever	6.8%	5.9%	5.1%	4.2%

Parameter	6 mo – 2 yrs	2 yrs – 5 yrs
Immunogenicity (GMTR)	1.19 (95% CI 1.00, 1.42)	1.30 (95% CI 1.13, 1.50)

Parameter	6 mo – 2 yrs	2 yrs – 5 yrs
Effectiveness	82.3% (95% CI -8.0, 98.3)	75.5% (95% CI -370.1, 99.6)

GMTR compared with 16 to 25 yrs.; Efficacy cases n = 2:5, 1:2 with 2:1 randomization

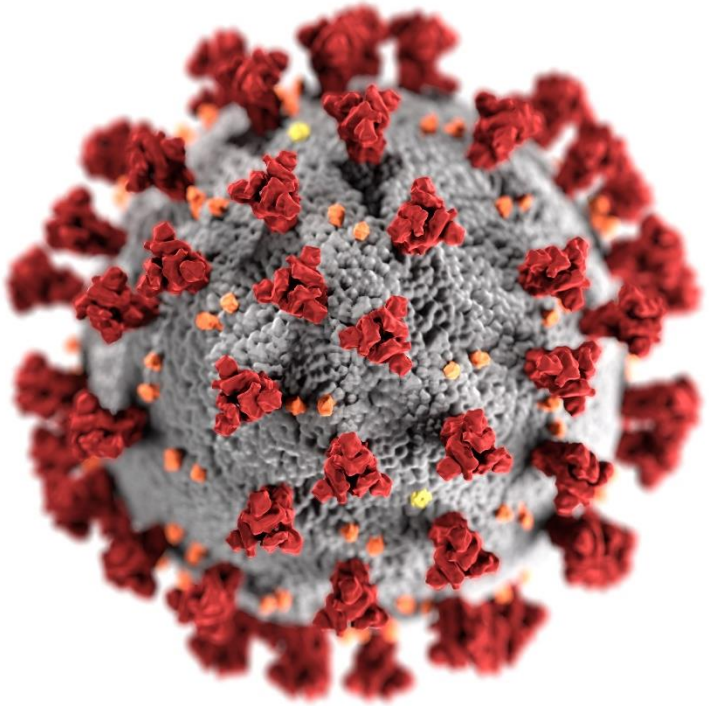
Vaccination in Children Under 5 Years: Re-Cap of Recent Decisions and the Data Underlying Them

ACIP Update

Sara Oliver, MD, MSPH

Recommendations for mRNA COVID-19 vaccines in children and adolescents

Sara Oliver, MD, MSPH



cdc.gov/coronavirus

Summary

- Since the beginning of the COVID-19 pandemic:
  Among U.S. children ages 6 months – 4 years of age, there have been
  - Over **2 million cases**
  - Over **20,000 hospitalizations**
  - Over **200 deaths**
- Among U.S. children ages 5 – 17 years of age, there have been
  - Over **10 million cases**
  - Over **45,000 hospitalizations**
  - Over **600 deaths**
- COVID-19 can cause severe disease and death among children and adolescents, including those without underlying medical conditions
- Future surges will continue to impact children, with **unvaccinated** children remaining at **higher risk** of severe outcomes

ACIP interpretation:

mRNA COVID-19 vaccines in young children

- mRNA COVID-19 vaccine clinical trials in young children both conducted during Omicron predominance, but different months and incidence levels
- **Efficacy estimates** for these two vaccines **cannot be directly compared**
- Both vaccines met non-inferiority criteria for neutralizing antibody levels
- Clinical trials were not powered to detect efficacy against severe disease in young children, but similar patterns in this age group are expected to what is seen in everyone ages 5 years and older
- Post-authorization effectiveness studies can help determine subsequent timing and need of **boosters**
  - Immunocompromised children may also need additional doses for optimal protection

Summary

mRNA COVID-19 vaccines in children and adolescents

- As with all other age groups, priority is **vaccination** of **unvaccinated individuals**
- **18.7 million** children ages 6 months–4 years now eligible
- **25 million** unvaccinated children and adolescents ages 5–11 and 12–17 years
- Benefits outweigh risks for mRNA COVID-19 vaccines in all ages: receipt of **primary series** continues to be the **safest** way to **prevent serious COVID-19**

ACIP Recommendation

A **two-dose** Moderna COVID-19 vaccine series (25µg) is recommended
for children ages **6 months –5 years,**
under the EUA issued by FDA

Two doses of 25µg Moderna COVID-19 vaccine, 28-days apart

A **three-dose** Pfizer-BioNTech COVID-19 vaccine series (3µg each) is recommended
for children ages **6 months – 4 years,**
under the EUA issued by FDA

Three doses of 3µg Pfizer-BioNTech COVID-19 vaccine
21 days and at least 8 weeks apart

ACIP Recommendation

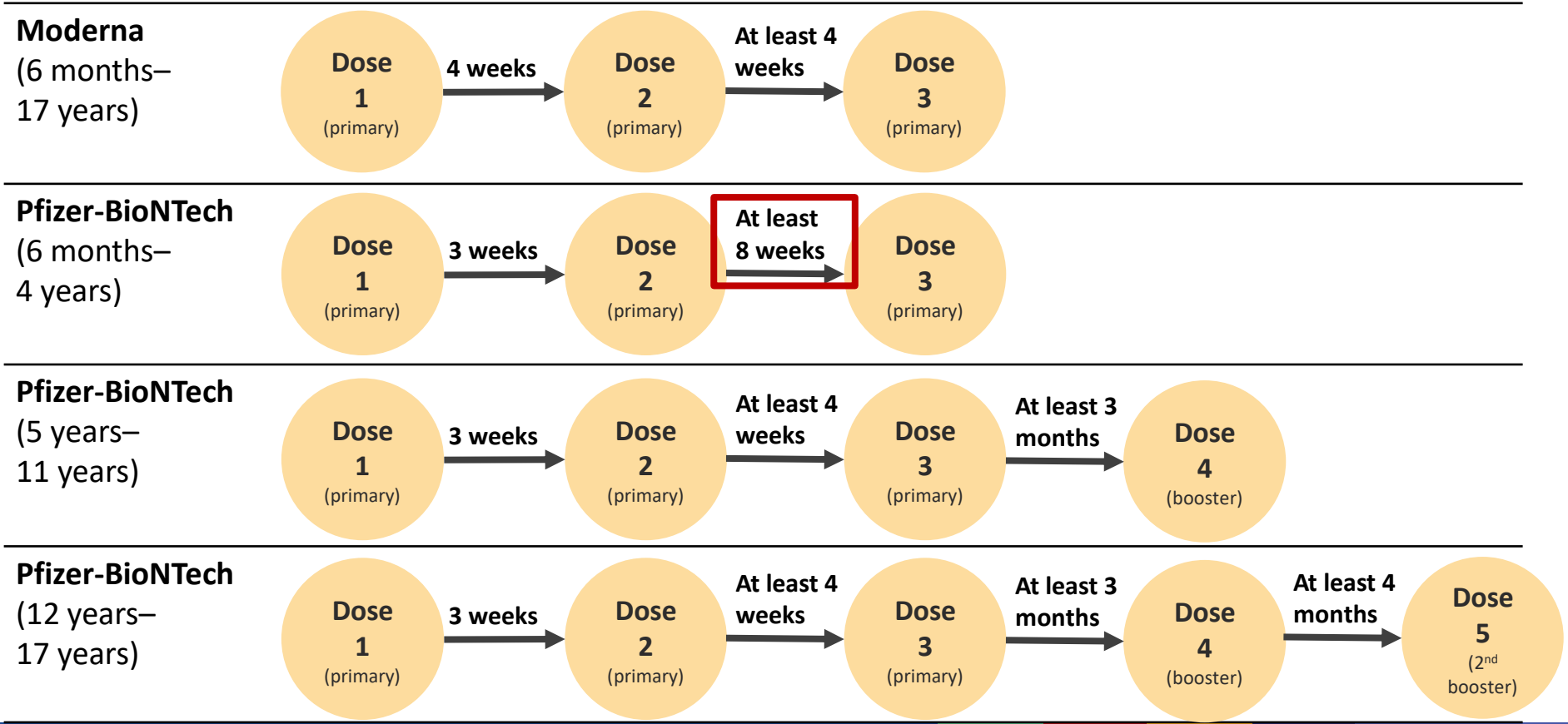
A **two-dose** Moderna COVID-19 vaccine series (50µg)
is recommended for children ages **6–11 years,**
under the EUA issued by FDA

A **two-dose** Moderna COVID-19 vaccine series (100µg) is recommended
for adolescents ages **12 – 17 years,**
under the EUA issued by FDA

