Washington State Department of Health

COVID-19 BIVALENT BOOSTER SAFETY AND VACCINE ADMINISTRATION

November 8, 2022

Before We Start…

- All participants will be muted for the presentation.
- You may ask questions using the Q&A box, and questions will be answered at the end of the presentation.
- Continuing education is available for nurses and pharmacists/pharmacy techs attending the webinar or watching the recording. If you're watching in a group setting and wish to claim CE credit, please make sure you register for the webinar and complete the evaluation as an individual.
- You can find more information on our Web Page.

Learning Objectives

1. Discuss safety studies for COVID-19 bivalent vaccines
2. Describe updated COVID-19 bivalent vaccine schedule
3. Identify ways to address COVID-19 bivalent vaccine administration errors

Presenters from the WA Department of Health

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Continuing Education

This continuing nursing education activity was approved by the Montana Nurses Association, an accredited approver with distinction by the American Nurses Credentialing Center's Commission on Accreditation. Upon successful completion of this activity, 1.0 contact hours will be awarded.

This knowledge activity was approved by the Washington State Pharmacy Association for 1.0 contact hours. The Washington State Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education.

Disclosures

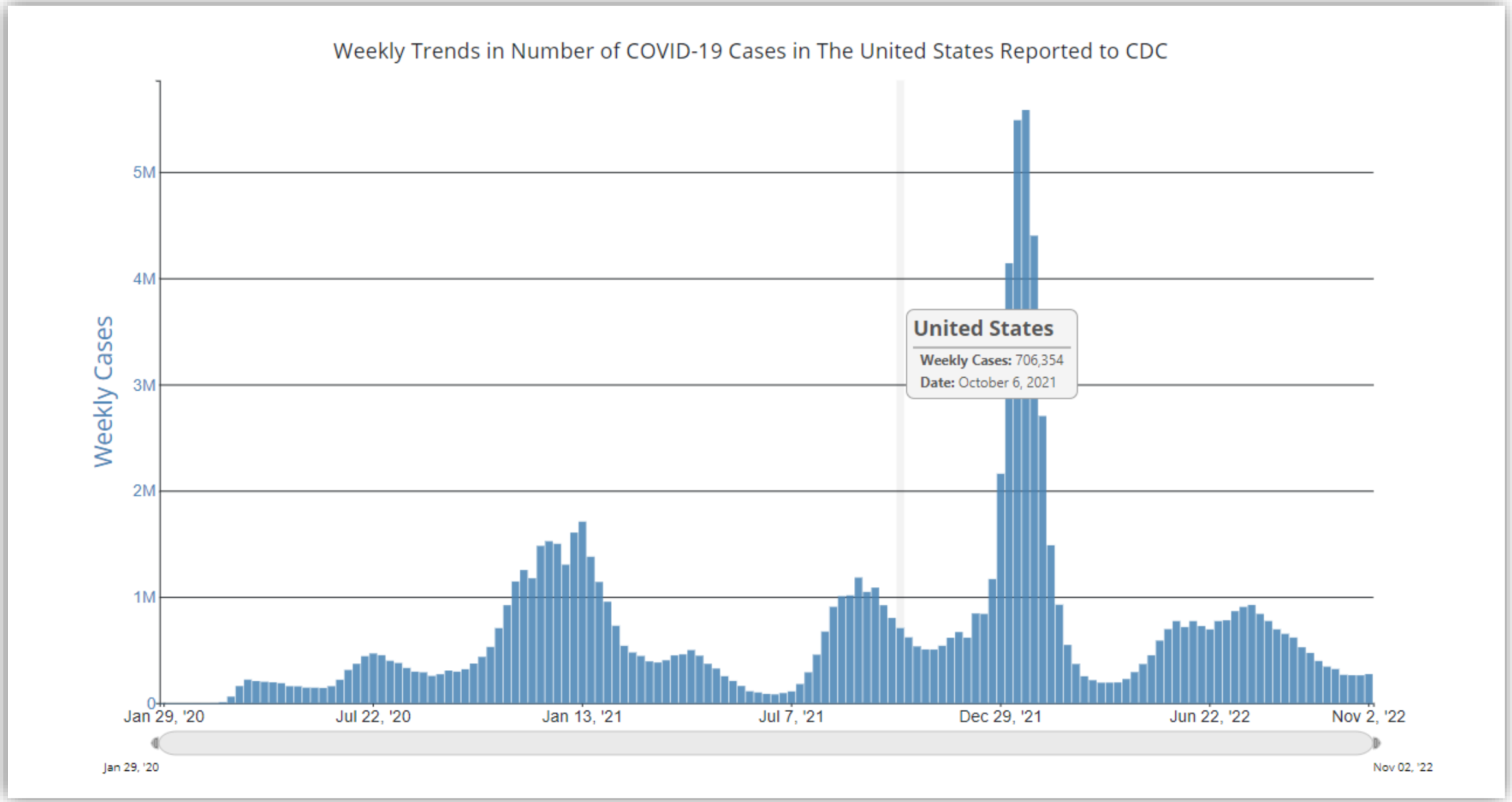
The planners and speaker of this activity have no relevant financial relationships with any commercial interests pertaining to this activity.

Information about obtaining CEs will be available at the end of this webinar.

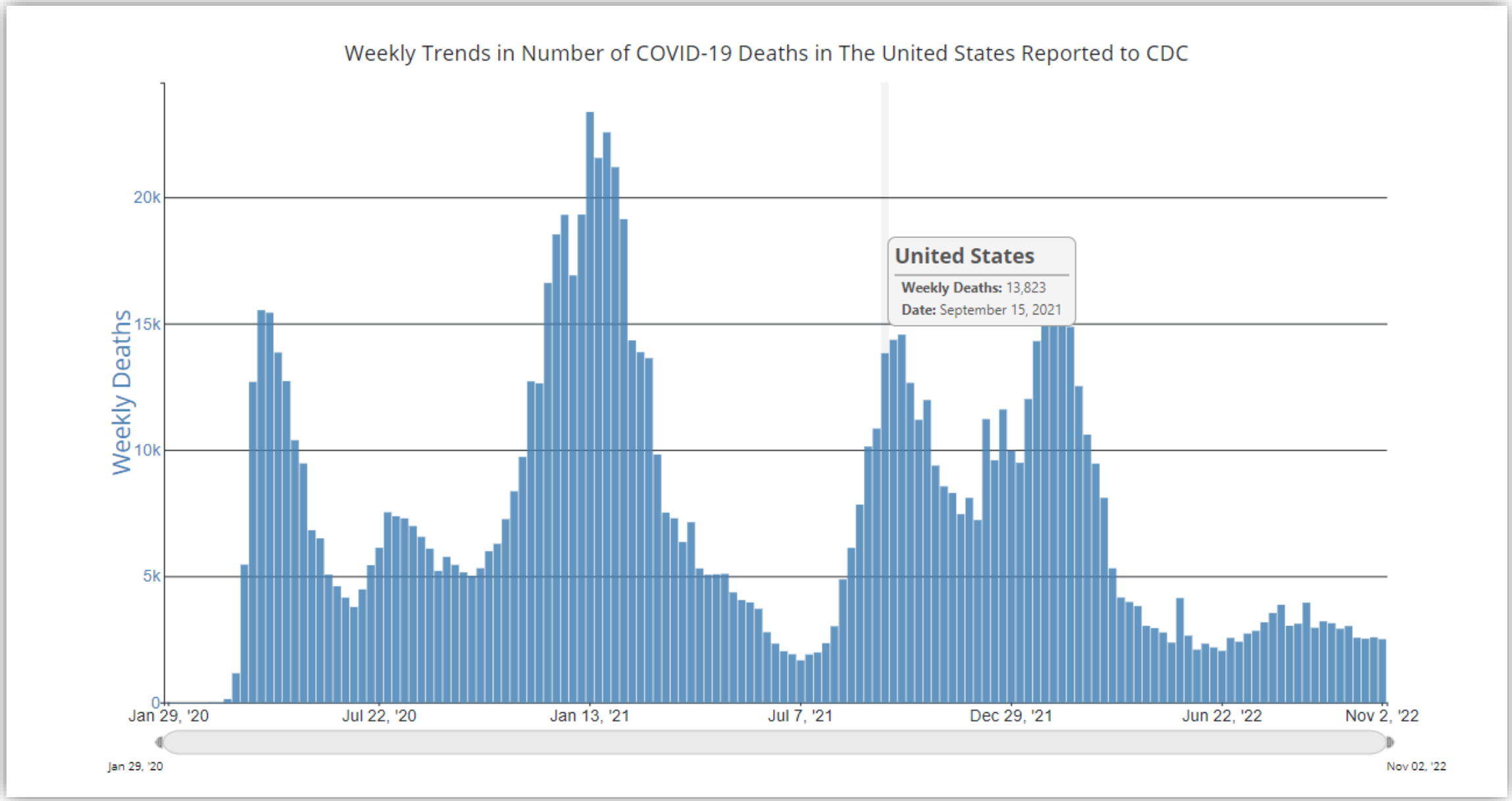
COVID-19 Vaccine Safety

KATHY BAY, DNP, RN, CENP

Why Vaccinate Against COVID-19?



CDC COVID data dashboard available at [CDC COVID Data Tracker: Daily and Total Trends](). Accessed 11-04-2022

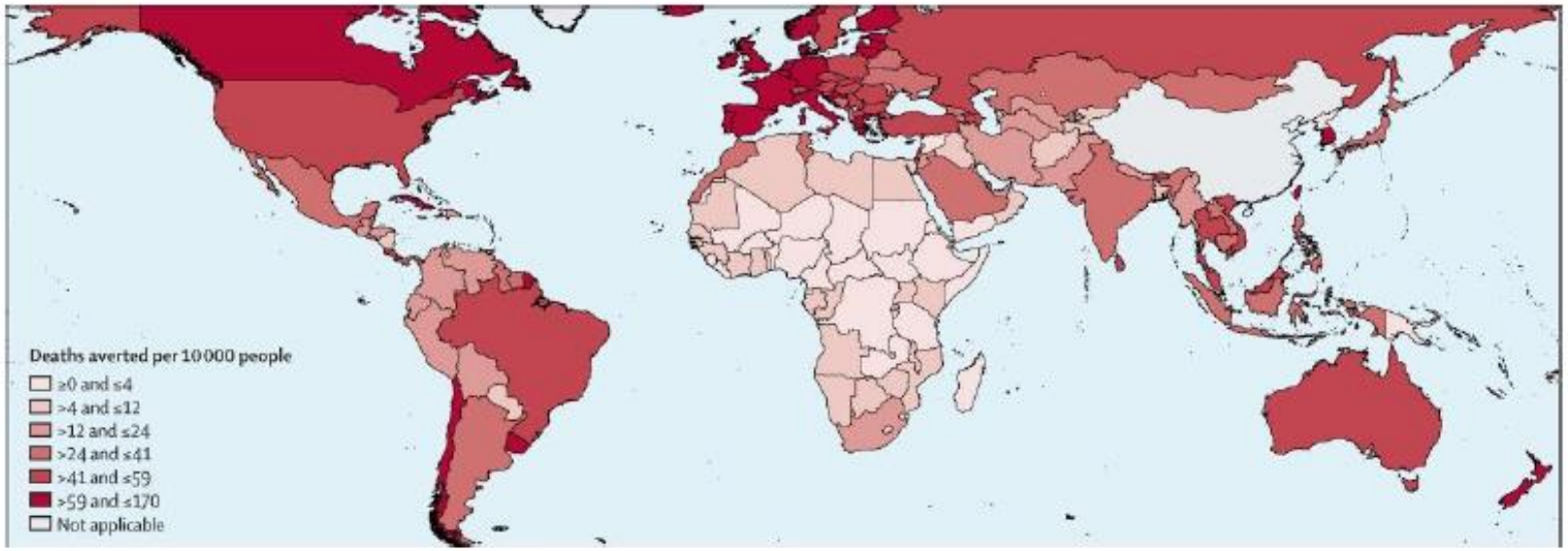


CDC COVID data dashboard available at [CDC COVID Data Tracker: Daily and Total Trends](). Accessed 11-04-2022

