SBOH TAG Presentation

Washington State Department of Health
www.doh.wa.gov

State Board of Health Meeting

February 17, 2022

@WaDeptHealth
@WaHealthSec

Speaker

Kathy Bay, RN, CENP
Department of Health

Professional – Current
Nurse Consultant Advisor
Manager, Clinical, Quality and School Team 2018–current
Office of Immunization
Washington State Department of Health

Professional – Previous
Director, Emergency Department
Associate Vice President and Chief Nursing Officer, Acute Care Hospital
U.S. Navy Nurse Corp Retired

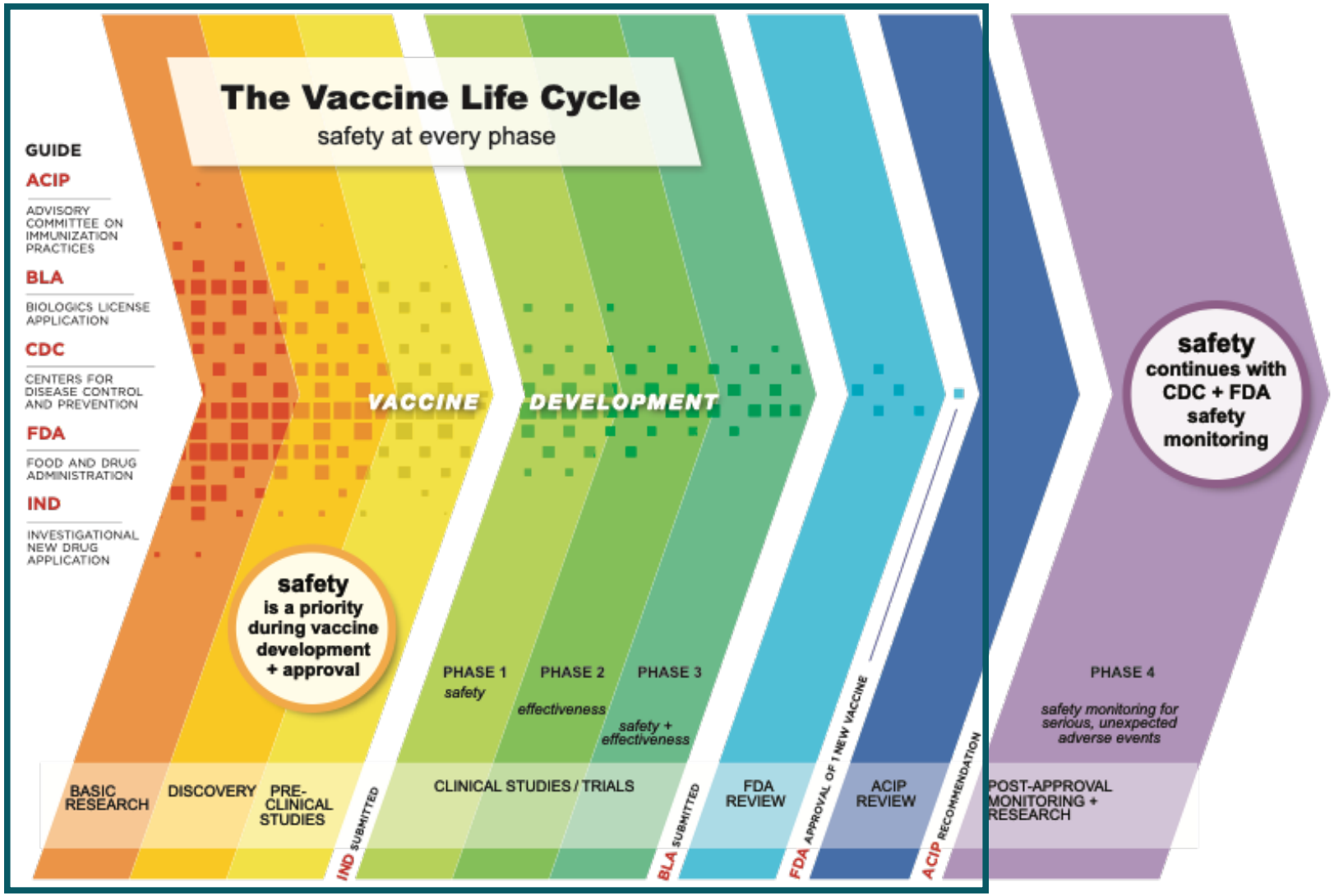
- Population Health
- Emergency Department, Leader and Clinical Nurse Specialist

Education
University of Tennessee, Bachelor of Science in Nursing
University of Washington, Master's of Nursing
University of San Francisco, Doctor of Nursing Practice

Criteria 1

A vaccine containing this antigen is recommended by the Advisory Committee on Immunization Practices (ACIP) and included on its Recommended Childhood & Adolescent Immunization Schedule.

Vaccine Life Cycle



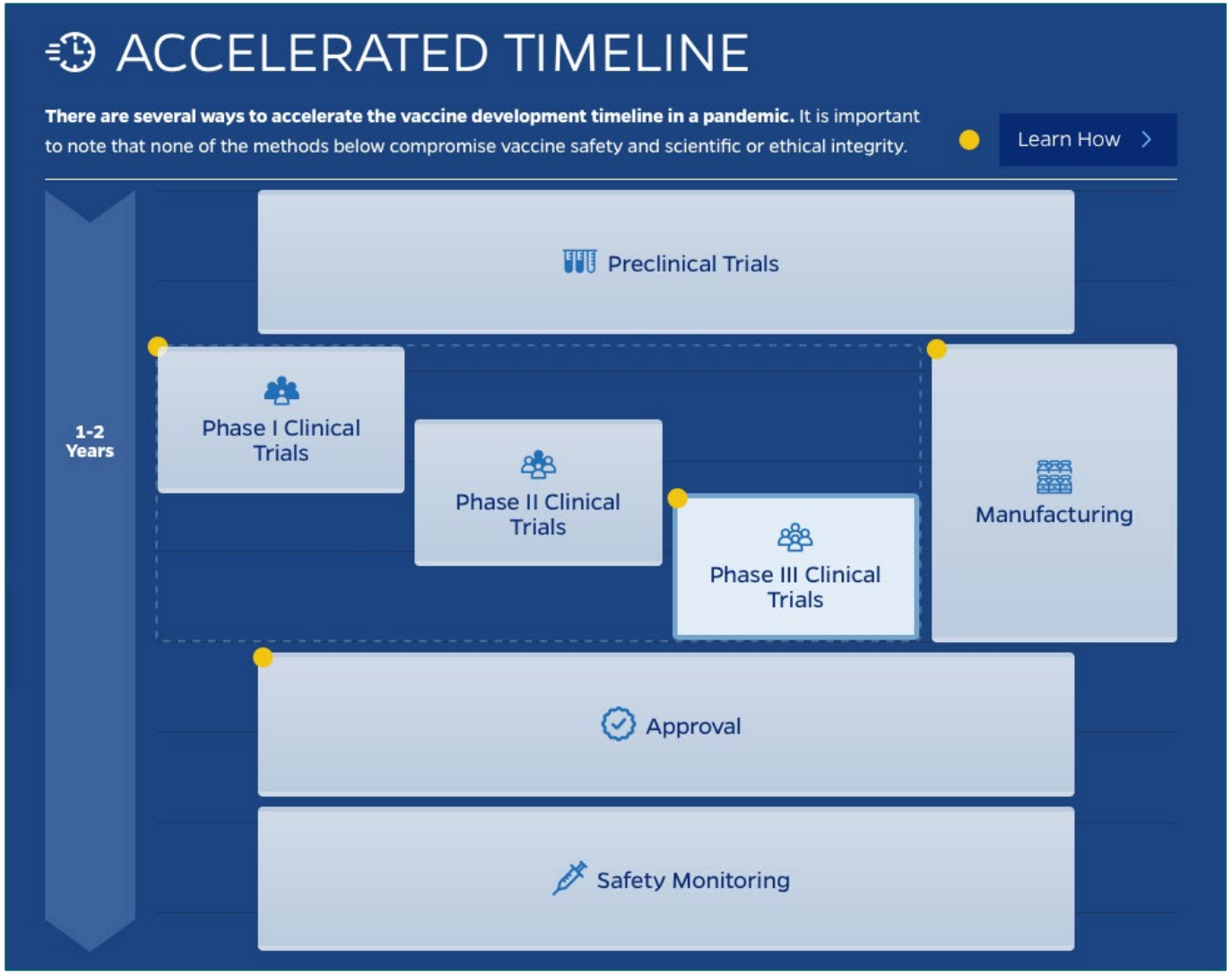
LEARN MORE

FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvvNd

CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvvNe

Vaccine Clinical Trials

- Typical vaccine development 5–10 years
- How did we get the COVID-19 vaccines so quickly
- How mRNA COVID-19 vaccines were developed (YouTube)



Source: Vaccine Research & Development - Johns Hopkins Coronavirus Resource Center (jhu.edu)

How the Pfizer mRNA Vaccine Works

- Messenger RNA, known as "mRNA" teaches your cells to produce a harmless piece of coronavirus spike protein
- After the spike protein is made the mRNA in the vaccine quickly breaks down and the body clears it away in a few days
- The spike protein produced by the cell gives the body a chance to see the protein before exposure to the virus allowing the immune response to happen in advance

The vaccine does not:

- Enter the cell's DNA or change the body's DNA
- Cause the individual to "catch" COVID19 or cause shedding that can spread the disease

mRNA technology has been:

- Studied before for Zika, flu, rabies and cytomegalovirus
- Used for cancer research to trigger the immune system to target specific cancer cells

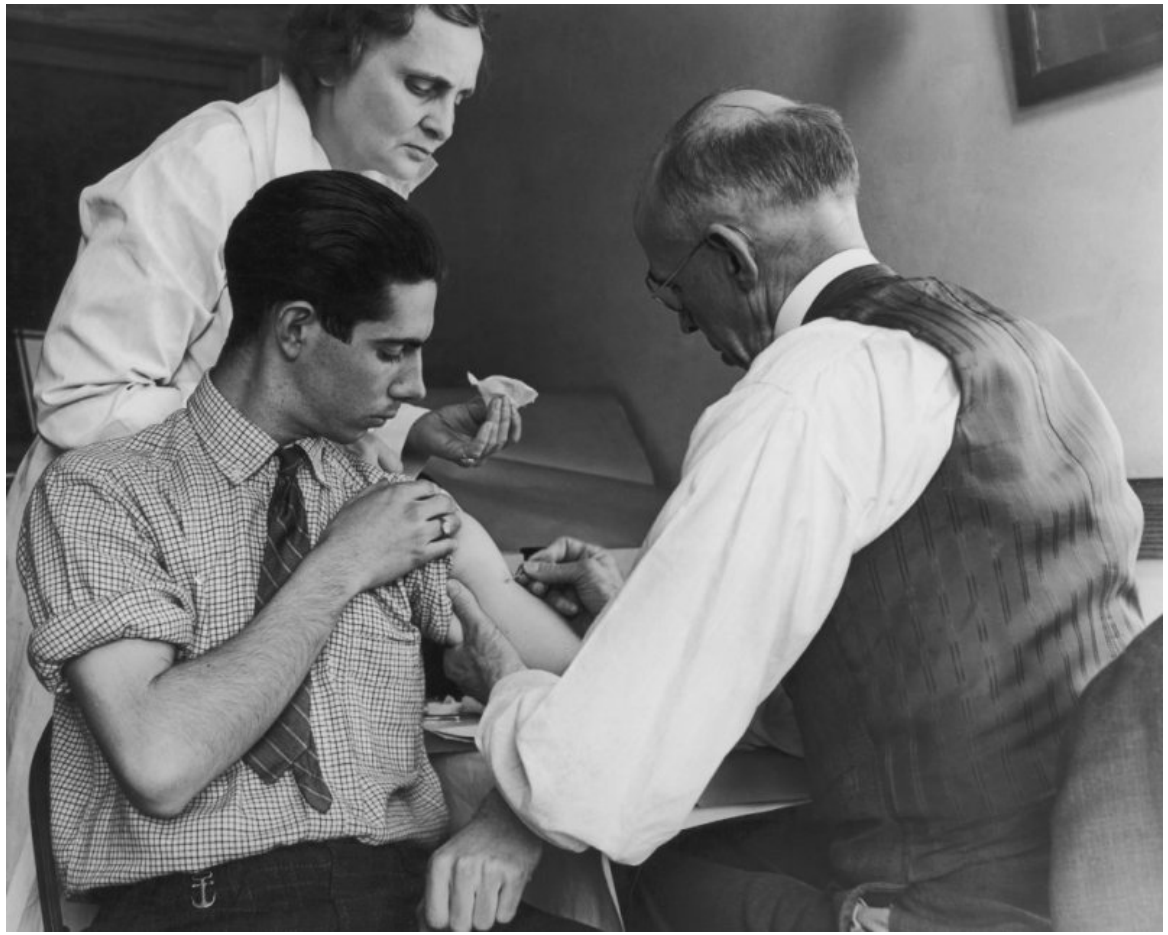
Vaccine Response to Outbreaks/Pandemic

- **Smallpox** late 19th and early 20th century

  Source: The U.S. Had 'Vaccine Passports' Long Before COVID-19 (Time.com)

- **Polio** 19th and 20th century

  Source: History of polio vaccination (nih.gov)



A teenage boy is vaccinated against smallpox by a school doctor and a county health nurse, Gasport, NY, March 15, 1938. Source: Time.com

Advisory Committee on Immunization Practices (ACIP)

- ACIP has 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 15th 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 recorded available via the link below

Source: ACIP General Information (cdc.gov)

ACIP Role and Recommendations

- Established in 1964, ACIP gives recommendations to CDC on both childhood and adult vaccinations schedules
- Vaccination schedules are posted annually, but recommendations can be made throughout the year
- On December 12, 2020, after an explicit, evidence-based review of all available data, ACIP issued an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in **persons aged ≥16 years** for the prevention of COVID-19
- On May 12, 2021, after a systematic review of all available data, ACIP made an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in **adolescents aged 12–15 years** for the prevention of COVID-19
- On November 2, 2021, after a systematic review of available data, ACIP made an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in **children aged 5–11 years** in the United States for the prevention of COVID-19

ACIP Recommended Child & Adolescent Immunization Schedule

- Updated annually, last update February 11, 2021
- Next update anticipated February 2022
- COVID-19 vaccine is currently included in the notes section of the schedule, which states:

  "ACIP recommends use of COVID-19 vaccines for everyone ages 5 and older within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine."