Pediatric Schedule: People Who Are NOT Moderately or Severely Immunocompromised

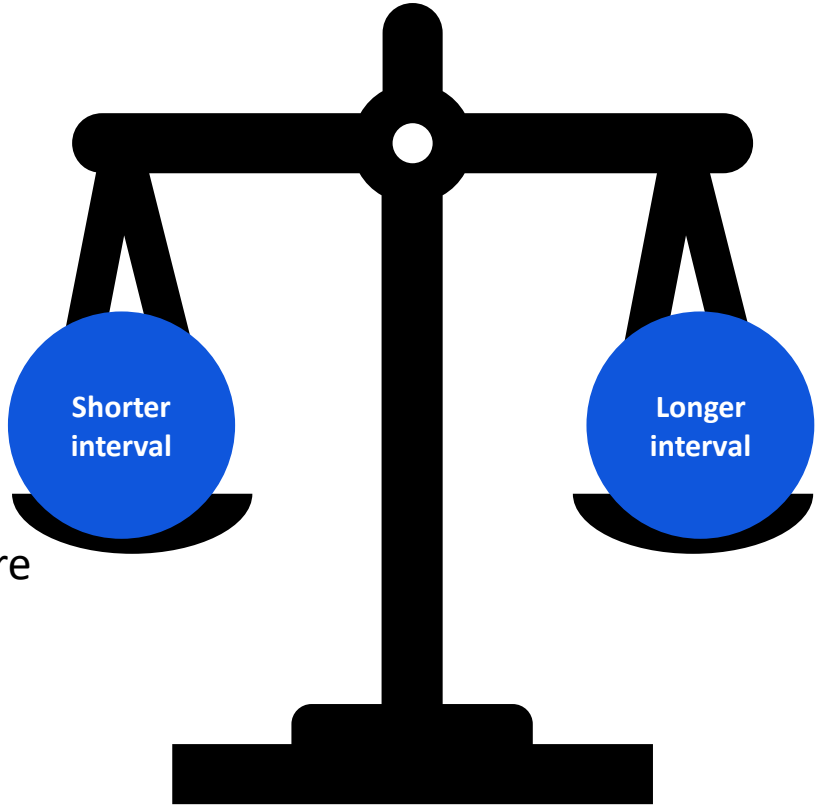
Moderna (6 months–17 years)	**Dose 1** (primary) → **4-8 weeks** → **Dose 2** (primary)
Pfizer-BioNTech (6 months–4 years)	**Dose 1** (primary) → **3-8 weeks** → **Dose 2** (primary) → **At least 8 weeks** → **Dose 3** (primary)
Pfizer-BioNTech (5 years–17 years)	**Dose 1** (primary) → **3-8 weeks** → **Dose 2** (primary) → **At least 5 months** → **Dose 3** (booster)

Pediatric Schedule: People Who ARE Moderately or Severely Immunocompromised



Considerations for Extended Interval Between Dose 1 & 2

- Immunocompromised
- High risk for severe disease
- Household members with high risk for severe disease
- High COVID-19 community levels

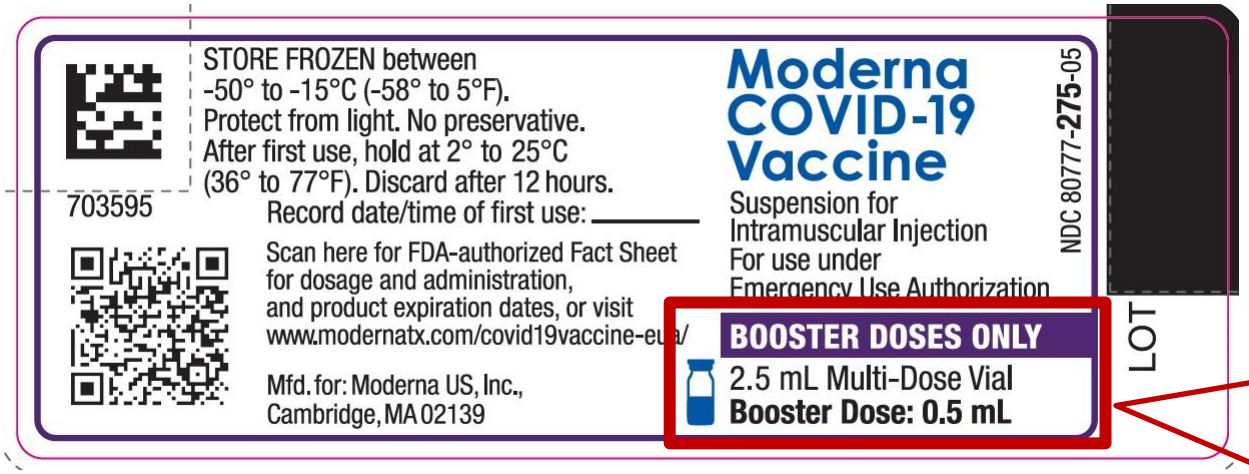


- Reduced myocarditis risk
- Adolescent and young adult males
- Optimize vaccine effectiveness

Moderna COVID-19 Vaccine Products

Authorized Age group	 **6 months–5 years** (primary series)	 • **6–11 years** (primary series) • **18 years and older** (booster doses)	 • **12 years and older** (primary series) • **18 years and older** (booster doses)
Vial cap color	Dark blue	Dark blue	Red
Label border color	Magenta	Purple	Light blue
Dose (mRNA concentration)	25 mcg	50 mcg	100 mcg
Injection volume volume	0.25 mL	0.5 mL	0.5 mL (primary, age 12+); 0.25mL (booster, age 18+)
Dilution required	No	No	No
Doses per vial	10	5	Maximum of 11

Moderna COVID-19 Vaccine Product for Ages 6–11 Years



Labeled for “BOOSTER DOSES ONLY” but is authorized for:

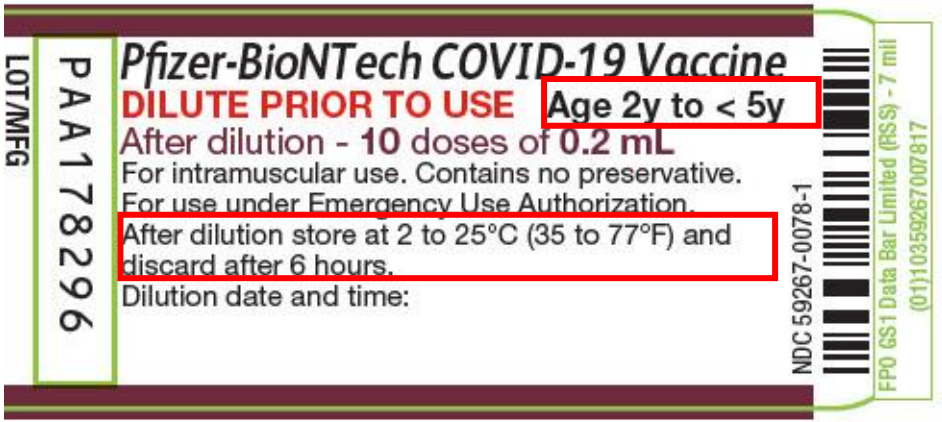
- Primary doses in children ages 6–11 years
- Booster doses in adults ages 18 years and older

Pfizer-BioNTech COVID-19 Vaccine Products

	 Product for ages 6 months–4 years	 Product for ages 5–11 years	 Product for ages 12 years and older
Authorized for ages	6 months–4 years	5–11 years	12 years and older
Vial cap color	Maroon	Orange	Gray
Dose (mRNA concentration)	3 mcg	10 mcg	30 mcg
Injection volume	0.2 mL	0.2 mL	0.3 mL
Dilution required	Yes—2.2 mL	Yes—1.3 mL	No
Doses per vial	10 (after dilution)	10 (after dilution)	6

Pfizer-BioNTech COVID-19 Vaccine Product for Ages 6 Months–4 Years

Vaccine may be discarded **12 hours** after dilution rather than **6 hours**.



Vial label states Age 2y to <5y but can be used in children ages 6 months−4 years.