Global impact of the first year of COVID-19 vaccinations:

Mathematical model of transmission and infection based on official reported COVID-19 deaths, 185 countries, December 2020—December 2021

- COVID-19 vaccinations are estimated to have prevented **13.7-15.9** million deaths
- This represents an estimated **63% reduction in** total COVID deaths globally

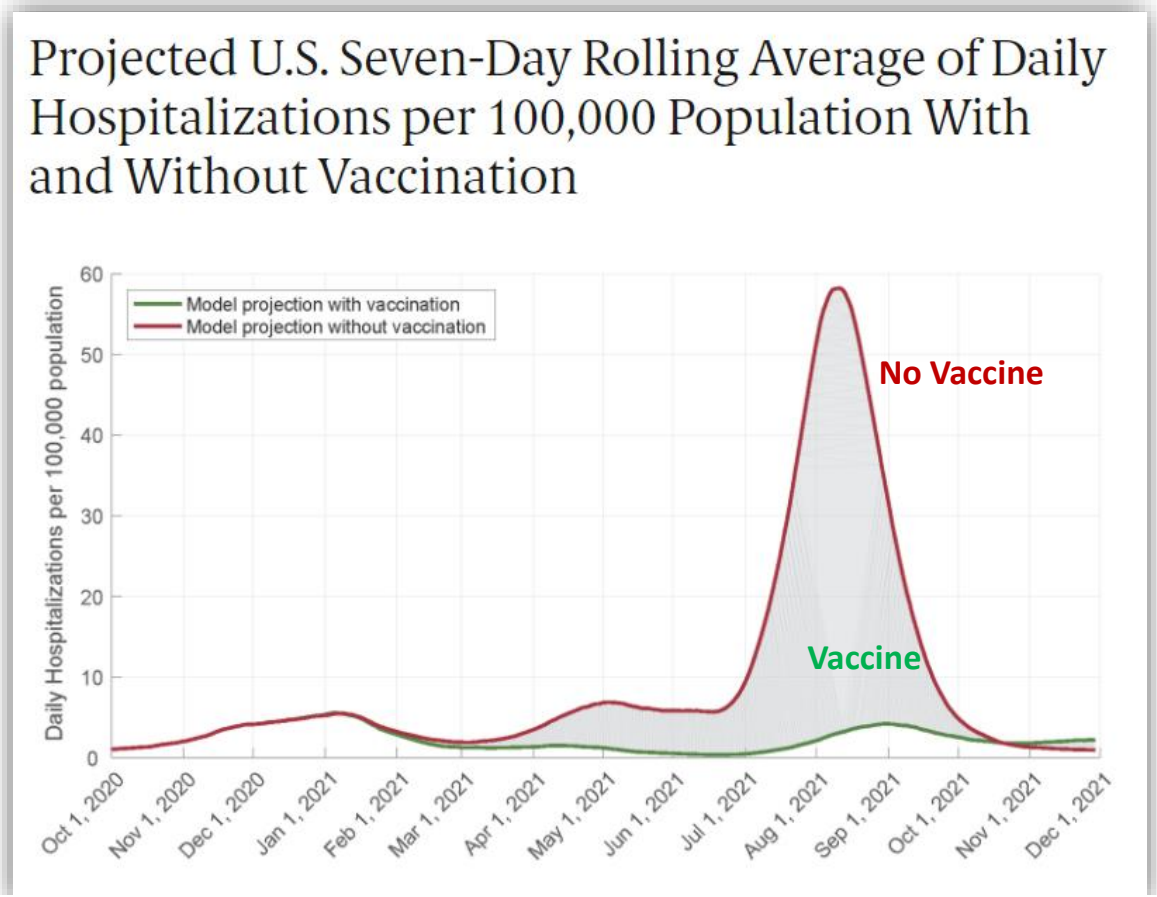


Watson, Barnsley, Toor et al. Lancet Infectious Diseases. 22:9(P1293-1302). https://doi.org/10.1016/S1473-3099(22)00320-6

Impact of U.S. Vaccination Program

The Commonwealth Fund Report: Improving Health Care Quality:

- Estimated U.S. vaccination program prevented more than 10.3 million additional COVID-19 cases
- 4.9 times higher than during 2021

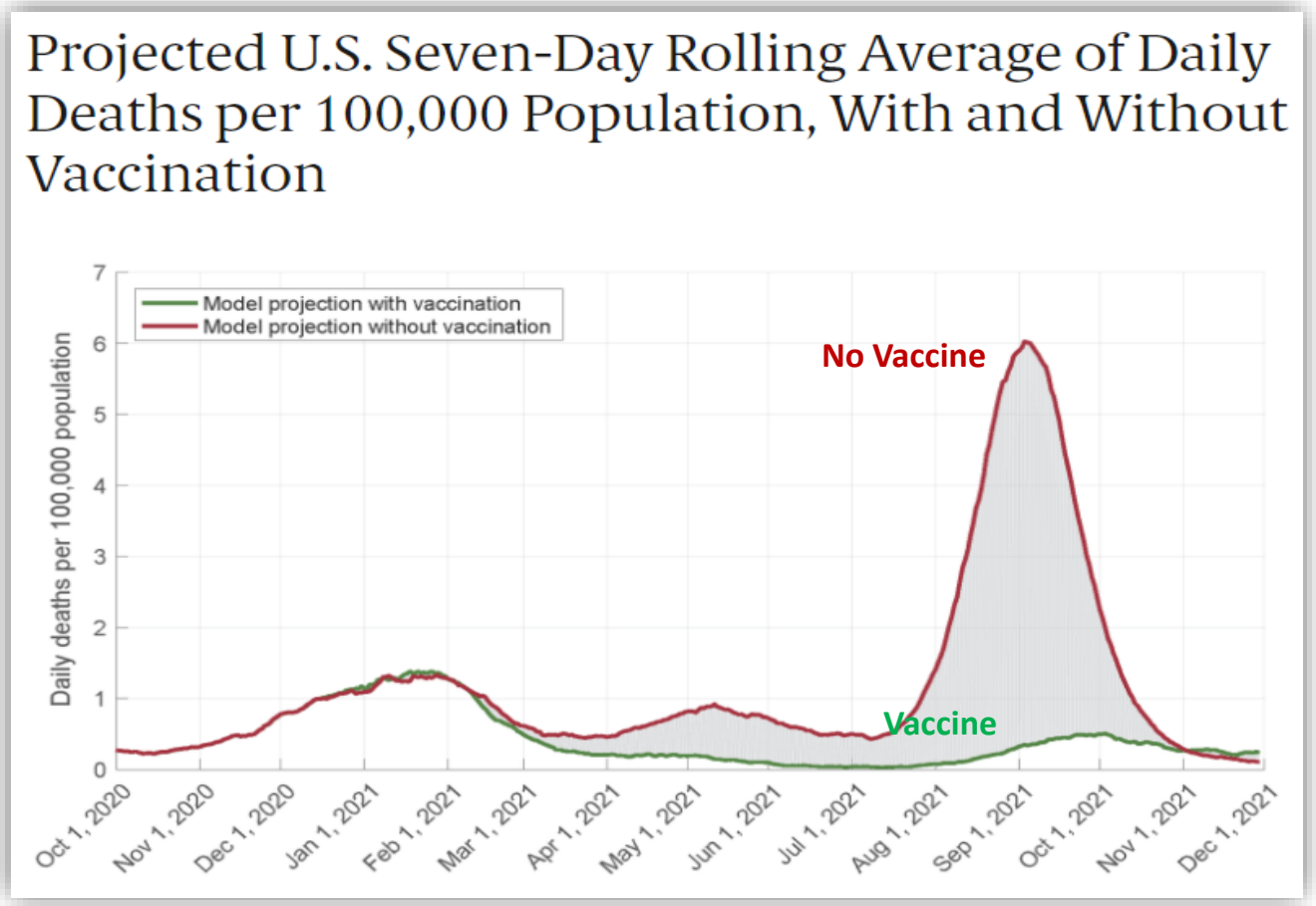


Source: Eric C. Schneider et al., *The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted?* (Commonwealth Fund, December 2021). https://doi.org/10.26099/3542-5n54

Impact of U.S. Vaccination Program

The Commonwealth Fund Report: Improving Health Care Quality:

- Estimated U.S. vaccination program prevented 1.1 million additional COVID-19 deaths by November 2021
- Without vaccinations, daily deaths could have:
  - Jumped as high as 21,00 per day
  - Nearly 5.2 times the level of record peak in January 2021
  - Overall been 3.2 times higher



Source: Eric C. Schneider et al., *The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted?* (Commonwealth Fund, December 2021). https://doi.org/10.26099/3542-5n54

Ongoing Impact of Vaccinations

The Commonwealth Fund Estimates of COVID-19 Attributable Deaths, Hospitalizations, Infections, and Health Care Costs Averted by the U.S. Vaccination Program December 12, 2020, and March 31, 2022

Deaths	2,265,222	2,051,041 to 2,467,683
Hospitalizations	17,003,960	15,680,556 to 18,250,413
Infections	66,159,093	58,774,953 to 73,787,291
Health care costs	$899.4 billion	$825.3 billion to $978.5 billion

* Credible intervals reflect the range of normal uncertainty associated with estimates.

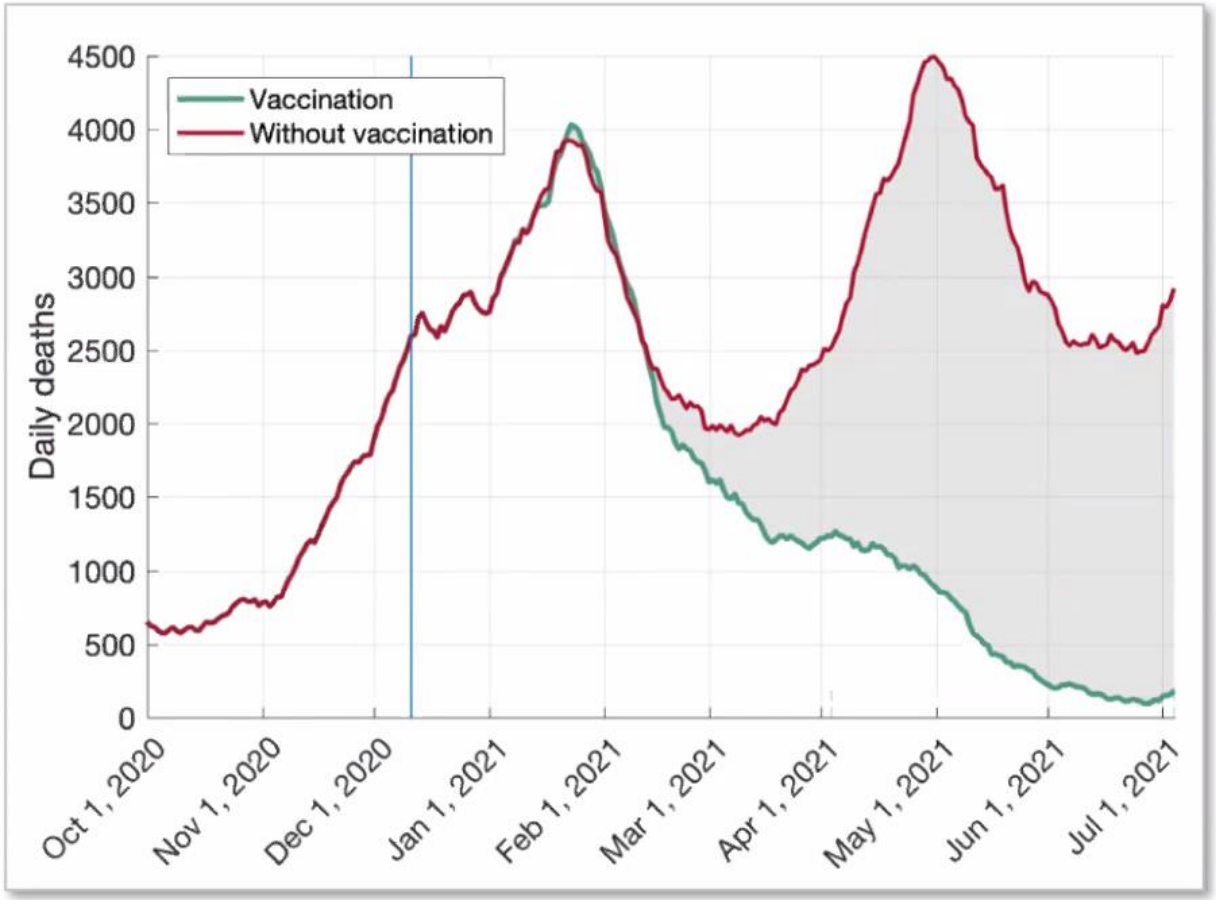
Data: Authors' analysis

Source: Eric C. Schneider et al., "Impact of U.S. COVID-19 Vaccination Efforts: An Update on Averted Deaths, Hospitalizations, and Health Care Costs Through March 2022," *To the Point* (blog), Commonwealth Fund, Apr. 8, 2022. https://doi.org/10.26099/d3dm-fa91