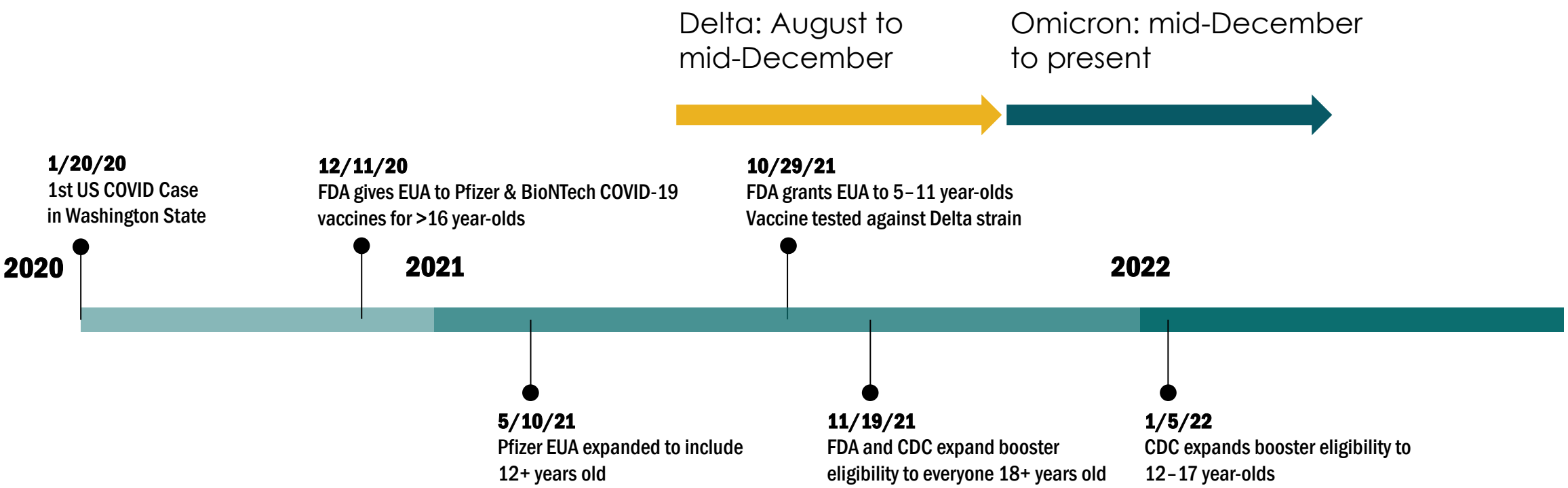
Criteria 2

The vaccine containing this antigen is effective as measured by immunogenicity and population-based prevention data in Washington State, as available.

Terminology

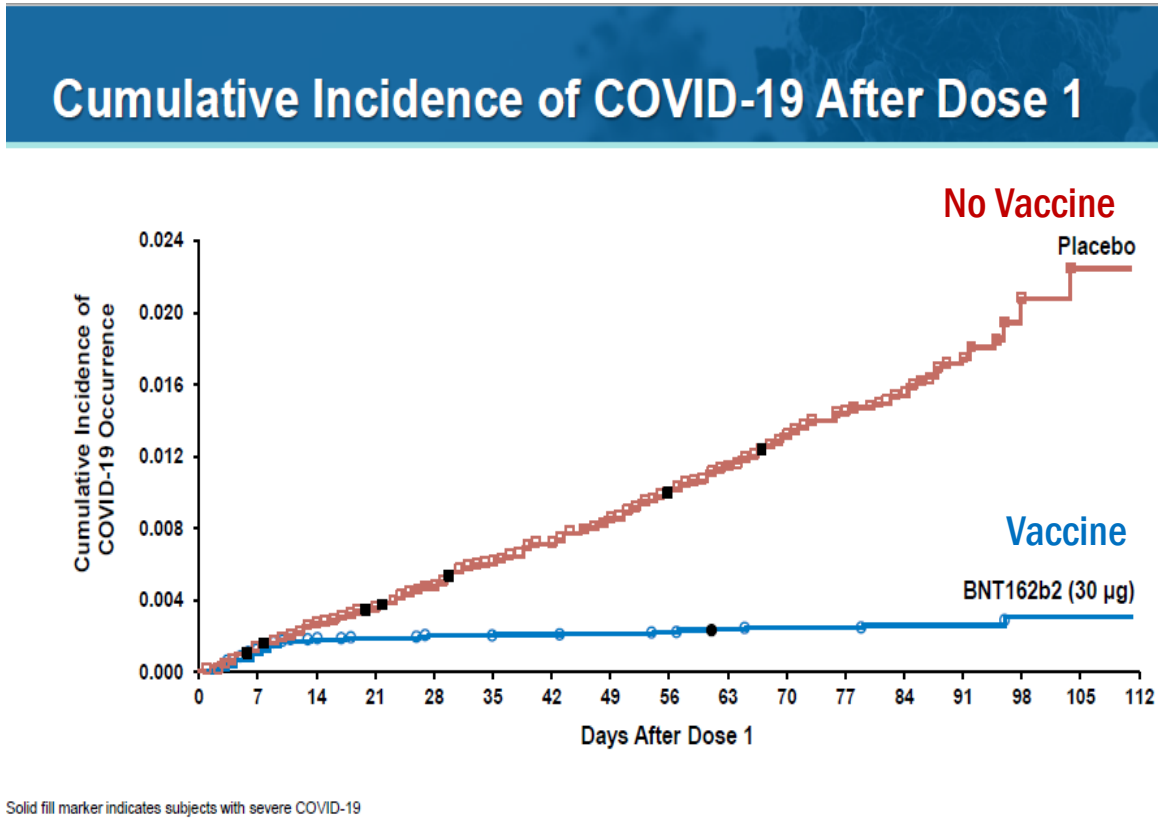
- **Vaccine Efficacy**: Measured in clinical trials to look at how well the vaccine seems to prevent the individual from getting sick from the identified disease
- **Immunogenicity**: The ability to generate an immune response

COVID-19 and Vaccine Timeline



Efficacy of Vaccine: Clinical Trial Ages 16 and Older

- Initial clinical trials with more than 36,000 people evenly split into two groups
- The red line is the number of cases in the individuals who received a placebo/saline injection
- Visible difference in the number of cases in those who received the vaccine from those who received placebo
  - 97% effective to prevent development of COVID-19
  - 100% effective to prevent hospitalization
- FDA authorized an Emergency Use Agreement on 12/11/2020; full license on 08/24/2021
- The Advisory Committee on Immunization Practices recommended use on 12/12/2021
- CDC recommended on 12/12/2021



Source: Gruber, W. 12/11/2020. Advisory Committee on Immunization Practice meetings: https://www.cdc.gov/vaccines/acip/meetings/index.html.

Efficacy of Vaccine: Clinical Trial 12–15 year-olds

- A clinical trial which included 2260 adolescents receiving the Pfizer vaccine or a placebo:
  - Higher immune response compared to 16–25 year-olds
  - No vaccine-related serious adverse events
  - Most common side effects:
    - Pain at site, tiredness and headache
    - Highly effective: 100% efficacy observed in study 4 months after second dose delivered
- FDA issued Emergency Use Authorization on 05/10/2021
- The Advisory Committee on Immunization Practices recommended use on 05/12/2021
- CDC recommended on 05/12/2021

Source: Frenck, et al 2021

Efficacy of Vaccine: Clinical Trial 5–11 year-olds

- A clinical trial which included 2250 children receiving the Pfizer vaccine or a placebo:
  - 90% effective to prevent disease
  - No severe cases of COVID-19 were reported
  - No cases of Multisystem inflammatory syndrome in children (MIS-C)
- FDA authorized an Emergency Use Agreement on 10/29/2021
- The Advisory Committee on Immunization Practices recommended use on 11/2/2021
- CDC recommended on 11/2/2021

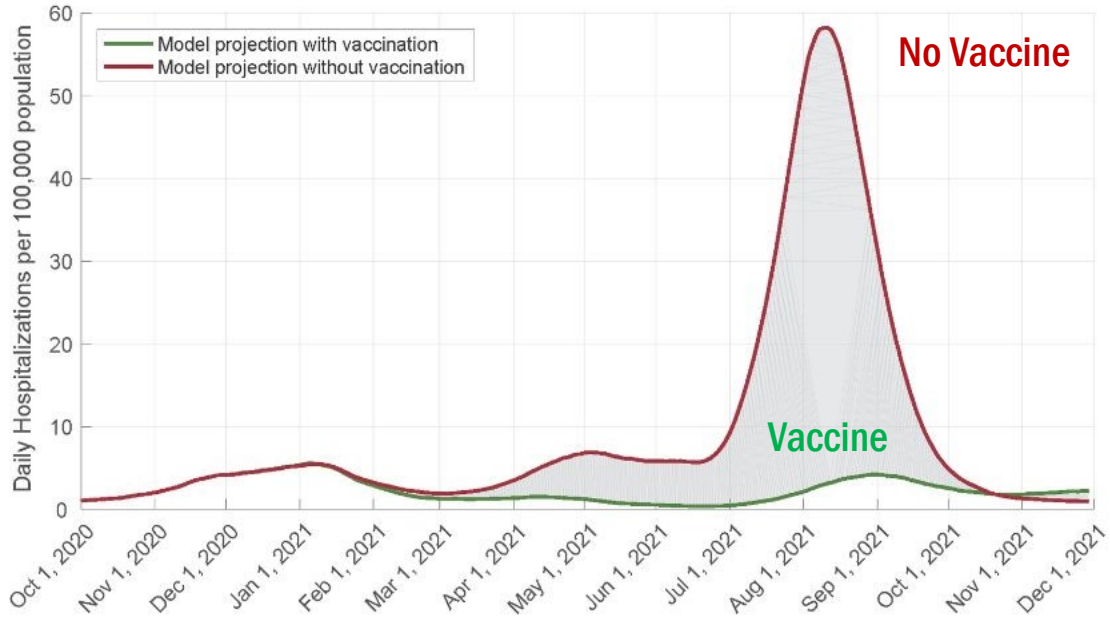
Source: Walter, et al 2022

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
- A 4.9 times higher than occurred during 2021

Projected U.S. Seven-Day Rolling Average of Daily Hospitalizations per 100,000 Population With and Without Vaccination



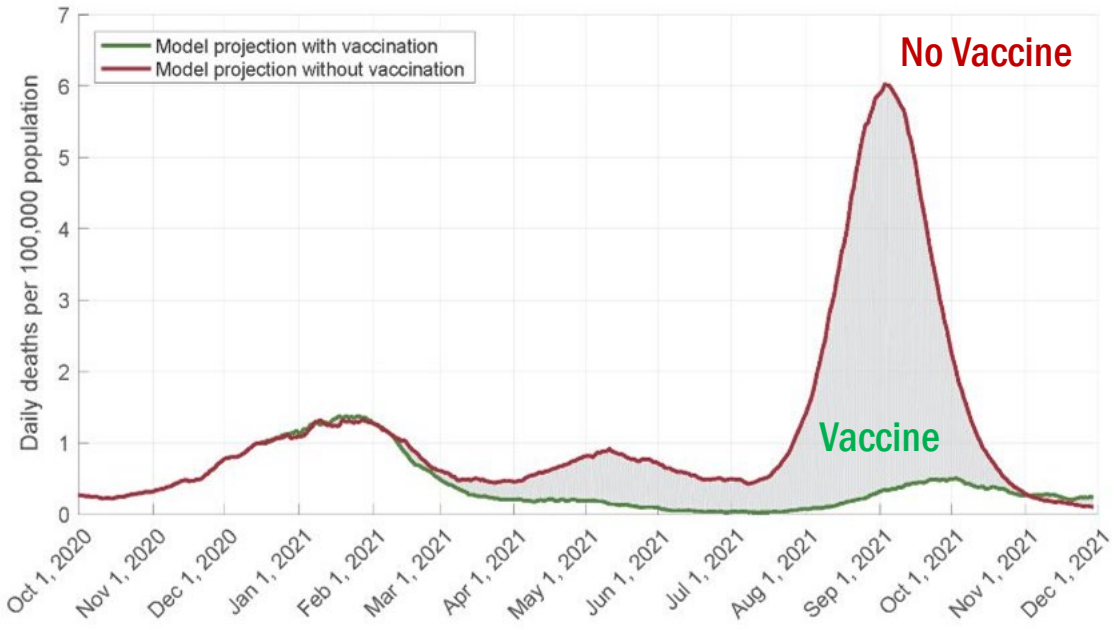
Source: Eric C. Schneider et al., The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted? Commonwealth Fund, December 2021. https://doi.org/10.26099/3542-5n54

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

Projected U.S. Seven-Day Rolling Average of Daily Deaths per 100,000 Population, With and Without Vaccination



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

Number of Deaths, Infections Prevented by Vaccine

Estimated number of U.S. COVID-19-related deaths, hospitalizations, and infections that were prevented by the COVID-19 vaccine since vaccine launch (December 12, 2020) through November 30, 2021.

