

DAILY NEWS

Hot Vaccine Updates – COVID Vaccine Updates

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Declarations

No Financial Conflict of Interest to Declare

Off Label

PCV20 in children

EUA only for some COVID vaccines

Objectives

- Compare and contrast influenza vaccines
- List three recent changes to COVID vaccine recommendations
- Identify which patients should receive which pneumococcal vaccine

Dengue Fever

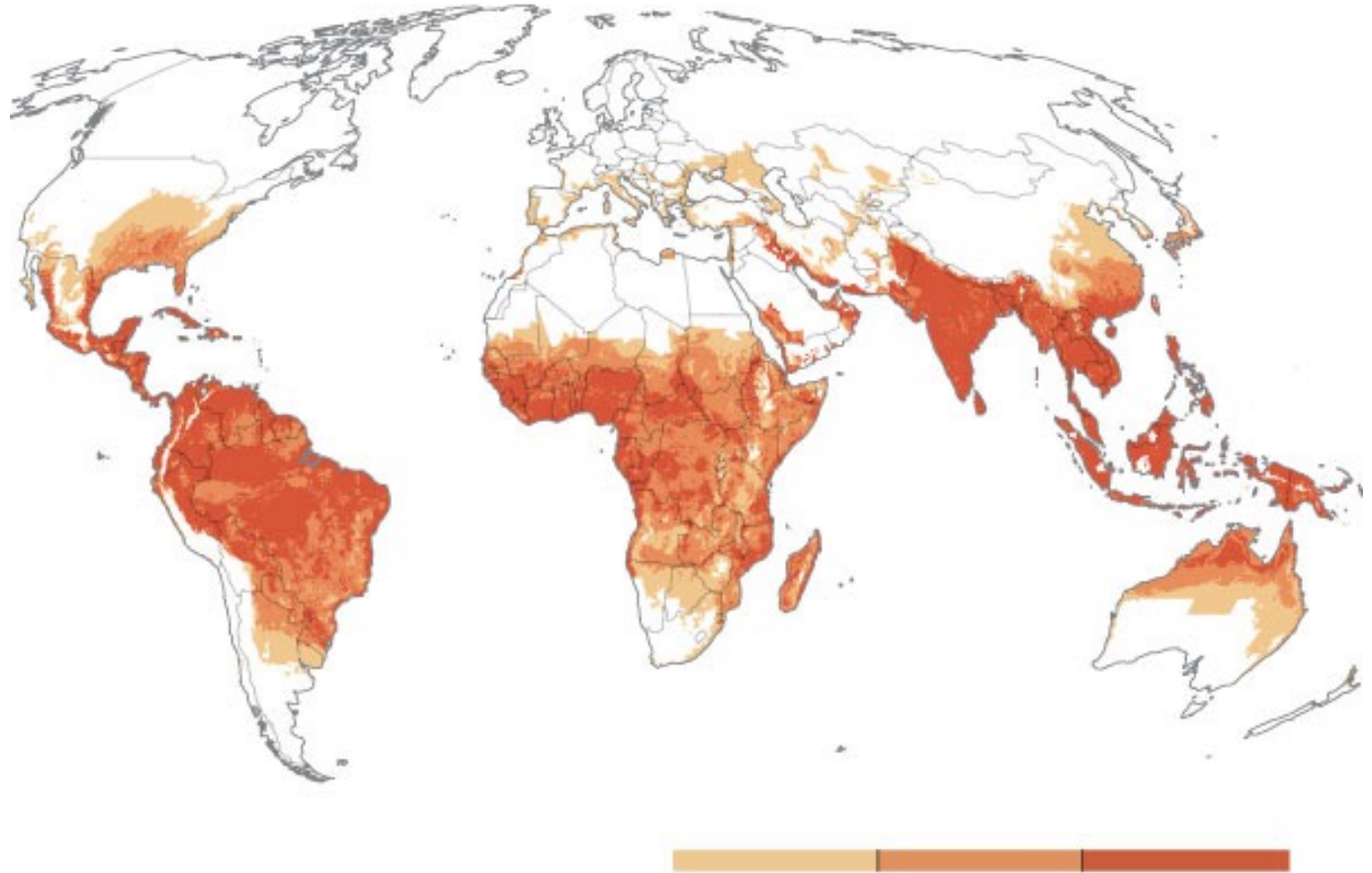
- 2.5 billion people – two fifths of the world's population in tropical and subtropical countries – are at risk.
- 50 million dengue infections occur worldwide annually.
- Dengue virus is a threat to 40% of the world
- Estimated 500 000 people with DHF require hospitalization each year.

US States

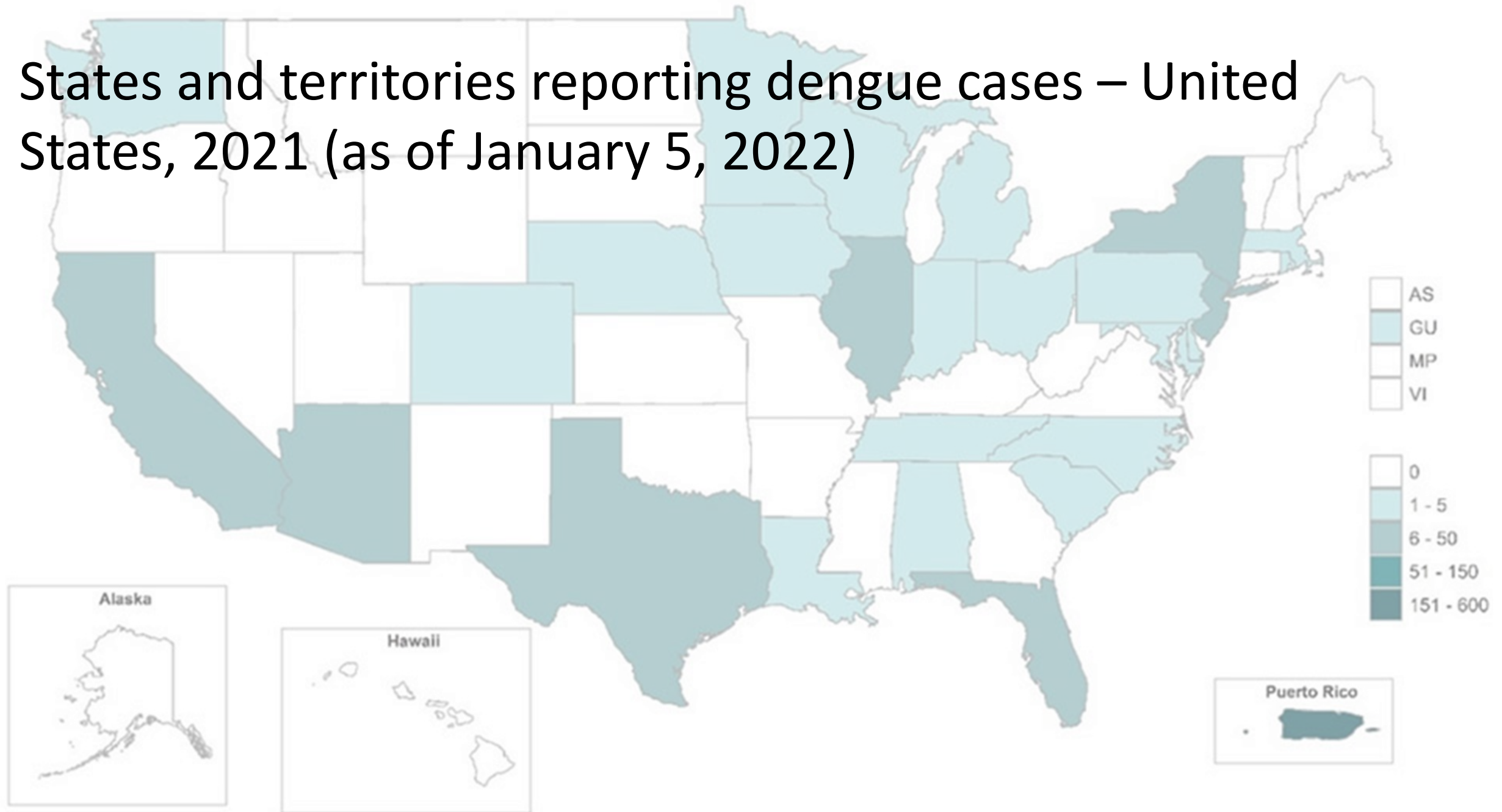
- 117 dengue cases reported

US Territories

- 513 dengue cases reported

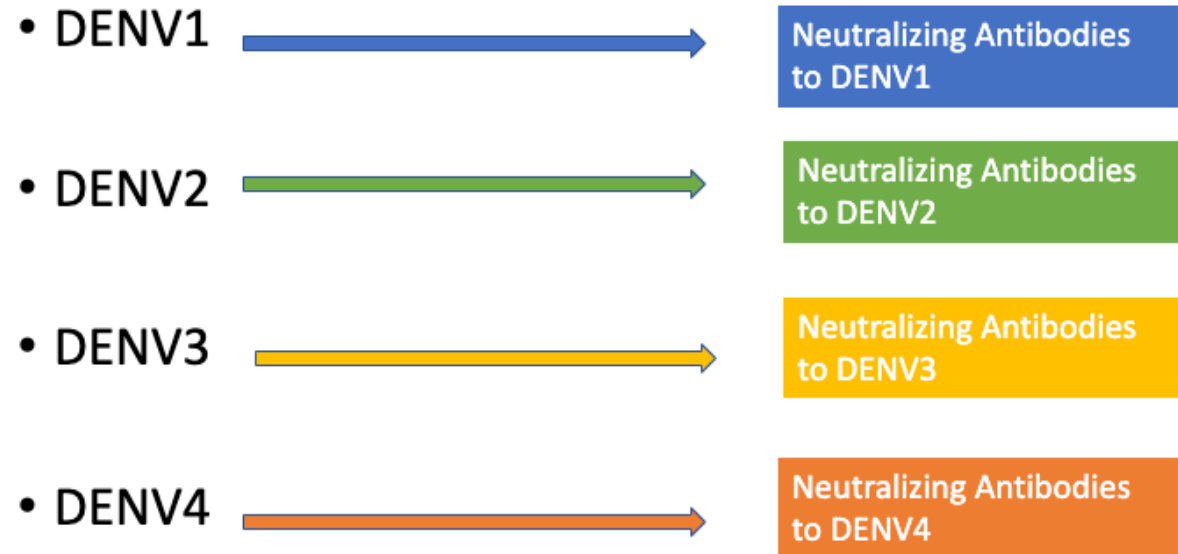


States and territories reporting dengue cases – United States, 2021 (as of January 5, 2022)