Source: Impact COVID Vaccination Efforts: Update Through March 2022 | Commonwealth Fund

The rapid COVID-19 vaccination rollout and collective efforts of CDC and partners ***saved many lives***

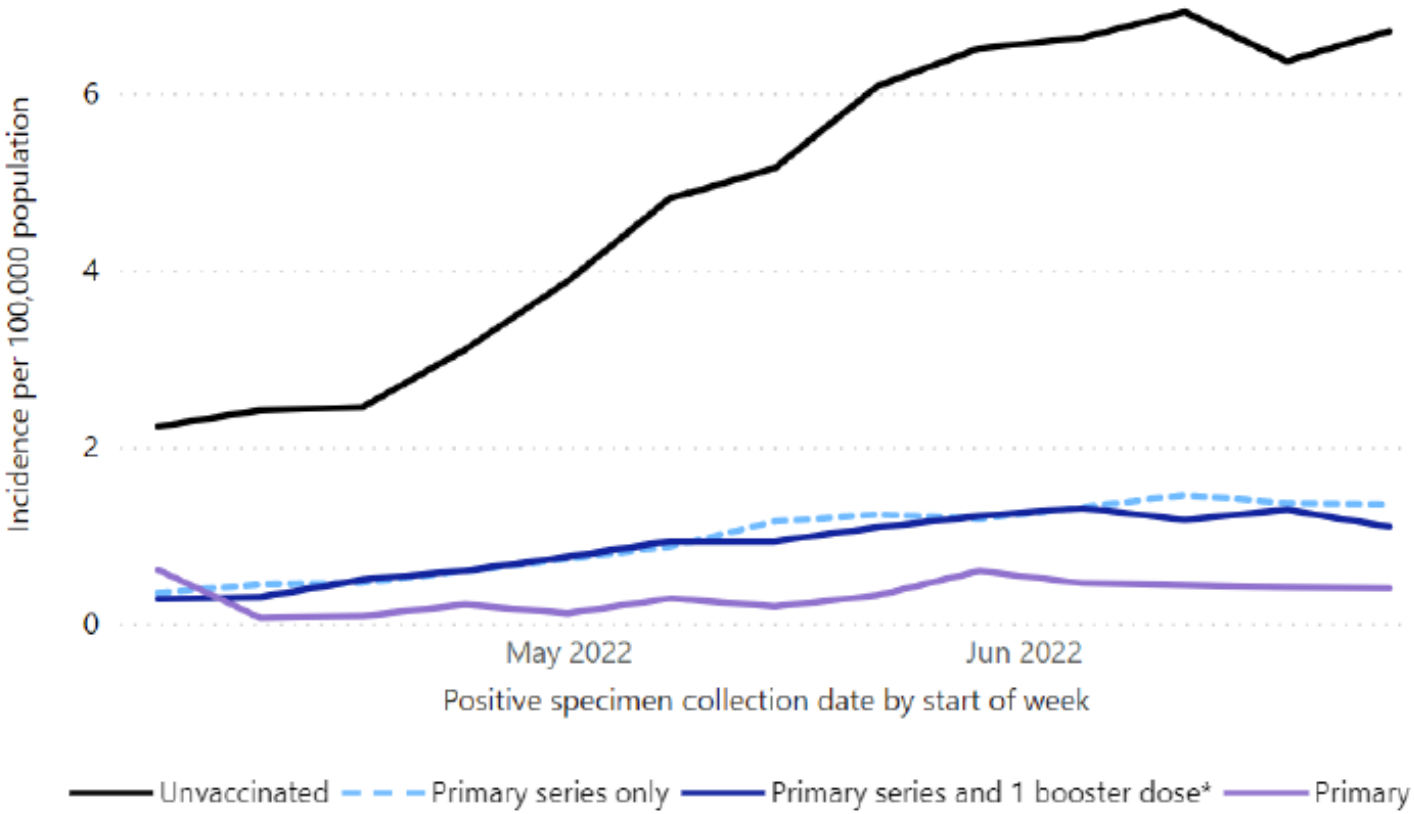
Estimated U.S. seven-day rolling average of daily deaths with and without vaccination



Data as of July 2021 suggest there had been **no COVID-19 vaccination program, daily deaths from COVID-19 would have created a second "2021 spring surge"— of nearly 4,500 deaths per day**—potentially larger than the first wave of the year, which peaked at 4,000 deaths per day in January 2021.

Source: Deaths & Hospitalizations Averted by Rapid US Vaccination Rollout | Commonwealth Fund

Death Rates by Vaccination Status and Receipt of 1st and 2nd Booster Doses Among People Ages ≥50 Years April 3–July 2, 2022 (25 U.S. Jurisdictions)



In June 2022, people ages 50 years and older with **≥2 booster doses** had **14 times** lower risk of dying from COVID-19, compared to **unvaccinated** people and **3 times** lower risk of dying from COVID-19 than people with **one booster dose**

*Includes either a booster or additional dose.
https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccinbooine-status. Accessed August 24, 2022

Source: H Scobie Advisory Committee on Immunization Practices presentation; 09-01-2022 meeting. Available at ACIP September 1-2, 2022 Presentation Slides | Immunization Practices | CDC

Risk of Severe COVID-19 Illness

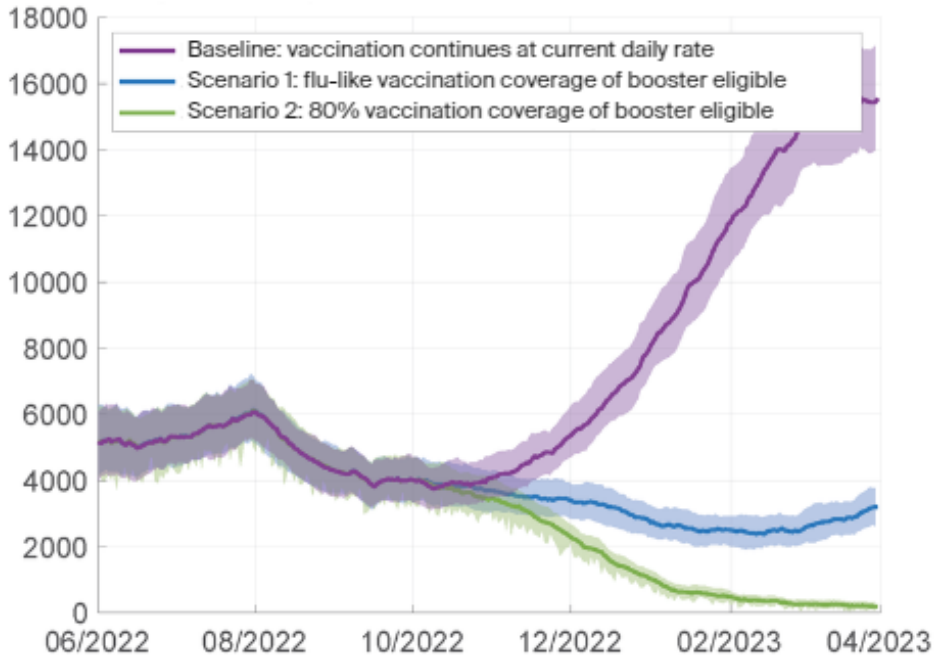
- Unvaccinated people at higher risk of severe illness compared with vaccinated people
- Most (75%) vaccinated people with severe COVID-19 illness have multiple risk factors:
  - Older age (most ≥65 years, but with risk increasing with age)
  - Underlying medical conditions (with risk increasing with number of underlying conditions)
    - Immunosuppression
    - Diabetes mellitus
    - Chronic kidney disease
    - Chronic lung disease
    - Chronic cardiovascular disease
    - Chronic neurologic disease
- Antiviral drugs can help reduce risk of severe illness in people at higher risk, regardless of vaccination status

Yek et al. MMWR 2022;71:19–25. https://www.cdc.gov/mmwr/volumes/71/wr/mm7101a4.htm; Taylor et al. MMWR 2022;71:466-473: http://dx.doi.org/10.15585/mmwr.mm7112e2 and unpublished COVID-NET data, as described here: Malden et al. MMWR 2022; 71(25);830-833: https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e2.htm ; Gold et al. MMWR 2022; 71(25);825-829: https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e1.htm ; Najjar-Debbiny et al. CID 2022;, ciac443, https://doi.org/10.1093/cid/ciac443 Dryden-Peterson et al. medRxiv 2022.06.14.22276393; https://doi.org/10.1101/2022.06.14.22276393

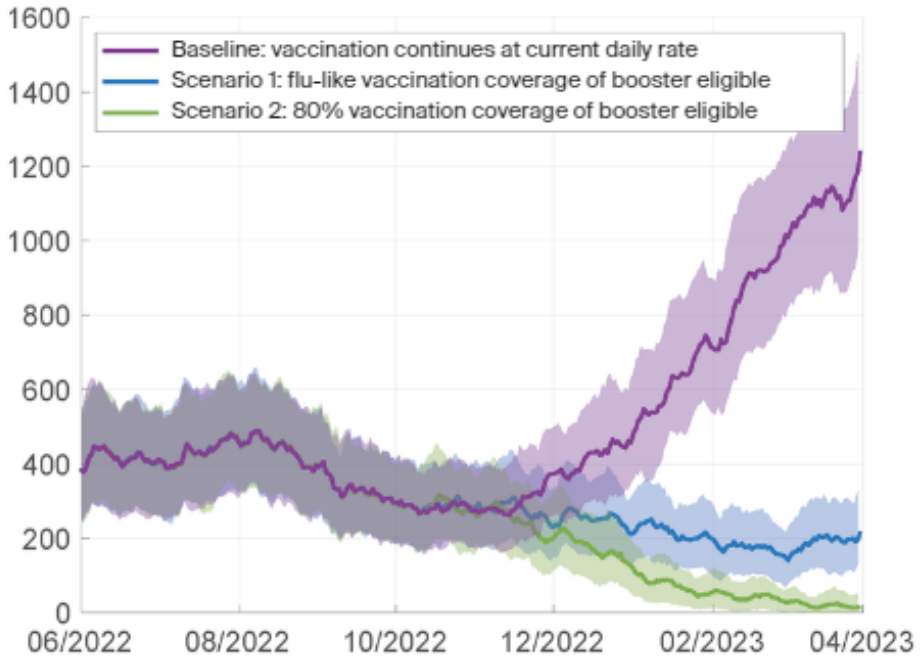
Source: H Scobie Advisory Committee on Immunization Practices presentation; 09-01-2022 meeting. Available at ACIP September 1-2, 2022 Presentation Slides | Immunization Practices | CDC

Projected Seven-Day Rolling Average of COVID-19 Hospitalizations and Deaths in the U.S., Under Different Booster Vaccination Coverage Scenarios

Projected hospitalizations



Projected deaths



Note: In the baseline scenario, vaccination rates are held constant at the average of the daily vaccination rate for August 2022 until the end of March 2023.
Data: Authors' analysis.