	Estimated number averted	Possible range or "credible interval"*
Deaths	Over 1 million	950,101 to 1,231,195
Hospitalizations	Over 10.3 million	9,016,329 to 11,748,945
Infections	About 36 million	29,840,604 to 41,843,396

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

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

COVID-19 Cases in Washington State 2021

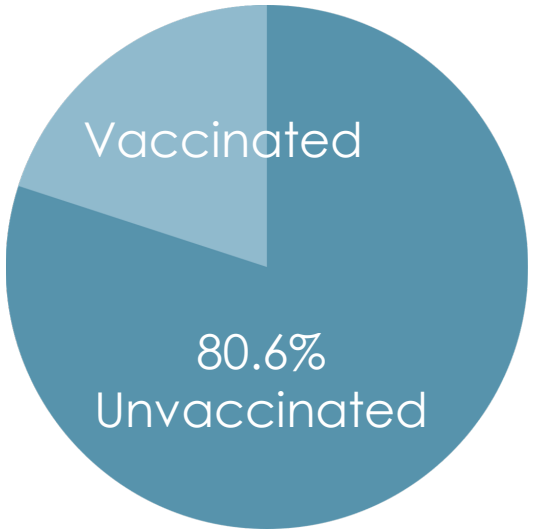
COVID-19 cases in unvaccinated and fully vaccinated individuals in Washington state by age group, February - December, 2021

Age group	Number (%) cases in unvaccinated individuals	Number (%) cases in fully vaccinated individuals	Percent of population who are unvaccinated	Percent of population who are fully vaccinated
12-17	38,954 (80.3%)	7,792 (16.1%)	33.4%	58.8%
18-34	128,945 (72.4%)	40,728 (22.9%)	22.4%	68.5%
35-49	86,061 (66.2%)	37,178 (28.6%)	16.5%	77.4%
50-64	53,958 (61.8%)	28,657 (32.8%)	16.8%	78.4%
65+	24,895 (52%)	20,274 (42.3%)	11.6%	83.4%
State total (12+)	**332,813 (67.7%)**	**134,629 (27.4%)**	**19.4%**	**74.8%**

Source: WA Department of Health COVID-19 Cases, Hospitalizations, and Deaths by Vaccination Status 01/26/2022; accessed 01/27/2022.

Vaccine Efficacy in the Delta Era

Washington State Department of Health, February to December 2021



8x

more likely in unvaccinated population

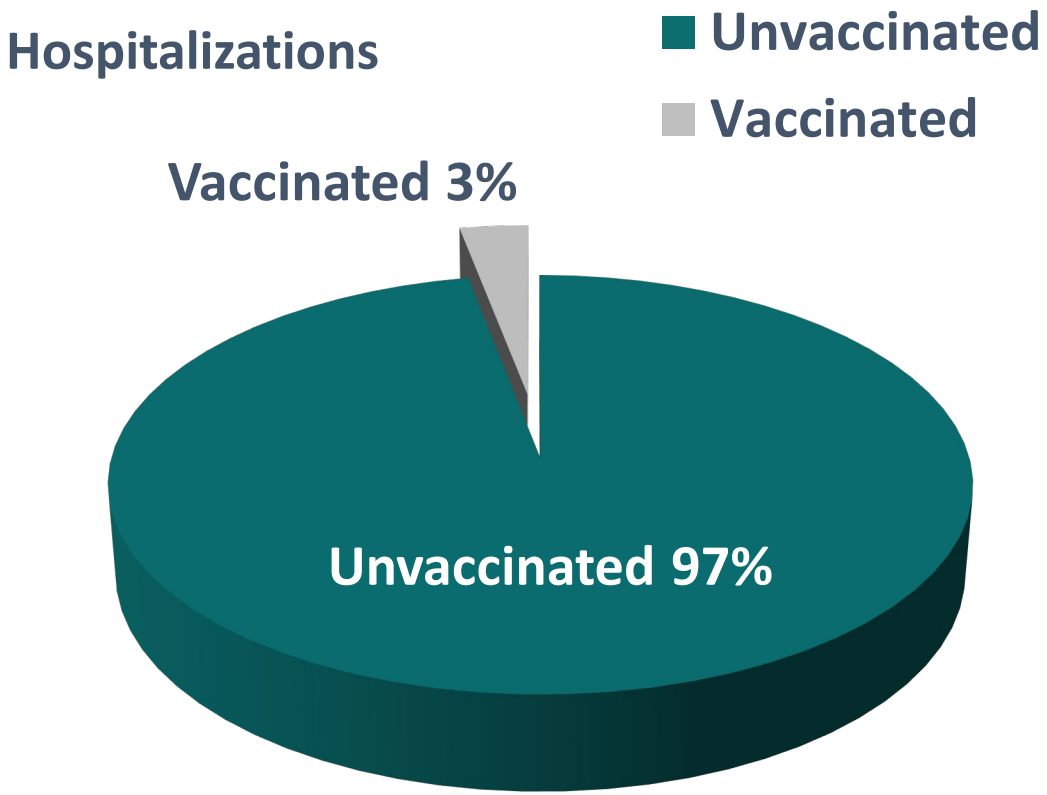
Cases
12–17 year-olds

Hospitalizations
12–34 year-olds

Source: https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/data-tables/421-010-CasesInNotFullyVaccinated.pdf

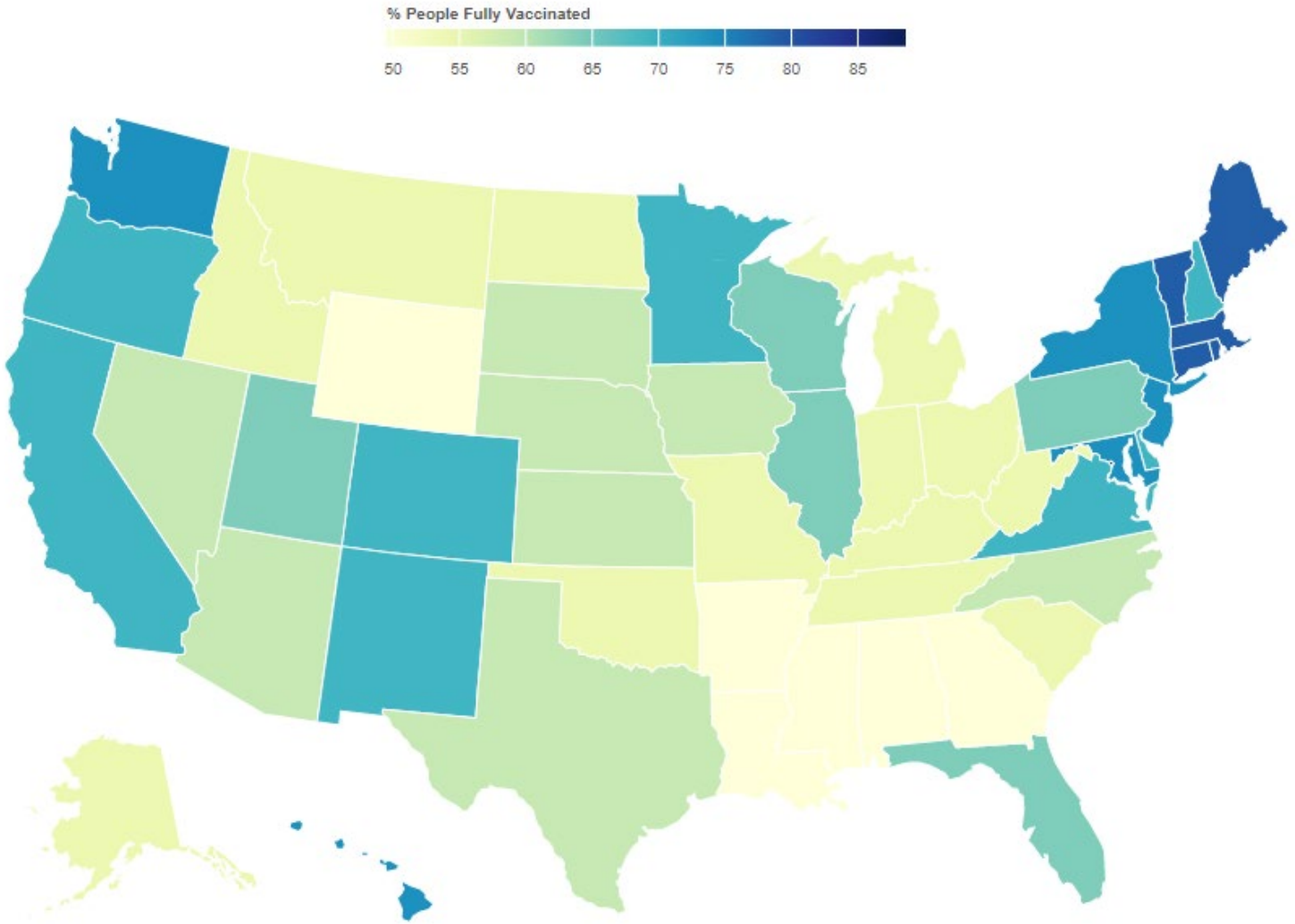
Pfizer Reduced Illness and Hospitalization

- 12–18 year-olds who received two doses of Pfizer, June–September 2021:
  - 93% effective against hospitalization
  - 100% effective against severe disease
- 97% of hospitalized teens (12–18 yo) were unvaccinated



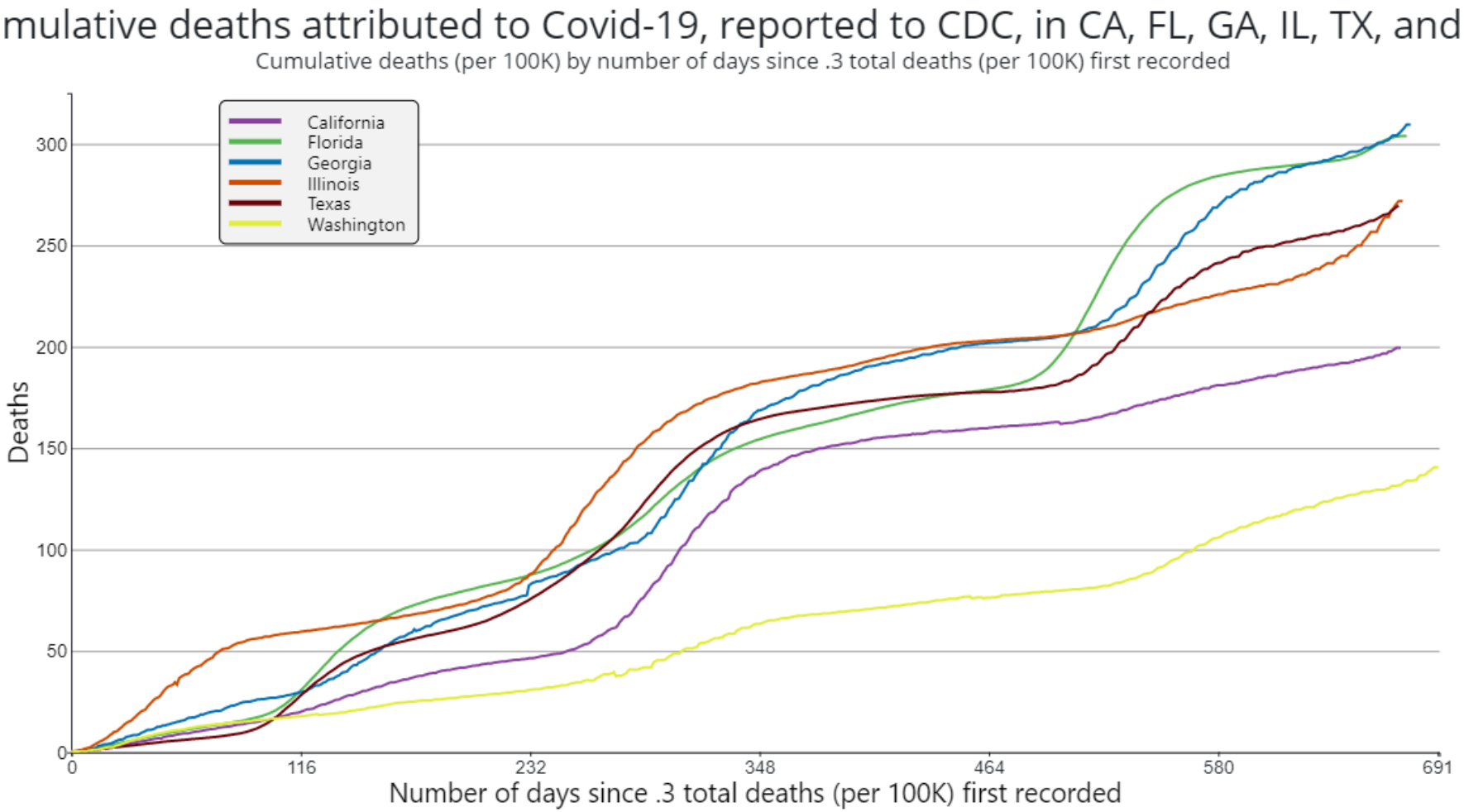
Source: Olson, et al (2021)

U.S. Vaccination Rates



Source: Understanding Vaccination Progress - Johns Hopkins Coronavirus Resource Center (jhu.edu); accessed 01/28/2022.

COVID-19 Cumulative Death Data, Six States



Source: CDC Data Tracker available at CDC COVID Data Tracker; accessed 01/31/2022.