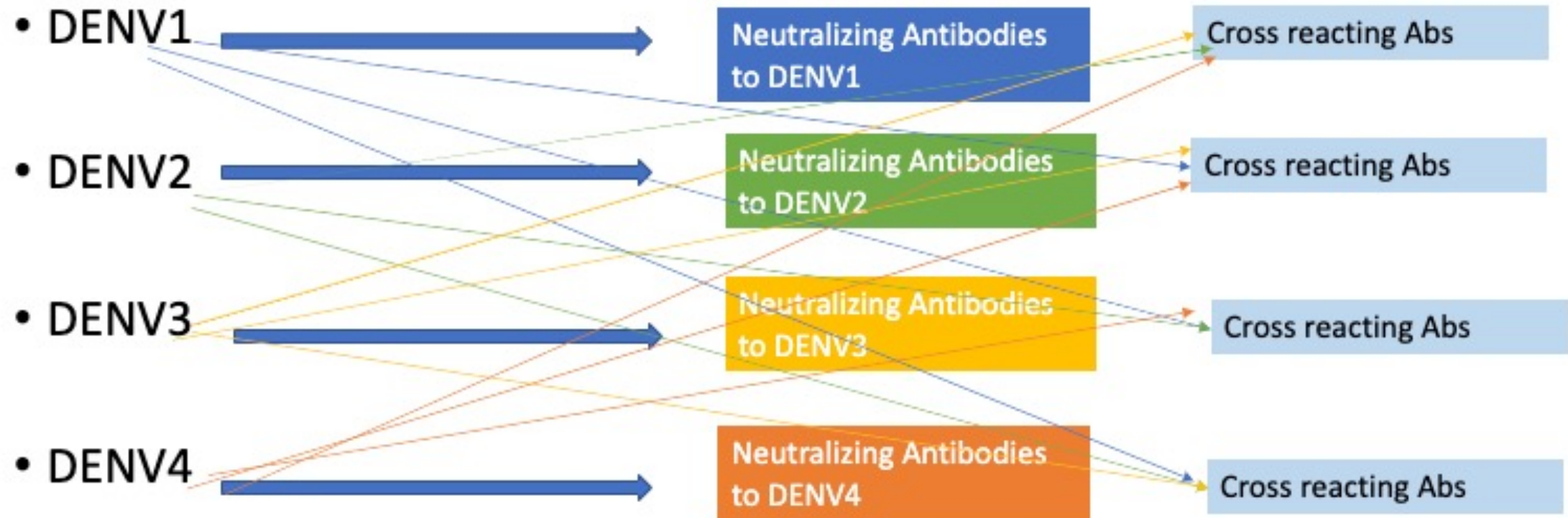


Primary Infection

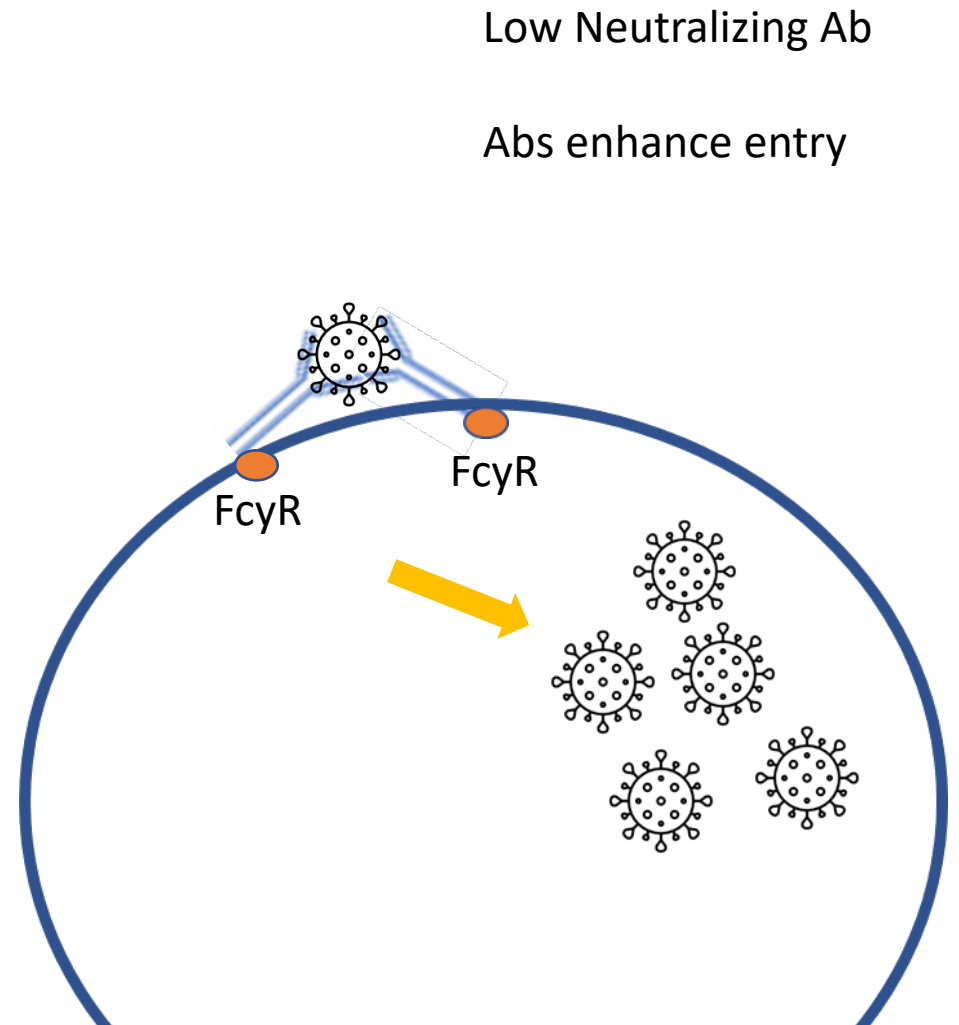
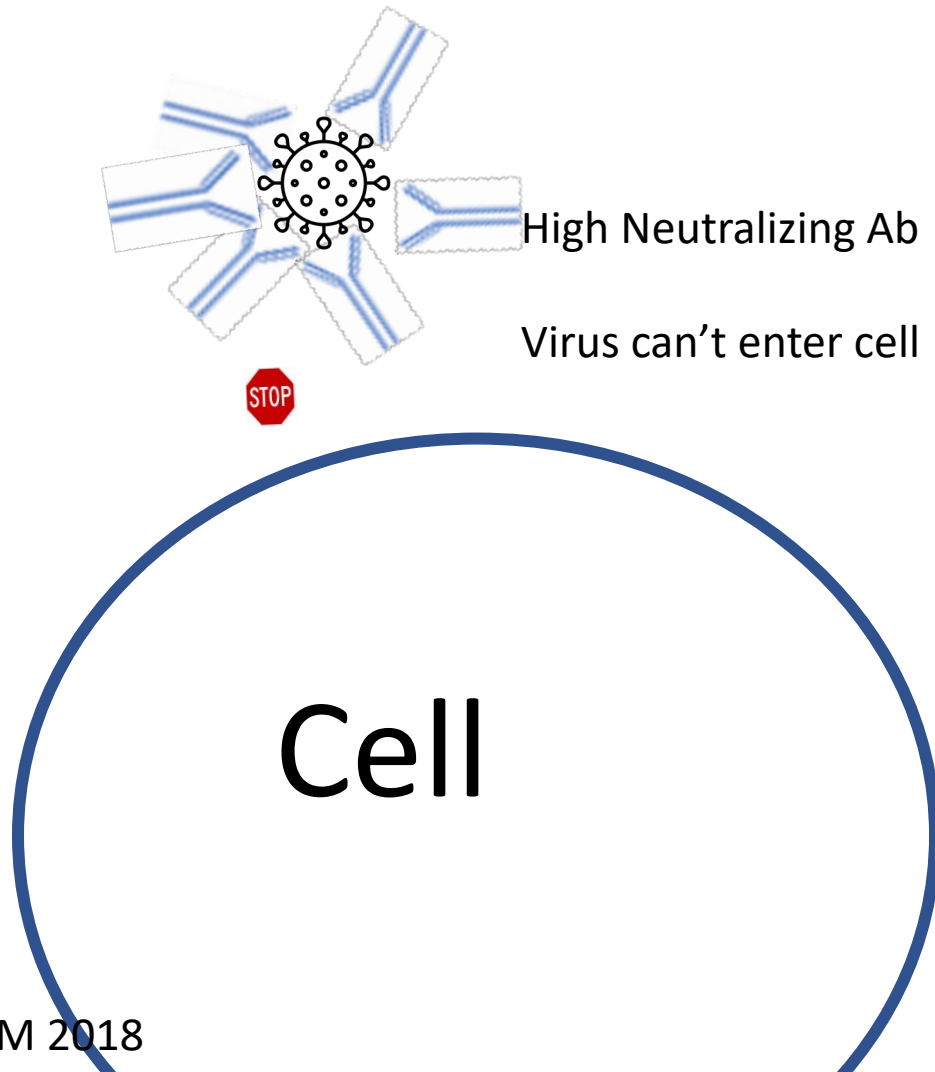
Neutralizing antibodies:
antibody that binds to a
virus and interferes with
its ability to infect a cell



Cross reacting antibodies



Antibody Dependent Enhancement



Antibody Dependent Enhancement

Second infection with other
DenV serotype

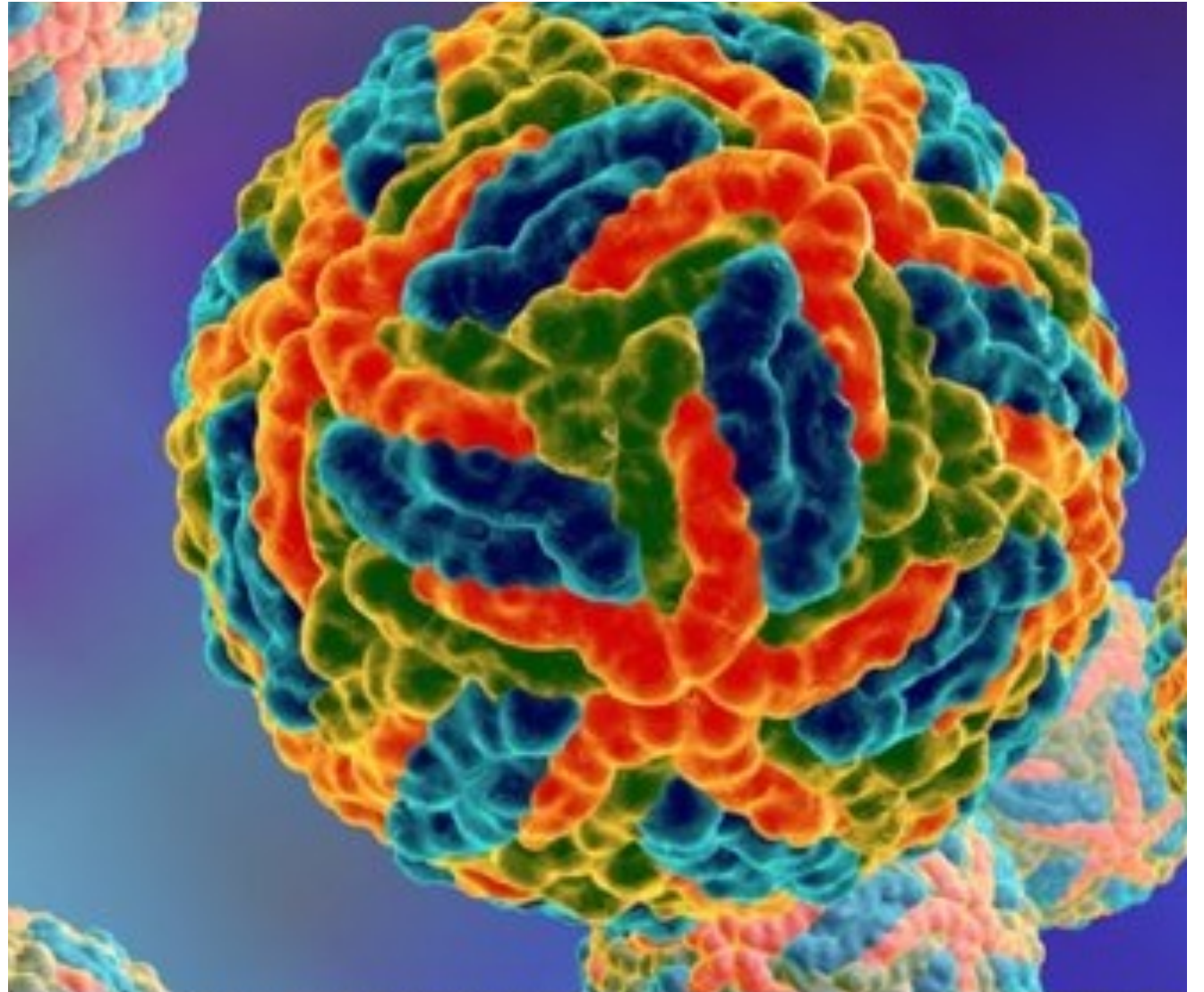
- More severe and lethal

Cross reactive antibodies
from:

- Previous infection
- Maternal passive immunity
- Vaccinations

Dengue Vaccine

- Tetravalent
 - Contains all four serotypes
- Live Attenuated
- Intended Function:
 - To create neutralizing antibodies for all four serotypes
 - Protect against ADE infection

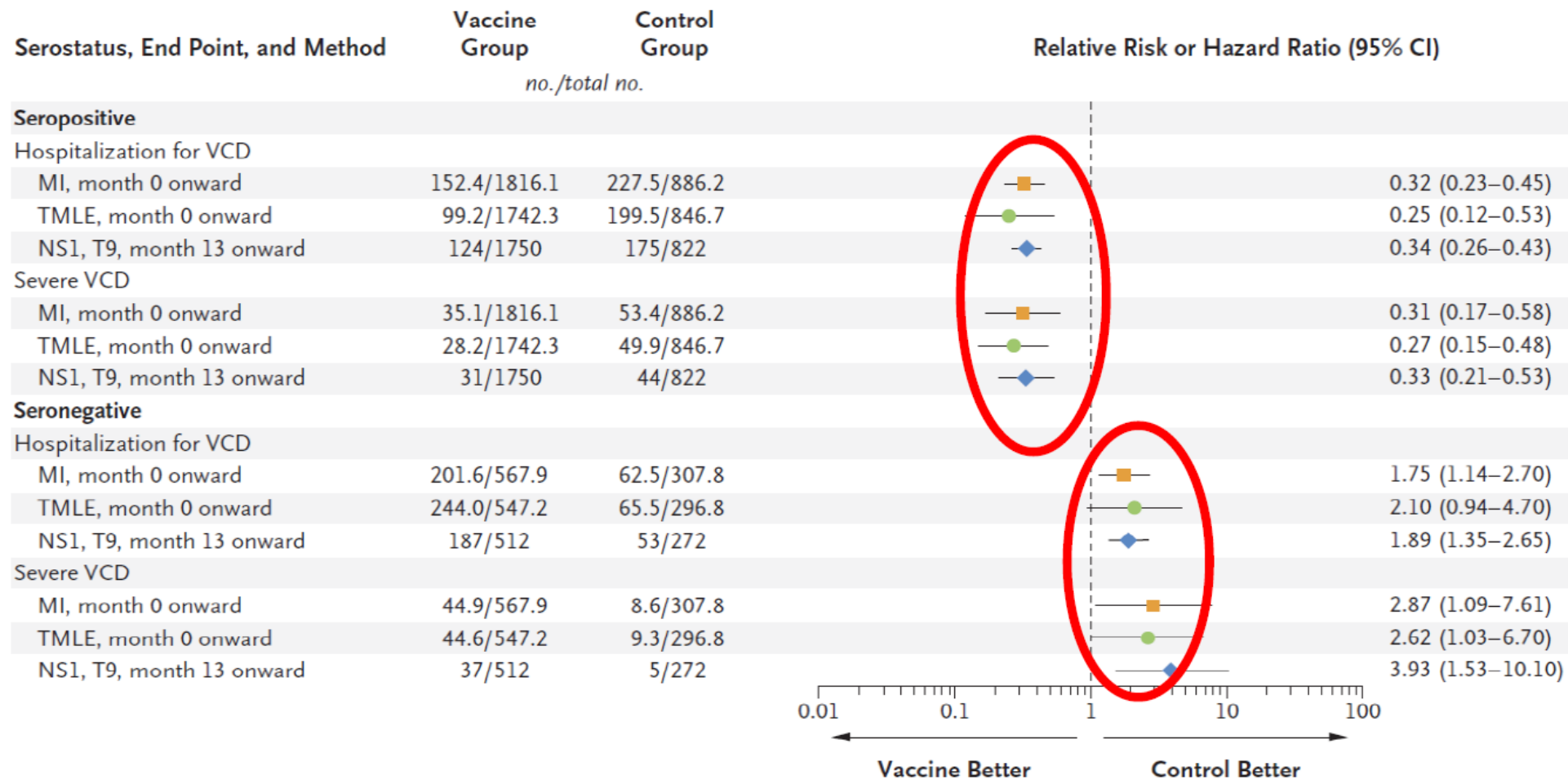


Risk for hospitalization seronegative versus seropositive participants

The cumulative incidence of dengue hospitalization over 5 years among seronegative vaccine recipients was 2%

Risk of Hospitalization for Virologically Confirmed Dengue (VCD) and of Severe VCD

B 2–16 Yr of Age

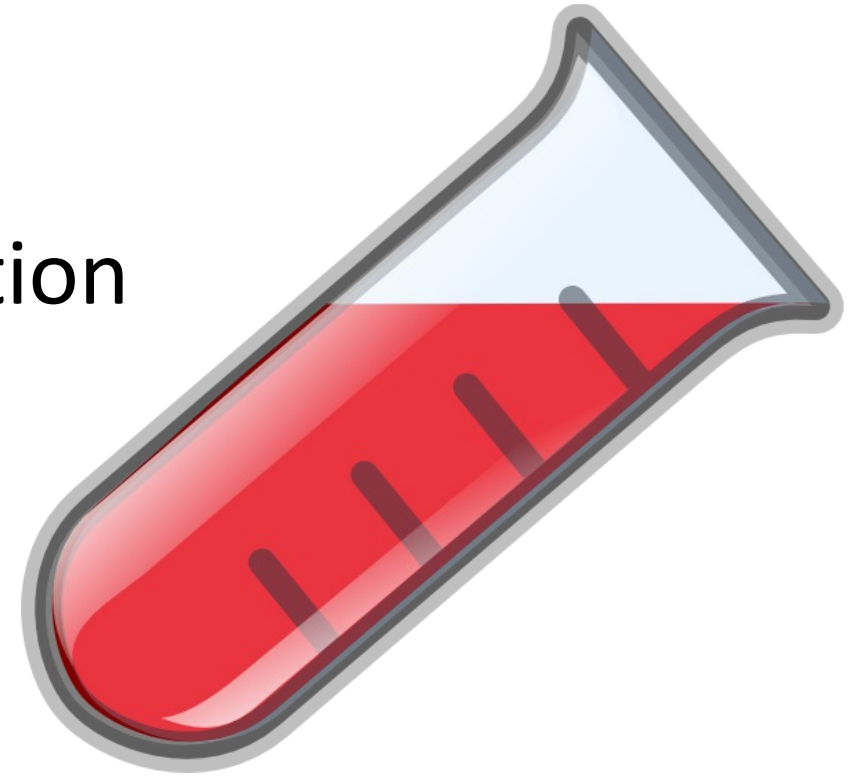


Dengue Vaccine Recommendation

Children aged 9–16

Living in endemic area

Evidence of a previous dengue infection





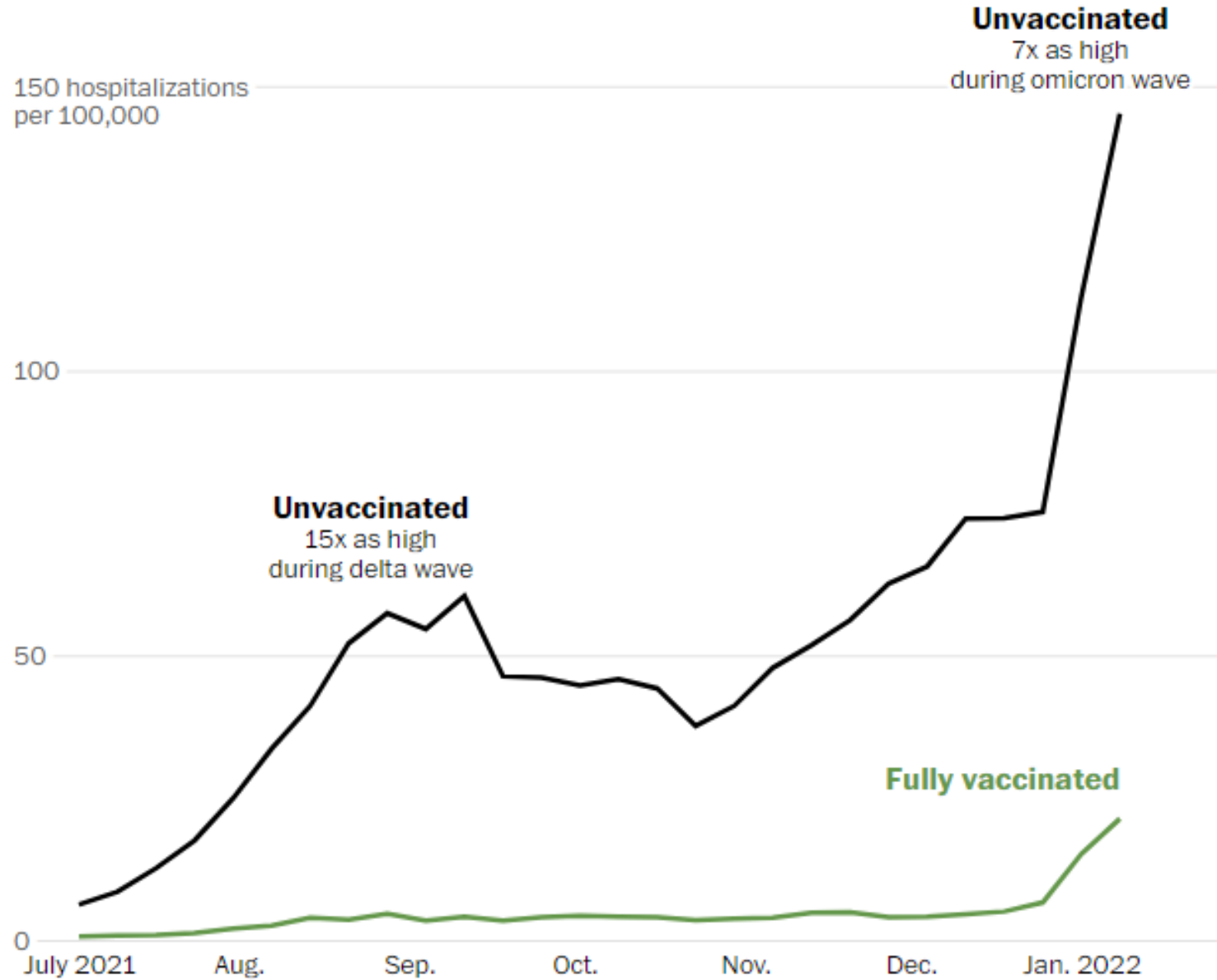
Lessons from Dengue Vaccine

- Not all vaccine candidates are safe
- The current system of monitoring and approval works