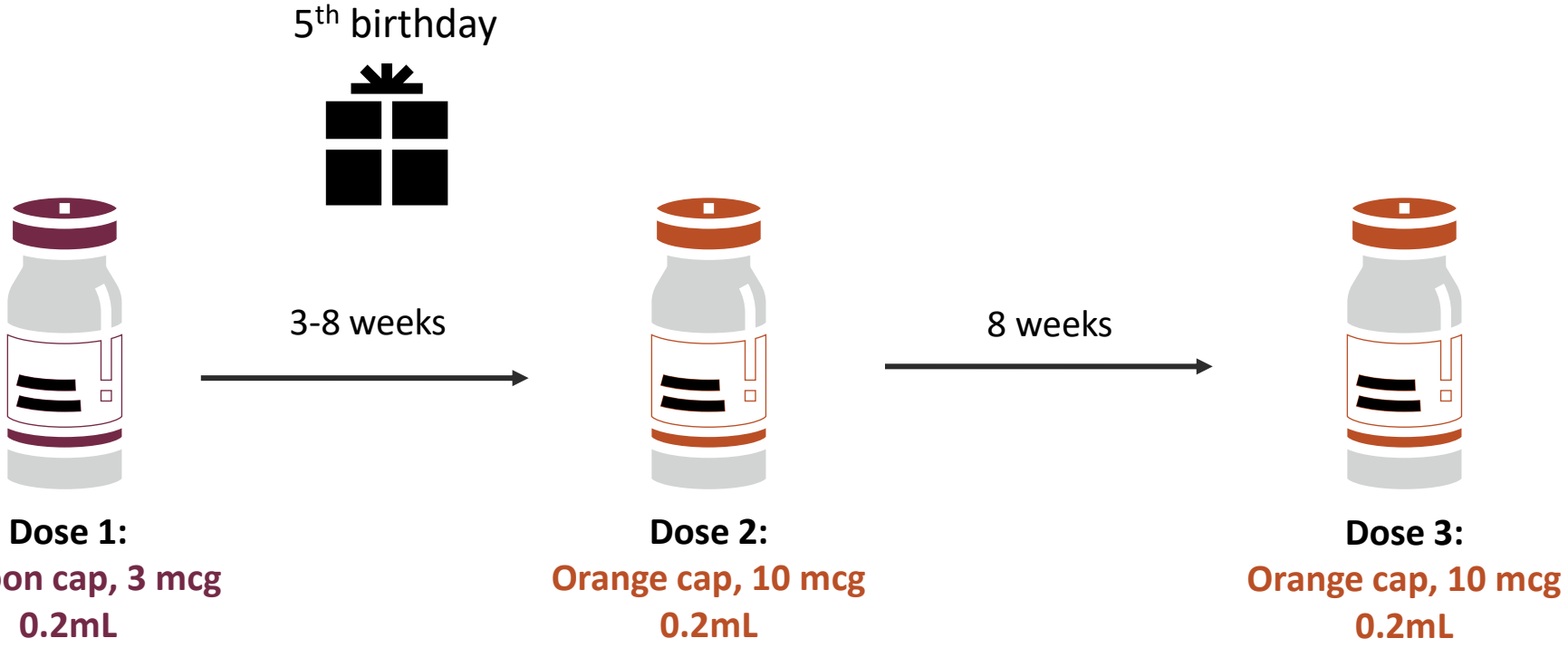
Vaccine Dosage

- Children should receive the age-appropriate vaccine product and follow the schedule based on their age **on the day of vaccination**, regardless of their size or weight.
- If a child moves from a younger age group to an older age group (e.g., moves from age 11 years to age 12 years) during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine dosage for the older age group for all subsequent doses.

Children who turn from age 4 to 5 years

Recommended

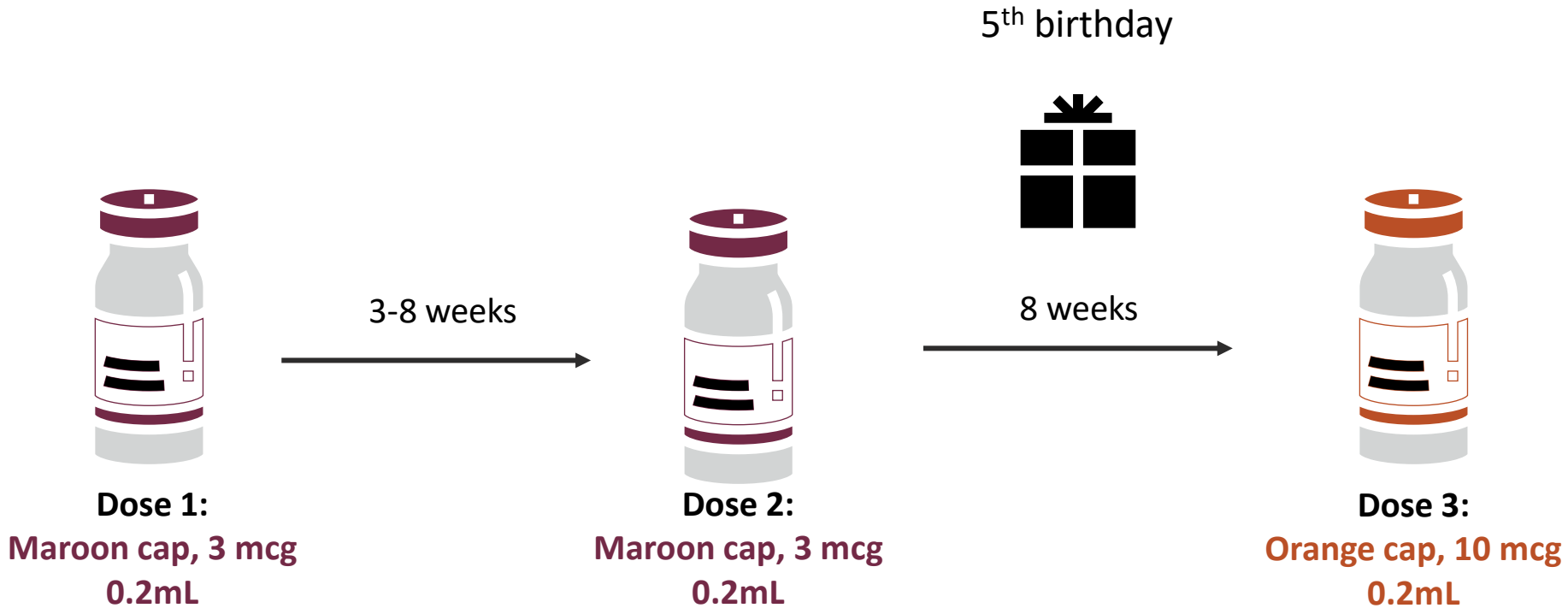
Pfizer-BioNTech COVID-19 vaccine



Children who turn from age 4 to 5 years

Recommended

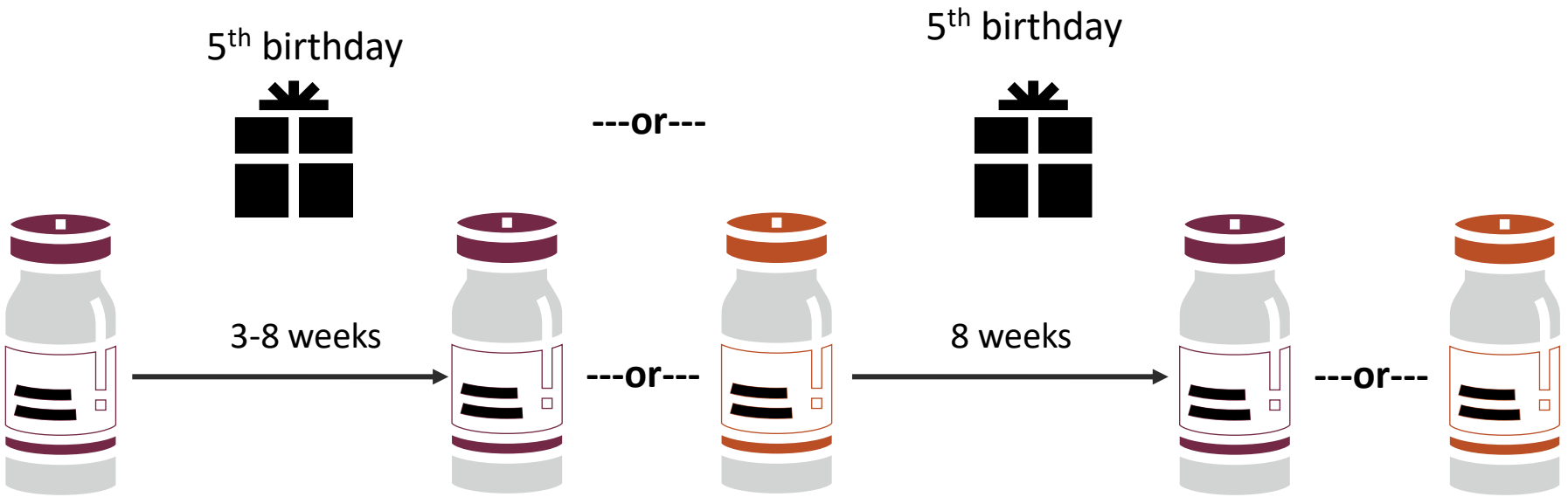
Pfizer-BioNTech COVID-19 vaccine



Children who turn from age 4 to 5 years

Allowed (not an administration error)

Pfizer-BioNTech COVID-19 vaccine



Dose 1:
Maroon cap, 3 mcg

Dose 2:
Orange cap, 10 mcg
---or---
Maroon cap, 3 mcg

Dose 3:
Orange cap, 10 mcg
---or---
Maroon cap, 3 mcg

Children who turn from age 5 to 6 years

Recommended

Moderna COVID-19 vaccine

Dose 1:

Dark blue cap, magenta label border

25mcg

0.25mL

Dose 2:

Dark blue cap, purple border

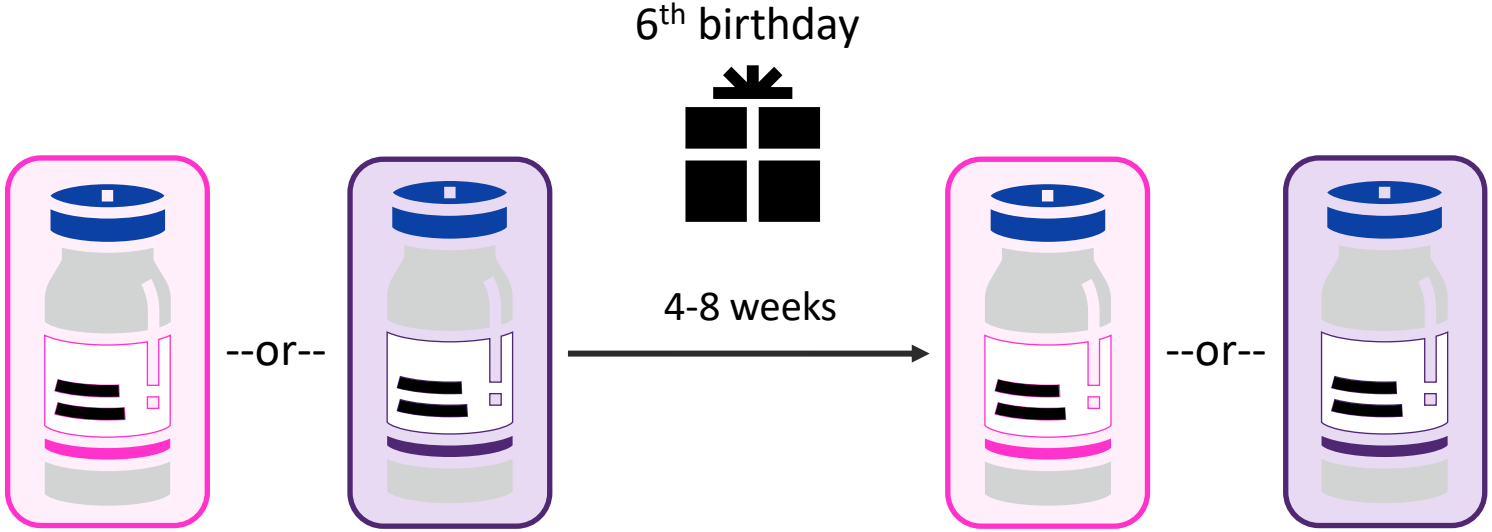
50mcg

0.5mL

Children who turn from age 5 to 6 years

Allowed (not an administration error)

Moderna COVID-19 vaccine



Dose 1:

Dark blue cap, magenta label border

---or---

Dark blue cap, purple border

Dose 2:

Dark blue cap, magenta label border

---or---

Dark blue cap, purple border

Children who turn from age 11 to 12 years

Recommended

Moderna COVID-19 vaccine

12th birthday

4-8 weeks

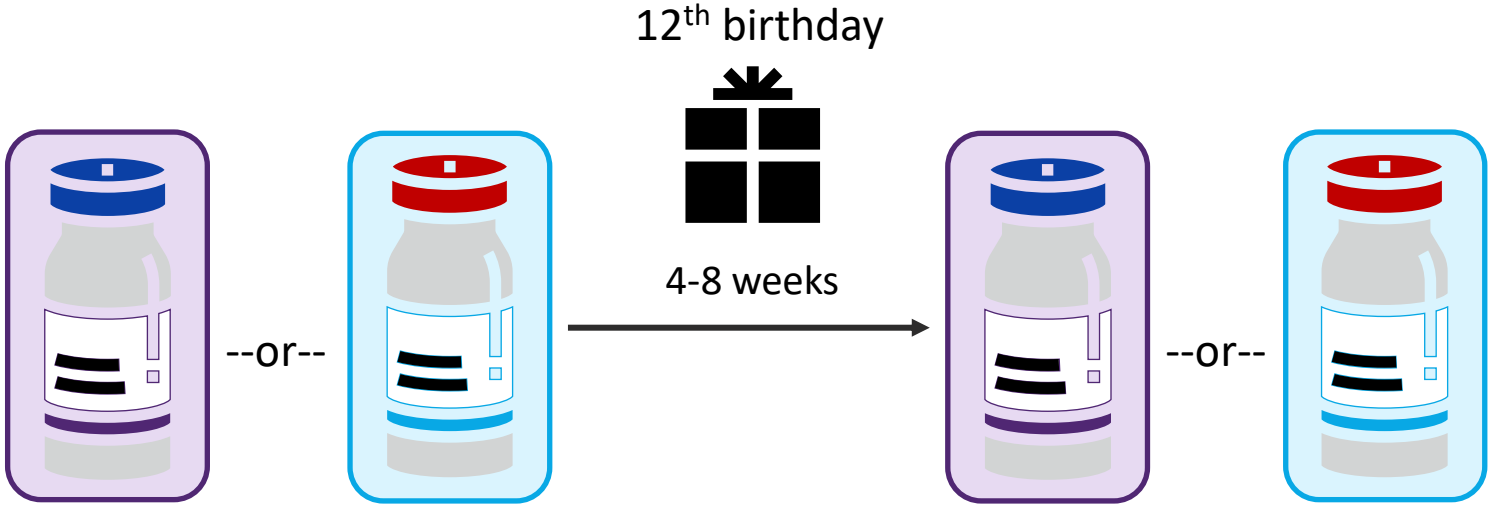
Dose 1:
Dark blue cap, purple border
50mcg
0.5mL

Dose 2:
Red cap, light blue border
100mcg
0.5mL

Children who turn from age 11 to 12 years

Allowed (not an administration error)

Moderna COVID-19 vaccine



Dose 1:

Dark blue cap, purple border

---or---

Red cap, light blue border

Dose 2:

Dark blue cap, purple border

---or---

Red cap, light blue border

Administration

- Existing guidance applies to children and adolescents
- Coadministration: COVID-19 vaccines **may be administered** without regard to timing of other vaccines
  - Considerations included in the interim clinical considerations
- Interchangeability: COVID-19 vaccines are not interchangeable. The same mRNA vaccine product should be used for all doses of the primary series

Mixed Series For Children Ages 6 months–4 Years

- Children ages 6 months–4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should receive a third dose of either mRNA vaccine 8 weeks after the second dose to complete the 3-dose primary series

Mixed Series For Children Ages 6 months–4 Years

- **Scenario 1**:

Dose 1:
Pfizer-BioNTech
Maroon cap, 3 mcg

Dose 2:
Moderna
Dark blue cap,
magenta label border, 25 mcg

Dose 3:
Pfizer-BioNTech
Maroon cap, 3 mcg
--or--
Moderna
Dark blue cap,
magenta label border, 25 mcg

Mixed Series For Children Ages 6 months–4 Years

- **Scenario 2**:

Dose 1:
Moderna
Dark blue cap,
magenta label border,
25 mcg

Dose 2:
Pfizer-BioNTech
Maroon cap, 3 mcg

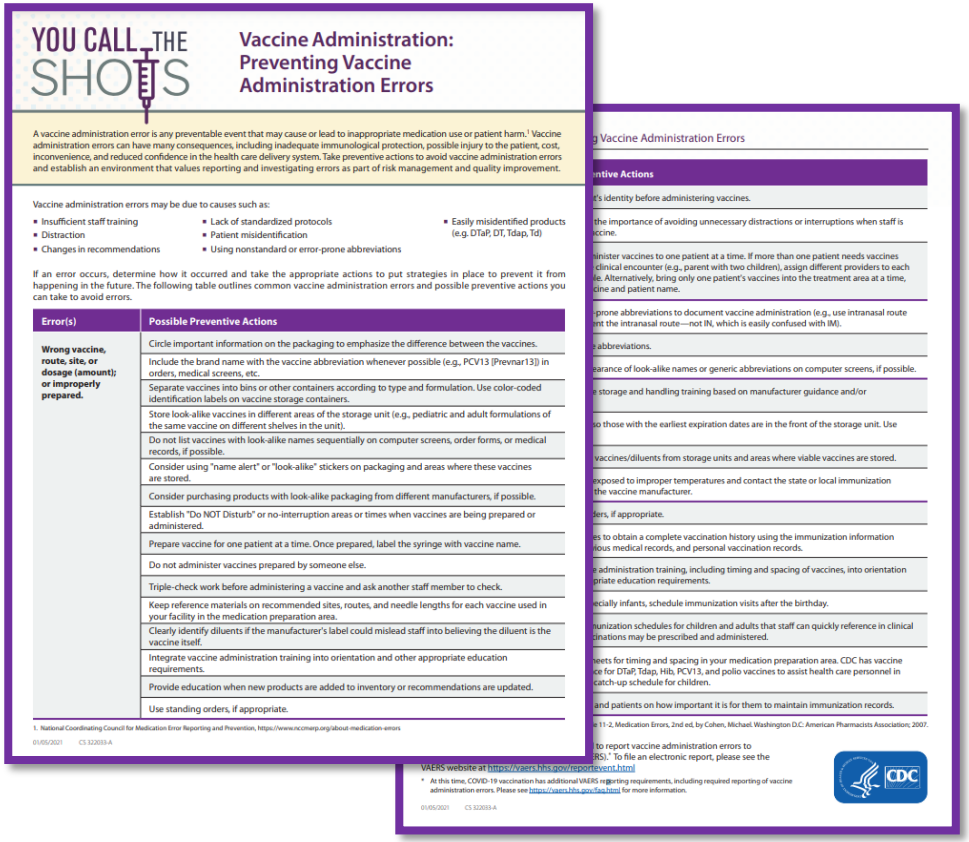
Dose 3:
Pfizer-BioNTech
Maroon cap, 3 mcg
--or--
Moderna
Dark blue cap,
magenta label border, 25 mcg