Vaccine effectiveness against hospitalization during Omicron surge

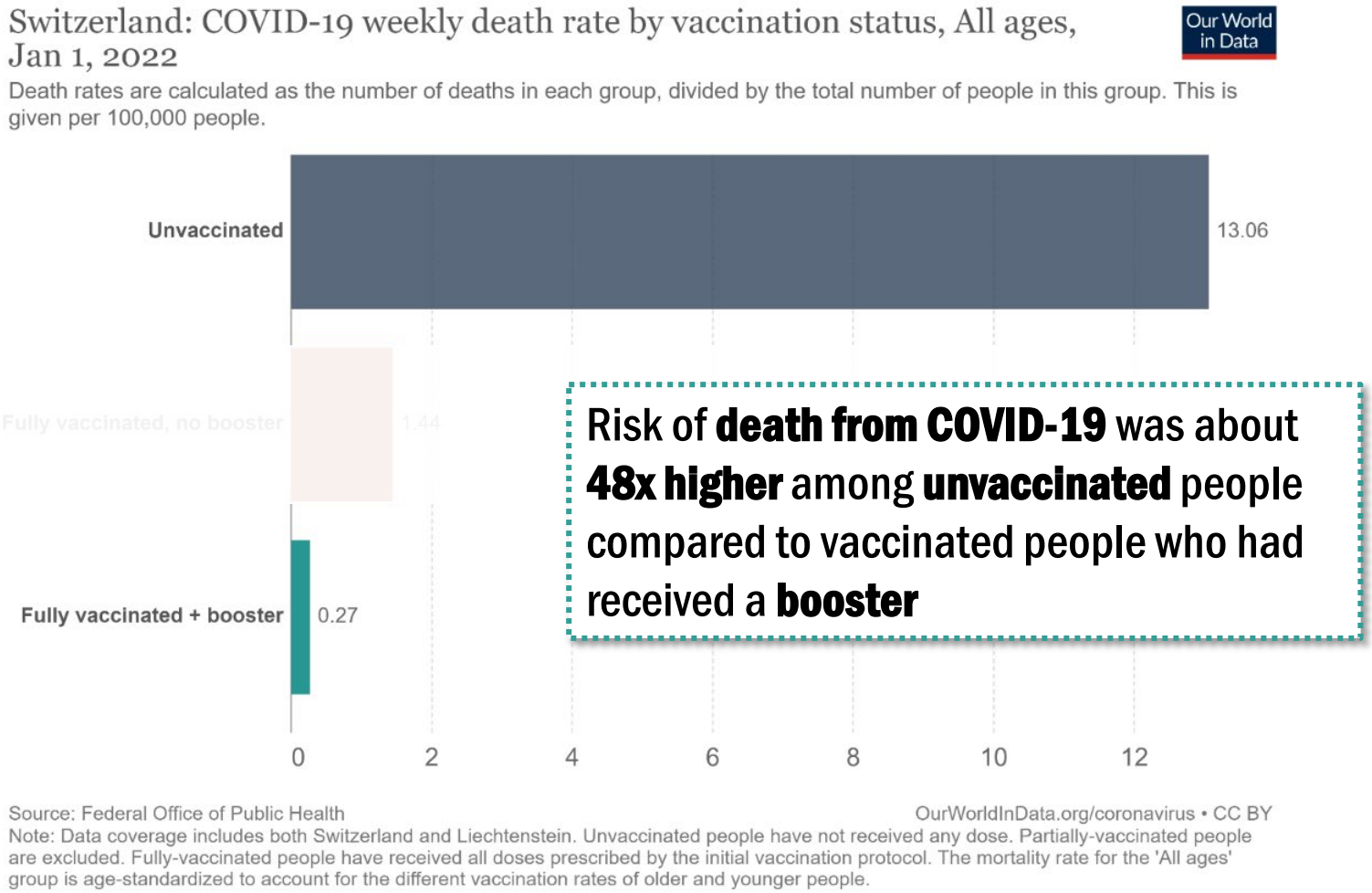
With a booster dose, **vaccine effectiveness** against **hospitalization** was…

in hospitals from 10 US states

in the UK

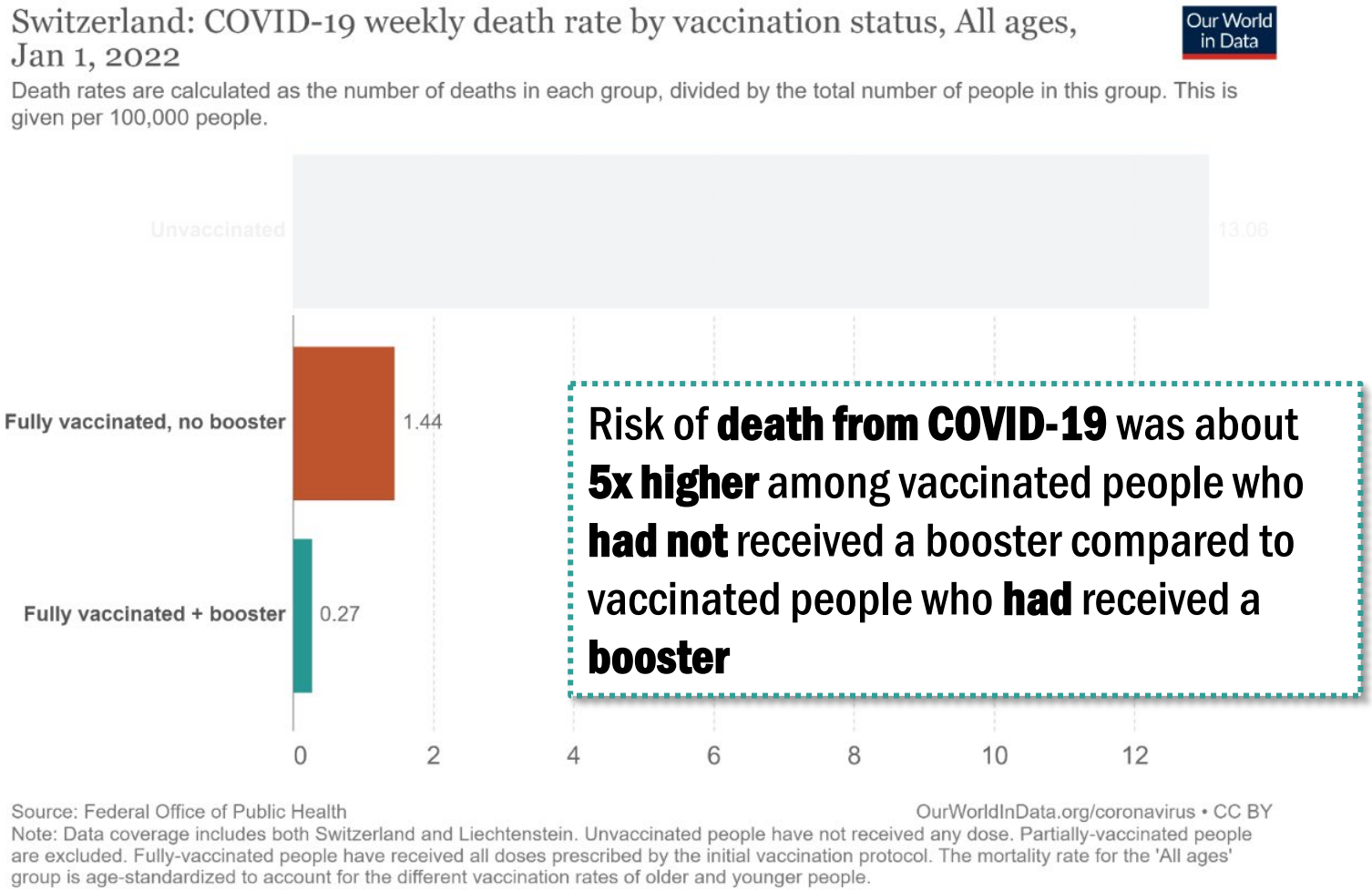
Source: UKHSA, SARS-CoV-2 Variant of Concern, 2022

Switzerland Study on Omicron Mortality Rate



Risk of **death from COVID-19** was about **48x higher** among **unvaccinated** people compared to vaccinated people who had received a **booster**

Switzerland Study on Omicron Mortality Rate



Risk of **death from COVID-19** was about **5x higher** among vaccinated people who **had not** received a booster compared to vaccinated people who **had** received a **booster**

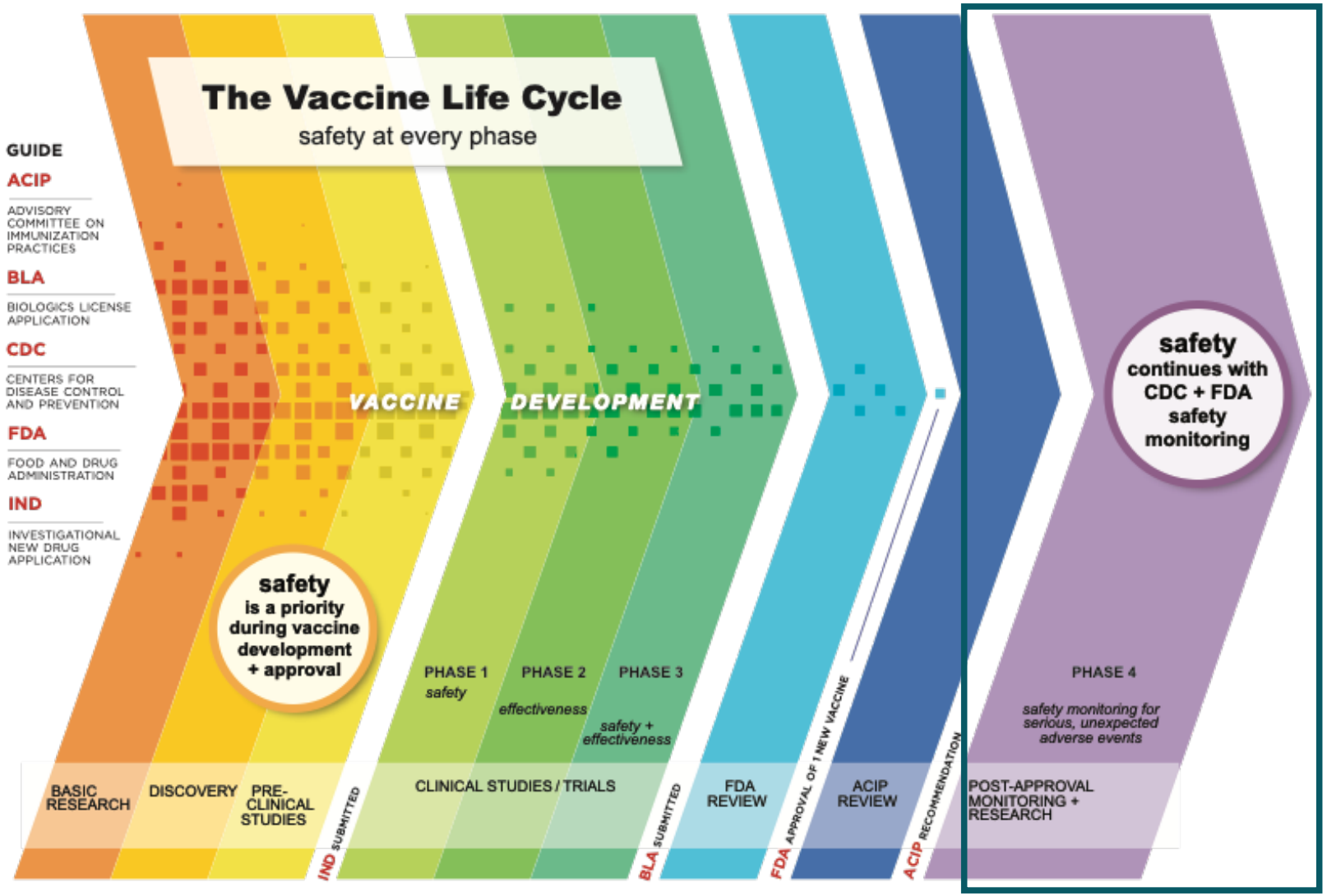
Summary

- Vaccines are an important part of public safety to reduce the spread of disease
- Although vaccines are never 100% effective, the COVID-19 vaccines have demonstrated the ability to reduce:
  - Severity of disease
  - Hospitalization
  - Death
- The full impact of COVID-19 virus on those with disease is unknown, but vaccines help support an individual's immune response without the burden of the disease

Criteria 4

Experience to date with the vaccine containing this antigen demonstrates that it is safe and has an acceptable level of side effects.

Vaccine Life Cycle



LEARN MORE

FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvvNd

CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvvNe

Common Side Effects

On the arm where you got the shot:

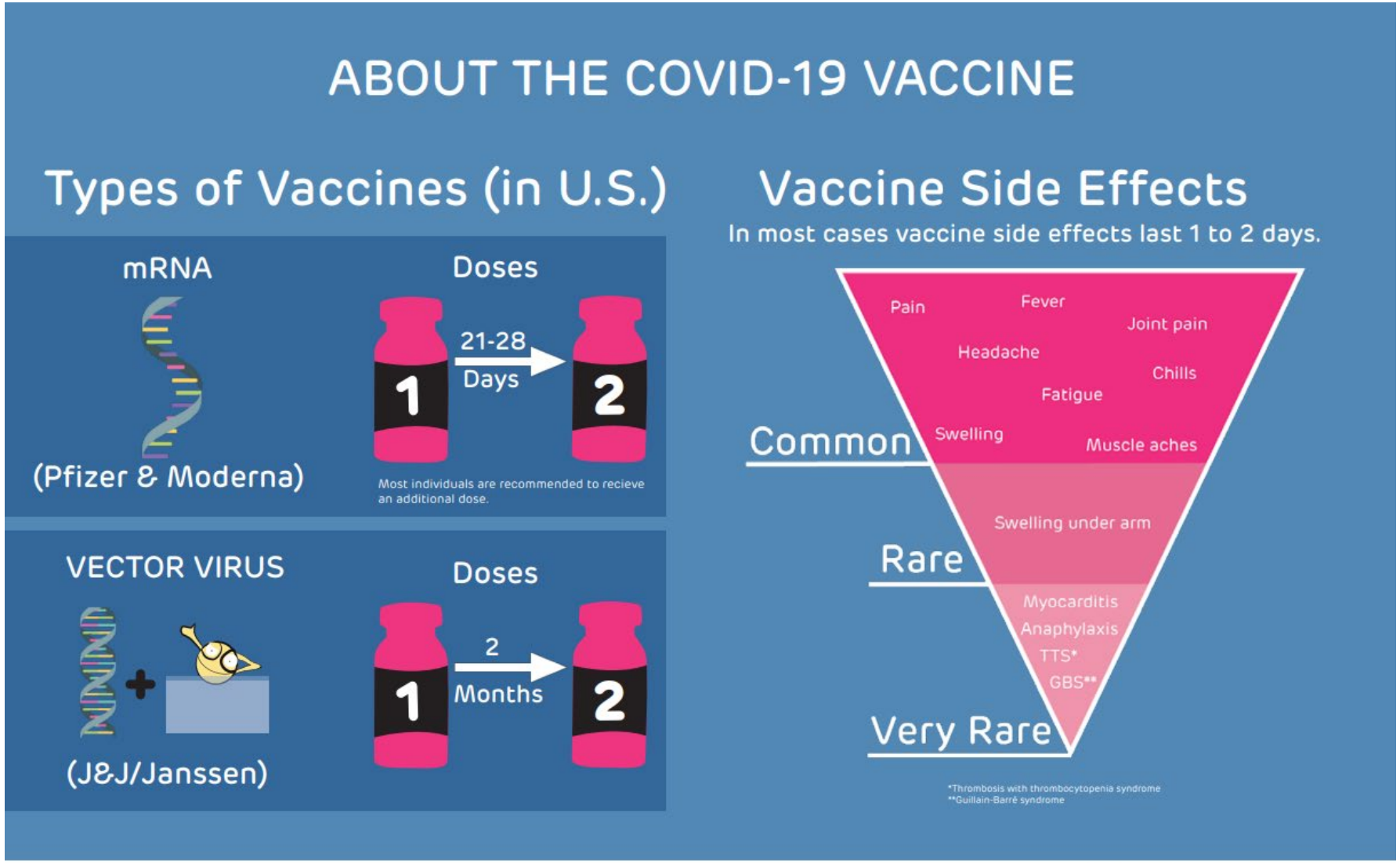
- Pain
- Redness
- Swelling

Throughout the rest of your body:

- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea

Source: Possible Side Effects After Getting a COVID-19 Vaccine (cdc.gov); accessed 01/28/2022.