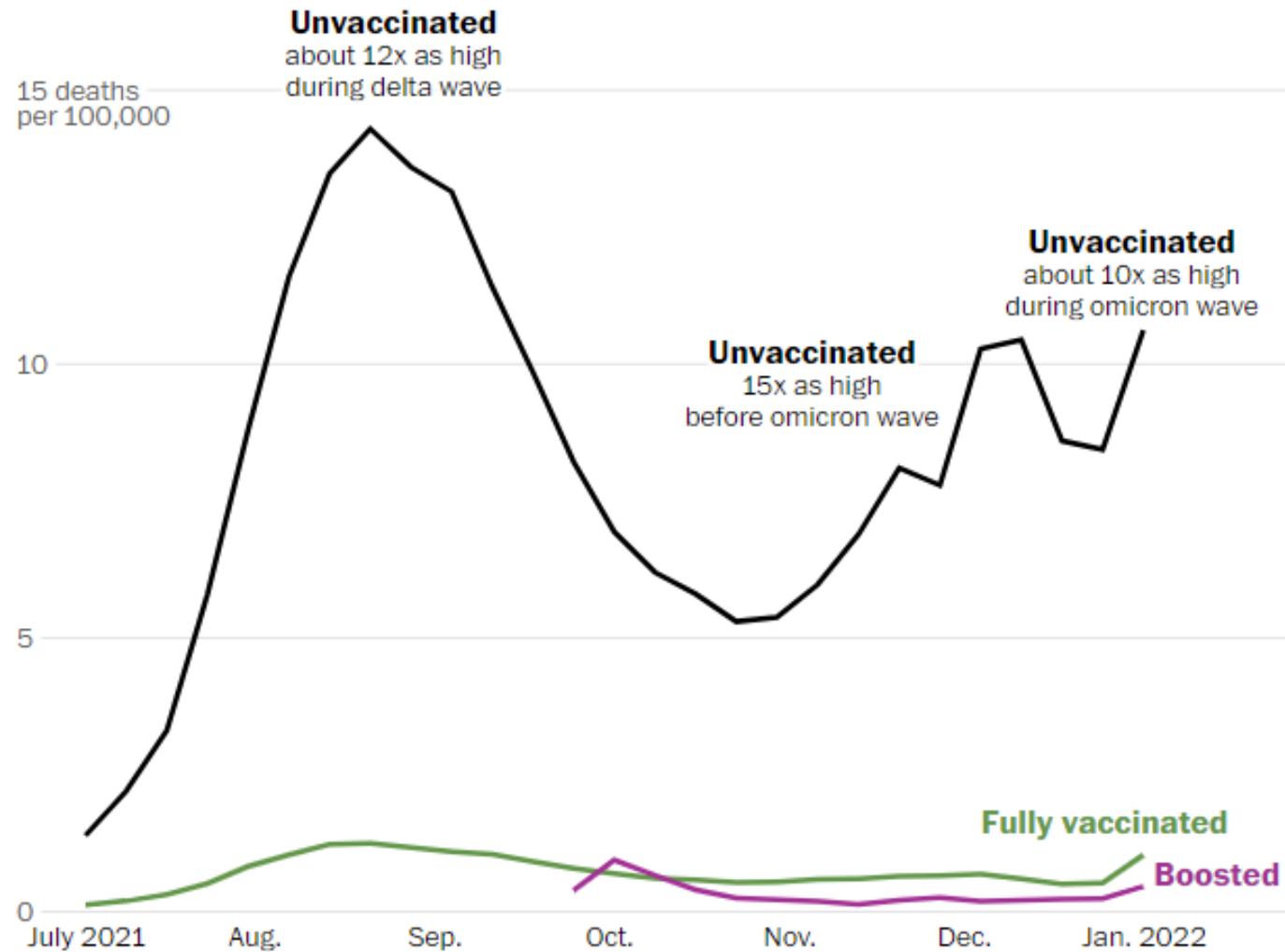
COVID Vaccine Safety Surveillance

- FDA's Centers for Medicare & Medicaid Services (CMS) data
- CDC's Vaccine Safety Datalink (VSD) (9 integrated health systems)
- Veterans Affairs (VA) data warehouse and electronic health record
- IHS
- Clinical Immunization Safety Assessment Project (7 research centers)
- Vaccine Adverse Event Reporting System (VAERS)
- V Safe

COVID Hospitalizations in US Adults per 100,000



Deaths in Adults in US per 100,000



Myocarditis and mRNA Vaccines

Most self-limiting with complete recovery

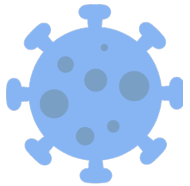
Rare occurrence 7-10 days after 2nd dose

Gender	Age	Rate per million second doses
Male	12-29	40.6
Male	>30	2.4
Female	12-29	4.2
Female	>30	1
Males	12-17	62.8
Males	18-24	50.5

COVID 19 Disease also causes myocarditis



mRNA COVID-19 (risk ratio = 3.24; 95% CI = 1.55–12.44)



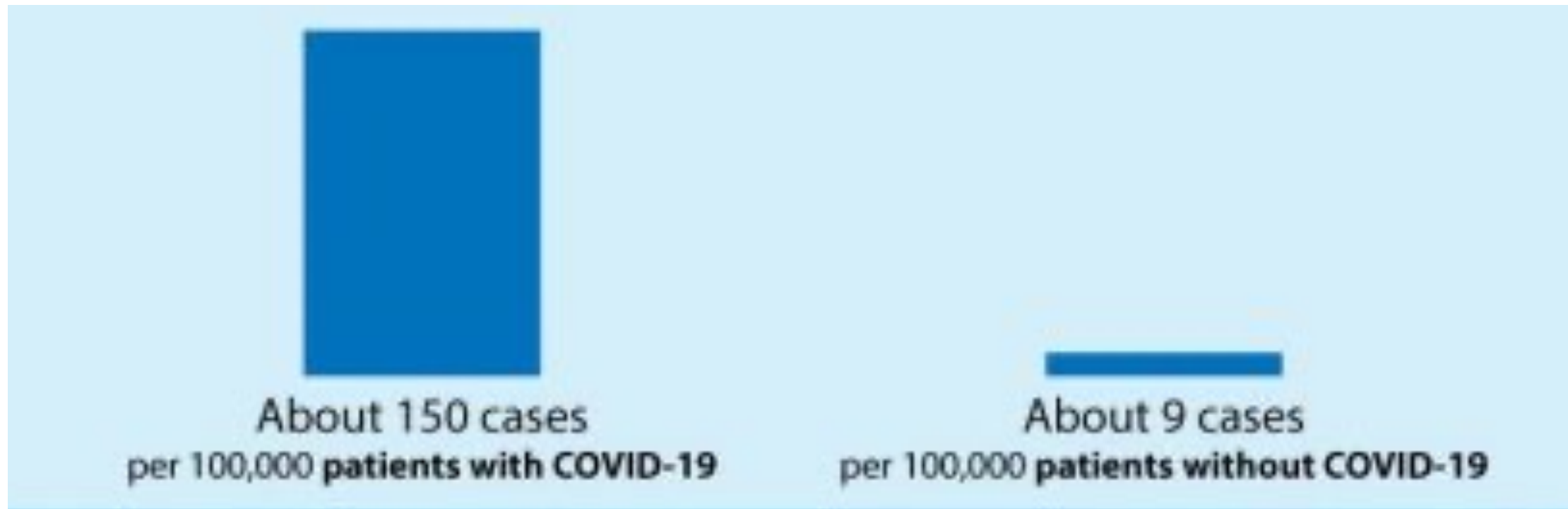
SARS-CoV-2 (risk ratio = 18.28, 95% CI = 3.95–25.12)

(Pfizer Vaccine in Israel)

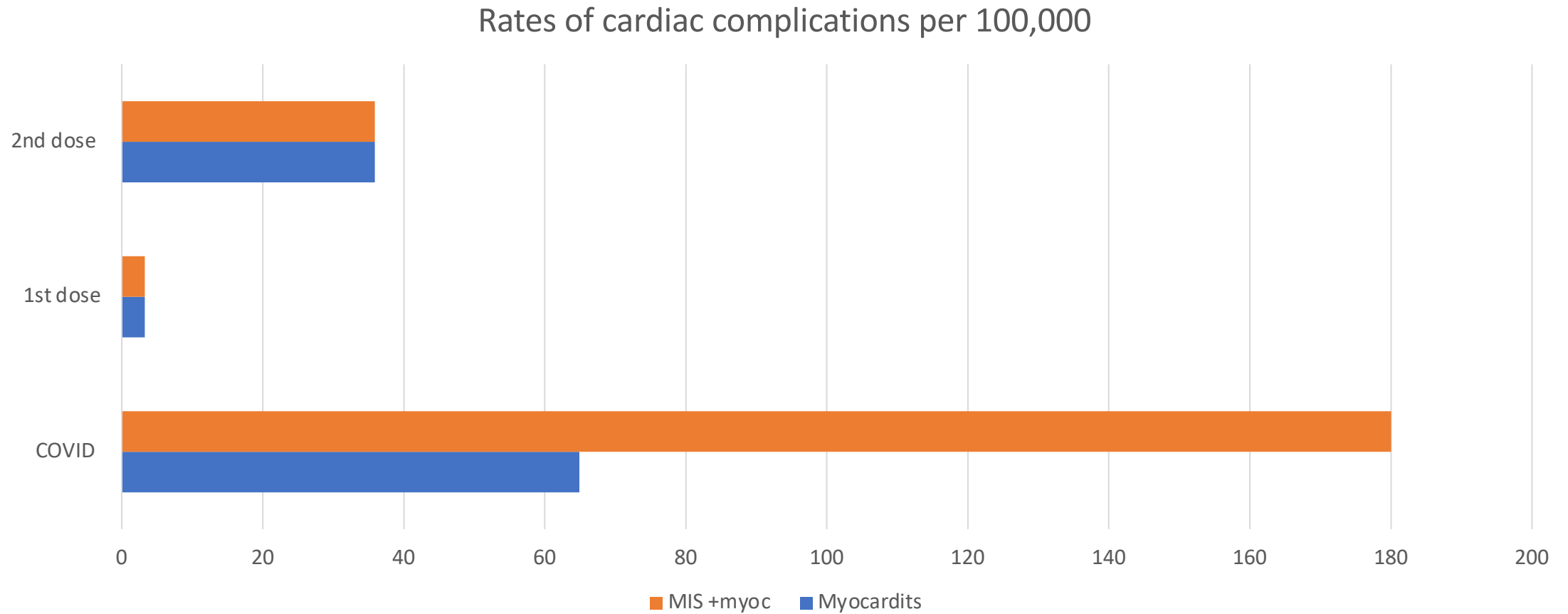
Less recovery from myocarditis caused by disease