Potential Vaccine Administration Errors

- More opportunities for errors with:
  - More products
  - Products not labeled for the indicated age group
  - New pediatric providers that may be unfamiliar with COVID-19 vaccines
- Most likely errors with this context:
  - Incorrect product and/or dose volume, resulting in a higher-than-authorized dose
  - Incorrect product and/or dose volume, resulting in a lower-than-authorized dose
  - Correct dose from an incorrect product
  - Vaccine administered past beyond-use date

Preventing Vaccine Administration Errors

- Clinical guidance for errors: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-c
- Handout: https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf



YOU CALL THE SHOTS

Vaccine Administration: Preventing Vaccine Administration Errors

A vaccine administration error is any preventable event that may cause or lead to inappropriate medication use or patient harm.[1] Vaccine administration errors can have many consequences, including inadequate immunological protection, possible injury to the patient, cost, inconvenience, and reduced confidence in the health care delivery system. Take preventive actions to avoid vaccine administration errors and establish an environment that values reporting and investigating errors as part of risk management and quality improvement.

Vaccine administration errors may be due to causes such as:

- Insufficient staff training
- Distraction
- Changes in recommendations
- Lack of standardized protocols
- Patient misidentification
- Using nonstandard or error-prone abbreviations
- Easily misidentified products (e.g. DTaP, DT, Tdap, Td)

If an error occurs, determine how it occurred and take the appropriate actions to put strategies in place to prevent it from happening in the future. The following table outlines common vaccine administration errors and possible preventive actions you can take to avoid errors.

Error(s)	Possible Preventive Actions
Wrong vaccine, route, site, or dosage (amount); or improperly prepared.	Circle important information on the packaging to emphasize the difference between the vaccines.
	Include the brand name with the vaccine abbreviation whenever possible (e.g., PCV13 [Prevnar13]) in orders, medical screens, etc.
	Separate vaccines into bins or other containers according to type and formulation. Use color-coded identification labels on vaccine storage containers.
	Store look-alike vaccines in different areas of the storage unit (e.g., pediatric and adult formulations of the same vaccine on different shelves in the unit).
	Do not list vaccines with look-alike names sequentially on computer screens, order forms, or medical records, if possible.
	Consider using "name alert" or "look-alike" stickers on packaging and areas where these vaccines are stored.
	Consider purchasing products with look-alike packaging from different manufacturers, if possible.
	Establish "Do NOT Disturb" or no-interruption areas or times when vaccines are being prepared or administered.
	Prepare vaccine for one patient at a time. Once prepared, label the syringe with vaccine name.
	Do not administer vaccines prepared by someone else.
	Triple-check work before administering a vaccine and ask another staff member to check.
	Keep reference materials on recommended sites, routes, and needle lengths for each vaccine used in your facility in the medication preparation area.
	Clearly identify diluents if the manufacturer's label could mislead staff into believing the diluent is the vaccine itself.
	Integrate vaccine administration training into orientation and other appropriate education requirements.
	Provide education when new products are added to inventory or recommendations are updated.
	Use standing orders, if appropriate.

1. National Coordinating Council for Medication Error Reporting and Prevention, https://www.nccmerp.org/about-medication-errors

01/05/2021 CS 322033-A

Vaccine Administration Errors

ntive Actions

's identity before administering vaccines.

the importance of avoiding unnecessary distractions or interruptions when staff is ccine.

inister vaccines to one patient at a time. If more than one patient needs vaccines clinical encounter (e.g., parent with two children), assign different providers to each e. Alternatively, bring only one patient's vaccines into the treatment area at a time, ine and patient name.

prone abbreviations to document vaccine administration (e.g., use intranasal route nt the intranasal route—not IN, which is easily confused with IM).

abbreviations.

earance of look-alike names or generic abbreviations on computer screens, if possible.

storage and handling training based on manufacturer guidance and/or

so those with the earliest expiration dates are in the front of the storage unit. Use

vaccines/diluents from storage units and areas where viable vaccines are stored.

exposed to improper temperatures and contact the state or local immunization the vaccine manufacturer.

ers, if appropriate.

es to obtain a complete vaccination history using the immunization information ious medical records, and personal vaccination records.

administration training, including timing and spacing of vaccines, into orientation priate education requirements.

ecially infants, schedule immunization visits after the birthday.

unization schedules for children and adults that staff can quickly reference in clinical cinations may be prescribed and administered.

eets for timing and spacing in your medication preparation area. CDC has vaccine ce for DTaP, Tdap, Hib, PCV13, and polio vaccines to assist health care personnel in catch-up schedule for children.

and patients on how important it is for them to maintain immunization records.

e 11-2, Medication Errors, 2nd ed, by Cohen, Michael. Washington D.C: American Pharmacists Association; 2007.

to report vaccine administration errors to HRS).* To file an electronic report, please see the VAERS website at https://vaers.hhs.gov/reportevent.html

* At this time, COVID-19 vaccination has additional VAERS reporting requirements, including required reporting of vaccine administration errors. Please see https://vaers.hhs.gov/faq.html for more information.

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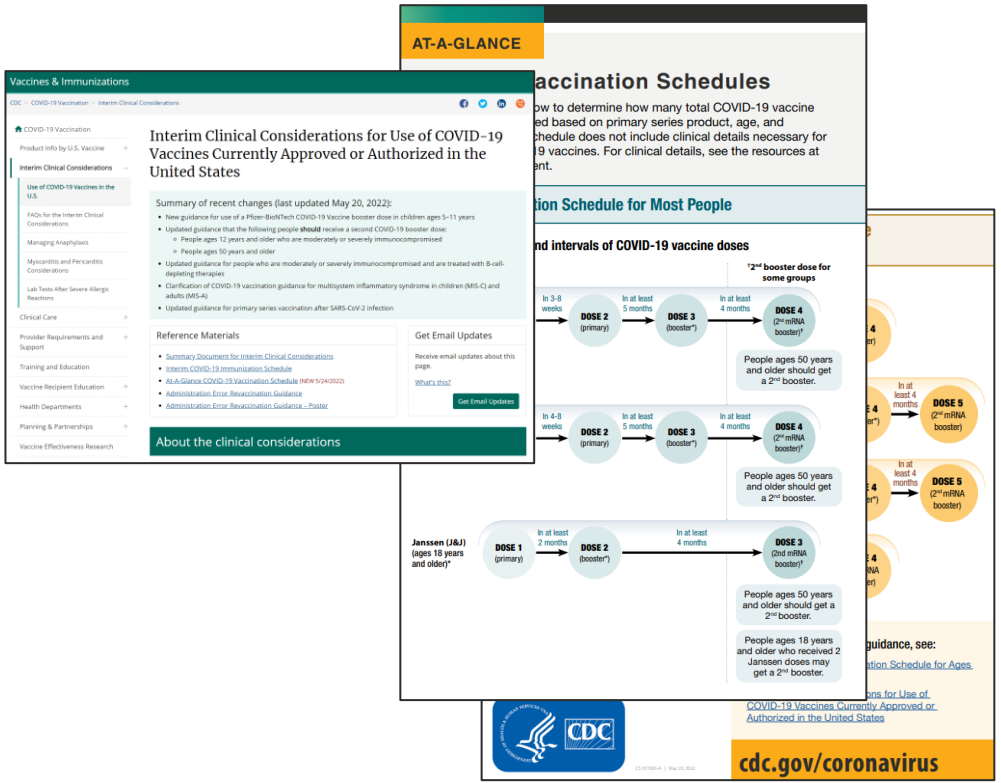
CDC

Interim Clinical Considerations

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
- FAQs for the Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html
- At-A-Glance COVID-19 Vaccination Schedule: https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vacc-schedule-at-a-glance-508.pdf