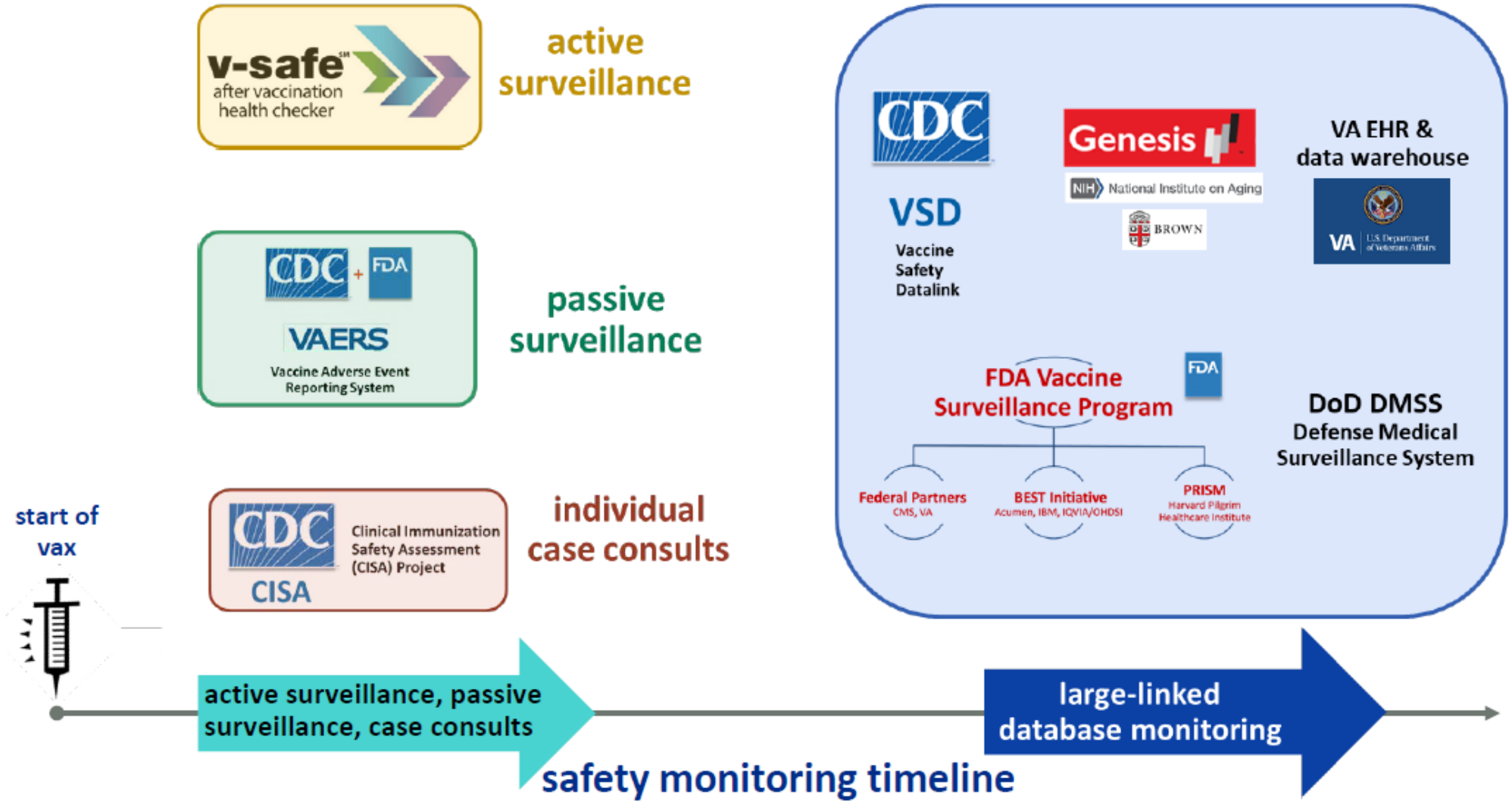
Vaccine Side Effects



Source: Vaccine Education Center at Children's Hospital of Philadelphia

Children's Hospital of Philadelphia
Vaccine Education Center

Vaccine Safety Monitoring Systems



Vaccine Safety Monitoring Systems

Monitoring systems and populations

	Monitoring systems	Population	Healthcare workers	LTCF residents
early	**VAERS** (CDC & FDA) VA ADERS DoD VAECS CDC NHSN	General U.S. population, VA and DoD patient populations, NHSN acute care and long-term care facilities	Yes	Yes
early	**V-safe** (CDC)	All COVID-19 vaccine recipients eligible	Yes	Limited
later	**VSD** (CDC)	Insured patients in VSD sites	Yes	Limited
later	**FDA-CMS**	Medicare recipients (90+% of 65 y/o in the U.S., including 650K LTCF residents)	Limited	Yes
later	**BEST & PRISM** (FDA)	Insured patients in BEST & PRISM sites	Yes	Limited
later	**VA EHR & data warehouse**	Enrolled VA patients	Limited	Yes
later	**DoD DMSS**	Active duty military (limited info on beneficiaries [i.e., family members, retirees])	Yes	Limited
later	**Genesis HealthCare** (Brown U. & NIH-NIA)	Long-term care facility residents (~35,000 long stay residents)	No	Yes

VAERS: Vaccine Adverse Event Reporting System

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

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

http://vaers.hhs.gov

VAERS: Vaccine Adverse Event Reporting System

VAERS accepts reports from everyone

Regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

Key strengths

- Rapidly detects potential safety problems
- Can detect rare adverse events

Key limitations

- Passive surveillance system
- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

Source: J. Su, ACIP Slide 1/5/22

VAERS Reports: Pediatric COVID-19 Vaccinations

- Vaccine distribution since authorization:
  - Children 5–11 have received 8.7 million doses
  - Children 12–15 have received 18.7 million doses
- Most reports for both groups (ages 5–15) were non-serious (92% or higher)
- Most frequently reported adverse events were well-known side effects from Pfizer-BioNTech. Other reported events were vaccination errors, myocarditis, or MIS-C
- Myocarditis among 5–11 year olds
  - Predominantly in males, and similar to older age groups after dose 2
  - **Substantially lower reporting rates than in ages 12–17**
- CDC will continue to monitor COVID-19 vaccine safety among these groups

Source: J. Su, ACIP Slide 1/5/22

VAERS Reports: Pediatric COVID-19 Vaccinations

Reports to VAERS among children and adolescents ages 5–11 and 12–15 years* after Pfizer-BioNTech COVID-19 vaccination, by race and ethnicity
(as of Dec 19, 2021)

Race and ethnicity	5–11 yrs, n (%)	12–15 yrs, n (%)
Unknown or not reported	1,694 (40)	2,631 (25)
Non-Hispanic White	1,439 (34)	3,973 (38)
Hispanic†	469 (11)	1,429 (14)
Non-Hispanic other	198 (5)	1,136 (11)
Non-Hispanic Black	170 (4)	478 (5)
Non-Hispanic Asian	166 (4)	482 (5)
Non-Hispanic multiracial	84 (2)	199 (2)
Non-Hispanic American Indian/Alaskan Native	22 (1)	112 (1)
Non-Hispanic Native Hawaiian or Other Pacific Islander	Not reported‡	18 (<1)
Total	**4,249**	**10,458**

* Among children ages 5–11 years vaccinated during Nov 3–Dec 19, 2021, and among children and adolescents ages 12–15 years vaccinated during May 12–Dec 19, 2021; reports received and processed as of Dec 19, 2021.

† Includes persons reported as of Hispanic ethnicity, but of unreported or unknown race.

Source: J. Su, ACIP Slide 1/5/22

VAERS Reports: Pediatric COVID-19 Vaccinations

Most frequently reported adverse events to VAERS after Pfizer-BioNTech COVID-19 vaccination, children and adolescents ages 12–15 years* (as of Dec 19, 2021)

Non-serious reports (n=9,612, 92%)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Dizziness	1,512 (16)
2	Syncope	1,057 (11)
3	Headache	888 (9)
4	Product Storage Error	886 (9)
5	Nausea	860 (9)
6	Fever	844 (9)
7	Vomiting	657 (7)
8	Fatigue	640 (7)

Serious reports (n=846, 8%)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Chest Pain	440 (52)
2	Troponin Increased	333 (39)
3	Myocarditis	327 (39)
4	SARS-CoV-2 Test Negative	276 (33)
5	C-Reactive Protein Increased	263 (31)
6	Fever	258 (31)
7	Echocardiogram Normal	249 (29)
8	Headache	221 (26)

- Reflect vaccination error and previously observed adverse events; workup for myocarditis or Multisystem Inflammatory Syndrome in Children (MIS-C)

* Reports among children ages 12–15 years vaccinated May 12–Dec 19, 2021

Source: J. Su, ACIP Slide 1/5/22

VAERS Reports: Pediatric COVID-19 Vaccinations

U.S. reports to VAERS among children and adolescents ages 5–11 and 12–15 years after Pfizer-BioNTech COVID-19 vaccination* (as of Dec 19, 2021)

Age group	Median age	Male n (%)	Female n (%)	Non-serious n (%)	Serious† n (%)	Total reports	Doses admin‡
5–11 years	8 years	1,896 (45)	1,911 (45)	**4,149 (98)**	100 (2)	4,249	8,674,378
12–15 years	13 years	4,946 (47)	5,381 (51)	**9,612 (92)**	846 (8)	10,458	18,707,169

- For both age groups, most reports (≥92%) were non-serious
- Distribution by sex similar

* Among children ages 5–11 years vaccinated during Nov 3–Dec 19, 2021, and among children and adolescents ages 12–15 years vaccinated during May 12–Dec 19, 2021; reports received and processed as of Dec 19, 2021.

† Includes 3 deaths (2 medically complex patients, 1 with influenza) among ages 5–11 years, and 12 deaths with no observable common mechanism among ages 12–15 years.

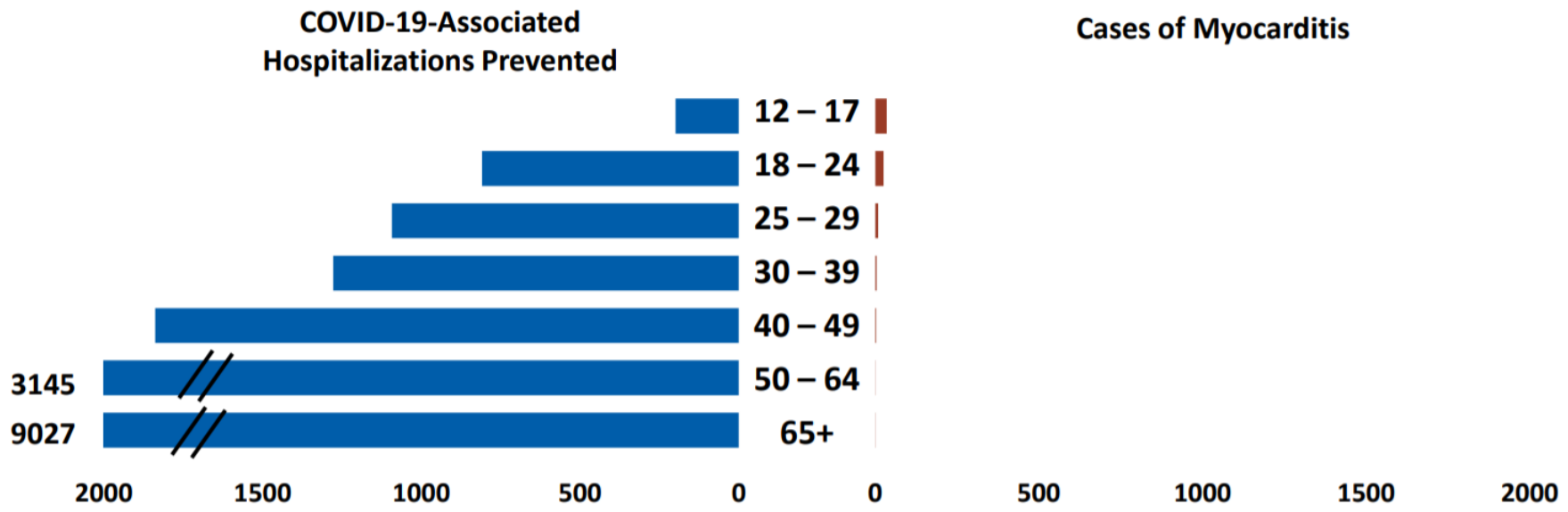
‡ Doses administered among children ages 5–11 years during Nov 4–Dec 16, 2021, and for children and adolescents ages 12–15 years during May 12–Dec 16, 2021.