US March 1, 2021-January 31, 2022
>15 million people 5 years and up

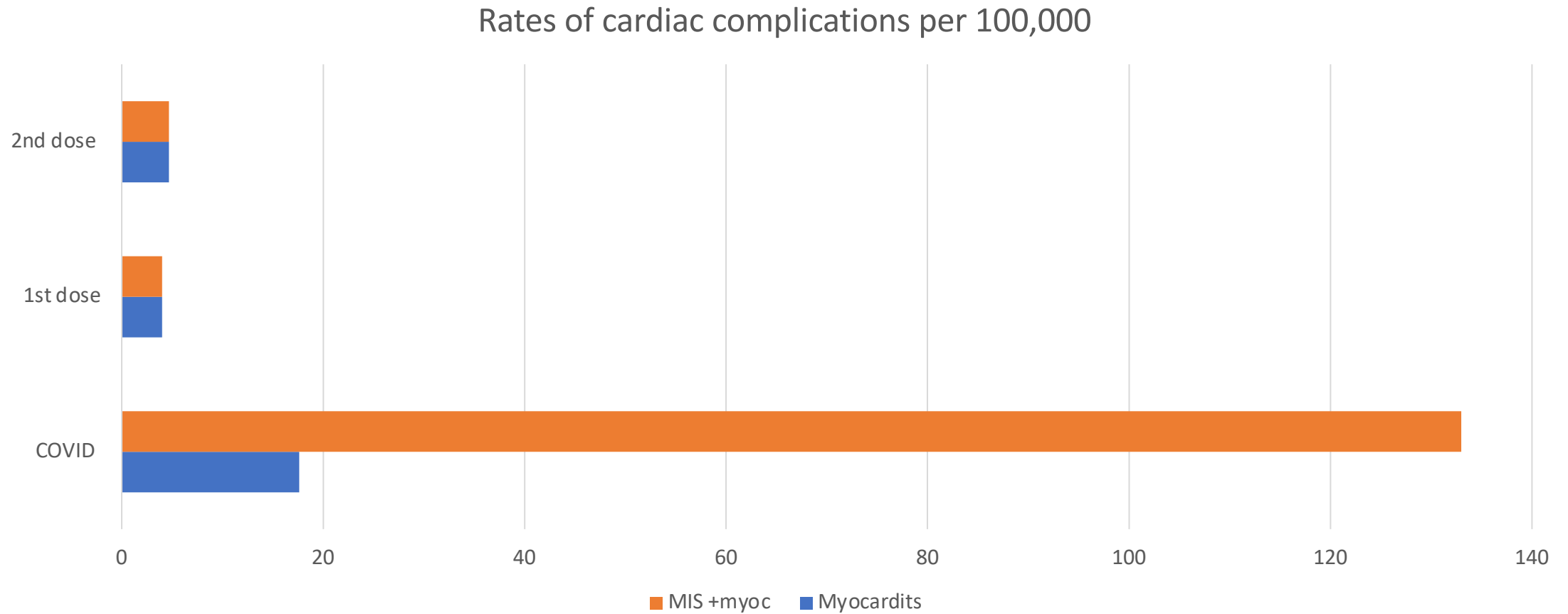
16 times higher risk of myocarditis with COVID than without COVID



Males 12-17 Years Old



Males 5-11 Years Old



Recent Changes in COVID Vaccine Recommendations

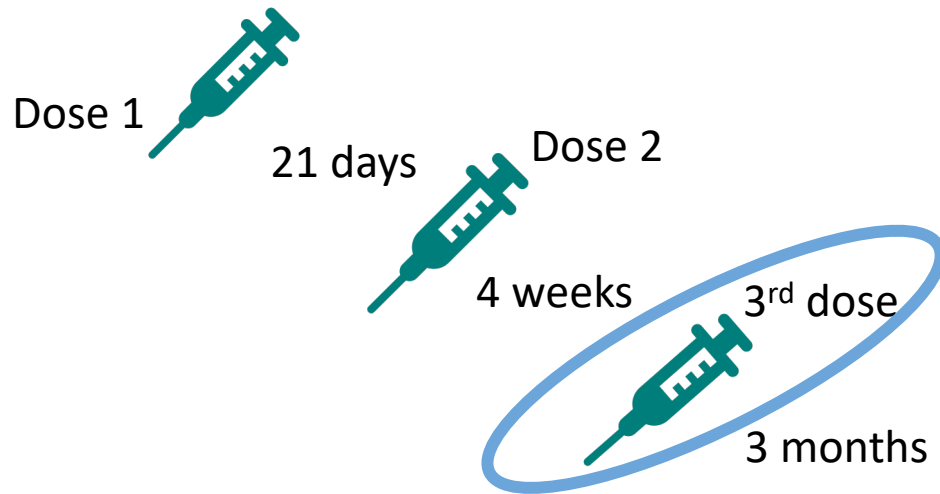
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January 2022	mRNA preferred over DNA Based Vaccines
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March 2022	2 nd booster option for age 50+ and immunocompromised
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Pending	Novavax EUA

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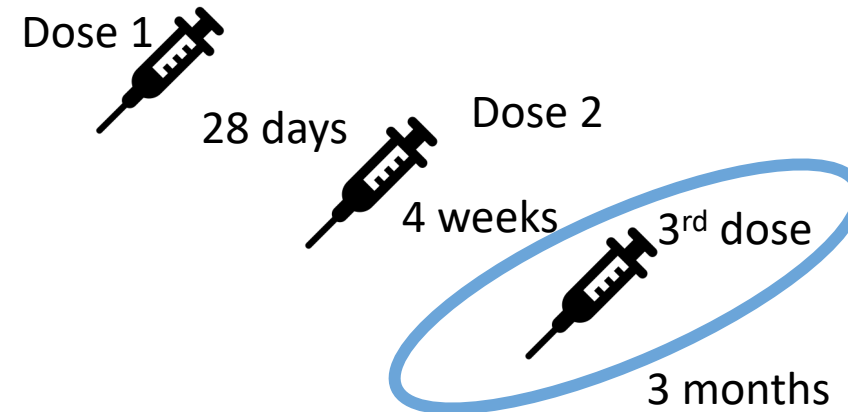
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mRNA Vaccines Immunocompromised

Pfizer (12 years and up)



Moderna (18 and up)

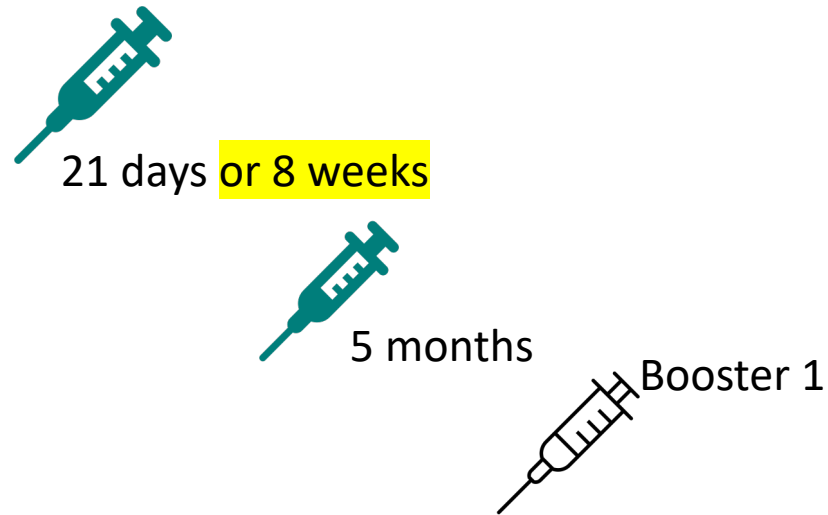


+ booster- later in this talk

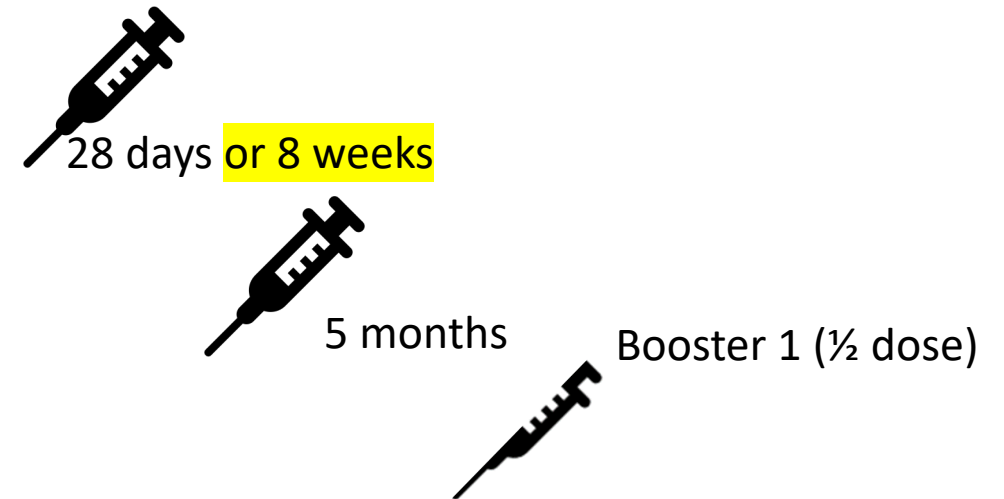
<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html>

mRNA Vaccines Immunocompetent

Pfizer (12 and up)



Moderna (18 and up)

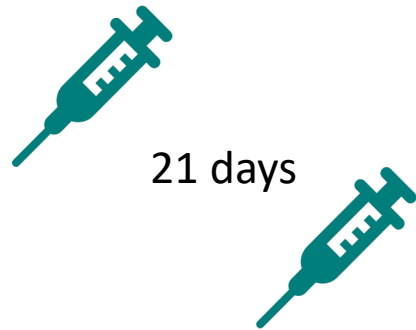


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Pfizer Age 5-12 Immunocompetent



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Thrombosis with Thrombocytopenia TTS