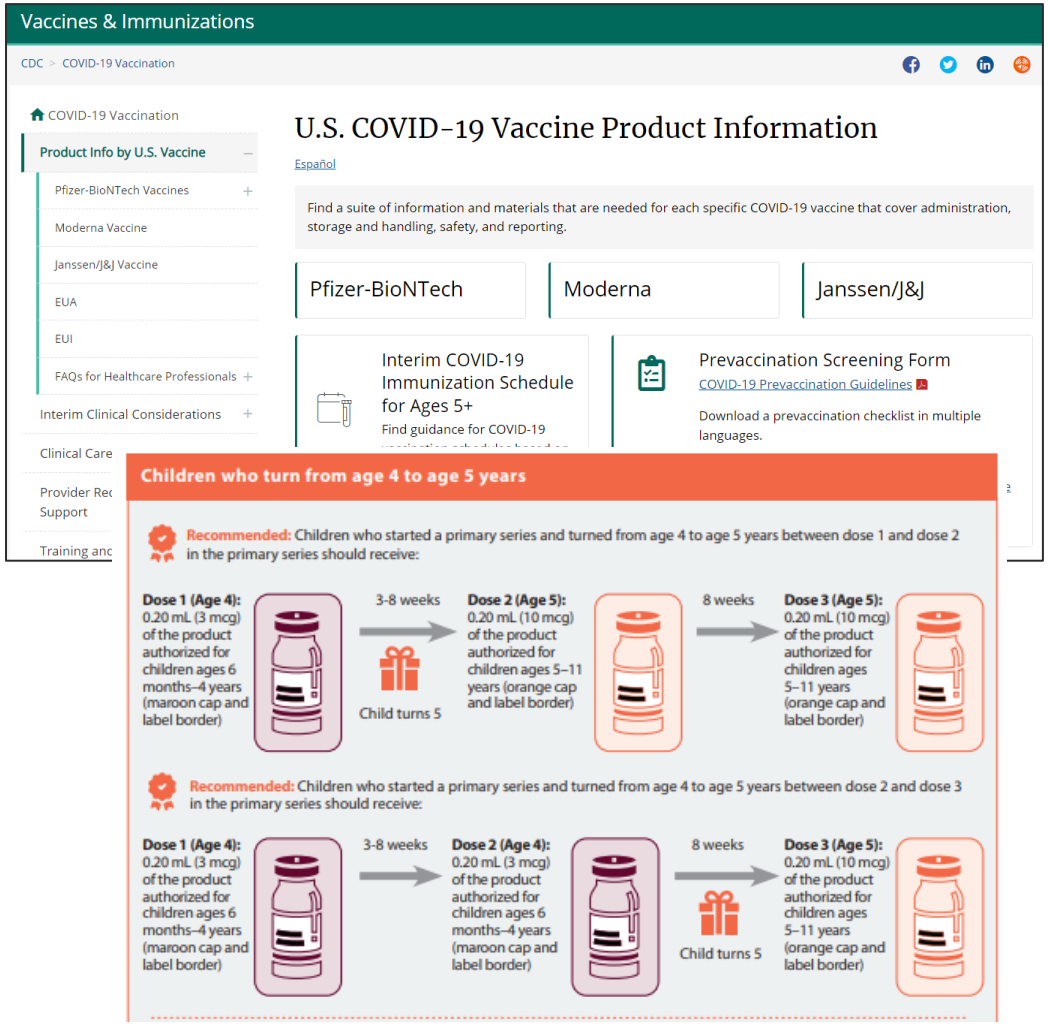


Clinical Resources

- US COVID-19 Vaccine Product Information: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
- Age transition job aids

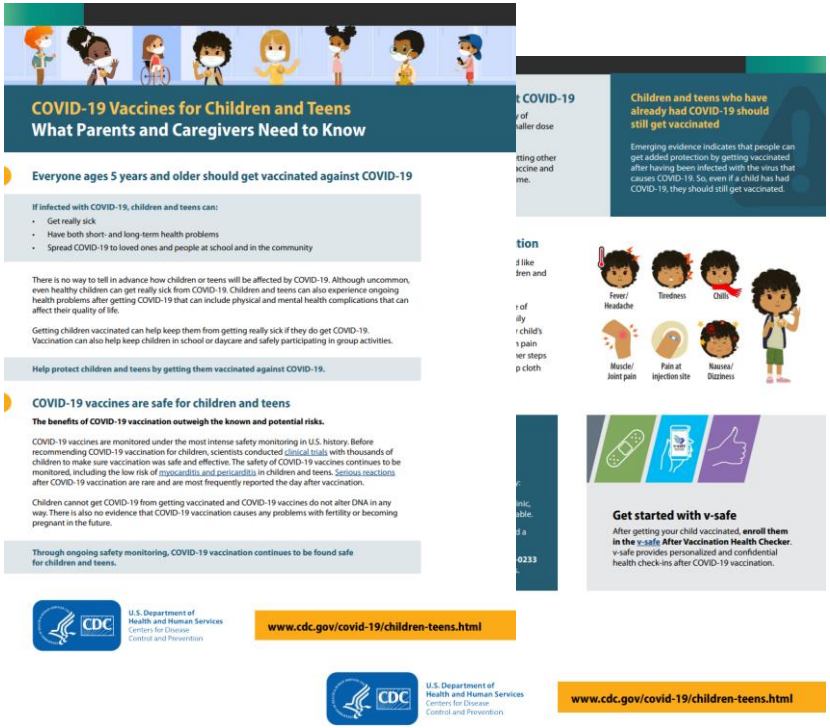
https://www.cdc.gov/vaccines/covid-19/downloads/Moderna-Child-Age-Transition-508.pdf

https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Child-Age-Transition-508.pdf



Resources for Vaccine Recipient Education

- Recipient Education: https://www.cdc.gov/vaccines/covid-19/hcp/index.html
- COVID-19 Vaccination for Children: https://www.cdc.gov/vaccines/covid-19/planning/children.html



Pediatric Vaccine Implementation: Key Considerations for Clinicians

Lisa M. Costello, MD, MPH, FAAP

Pediatric COVID-19 Vaccine Implementation: Key Considerations for Clinicians

June 25, 2022

Lisa M. Costello, MD, MPH, FAAP
Immediate Past President, AAP West Virginia Chapter
Member, AAP Committee on State Government Affairs (COSGA)

American Academy of Pediatrics
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No financial disclosures

Hope For the Future: Covid-19 Vaccination for Children 6 Months and Older

News Release

American Academy of Pediatrics Applauds CDC Approval of Safe, Effective COVID-19 Vaccines for Children Ages 6 Months and Older

Home / News Room / American Academy of Pediatrics Applauds CDC Approval of Safe, Effective COVID-19 Vaccines for Children Ages 6 Months and Older

ITASCA, IL—Today, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommended two COVID-19 vaccines: one for children ages 6 months through 4 years and one for ages 6 months through 5 years. The American Academy of Pediatrics (AAP) supports this recommendation and encourages pediatricians to promote vaccination and give COVID-19 vaccines. The AAP urges families to check with their pediatrician and community health care providers about how to get their children vaccinated, pending a final recommendation from the CDC.

Speaking at the ACIP meeting, pediatrician Yvonne "Bonnie" Maldonado, MD, FAAP, chair of the AAP Committee on Infectious Diseases, emphasized the importance of these vaccines for the youngest members of our community, who have waited the longest for this protection.

"Pediatricians know the power of vaccines to protect infants, children, adolescents and entire communities against deadly and debilitating infectious diseases," Dr. Maldonado said. "We've successfully immunized millions of children and adolescents to protect them from COVID-19. Families with infants and toddlers need and deserve the same chance to protect their children against this virus."

Authorization of the Moderna and Pfizer-BioNTech vaccines for children ages 6 months and older will extend the protection of immunization to the last segment of our population awaiting protection. More work remains to vaccinate older children and adolescents, as well. As of June 8, more than 23 million children ages 5 to 17 have received two doses of COVID vaccine. Another 26 million in this age group have yet to receive any doses.

"We must not let up in our efforts to make sure all families can benefit from the protection of these vaccines," said AAP President Moira Szilagyi, MD, PhD, FAAP. "Pediatricians are ready to have these conversations, and parents and caregivers should feel comfortable bringing their questions to their trusted pediatrician to have their questions addressed."

Immediately after the ACIP vote to recommend the Moderna and Pfizer-BioNTech COVID-19 vaccines for children ages 6 months and older, the AAP published its updated recommendations for COVID-19 vaccine, including a strong recommendation for children in this age group to receive the vaccine pending the final decision by the CDC. The AAP recommends COVID-19 vaccination for all children and adolescents 6 months of age and older who do not have contraindications using a vaccine authorized for use for their age. The AAP encourages all states to work with pediatrician practices to make accessing COVID vaccine as simple as possible.

The updated AAP policy statement will be published online in *Pediatrics* and also can be found by visiting the AAPorg website.