Source: J. Su, ACIP Slide 1/5/22

Vaccine Safety in Context

Benefits and risks after dose 2, by age group

For every **million** doses of mRNA vaccine given with current US exposure risk[1]



Source: CDC file:///home/chronos/u-511a8c8c7653c0da4b629af414dc6a931c09cf0f/MyFiles/Downloads/cdc_108331_DS1.pdf

v-safe

What is v-safe

Get vaccinated. Get your smartphone. Get started with v-safe.

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from ***v-safe*** around 2pm local time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions ***v-safe*** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, ***v-safe*** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in ***v-safe*** is protected so that it stays confidential and private.*

*To the extent ***v-safe*** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. Those measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

12/01/20

v-safe℠
after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

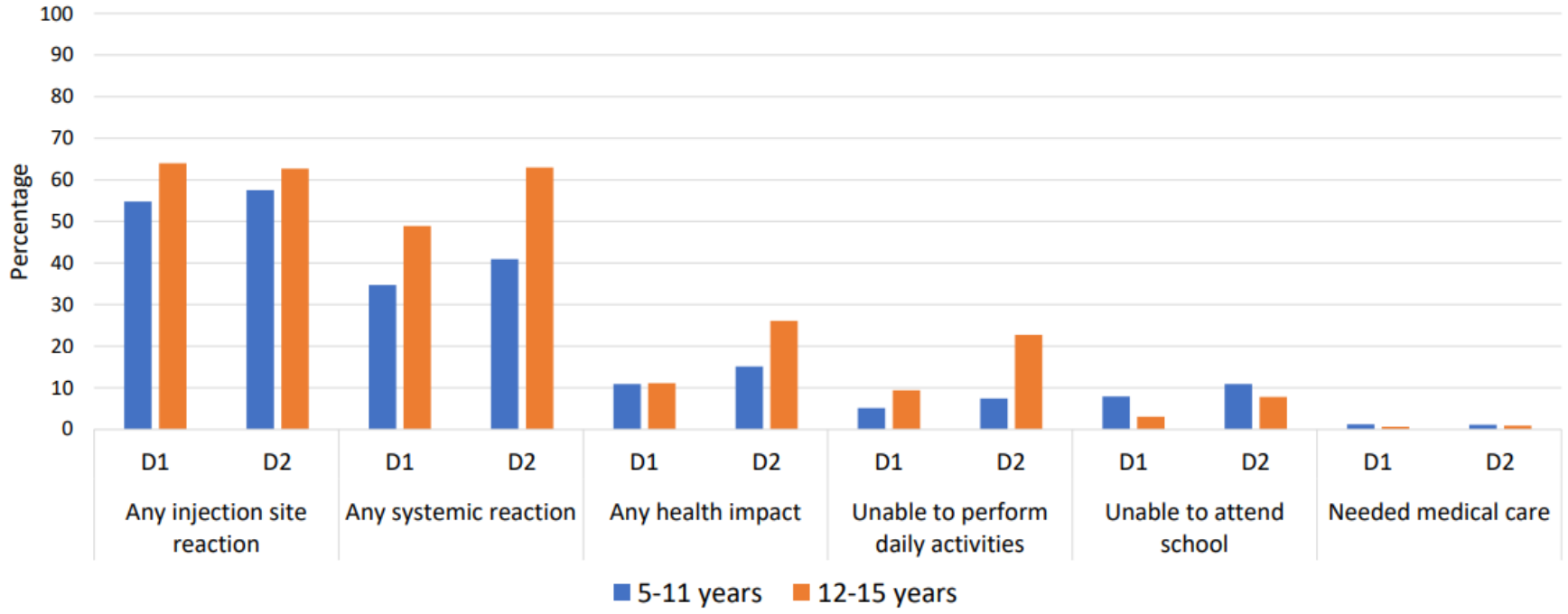
Sign up with your smartphone's browser at
vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

v-safe Reports: Pediatric COVID-19 Vaccinations

Reactions and health impact events reported at least once in days 0-7 after Pfizer-BioNTech vaccination for children and adolescents ages 5-11 and 12-15 years,* by dose

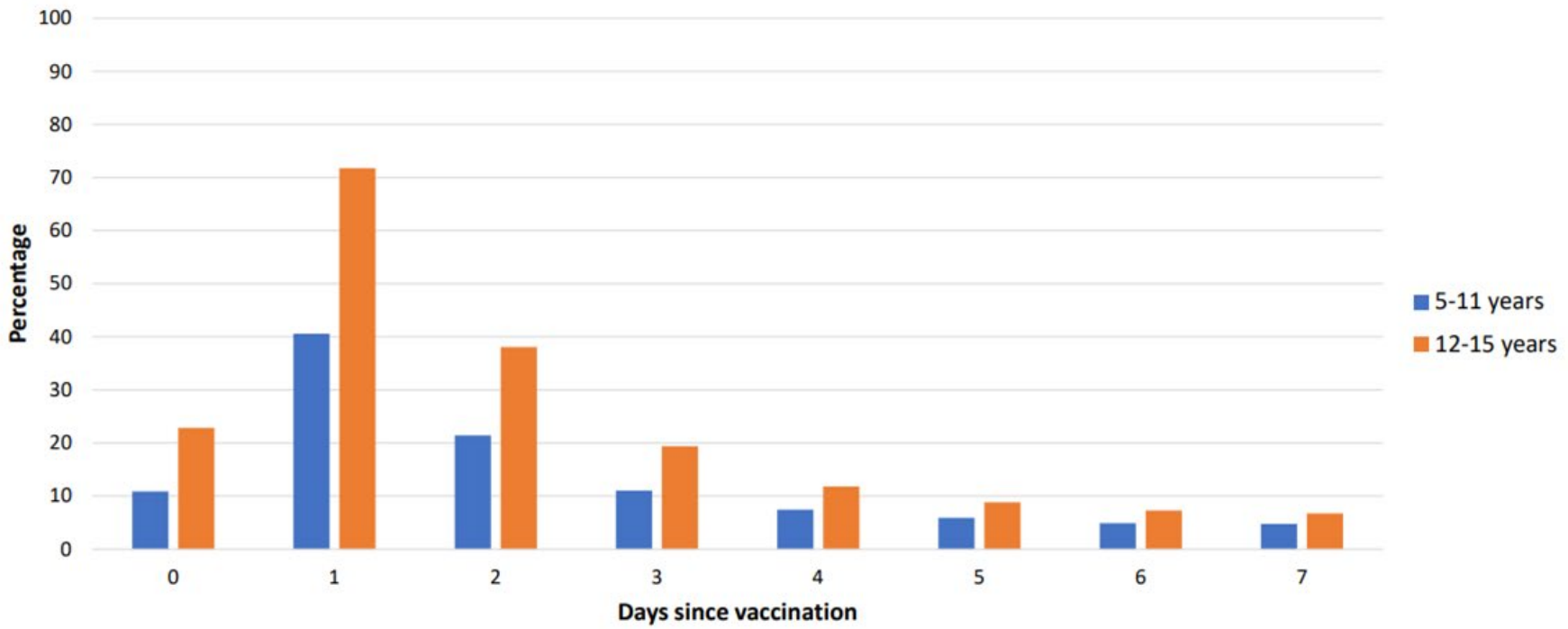


* The dosage for children ages 5-11 years (10 µg) is smaller than that recommended for persons ages ≥12 years (30 µg).
Includes 77,747 participants who completed at least one survey in the first week after dose 2, data as of December 19, 2021

Source: A. Hause, ACIP Slide 1/5/22

v-safe Reports: Pediatric COVID-19 Vaccinations

Any systemic reaction reported for children ages 5–11 and 12-15 years* at least once in 0–7 days after dose 2 of Pfizer-BioNTech vaccine, by days since vaccination



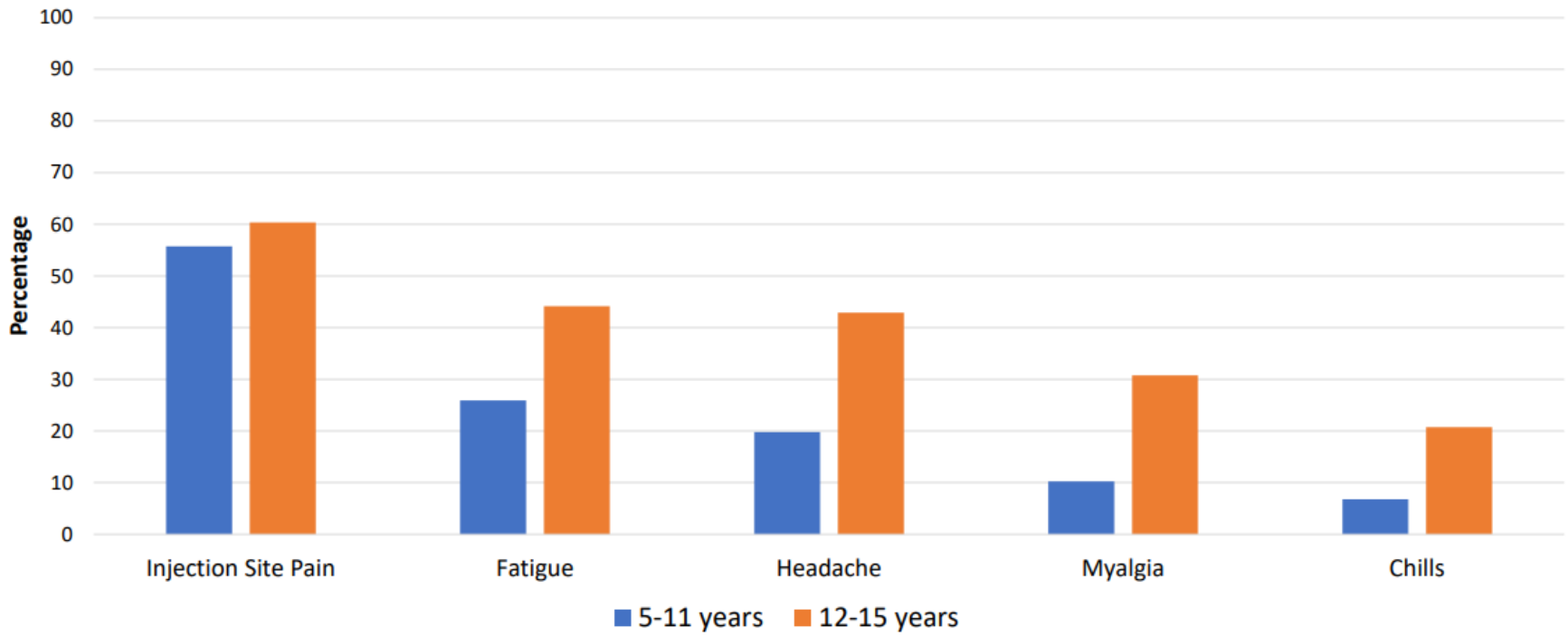
CDC

* The dosage for children ages 5-11 years (10 µg) is smaller than that recommended for persons ages ≥12 years (30 µg).
Includes 77,747 participants who completed at least one survey in the first week after dose 2, data as of December 19, 2021

Source: A. Hause, ACIP Slide 1/5/22

v-safe Reports: Pediatric COVID-19 Vaccinations

Top 5 reactions reported at least once in 0–7 days after dose 2 of Pfizer-BioNTech vaccine for children ages 5-11 and 12-15 years*

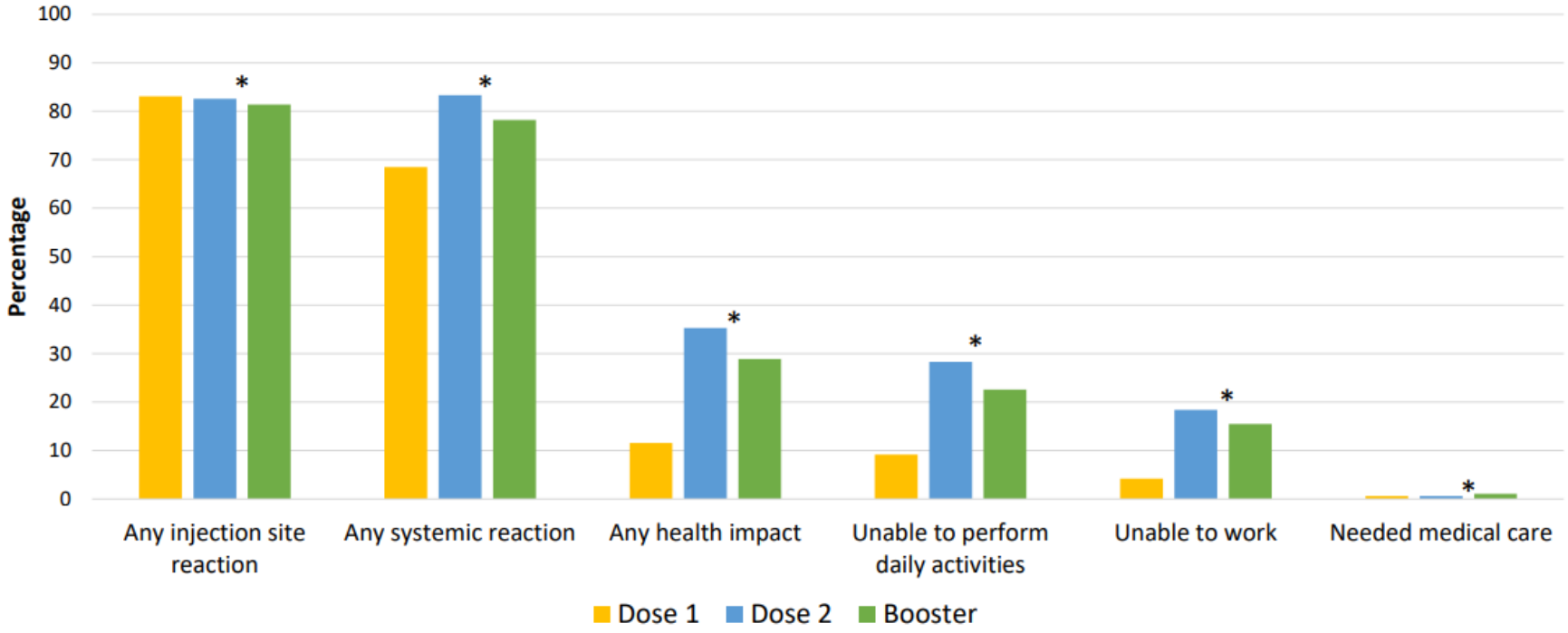


* The dosage for children ages 5-11 years (10 µg) is smaller than that recommended for persons ages ≥12 years (30 µg).
Includes 77,747 participants who completed at least one survey in the first week after dose 2, data as of December 19, 2021