J&J/Janssen Vaccine

July 2021-December 2021

9.7 per million doses in **women** ages: 30-49

3.17 per million doses in **men** ages: 30-49

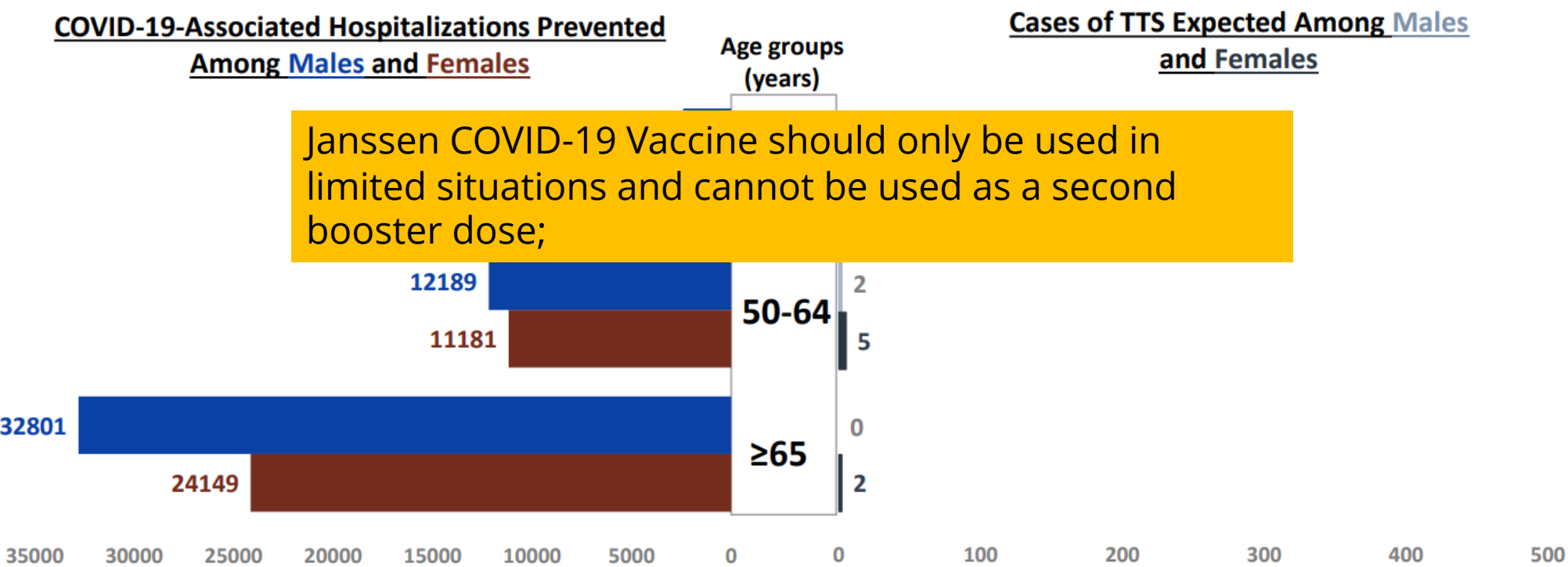
Overall: 3.7 per million doses

<https://www.cdc.gov/vaccines/acip/meetings/live-mtg-2021-12-16.html>

Benefits and risks after Janssen COVID-19 vaccine

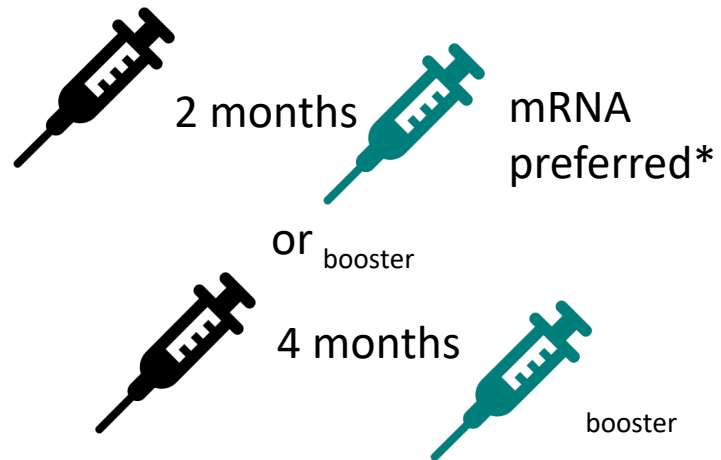
per million fully vaccinated people

- COVID-19-associated hospitalizations prevented by Janssen COVID-19 vaccine compared with TTS cases expected
- Presented by age groups and sex



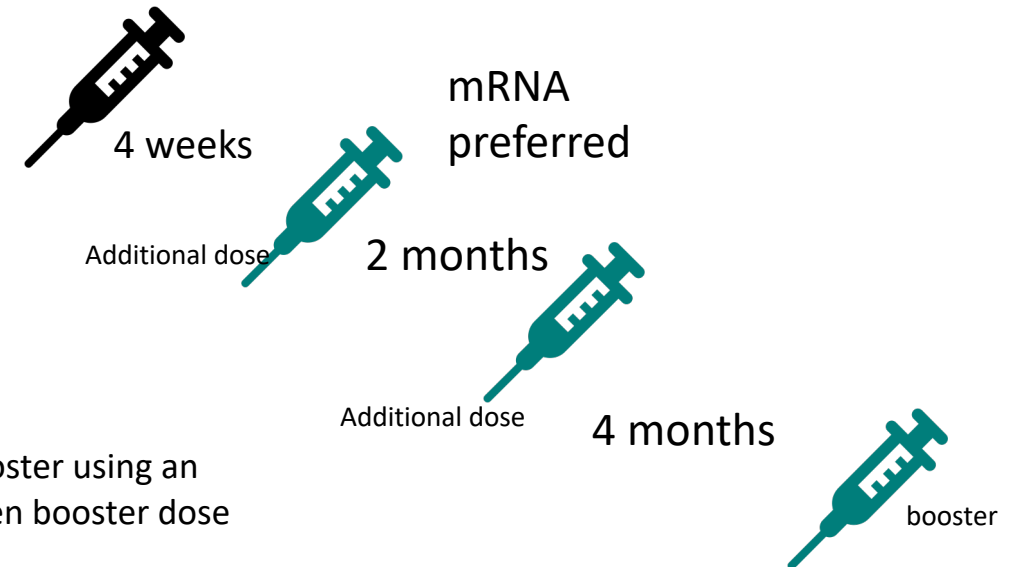
Janssen J&J (Adults)

Immunocompetent (3)



Janssen primary series dose and booster dose may second booster using an mRNA COVID-19 vaccine at least 4 months after the first Janssen booster dose

Immunocompromised (4)



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Intervals 1st to 2nd dose to 8 weeks

8 Weeks

Ages 12 through 64 years

Moderate or lower risk of community spread

Especially males ages 12 through 39 year

3-4 Weeks

Higher risk of inadequate response to the first mRNA vaccine dose

Moderately or severely immunocompromised

Higher risk for severe COVID-19

Adults ages 65+ years

Rapid protection during high levels of community transmission

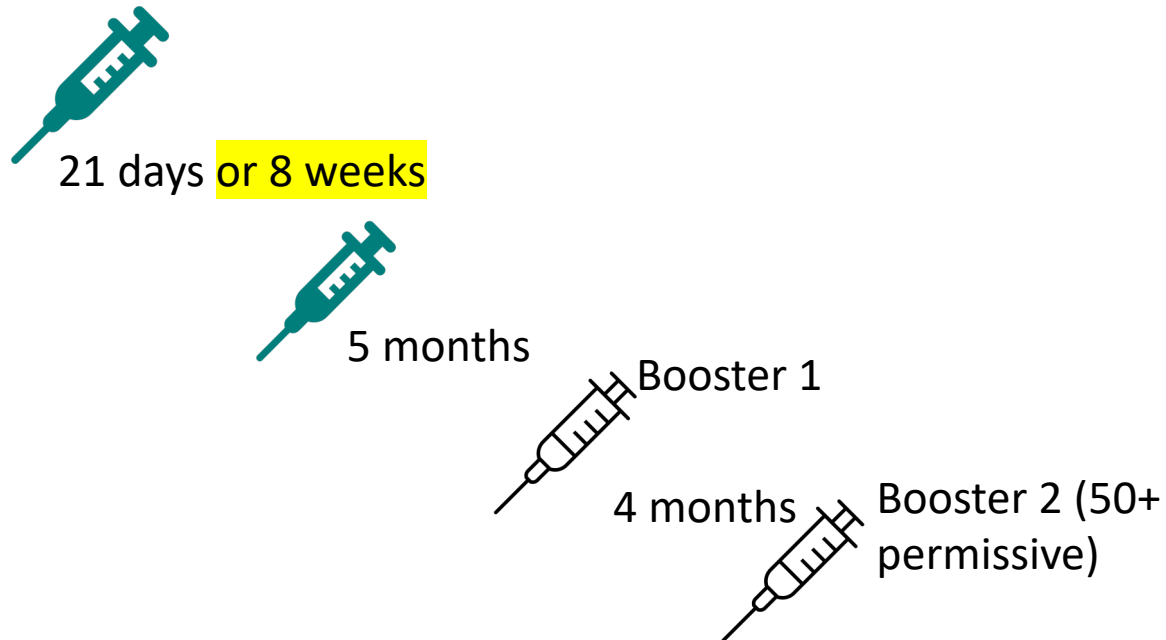
Children ages 5–11 years

Recent Changes in COVID Vaccine Recommendations

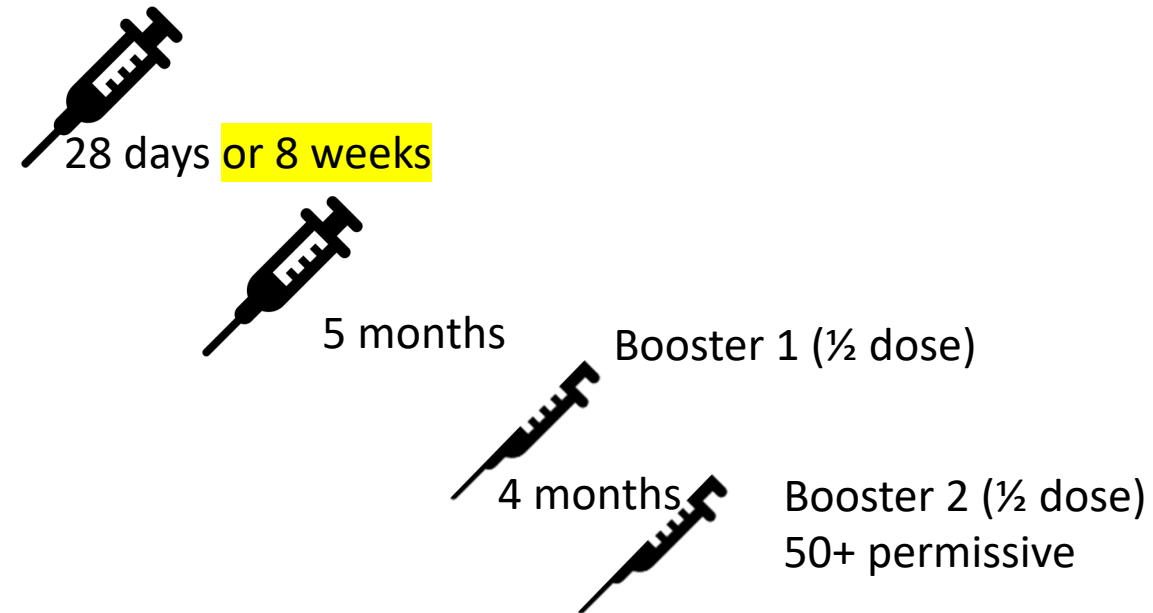
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Pfizer (12 and up)