Source: Meagan C. Fitzpatrick et al., "A Fall COVID-19 Booster Campaign Could Save Thousands of Lives, Billions of Dollars," *To the Point* (blog), Commonwealth Fund, Oct. 5, 2022. https://doi.org/10.26099/hy8p-mf92

Source: The Commonwealth Fund available: Fall COVID Booster Campaign Save Thousands Lives, Billions Dollars | Commonwealth Fund. Accessed 11-04-2022

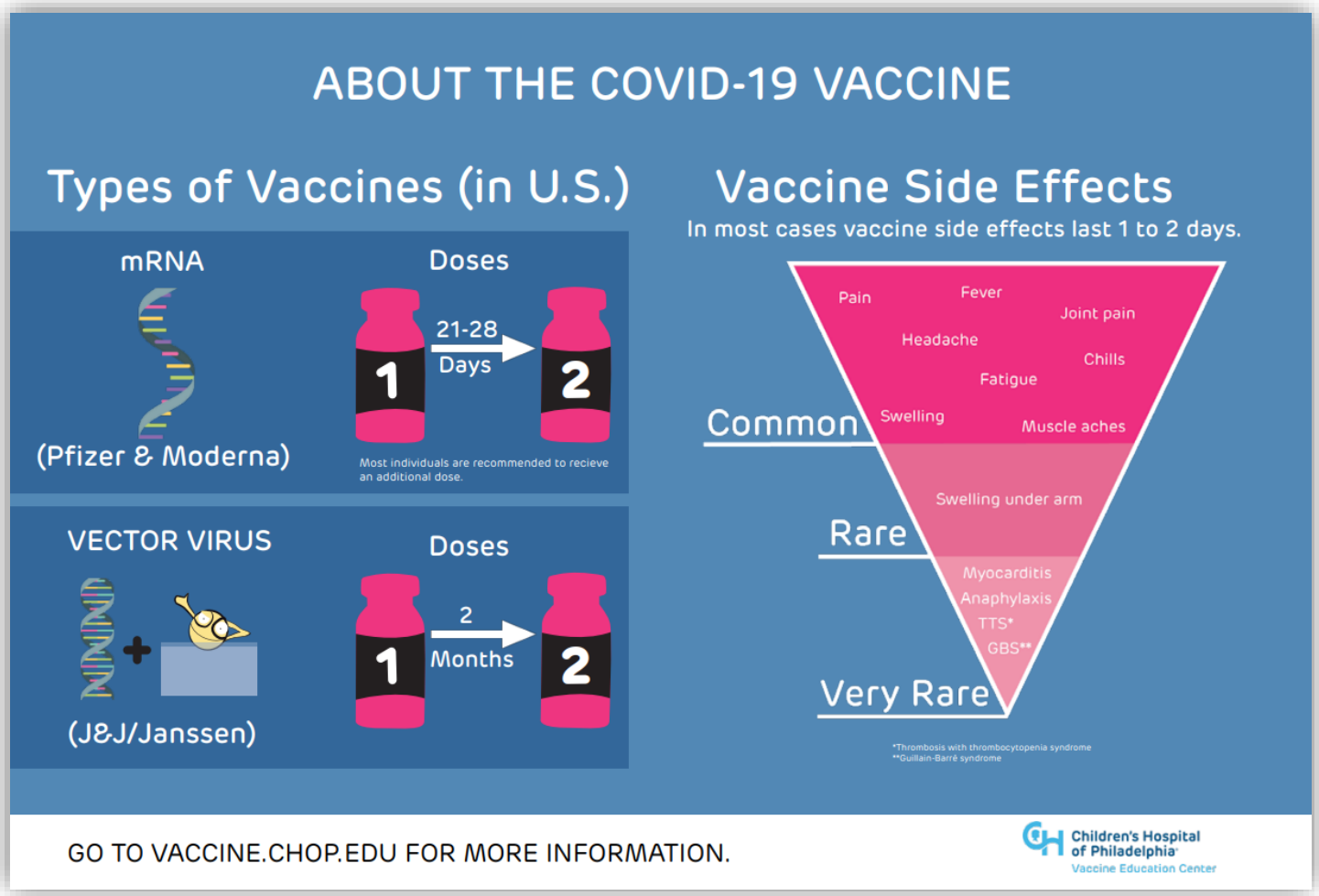
Vaccine Side Effects and Safety

Vaccine Safety

- COVID-19 vaccines were evaluated in tens of thousands of people during clinical trials
- Pfizer and Moderna vaccines are both fully licensed for adults
- Ongoing safety monitoring is done even with full licensing
- More than 636 million doses of COVID-19 vaccine have been given in the United States from December 14, 2020 through October 27, 2022
- All of the U.S. vaccines are also being used in other countries where additional testing and monitoring occurs

Source: Safety of COVID-19 Vaccines | CDC

Vaccine Side Effects



Source: Vaccine Education Center at CHOP

COVID-19 Vaccine Safety

- More than 636 million doses of COVID-19 vaccine given.
- COVID-19 vaccines were evaluated on tens of thousands in clinical trials.
- COVID-19 vaccines met rigorous safety, effectiveness and quality standards set by the FDA.
- COVID-19 vaccine manufacturers continue to undergo intensive safety monitoring.

SOURCE: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html

COVID-19 Vaccination Adverse Events

The CDC provides updates on the following rare adverse events following administration of Covid-19 vaccinations:

- Anaphylaxis: 5 cases per one million vaccine doses administered
- Thrombosis with thrombocytopenia syndrome (TTS) after Janssen Covid-19 vaccination: 4 cases per one million doses administered
- Guillain-Barre Syndrome (GBS) after Janssen COVID-19 vaccine rare disorder

Source: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

Myocarditis and Pericarditis After COVID-19 Vaccination

- As of October 27, 2022, there have been 1,037 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 251 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 690 reports have been verified to meet CDC's working case definition for myocarditis. See below for counts of verified reports of myocarditis by age group.
- 5-11 years: 22 verified reports of myocarditis after 21,680,729 doses administered
- 12-15 years: 358 verified reports of myocarditis after 24,500,294 doses administered
- 16-17 years: 310 verified reports of myocarditis after 13,445,905 doses administered

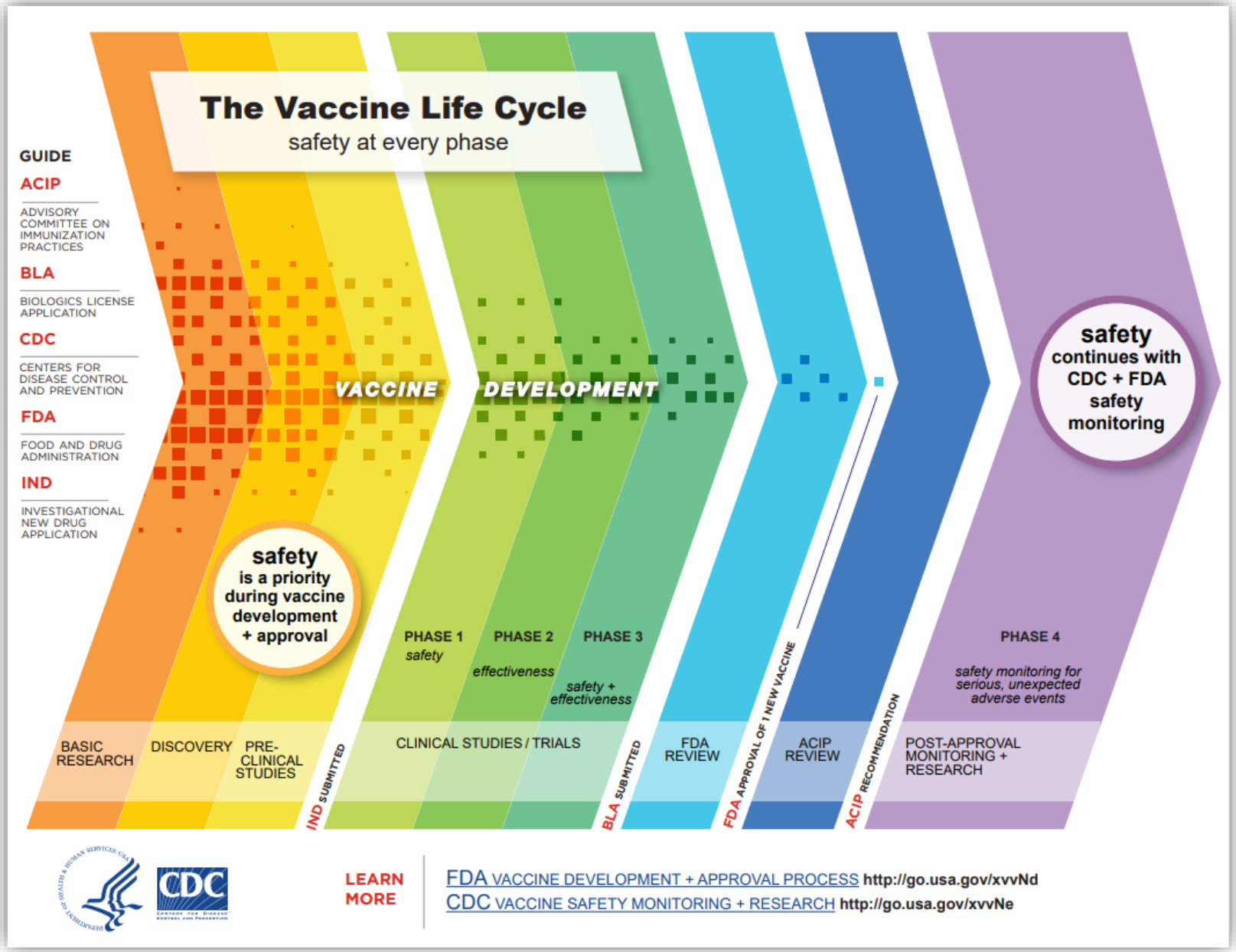
Source: Selected Adverse Events Reported after COVID-19 Vaccination | CDC. Accessed 11-04-2022

COVID-19 Vaccine Safety and Efficacy

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

Source: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-10-19-20/05-COVID-Oliver-508.pdf


The Vaccine Life Cycle
safety at every phase
GUIDE
ACIP
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES
BLA
BIOLOGICS LICENSE APPLICATION
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
FDA
FOOD AND DRUG ADMINISTRATION
IND
INVESTIGATIONAL NEW DRUG APPLICATION
VACCINE
DEVELOPMENT
safety is a priority during vaccine development + approval
PHASE 1
safety
PHASE 2
effectiveness
PHASE 3
safety + effectiveness
PHASE 4
safety monitoring for serious, unexpected adverse events
safety continues with CDC + FDA safety monitoring
BASIC RESEARCH
DISCOVERY
PRE-CLINICAL STUDIES
IND SUBMITTED
CLINICAL STUDIES / TRIALS
BLA SUBMITTED
FDA REVIEW
FDA APPROVAL OF 1 NEW VACCINE
ACIP REVIEW
ACIP RECOMMENDATION
POST-APPROVAL MONITORING + RESEARCH
LEARN MORE
FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvvNd
CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvvNe

Advisory Committee on Immunization Practices (ACIP)

- 15 voting members responsible for making vaccine recommendations to CDC
- 14 of the members have expertise in vaccinology, immunology and other clinical practice areas
- The 115th member is a consumer representative who provides community and social aspects of vaccination
- There are also eight ex officio members who represent other federal agencies with responsibility for immunization programs in the U.S. and 30 non-voting representatives of liaison organizations such as:
  - American Academy of Pediatrics
  - American Academy of Family Physicians
  - American College of Nurse Midwives
  - American College of Obstetricians and Gynecologists
  - American College of Physicians
- Members and representatives serve on the Committee voluntarily
- Meetings are open to the public with a published agenda, slides and recording available