Source: A. Hause, ACIP Slide 1/5/22

v-safe Reports: Young Adult COVID-19 Vaccinations

Reactions and health impact events reported by v-safe participants ages 16-24 years at least once in days 0-7 after Pfizer-BioNTech vaccination, by dose

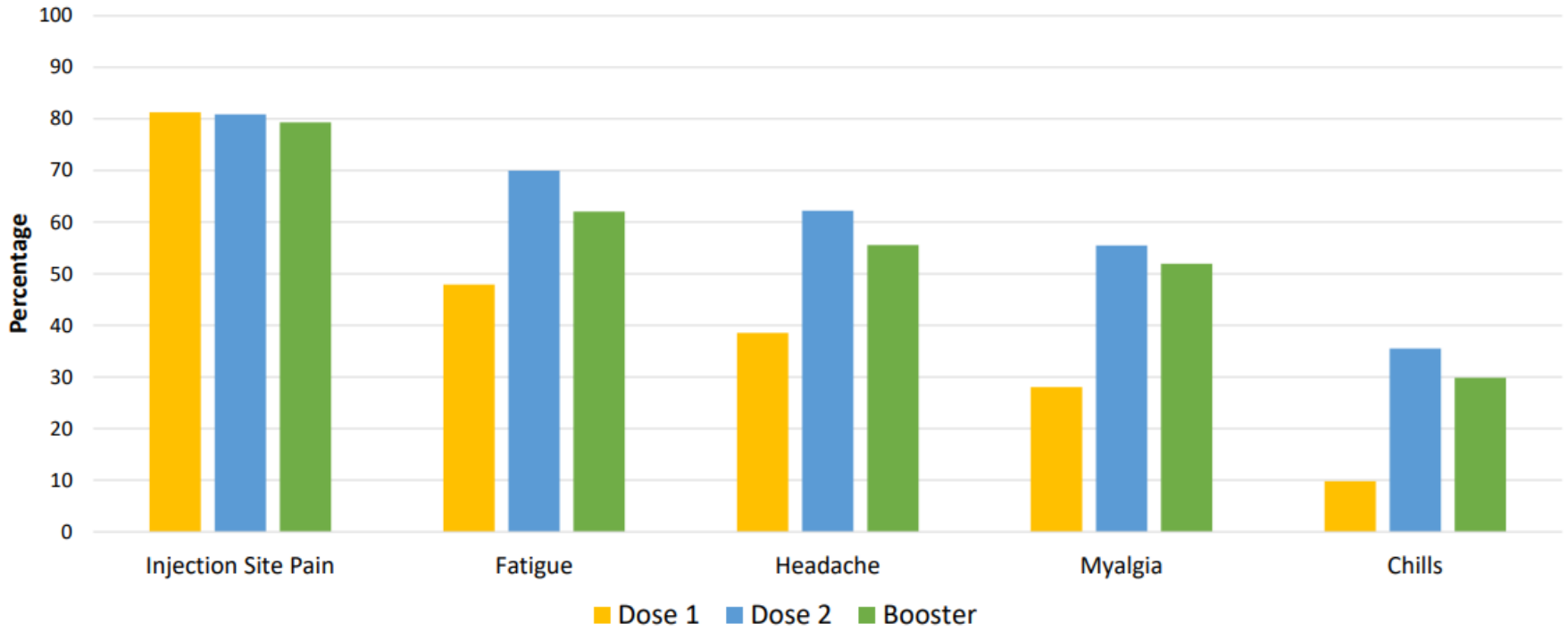


Includes 7,088 participants who completed at least one survey in the first week after each dose, data collected during September 22–December 19, 2021
* Dose 2 compared to dose 3: statistically significant difference (p-value <0.05) using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables. All differences were reported less frequently following booster dose than dose 2, except "needed medical care" which was more frequently reported.

Source: A. Hause, ACIP Slide 1/5/22

v-safe Reports: Young Adult COVID-19 Vaccinations

Top 5 reactions reported by v-safe participants ages 16-24 years at least once 0-7 days following Pfizer-BioNTech vaccination, by dose



Includes 7,088 participants who completed at least one survey in the first week after each dose, data collected during September 22–December 19, 2021

Source: A. Hause, ACIP Slide 1/5/22

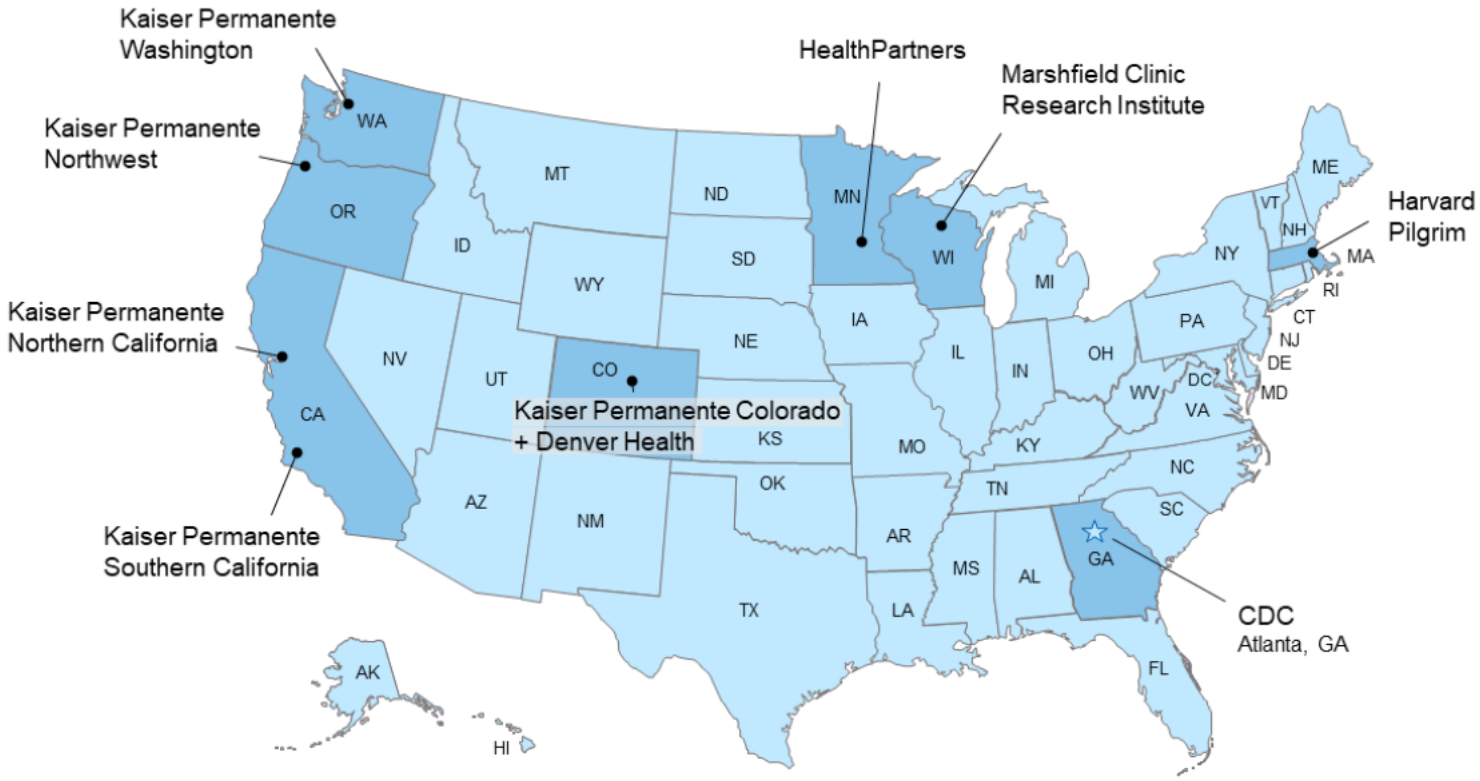
v-safe Summary

- Over 115,208 v-safe participants ages 5–15 years have reported Pfizer-BioNTech vaccination
  - Reactions were generally mild to moderate and most frequently reported the day after vaccination
  - Reactions were more frequently reported after dose 2 than dose 1
  - Participants ages 5–11 years reported reactions less frequently than participants ages 12–15 years
- Over 7,088 v-safe participants ages 16–24 years reported a homologous Pfizer-BioNTech booster dose
  - Reactions were generally mild to moderate and most frequently reported the day after vaccination
  - Reactions were less frequently reported after booster dose than dose 2

Source: A. Hause, ACIP Slide 1/5/22

Vaccine Safety

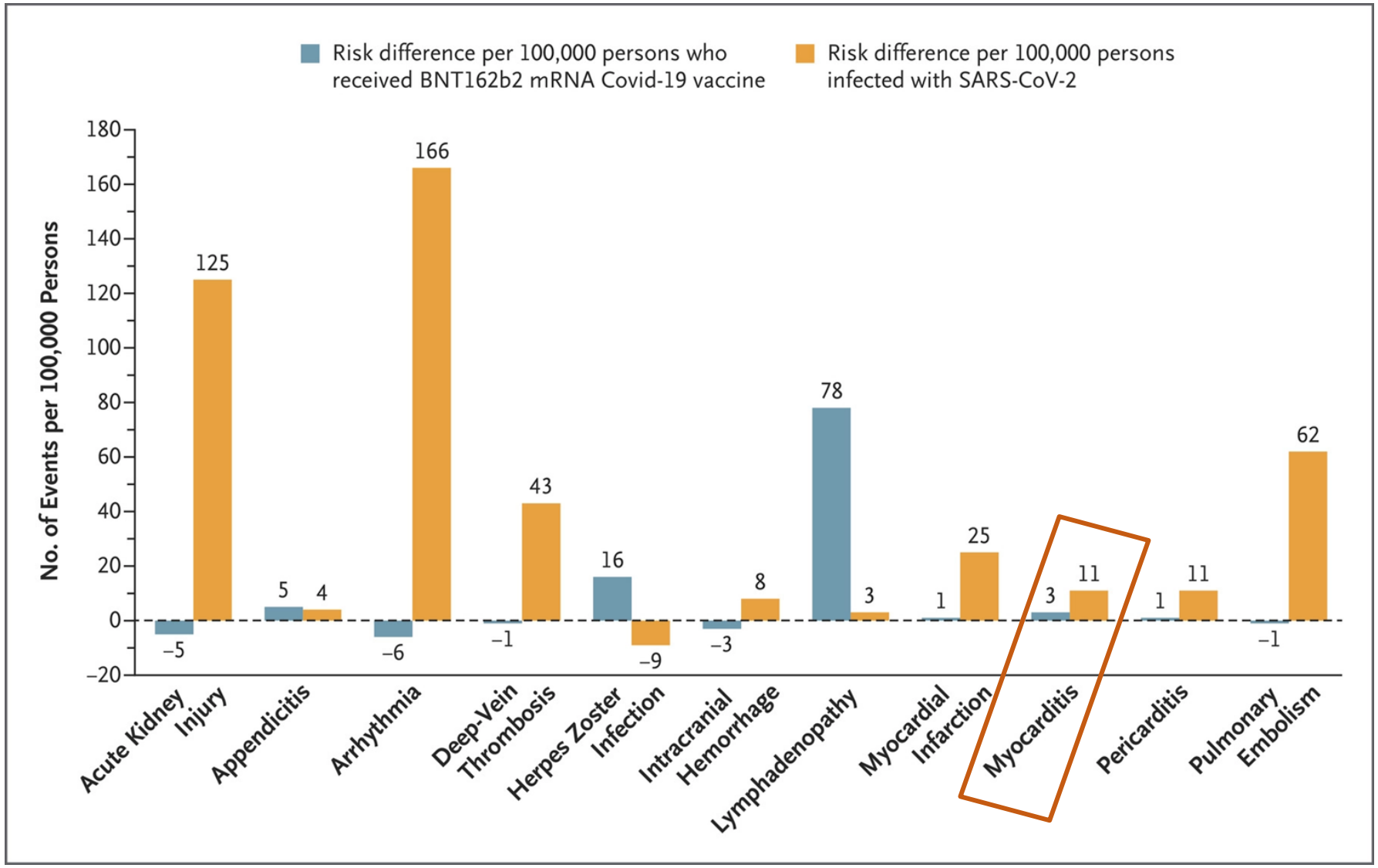
The Vaccine Safety Datalink (VSD)



- Established in 1990
- Collaborative project between CDC and 9 integrated healthcare organizations