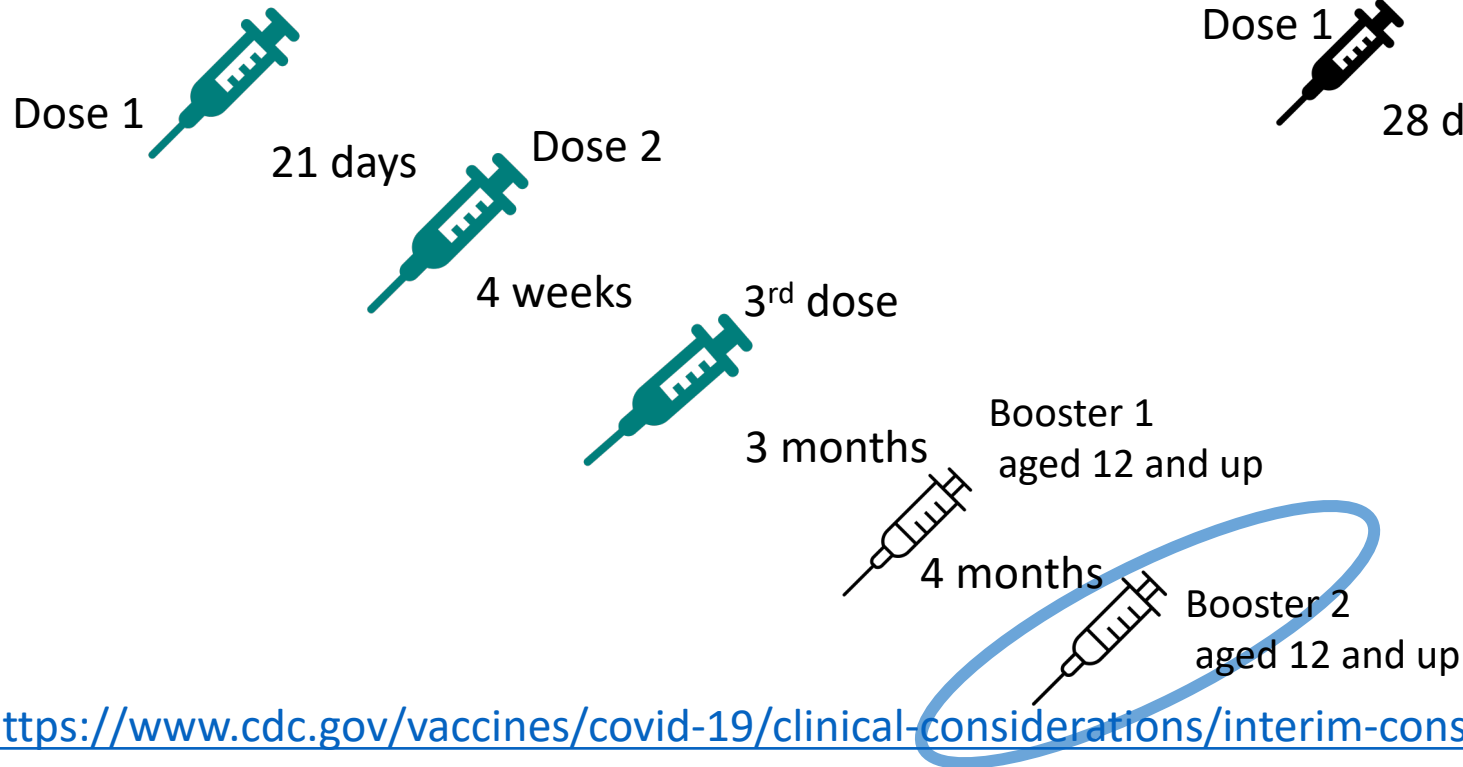
Moderna (18 and up)



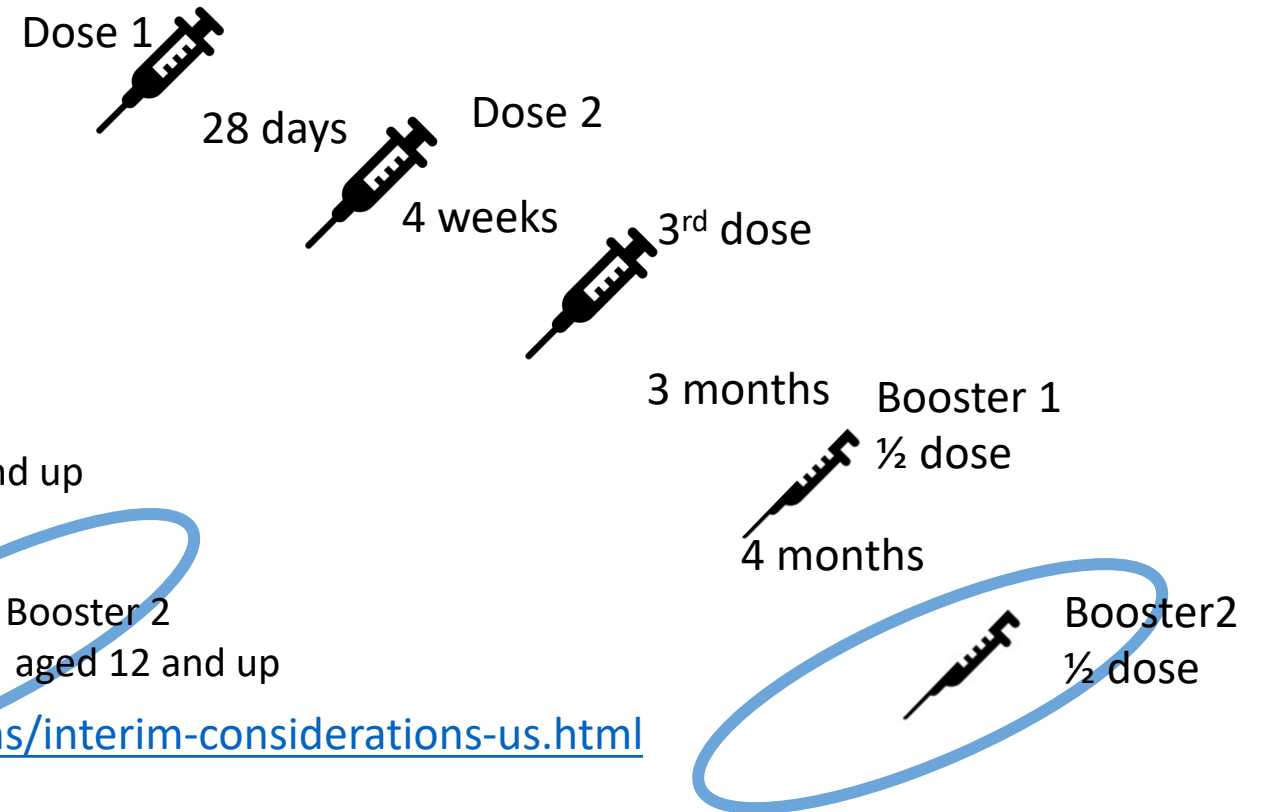
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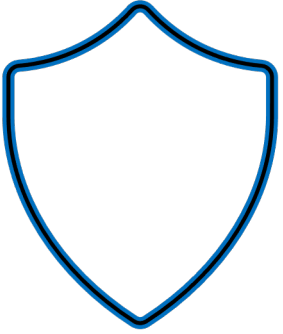


Moderna (18 and up)



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

Evusheld: Tixagevimab plus Cilgavimab

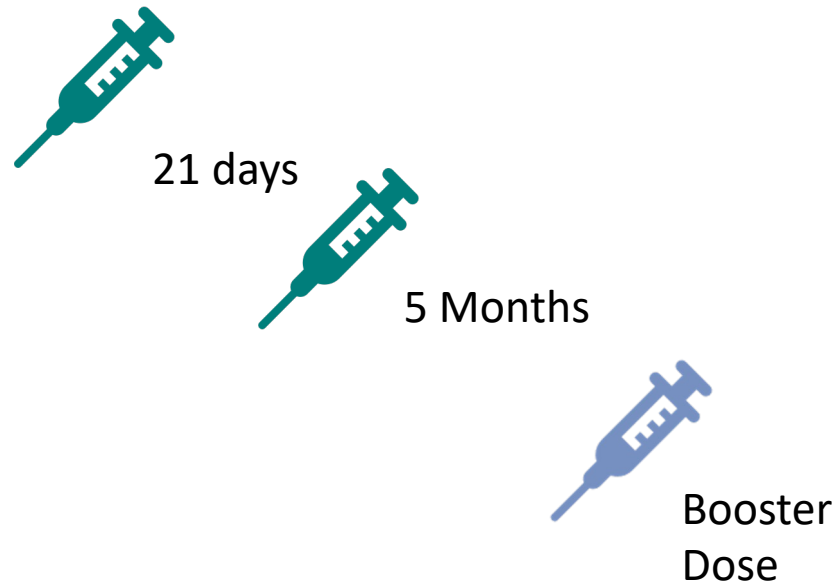


- Moderate to severe immunocompromising conditions that may result in an inadequate immune response to COVID-19 vaccination
- Not authorized for use in unvaccinated individuals unless full vaccination is not possible due to a history of severe allergic reaction to the COVID-19 vaccine.

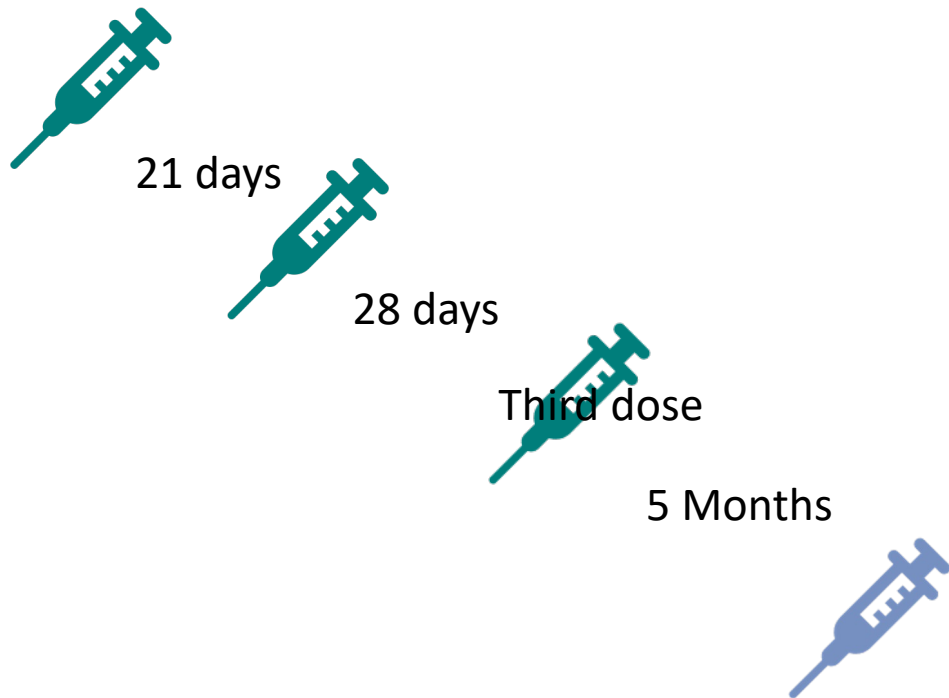
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Pfizer Age 5-12 Immunocompetent