More resources:

- HealthyChildren.org: **What Should Parents Know About the COVID Vaccine for Kids Under 5?**
- AAPorg: **Critical updates on COVID-19**
- AAP News: **COVID-19 collection**

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For Release:
6/18/2022

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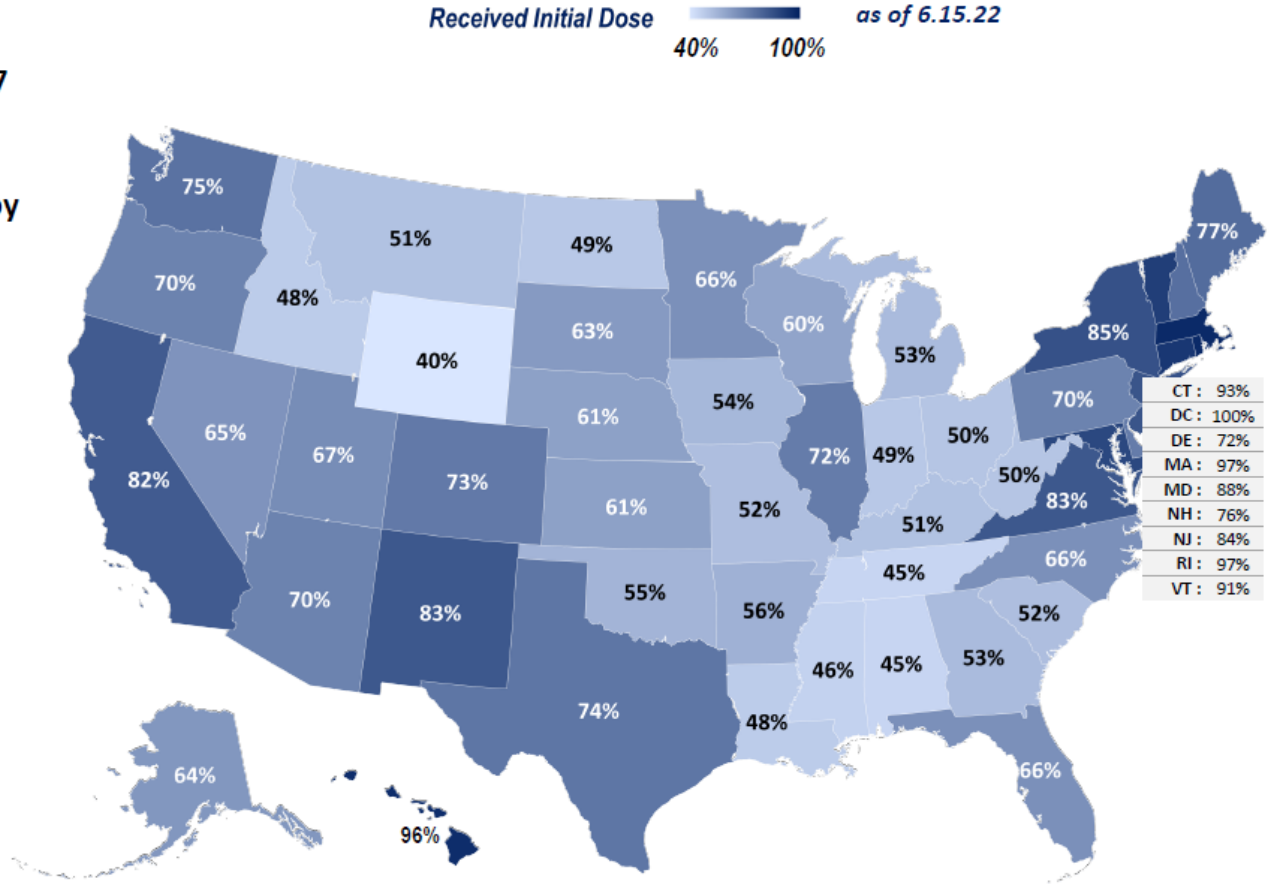
The Challenges Ahead

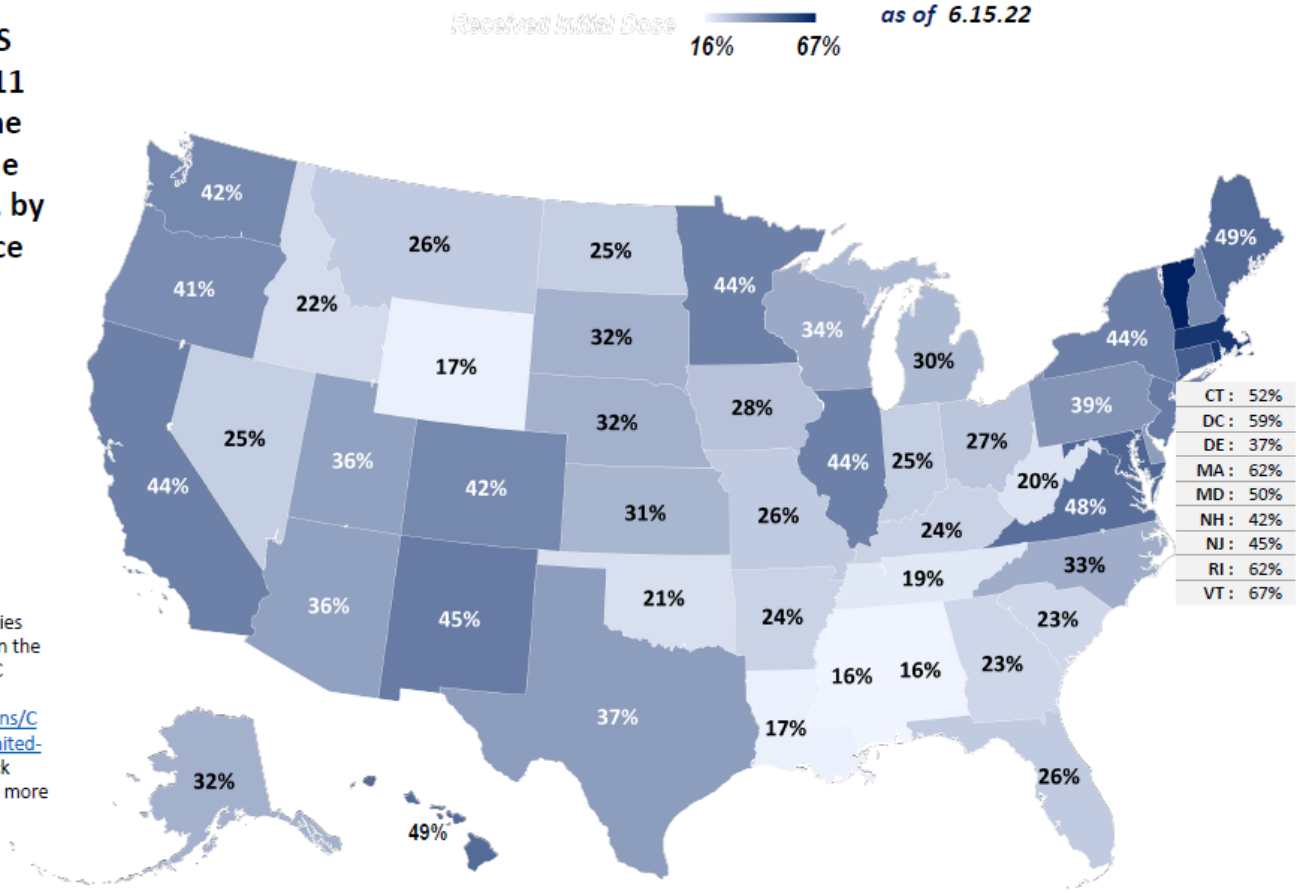
Access Communication Education

Proportion of US Children Ages 12-17 Who Received the Initial Dose of the COVID-19 Vaccine, by State of Residence



Source: AAP analysis of data series titled "COVID -19 Vaccinations in the United States, Jurisdiction". CDC COVID -19 Data Tracker (URL: https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdi/unsk-b7fc). Check state web sites for additional or more recent information.

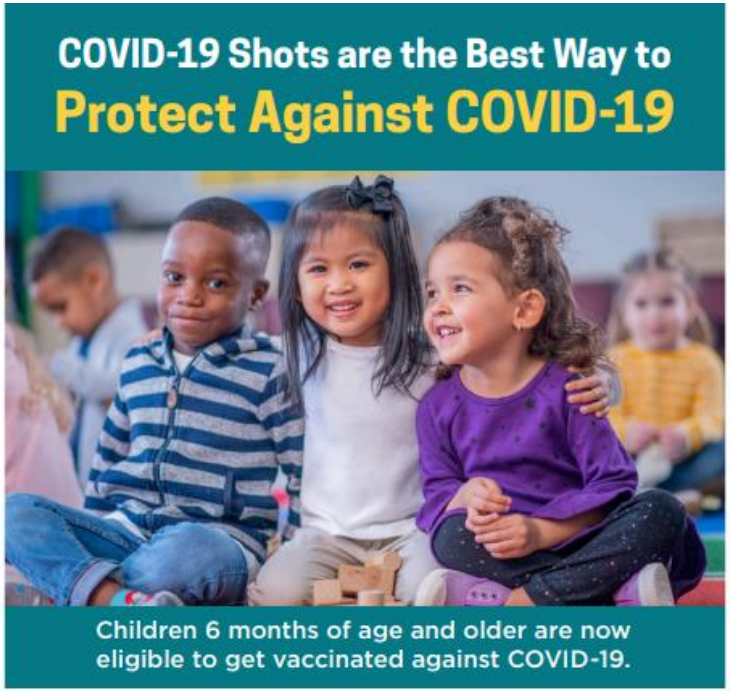
Proportion of US Children Ages 5-11 Who Received the Initial Dose of the COVID-19 Vaccine, by State of Residence



Source: AAP analysis of data series titled "COVID -19 Vaccinations in the United States, Jurisdiction". CDC COVID -19 Data Tracker (URL: https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdi/unsk-b7fc). Check state web sites for additional or more recent information.