Source: ACIP General Information | CDC

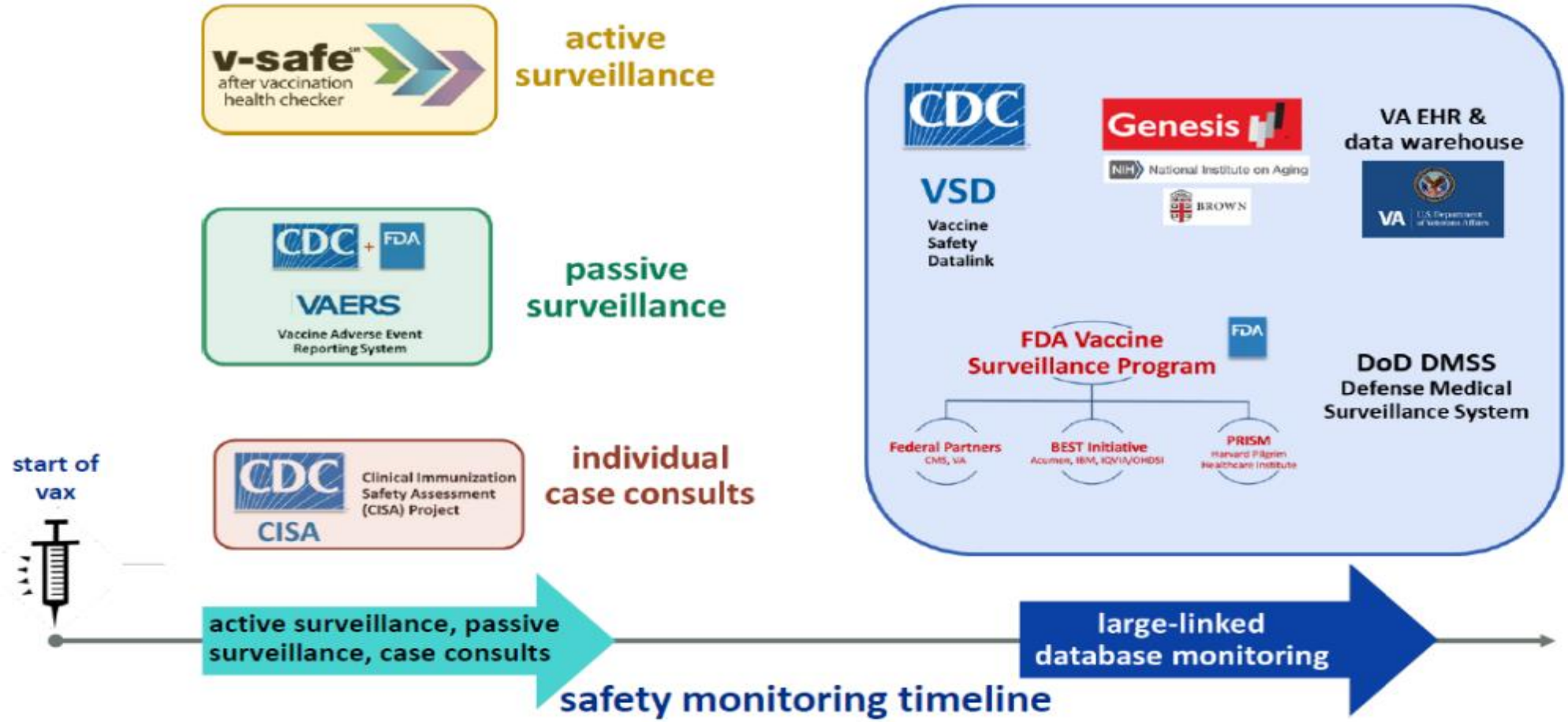
Ongoing Monitoring by ACIP

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

Source: Dr. S Oliver presentation 10/19/2022 presentation to Advisory Committee on Immunization Practices; available[COVID-19 vaccines in Children (cdc.gov)](). Accessed 11/07/2022

Vaccine Safety Monitoring Systems



Source: N. Klein MD Advisory Committee on Immunization Practices presentation; 04-20-2022 meeting. Available at ACIP April 20, 2022 Presentation Slides | Immunization Practices | CDC

VAERS is the nation's early warning system for vaccine safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

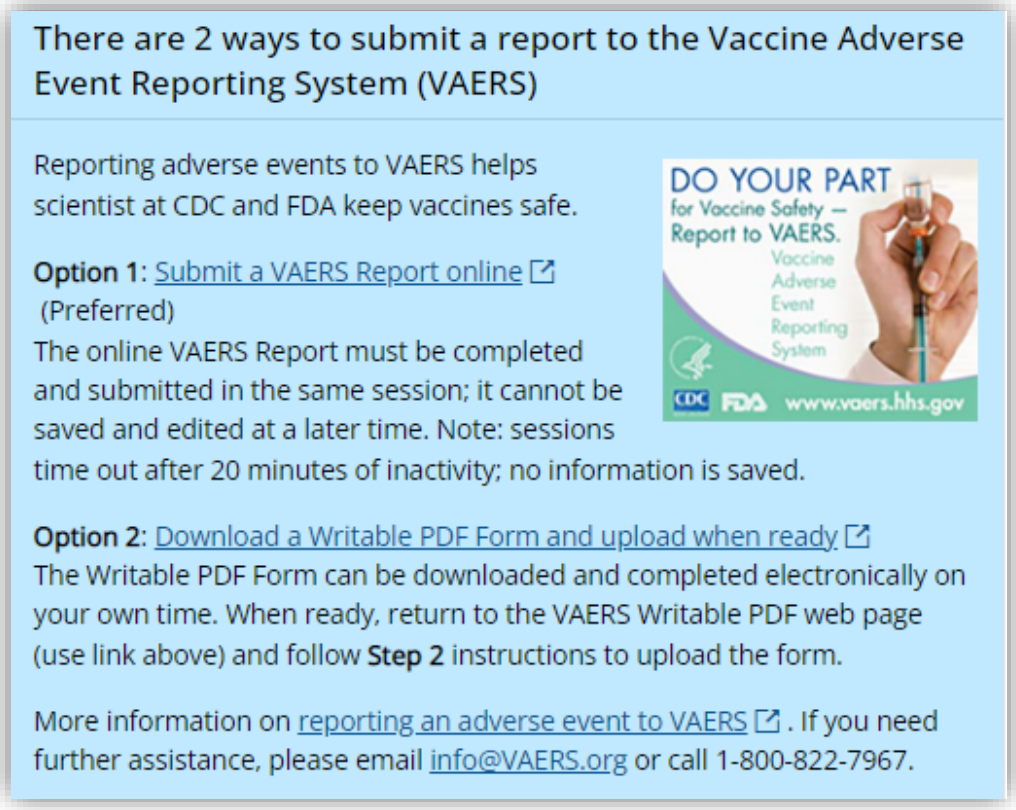
http://vaers.hhs.gov

Source: T Shimabukuro, Advisory Committee on Immunization Practices presentation; 04-20-2022 meeting. Available at ACIP April 20, 2022 Presentation Slides | Immunization Practices | CDC

How reports come into VAERS

Reports come from:

- Patients
- Parents/family member
- Caregivers
- Those who administer vaccines
- Healthcare providers
- Vaccine manufacturers



There are 2 ways to submit a report to the Vaccine Adverse Event Reporting System (VAERS)

Reporting adverse events to VAERS helps scientist at CDC and FDA keep vaccines safe.

Option 1: Submit a VAERS Report online
(Preferred)
The online VAERS Report must be completed and submitted in the same session; it cannot be saved and edited at a later time. Note: sessions time out after 20 minutes of inactivity; no information is saved.

Option 2: Download a Writable PDF Form and upload when ready
The Writable PDF Form can be downloaded and completed electronically on your own time. When ready, return to the VAERS Writable PDF web page (use link above) and follow **Step 2** instructions to upload the form.

More information on reporting an adverse event to VAERS. If you need further assistance, please email info@VAERS.org or call 1-800-822-7967.

SOURCE: www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html#anchor_1616772696807

How VAERS Works

- Assess the safety of newly licensed vaccines
- Detect new, unusual, or rare adverse events that happen after vaccination
- Monitor increases in known side effects, like arm soreness where a shot was given
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Identify and address possible reporting clusters
- Recognize persistent safe-use problems and administration errors
- Watch for unexpected or unusual patterns in adverse event reports
- Serve as a monitoring system in public health emergencies

SOURCE: www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html#anchor_1616772696807

Legal Requirements

1. Under the National Childhood Vaccine Injury Act (NCVIA), healthcare providers are **required by law** to report to VAERS:
   - Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination [PDF – 5 Pages] that occurs within the specified time period after vaccinations
   - An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

2. Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.

SOURCE: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html#anchor_1616772696807

Reporting of vaccine adverse events

- Adverse events in COVID-19 vaccine recipients are required to be reported to VAERS.*
- FDA's COVID-19 vaccine EUAs and EUA/BLA require vaccination providers to report
  - Vaccine administration errors
  - Serious adverse events
  - Cases of multisystem inflammatory syndrome
  - Cases of COVID-19 that result in hospitalization or death

  Reporting is encouraged for all other clinically significant adverse events, even those not clearly attributable to vaccination.

*Instructions for submitting a report to VAERS is available at https://vaers.hhs.govexternal or by calling 1-800-822-7967.

Filing a Report With No Adverse Reaction Noted

Reports should be filed for all errors

- Site/Route
- Age
- Formulation and Dosage
- Storage and Handling
- Intervals
- Mixed primary series
- Diluent

Checklist of Items Needed

What will I need to fill out the report?

- Patient information (age, date of birth, sex)
- Vaccine information (brand name, dosage)
- Date, time, and location administered
- Date and time when adverse event(s) started
- Symptoms and outcome of the adverse event(s) (if applicable)
- Medical tests and laboratory results (if applicable)
- Physician's contact information (if applicable)

Essential Items to fill out on VAERS Form

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination.
Items **2, 3, 4, 5, 6, 17, 18 and 21** are **ESSENTIAL** and should be completed.
Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use **Continuation Page** if needed)

1. Patient name: (first) _____ (last) _____
Street address: _____
City: _____ State: _____ County: _____
ZIP code: _____ Phone: ( ) _____ Email: _____

2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: ☐ Male ☐ Female ☐ Unknown