Myocarditis

Myocarditis: Vaccine Safety in Context

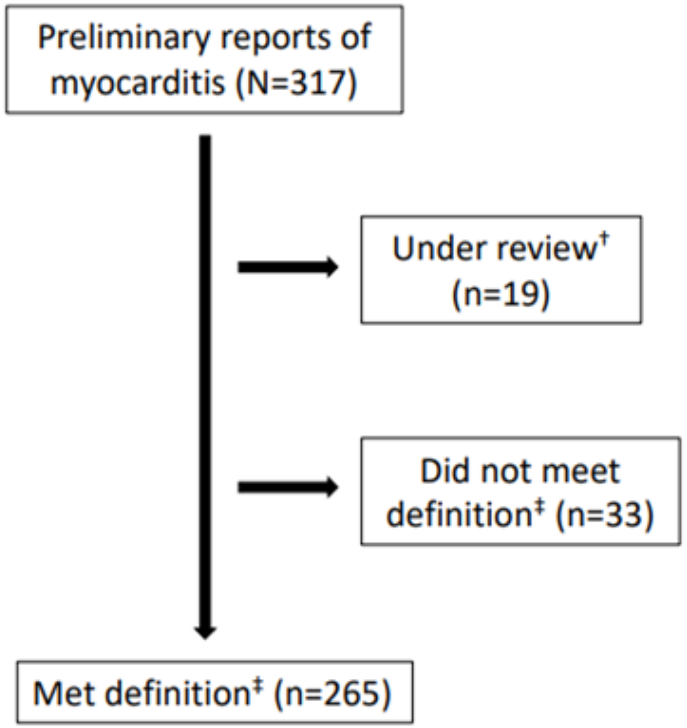


Source: Barda, et al (2021)

Myocarditis

Reports to VAERS of myocarditis after Pfizer-BioNTech COVID-19 vaccination among children and adolescents ages 12–15 years* (as of Dec 19, 2021)

- 265 reports of myocarditis verified to meet case definition
  - Median age: 14 years (IQR: 13–15 years)
  - Median time to onset: 2 days (IQR: 1–3 days)
  - After dose 1 = 41; after dose 2 = 221
  - 238 (90%) males, 27 (10%) females
    - 251 hospitalized patients (241 discharged home)
    - 224 patients with known outcomes
      - 208 (92%) recovered from symptoms at time of report
      - 16 (8%) mostly reported improved, or resolved, symptoms, but ongoing physical restrictions or still under investigation
- Doses administered = 18,707,169§



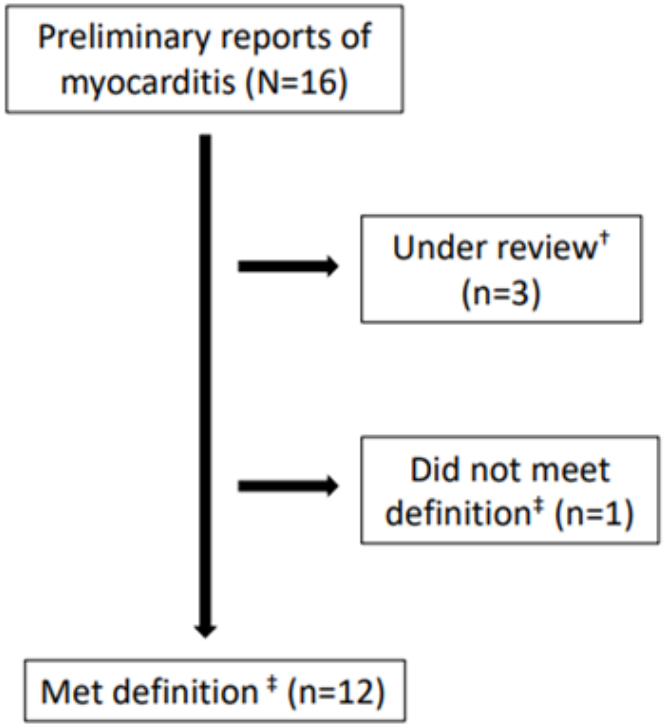
* Reports of children and adolescents ages 12–15 years vaccinated May 12–Dec 19, 2021
† Awaiting medical records and/or healthcare provider interview; some still processing
‡ Adjudicated after healthcare provider interview and/or medical record review
§ Doses administered among children and adolescents ages 12–15 years May 12–Dec 16, 2021

Source: J. Su, ACIP Slide 1/5/22

Myocarditis

Reports to VAERS of myocarditis after Pfizer-BioNTech COVID-19 vaccination among children ages 5–11 years* (as of Dec 19, 2021)

- 12 reports of myocarditis verified to meet case definition
  - Median age: 10 years (IQR: 9–11 years)
  - Median time to onset: 2 days (IQR: 2–3 days)
  - After dose 1 = 2; after dose 2 = 9; not reported = 1
  - 8 (67%) males, 4 (33%) females
    - All discharged home
    - 8 recovered from symptoms at time of report
    - 4 still recovering at time of report
    - None reported a vaccination error
- Doses administered = 8,674,378§



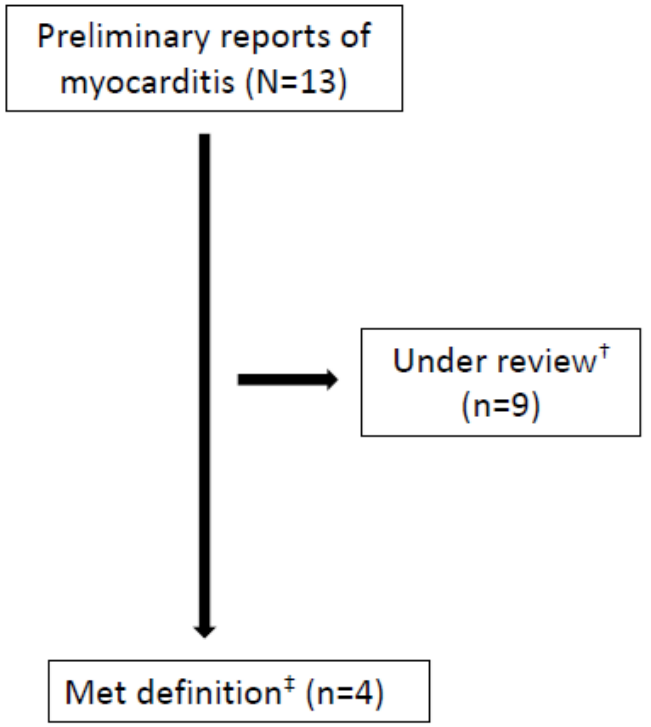
* Reports of children ages 5–11 years vaccinated Nov 3–Dec 19, 2021
† Awaiting medical records and/or healthcare provider interview; some still processing
‡ Adjudicated after healthcare provider interview and/or medical record review
§ Doses administered among children ages 5–11 years Nov 4–Dec 16, 2021

Source: J. Su, ACIP Slide 1/5/22

Myocarditis

Reports of myocarditis to VAERS after Pfizer-BioNTech COVID-19 booster vaccination among persons ages 16–24 years*

- 13 preliminary reports of myocarditis
  - Median age: 21 years (IQR: 20–22 years)
  - Median time to onset: 1 day (IQR: day of vaccination–1 day)
  - 9 (69%) males, 4 (31%) females
  - 4 reports met case definition
    - 2 reports among ages 16–17 years§
    - 2 reports among ages 18–24 years
    - All reported patients recovered at time of report
- Doses administered = 976,882¶



* Among adolescents ages 16–17 years receiving dose 3 of Pfizer-BioNTech vaccine Dec 9–Dec 19, 2021, and persons ages 18–24 years receiving dose 3 of Pfizer-BioNTech vaccine Sep 22–Dec 19, 2021; reports processed and received as of Dec 19, 2021.

† Awaiting medical records and/or healthcare provider interview; some still processing.

‡ Adjudicated after healthcare provider interview and/or medical record review.

§ One report identified after Dec 19 but vaccinated during Sep 22–Dec 19, 2021.

¶ Doses administered as of Dec 16, 2021.

Source: J. Su, ACIP Slide 1/5/22

Myocarditis Risk, USA

Myocarditis risk from COVID-19

- myocarditis risk is **37 times higher** for infected children under 16 years compared to uninfected children
- Risk: 0.133% (<16yo)

Myocarditis risk from mRNA vaccine per million doses

- Males (5–11yo): 4.3
- Males (12–15yo): 45.7
- Female (5–11yo): 2
- Female (12–15yo): 3.8

Source: Boehmer, et al (2021)

Myocarditis

Reporting rates of myocarditis (per 1 million doses administered) after Pfizer-BioNTech COVID-19 vaccination, 7-day risk interval*

	Males		Females	
Age group	**Dose 1**	**Dose 2**	**Dose 1**	**Dose 2**
5–11 years	0.0	4.3	Not calculated†	2.0
12–15 years	4.8	45.7	1.0	3.8
16–17 years (included for reference)	6.1	70.2	0.0	7.6

- **37,810,998** total doses 1 and 2 of vaccine administered‡
- Reporting rates exceed background incidence (peach shaded cells) §
  - Males: after dose 1 (ages 12–15 and 16–17 years) and after dose 2 (ages 5–11, 12–15, and 16–17 years)
  - Females: after dose 2 (ages 12–15 and 16–17 years)
  - Reporting rates among males substantially lower among ages 5–11 vs. 12–15 and 16–17 years

* Reports of myocarditis after doses 1 and 2 of Pfizer-BioNTech COVID-19 vaccine during a 7-day risk interval after vaccination (as of Dec 19, 2021); reports verified to meet case definition by healthcare provider interview and/or medical record review.

† Too few reports of females ages 5–11 years to calculate a stable rate.

‡ Children ages 5–11 years vaccinated Nov 3–Dec 19, 2021, children and adolescents ages 12–15 years vaccinated May 12–Dec 19, 2021.

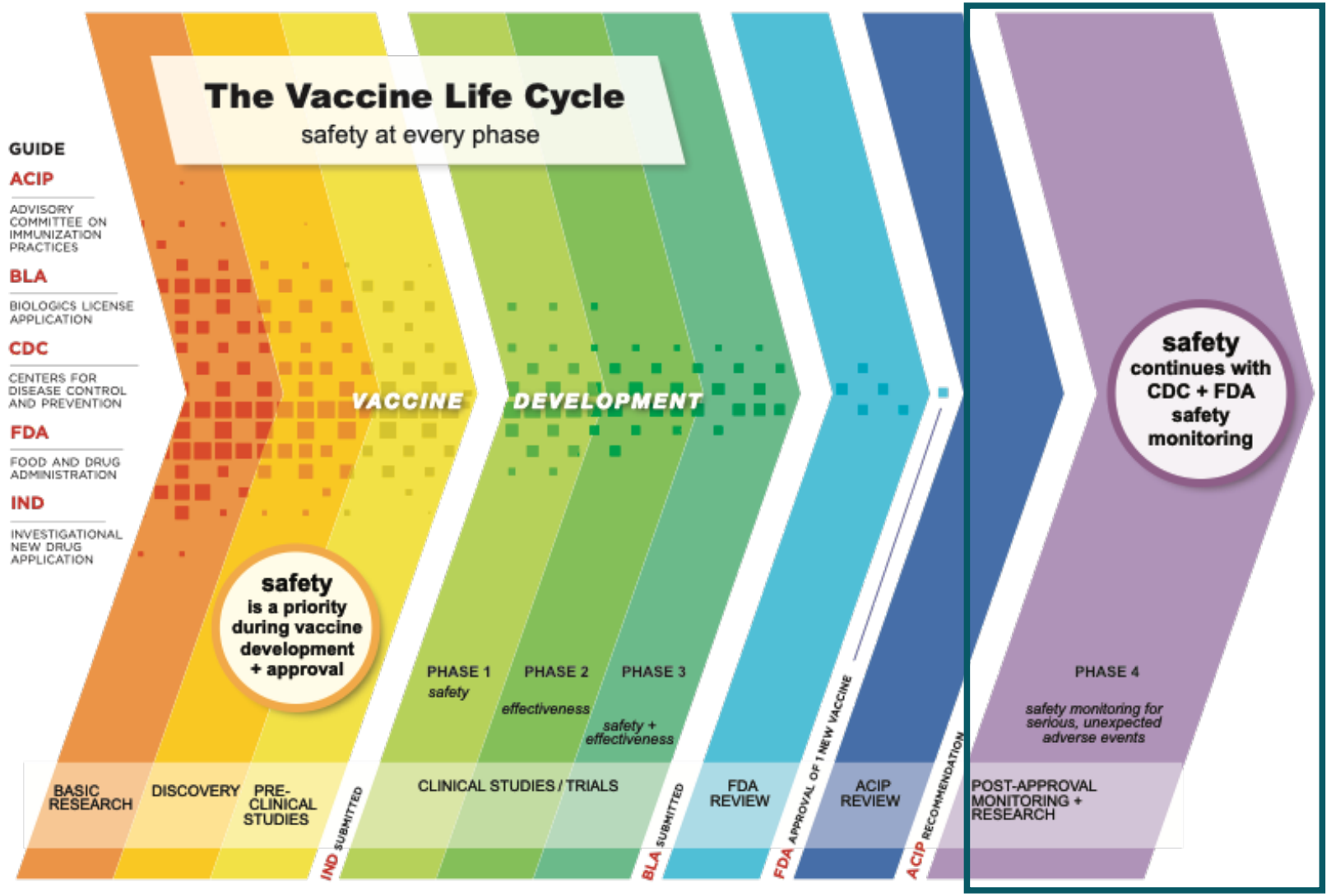
§ An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for the 7-day risk period, this estimated background is 0.2 to 1.9 per 1 million person 7-day risk period.

Source: J. Su, ACIP Slide 1/5/22

Vaccine Life Cycle

Ongoing Safety Assessment

- Currently the CDC Vaccine Safety team is continuing to follow-up on reported myocarditis cases
- Other work continues to identify possible trends and as needed additional follow up to ensure safety
- Ongoing reports to ACIP and as needed updates in recommendations or guidance information



LEARN MORE

FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvvNd

CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvvNe

Summary

- Vaccines are an important part of public safety to reduce the spread of disease
- Although vaccines are never 100% effective, the COVID19 vaccines have demonstrated the ability to reduce:
  - Severity of disease
  - Hospitalization
  - Death
- The COVID-19 vaccines have completed rigorous testing, safety review and approval by healthcare experts and advisory group members for both FDA and CDC
- The full impact of COVID-19 virus on those with disease is unknown, but vaccines help an individual's immune response without the burden of the disease
- Getting sick with COVID-19 can cause severe illness or death and it is not always possible to know who will become more ill

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