Help Promote a Culture of Vaccination

- Emphasize your state's track record of success in delivering immunizations to children
- Talk about childhood immunizations as the norm
- Emphasize safety—child safety, school safety, community safety
- Improve access and availability of vaccines
- Cost savings attributed to childhood immunizations are immense—remind the public of this fact
- Engage trusted voices—pediatricians are here to help
- Offer education and communication resources


COVID-19 Shots are the Best Way to
Protect Against COVID-19
Children 6 months of age and older are now eligible to get vaccinated against COVID-19.
Learn more: vaccinate.wv.gov
WV COVID-19 Vaccine Info Line:
1-833-734-0965

Joint Interagency Task Force on COVID-19

June 20, 2022

Training for COVID-19 Vaccines:
Pfizer BioNTech ages 6 month through 4 years
Moderna* ages 6 months through 5 years

Krista D. Capehart, PharmD, MS, BCACP, FAPhA
WV Board of Pharmacy
WVU School of Pharmacy

Lisa M. Costello, MD, MPH, FAAP
WV Chapter American Academy of Pediatrics
WVU School of Medicine

VACCINATE.WV.GOV
#CommunityImmunityWV

*Note: The ACIP will meet June 23, 2022 to discuss recommendations for Moderna COVID-19 vaccine for ages 6 through 17 years. Information forthcoming.

Sponsored by:

West Virginia Immunization Network

West Virginia Chapter
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American Academy of Pediatrics
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Join Us for Our Upcoming Webinar:

COVID-19 Vaccination of Children 6 Months of Age and Up

June 29, 2022 • 12:00 PM - 1:00 PM

Speakers:

Krista D. Capehart, PharmD, MS, BCACP, FAPhA is a Clinical Professor in the Department of Clinical Pharmacy and Director of the Wigner Institute for Advanced Pharmacy Practice, Education and Research at West Virginia University School of Pharmacy. She is also the Director of Professional and Regulatory Affairs at the West Virginia Board of Pharmacy. *More details **here**.*

Jacob T. Kilgore, MD, MPH, FAAP, is an Assistant Professor in the Department of Pediatrics, Division of Pediatric Infectious Diseases at the Marshall University Joan C. Edwards School of Medicine (MU-JCESOM). *More details **here**.*

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AAP State Chapters: Pulling in the Same Direction

https://www.aap.org/en/community/chapter-websites/

More from the AAP

https://www.healthychildren.org/

https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/

Contact stgov@aap.org for more information on connecting with the AAP chapter in your state. Reach me at costello.lisa@gmail.com.

Q&A/Discussion

Selected Resources

Dr. Jackson

- Slide 7 - https://covid19.who.int/
- Slide 8 - https://covid.cdc.gov/covid-data-tracker/#county-view
- Slide 12 - https://covid.cdc.gov/covid-data-tracker/#wastewater-surveillance
- Slide 13 - https://covid.cdc.gov/covid-data-tracker/#variant-proportions
- Slide 14 - https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total
- Slide 15 - https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends
- Slide 18 - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html
- Slide 22 - https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/interactive-ventilation-tool.html

Dr. Oliver

- Slide 69 - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-c
- Slide 69 - https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf
- Slide 70 - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
- Slide 70 - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html
- Slide 70 - https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vacc-schedule-at-a-glance-508.pdf
- Slide 71 - https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
- Slide 71 – https://www.cdc.gov/vaccines/covid-19/downloads/Moderna-Child-Age-Transition-508.pdf
- Slide 71 - https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Child-Age-Transition-508.pdf
- Slide 72 - https://www.cdc.gov/vaccines/covid-19/hcp/index.html
- Slide 72 - https://www.cdc.gov/vaccines/covid-19/planning/children.html

Selected Resources

Dr. Costello

- Slide 84 - https://www.aap.org/en/community/chapter-websites/
- Slide 85 - https://www.healthychildren.org/English/Pages/default.aspx
- Slide 85 - https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/

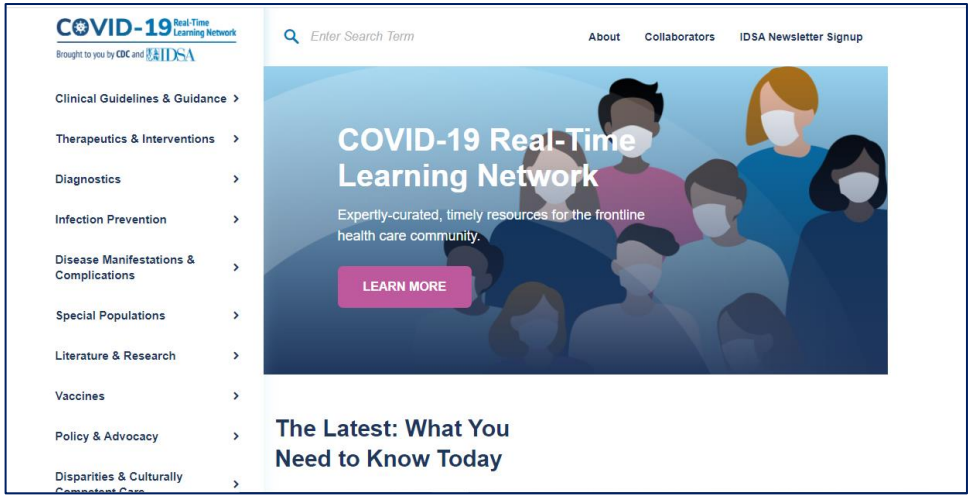
Program Links:

- This webinar is being recorded and can be found with the slides online at https://www.idsociety.org/cliniciancalls
- COVID-19 Real-Time Learning Network: https://www.idsociety.org/covid-19-real-time-learning-network/
- Vaccine FAQ: https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/

COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.



Specialty Society Collaborators

American Academy of Family Physicians
American Academy of Pediatrics
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American College of Physicians
American Geriatrics Society
American Thoracic Society
Pediatric Infectious Diseases Society
Society for Critical Care Medicine
Society for Healthcare Epidemiology of America
Society of Hospital Medicine
Society of Infectious Diseases Pharmacists

www.COVID19LearningNetwork.org
@RealTimeCOVID19
#RealTimeCOVID19

CDC-IDSA Partnership: Clinical Management Call Support

FOR WHOM?

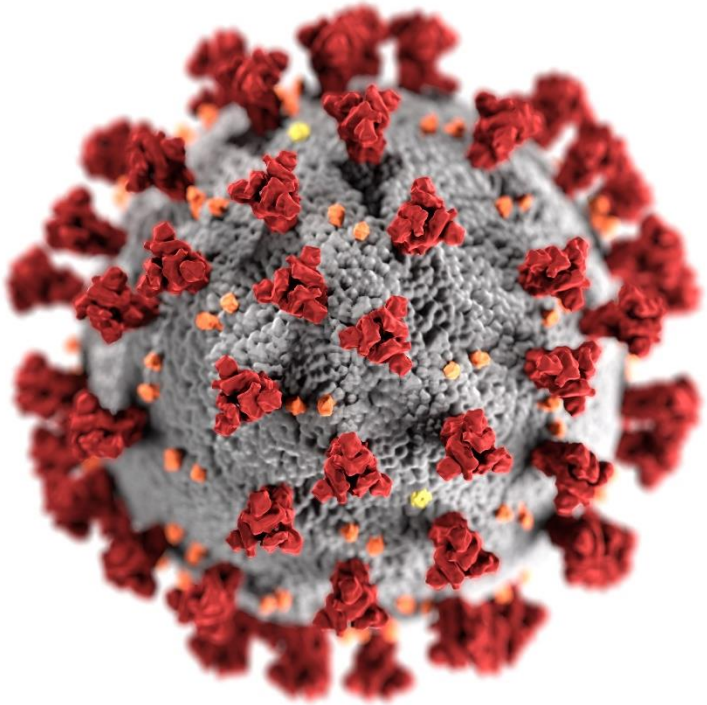
- Clinicians who have questions about the clinical management of COVID-19

WHAT?

- Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

HOW?

- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form



IDSA
Infectious Diseases Society of America

cdc.gov/coronavirus

Continue the conversation on Twitter

@RealTimeCOVID19
#RealTimeCOVID19

We want to hear from you!

Please complete the post-call survey.

A recording of this call, slides and the answered Q&A will be posted at **www.idsociety.org/cliniciancalls**

-- library of all past calls available --

Contact Us:

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