4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM

5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM

6. Age at vaccination: ___ Years ___ Months 7. Today's date: (mm/dd/yyyy) _____

8. Pregnant at time of vaccination?: ☐ Yes ☐ No ☐ Unknown
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)

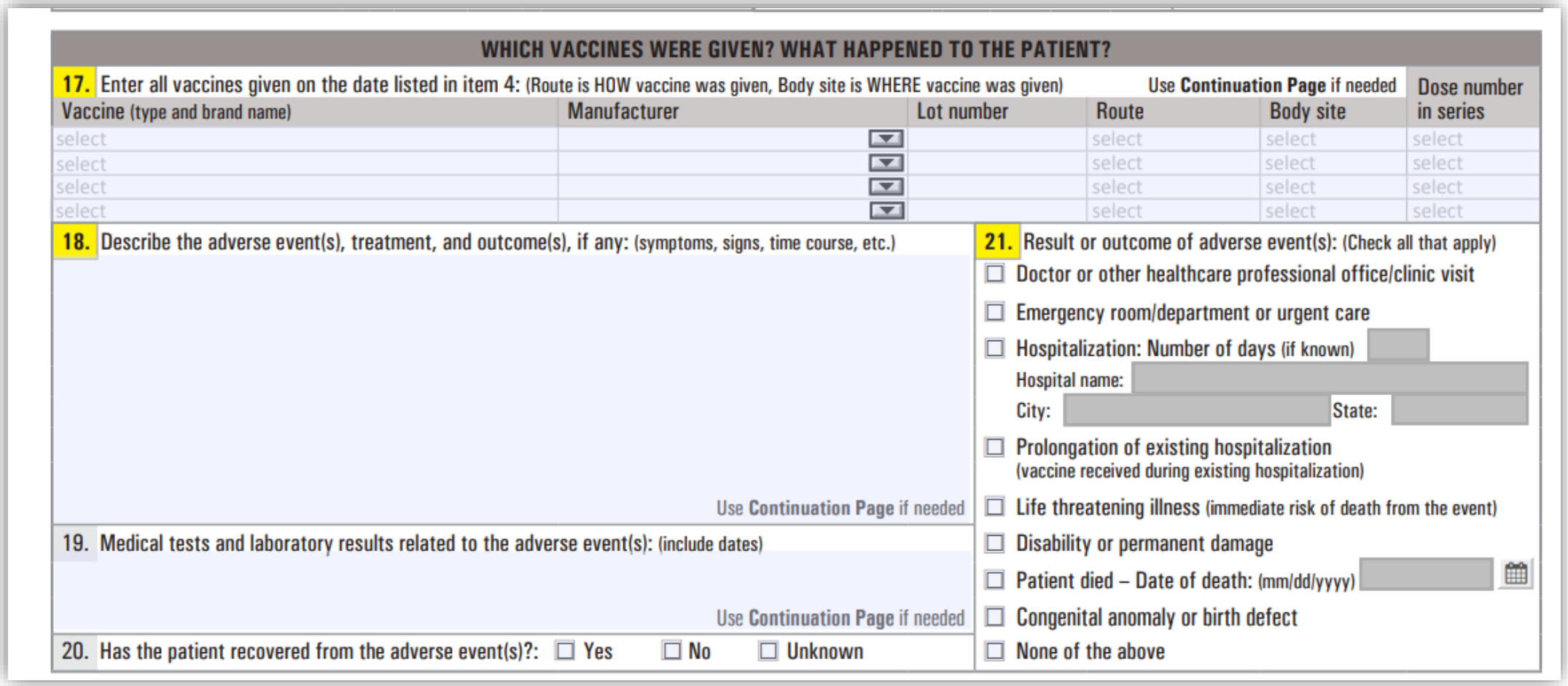
9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

Essential Items to fill out on VAERS Form



WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use **Continuation Page** if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)

Use **Continuation Page** if needed

19. Medical tests and laboratory results related to the adverse event(s): (include dates)

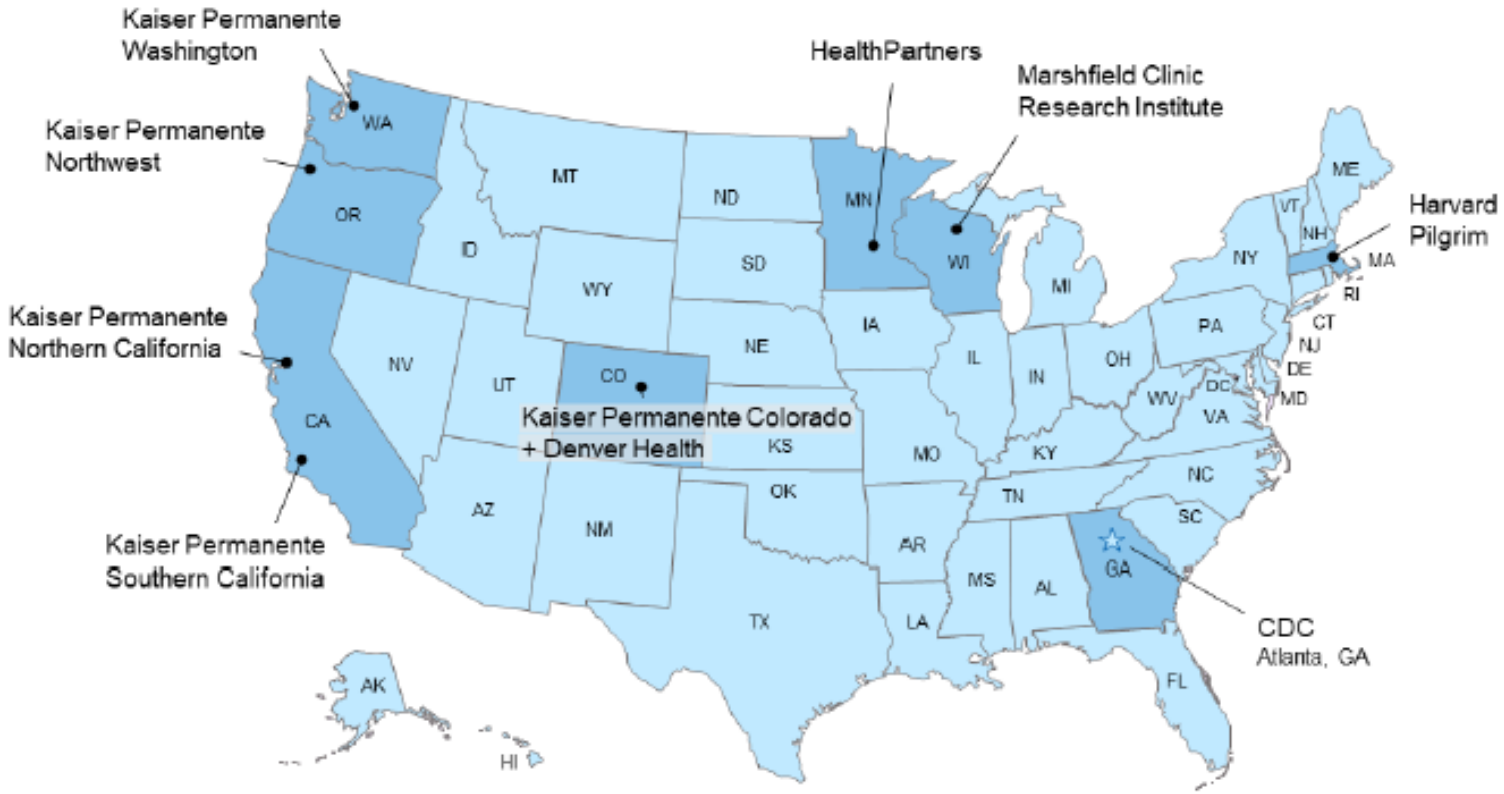
Use **Continuation Page** if needed

20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown

21. Result or outcome of adverse event(s): (Check all that apply)

- ☐ Doctor or other healthcare professional office/clinic visit
- ☐ Emergency room/department or urgent care
- ☐ Hospitalization: Number of days (if known)
  - Hospital name:
  - City: State:
- ☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
- ☐ Life threatening illness (immediate risk of death from the event)
- ☐ Disability or permanent damage
- ☐ Patient died – Date of death: (mm/dd/yyyy)
- ☐ Congenital anomaly or birth defect
- ☐ None of the above

Vaccine Safety Datalink (VSD)



- Established in 1990
- Collaborative project between CDC and 9 integrated healthcare organizations
- Includes ~ 12 million individuals across all sites

Source: N. Klein MD Advisory Committee on Immunization Practices presentation; 04-20-2022 meeting. Available at ACIP April 20, 2022 Presentation Slides | Immunization Practices | CDC

VSD signals for pre-specified outcomes in 21-day risk interval after 1st booster in people ages 12 years and older

Results through Aug 13, 2022

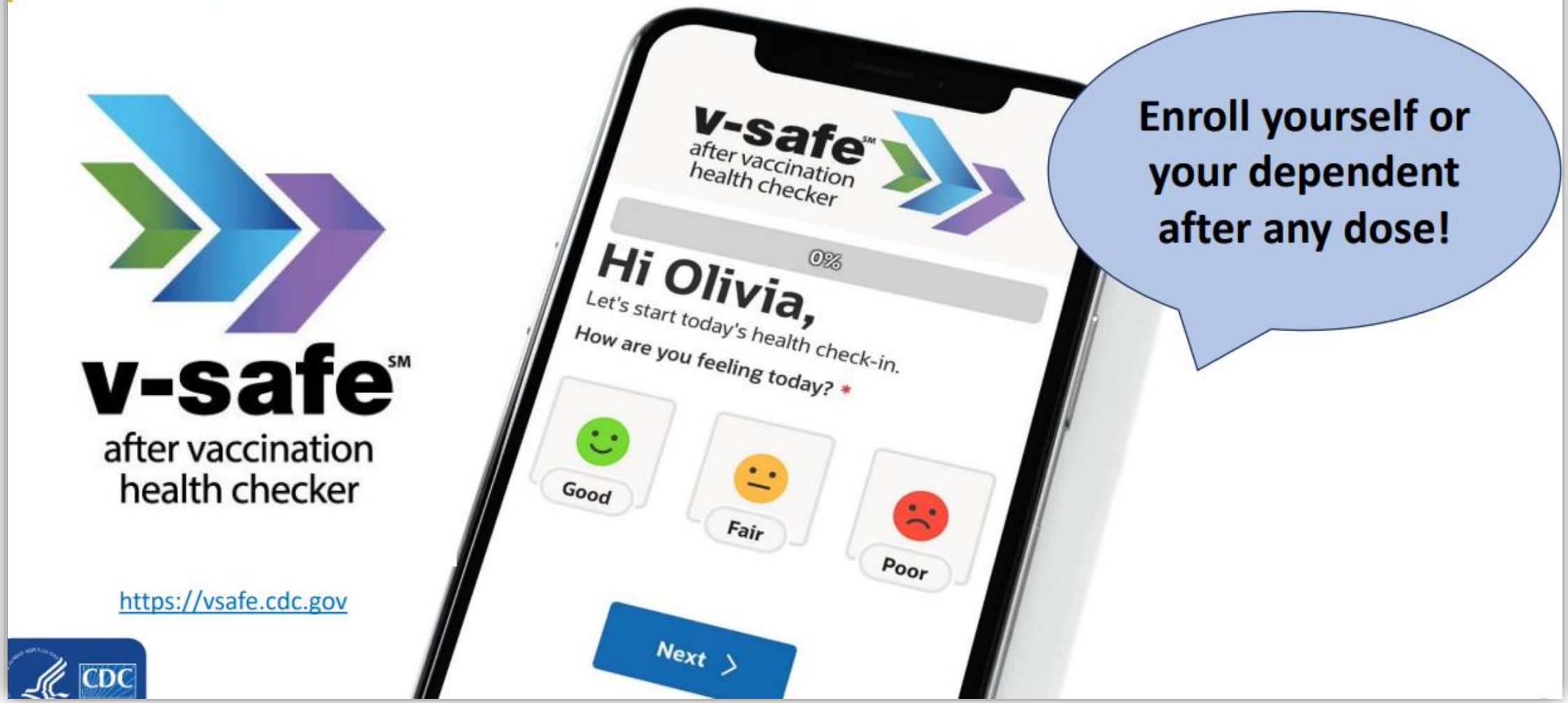
* Analyses not yet possible

Primary series with	Pfizer-Pfizer OR Moderna-Moderna	Pfizer-Pfizer	Moderna-Moderna
Signal after 1st booster	Pfizer OR Moderna	Pfizer	Moderna
VSD RCA pre-specified outcomes		Signal?	
Acute disseminated encephalomyelitis	No	No	-*
Acute myocardial infarction	No	No	No
Appendicitis	No	No	No
Bell's palsy	No	No	No
Cerebral venous sinus thrombosis	No	No	No
Disseminated intravascular coagulation	No	No	No
Encephalitis / myelitis / encephalomyelitis	No	No	No
Guillain-Barre syndrome	No	No	No
Stroke, hemorrhagic	No	No	No
Stroke, ischemic	No	No	No
Immune thrombocytopenia	No	No	No
Myocarditis / pericarditis	**Yes**	No	No
Seizures	No	No	No
Transverse myelitis	No	No	No
Thrombotic thrombocytopenic purpura	No	No	No
Thrombosis with thrombocytopenia syndrome	No	No	No
Venous thromboembolism	No	No	No
Pulmonary embolism	No	No	No

VSD vaccine safety datalink

Source: T. Shimabukuro Advisory Committee on Immunization Practices presentation; 09-01-2022 meeting. Available at ACIP September 1-2, 2022 Presentation Slides | Immunization Practices | CDC

Smartphone-based active safety monitoring



Source: T Shimabukuro, Advisory Committee on Immunization Practices presentation; 04-20-2022 meeting. Available at ACIP April 20, 2022 Presentation Slides | Immunization Practices | CDC

Resources

- How to access data from CDC's VAERS WONDER System
- VAERS brochure (cdc.gov)
- The Vaccine Adverse Event Reporting System (VAERS) About (cdc.gov)
- Reporting Adverse Events to VAERS | Vaccine Safety | CDC
- Fall COVID Booster Campaign Save Thousands Lives, Billions Dollars | Commonwealth Fund

COVID-19 Bivalent Booster Schedule and Addressing Errors

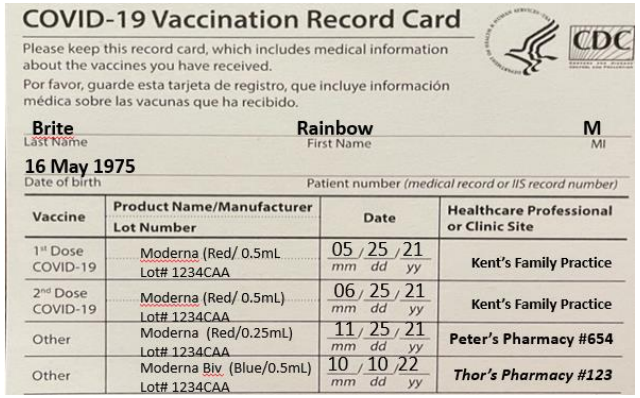
HEIDI KELLY, RN-BC, MS

Updated COVID-19 Vaccination Schedule Review

Who Should Get COVID-19 Vaccination?

- COVID-19 vaccination is recommended for everyone ages 6 months and older in the United States for the prevention of COVID-19.

- People can stay up to date with COVID-19 vaccination by completing a primary series and receiving the most recent booster dose recommended for them by CDC



COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

CDC

Brite	Rainbow	M
Last Name	First Name	MI

16 May 1975
Date of birth

Patient number *(medical record or IIS record number)*

Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1st Dose COVID-19	Moderna (Red/ 0.5mL Lot# 1234CAA	05 / 25 / 21 mm dd yy	Kent's Family Practice
2nd Dose COVID-19	Moderna (Red/ 0.5mL) Lot# 1234CAA	06 / 25 / 21 mm dd yy	Kent's Family Practice
Other	Moderna (Red/0.25mL) Lot# 1234CAA	11 / 25 / 21 mm dd yy	Peter's Pharmacy #654
Other	Moderna Biv (Blue/0.5mL) Lot# 1234CAA	10 / 10 / 22 mm dd yy	*Thor's Pharmacy #123*

SOURCE: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines

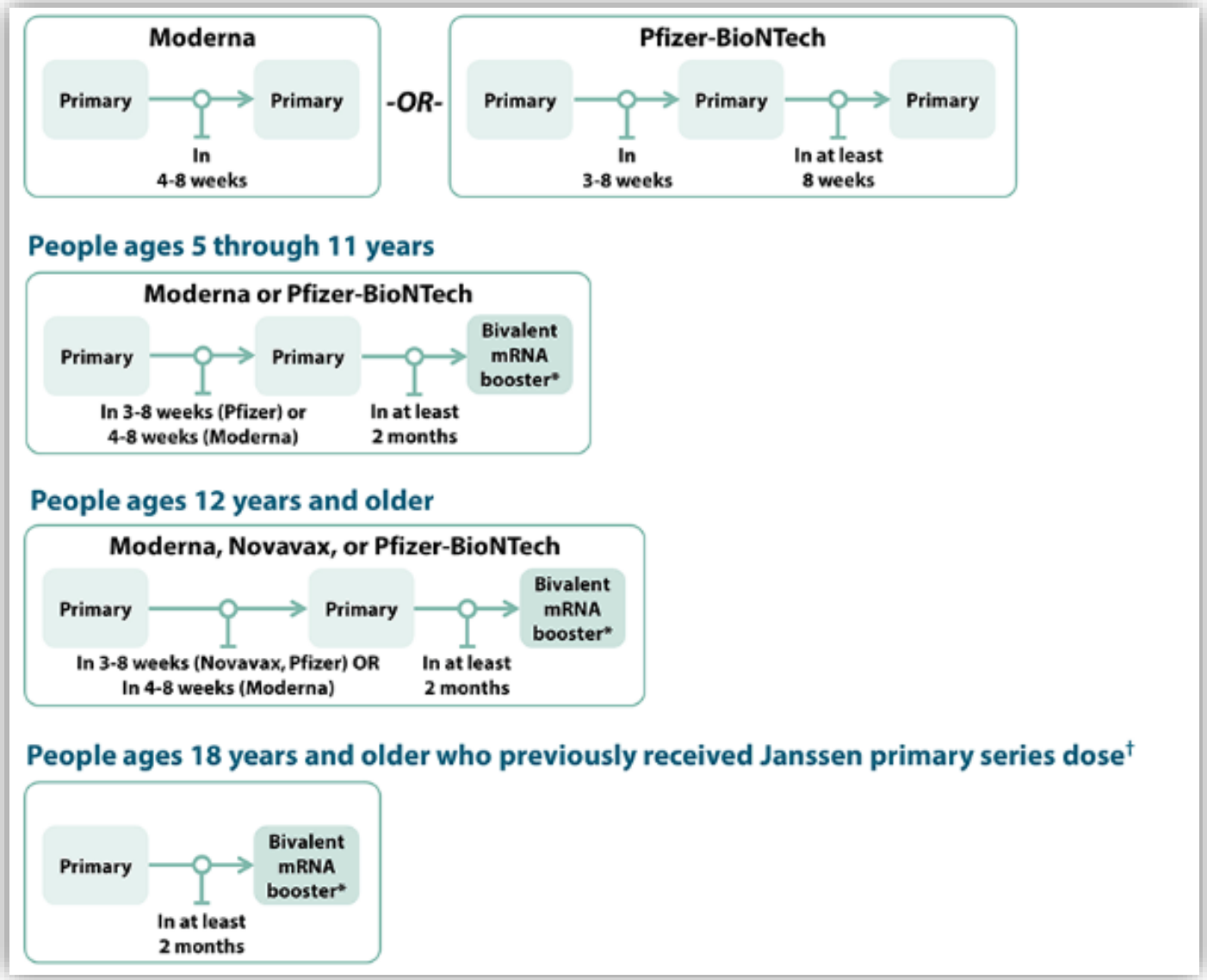
Booster Doses

- 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).

- A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose)
  - ✓ Limited Situations
  - ✓ 18 years and older
  - ✓ Have not received any other booster dose
  - ✓ Unable to receive mRNA vaccine

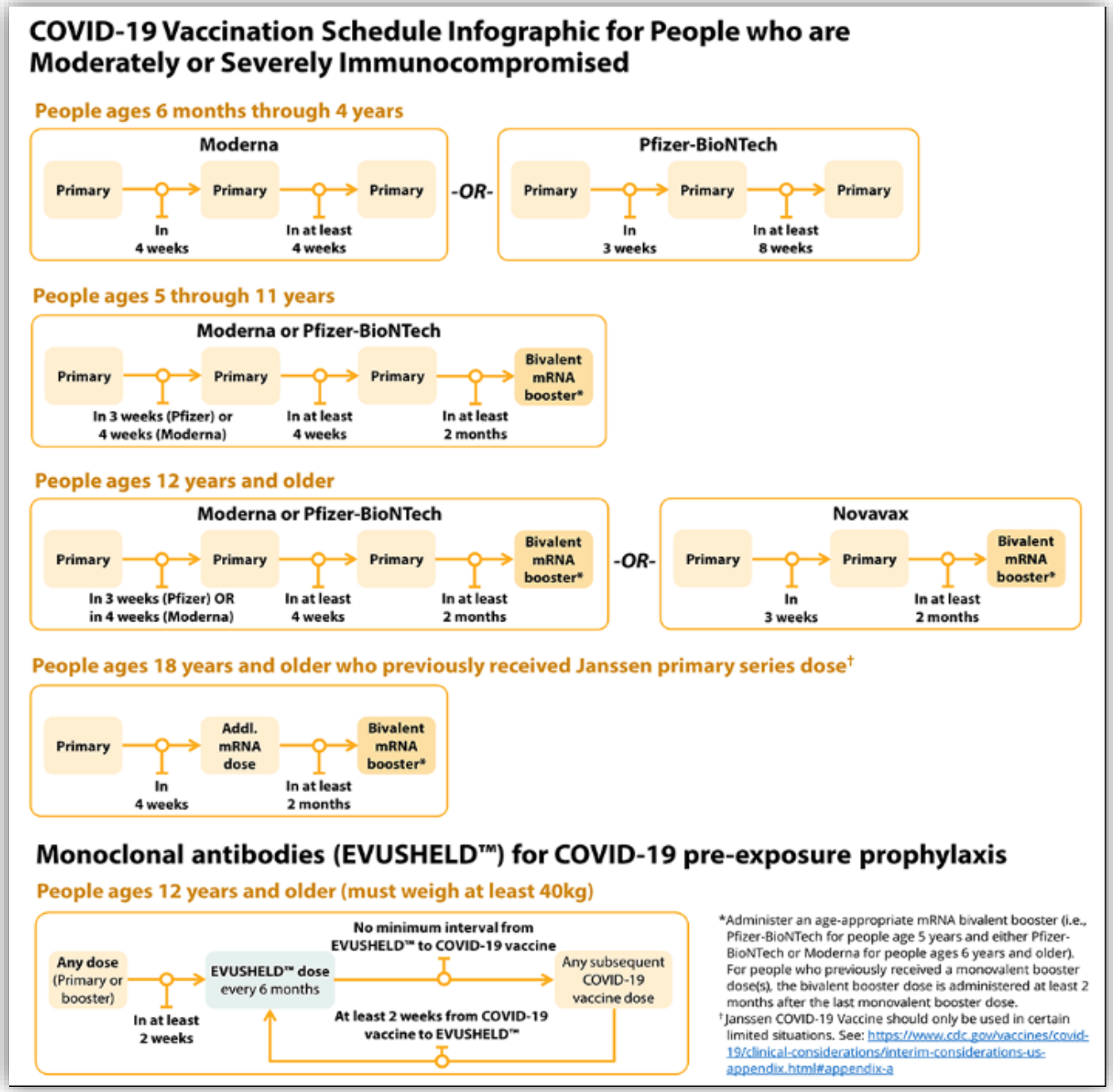
NO MONOVALENT mRNA BOOSTER DOSES AUTHORIZED.

People ages 6mos through 4 years



COVID-19 Vaccination Schedule Infographic for People who are NOT Moderately or Severely Immunocompromised

SOURCE: https://www.cdc.gov/vaccines/covid-19/images/COVID19-vaccination-schedule-most-people.png



COVID-19 Vaccination Schedule Infographic for People who are Moderately or Severely Immunocompromised

SOURCE: https://www.cdc.gov/vaccines/covid-19/images/COVID19-vaccination-schedule-immunocompromised.png

For All Vaccination Errors

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program.
- Follow the revaccination guidance.
- Report all COVID-19 vaccine administration errors—even those not associated with an adverse reaction—to VAERS (https://vaers.hhs.gov/).
- Determine how the error occurred and implement strategies to prevent it from happening again.

Errors and Deviations

Table D. Interim recommendations for COVID-19 vaccine administration errors and deviations

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle or vastus lateralis muscle)	• Do not repeat dose.
	• Incorrect route (e.g., subcutaneous)	• Do not repeat dose. • Inform the recipient of the potential for local and systemic adverse events.
Age	• Unauthorized age group (recipients younger than age 6 months)	• Do not give another dose at this time.*
Product and dosage	• Higher-than-authorized dose administered (e.g., incorrect dose volume, incorrect product resulting in higher-than-authorized dose)	• Do not repeat dose.††
	• Lower-than-authorized dose administered (e.g., leaked out of the syringe, equipment failure, recipient pulled away, incorrect product resulting in lower-than-authorized dose)	• Repeat dose immediately (no minimum interval).[†§] • However, if a half-volume dose of vaccine is administered to a patient recommended for the full volume, another half-volume dose can be administered on the same clinic day, and the 2 doses can count as 1 full dose.
	• Bivalent vaccine incorrectly administered for the primary series	• Bivalent Pfizer-BioNTech vaccine: Do not repeat dose. • Bivalent Moderna vaccine: Repeat 1 monovalent dose immediately (no minimum interval)[§] because administration of the booster dose will result in a lower-than-authorized dose.
	• Monovalent vaccine incorrectly administered for a booster dose (if bivalent booster indicated)	• In general, do not repeat dose. • However, providers may administer 1 bivalent booster dose as a repeat dose based on clinical judgement and patient preference. In this case, space the repeat dose after the dose given in error by at least 2 months.

SOURCE:https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-d

Case Study

Cali is a 22 y/o immunocompromised person who has received 2 doses of Pfizer COVID-19 monovalent vaccine. She is in the clinic to receive her next dose, it has been 2 months since her last dose. She receives one dose of Bivalent Pfizer COVID-19 vaccine. What should happen next?

a. Nothing, she is now up-to-date with her COVID-19 vaccinations
b. She should receive a monovalent COVID-19 vaccine dose immediately.
c. She needs to be told of error, given the correct vaccine, and it needs to be reported to VAERS.
d. She needs to be told of the error, no further vaccine dose is recommended at this time, and the error needs to be reported in VAERS

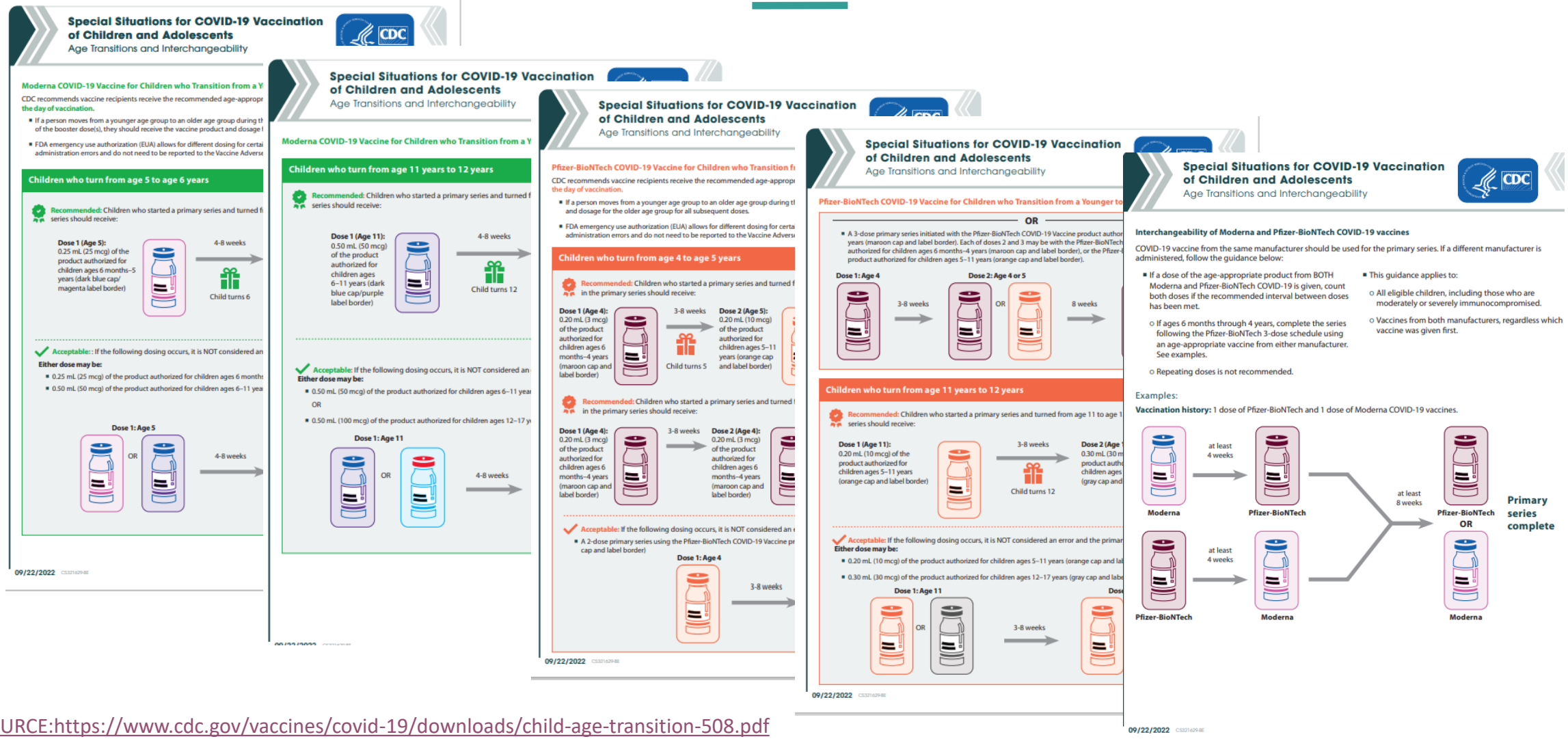
Case Study Answer

ANSWER D: She needs to be told of the error, no further vaccine dose is recommended at this time, and the error needs to be reported in VAERS.

• Bivalent vaccine incorrectly administered for the primary series	• Bivalent Pfizer-BioNTech vaccine: Do not repeat dose. • Bivalent Moderna vaccine: Repeat 1 monovalent dose immediately (no minimum interval)[5] because administration of the booster dose will result in a lower-than-authorized dose.

SOURCE: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-d

Special Situations for COVID-19 Vaccination in Children



SOURCE:https://www.cdc.gov/vaccines/covid-19/downloads/child-age-transition-508.pdf

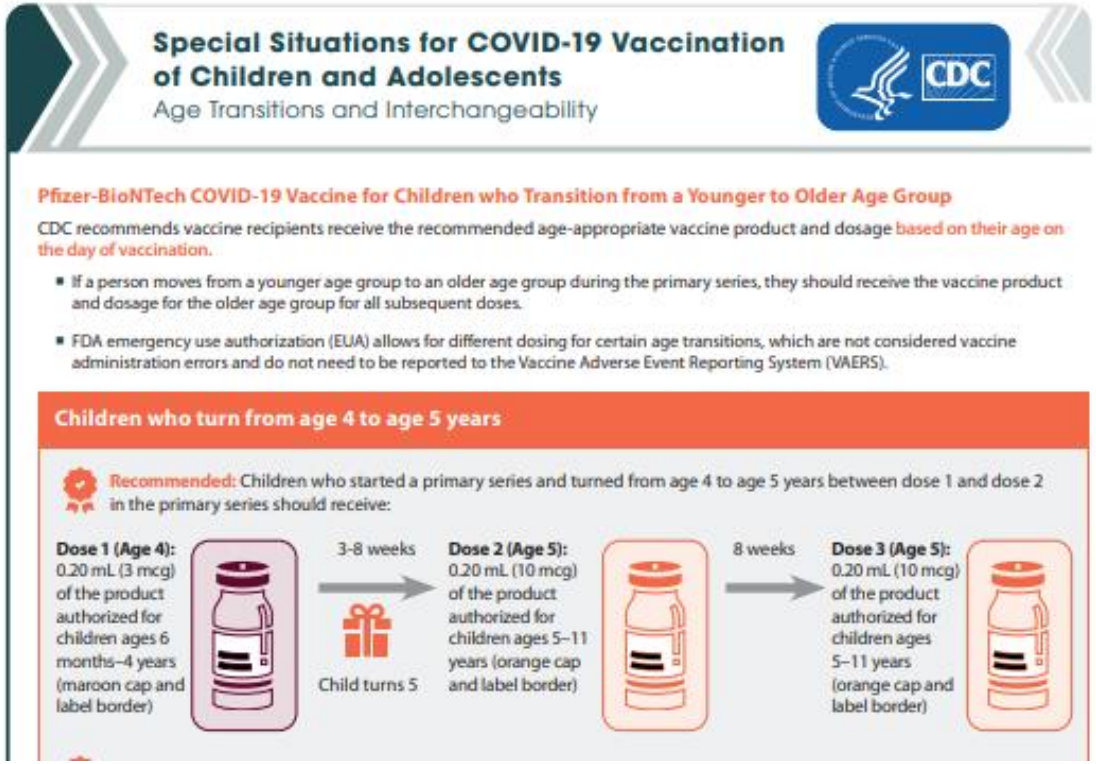
Case Study Child

June is a 4 y/o child that just received their second dose of COVID-19 vaccine Pfizer 5-11 formulation. After giving the vaccine, the vaccinator noticed June had received Pfizer 6mo-4 years old formulation for their first dose of their COVID-19 series. What is the next step in providing the recommended care according to the CDC?

a. June has completed her COVID-19 primary series. No further doses needed at this time.
b. Parents should be made aware she received Pfizer COVID-19 5-11 years old formulation and then schedule their 3rd dose in 8 weeks.
c. Parents should be made aware she received Pfizer COVID-19 5-11 years old formulation and immediately revaccinate with Pfizer COVID-19 6mos-4 years old formulation. Once revaccinated, report in VAERS.

Case Study Child Answer

ANSWER B: Parents should be made aware she received Pfizer COVID-19 5-11 years old and then schedule their 3rd dose in 8 weeks.



Special Situations for COVID-19 Vaccination of Children and Adolescents

Age Transitions and Interchangeability

CDC

Pfizer-BioNTech COVID-19 Vaccine for Children who Transition from a Younger to Older Age Group

CDC recommends vaccine recipients receive the recommended age-appropriate vaccine product and dosage based on their age on the day of vaccination.

- If a person moves from a younger age group to an older age group during the primary series, they should receive the vaccine product and dosage for the older age group for all subsequent doses.
- FDA emergency use authorization (EUA) allows for different dosing for certain age transitions, which are not considered vaccine administration errors and do not need to be reported to the Vaccine Adverse Event Reporting System (VAERS).

Children who turn from age 4 to age 5 years

Recommended: Children who started a primary series and turned from age 4 to age 5 years between dose 1 and dose 2 in the primary series should receive:

Dose 1 (Age 4): 0.20 mL (3 mcg) of the product authorized for children ages 6 months–4 years (maroon cap and label border)

3-8 weeks

Child turns 5

Dose 2 (Age 5): 0.20 mL (10 mcg) of the product authorized for children ages 5–11 years (orange cap and label border)

8 weeks

Dose 3 (Age 5): 0.20 mL (10 mcg) of the product authorized for children ages 5–11 years (orange cap and label border)

- FDA emergency use authorization (EUA) allows for different dosing for certain age transitions, which are not considered vaccine administration errors and do not need to be reported to the Vaccine Adverse Event Reporting System (VAERS).

Obtaining Nursing Continuing Education Contact Hours

- Continuing education (CE) contact hours are available for nurses and pharmacists/pharmacy techs
  - There is no cost for CEs
- Expiration date is 02/08/23
- Successful completion of this continuing education activity includes the following:
  - Attending the entire live webinar or watching the webinar recording
  - Completing the evaluation available after the webinar or webinar recording
- **Please note:** CE certificates are NOT generated after evaluation completion—CE certificates will be sent by DOH via email within a few weeks after evaluation completion
- If you have any questions about CE credit, contact Trang Kuss at trang.kuss@doh.wa.gov

Questions?

For persons with disabilities, this document is available in other formats.
Please call 711 Washington Relay Service or email civil.rights@doh.wa.gov.