Pfizer Age 5-12 Immunocompromised



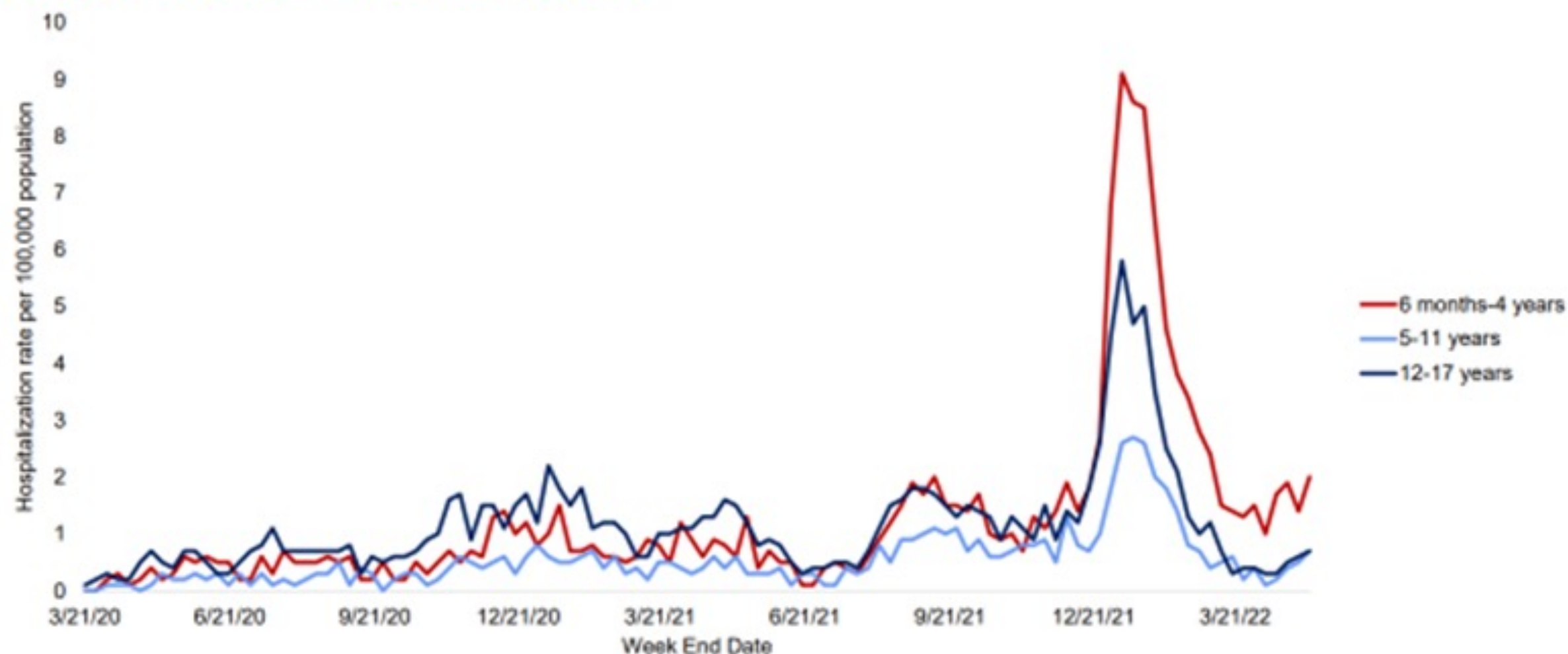
<https://www.cdc.gov/vaccines/acip/recs/grade/pfizer-biontech-covid19-booster-children-etr.html>

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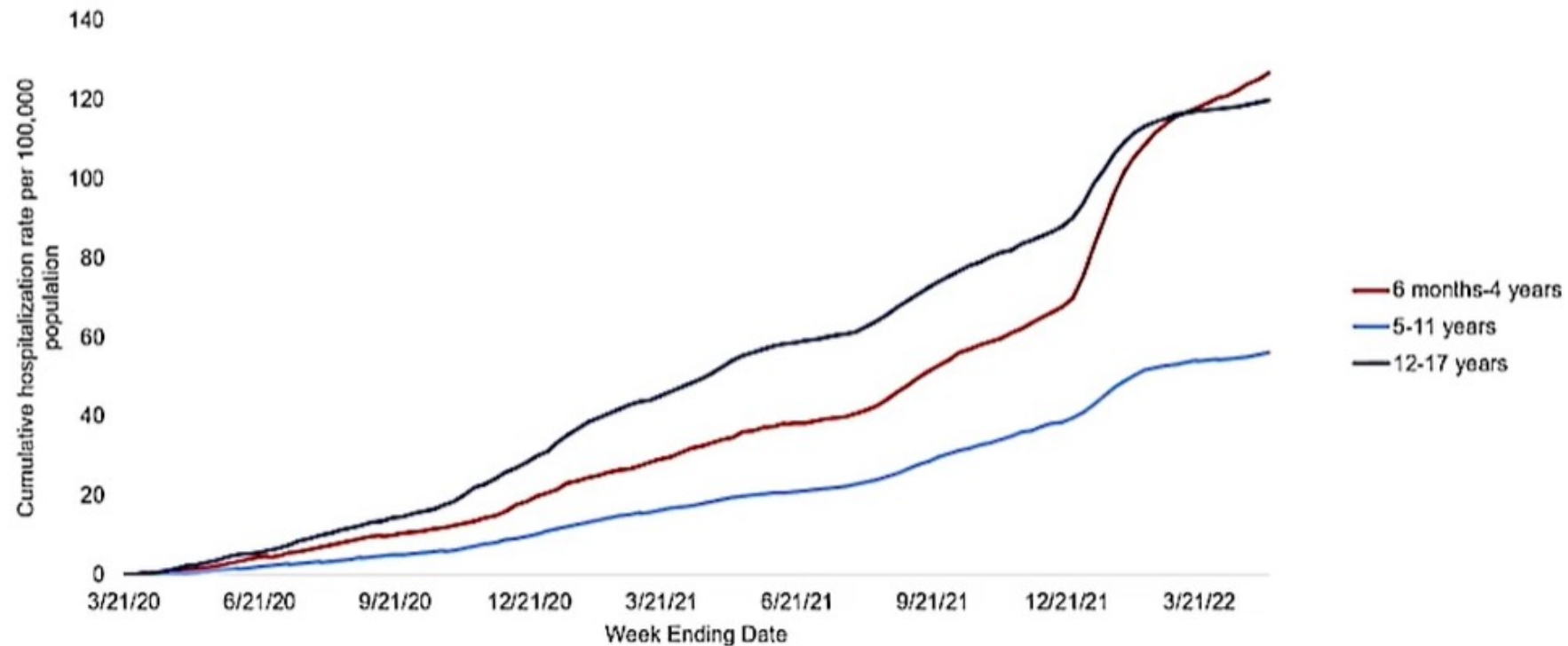
COVID-19-associated hospitalizations among children and adolescents 6 months–17 years, COVID-NET

March 2020 – March 2022



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

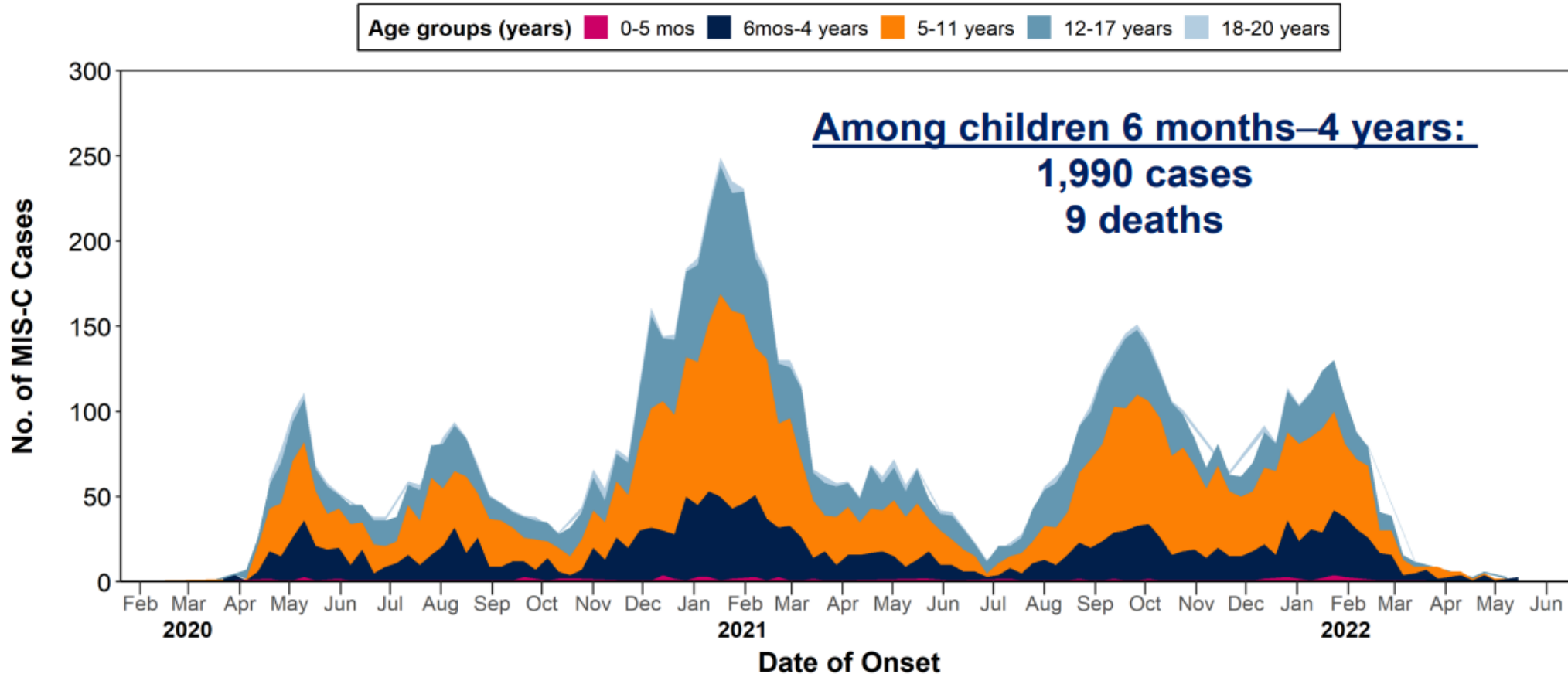
March 21, 2020 – May 7, 2022



Source: COVID-NET, https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html. Accessed 5/21/2022

Weekly MIS-C case counts among persons ages 0–20 years by age group (N=8,525)

February 1, 2020 – May 31, 2022



CDC Data. Age is missing for 1 case

Pediatric vaccine preventable diseases: Deaths per year in the United States prior to recommended vaccines

	Hepatitis A ¹	Meningococcal (ACWY) ²	Varicella ³	Rubella ⁴	Rotavirus ⁵	COVID-19 ⁶
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	6 months – 4 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	Jan 2020–May 2022
Average deaths per year	3	8	16	17	20	86

¹Vogt TM, Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. J Infect Dis 2008; 197:1282–8.

²National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015–2019.

³Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970–1994. J Infect Dis. 2000;182(2):383–390. doi:10.1086/315714

⁴Roush SW, Murphy TV. Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 2007; 298:2155–63.

⁵Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. J Infect Dis. 1996 Sep;174 Suppl 1:S5–11.

⁶<https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Counts-by-Age-in-Years/3apk-4u4f/data>. Accessed May 14, 2022

EUA 6 months to 4 or 5 years

Pfizer

6 months to 4 Years

3μ

0.2mL

Marron top

3 Primary doses

Dose 1 to 2 (3 to 8 weeks)

Dose 2-3 (at lease 8 weeks)

Moderna

6 months to 5 years

25μ

0.25mL

Dark Blue Top

2 Primary doses

Dose 1 to 2 (4 to 8 weeks)



Criteria for Approval

Moderna

2 dose

GMT **not inferior** to 18–25-year-olds

Vaccine efficacy 37.8% (CI 20.9-51.1)

181/4791 vaccine

97/1597 placebo

Pfizer

2 dose

GMT inferior to 16–24-year-olds

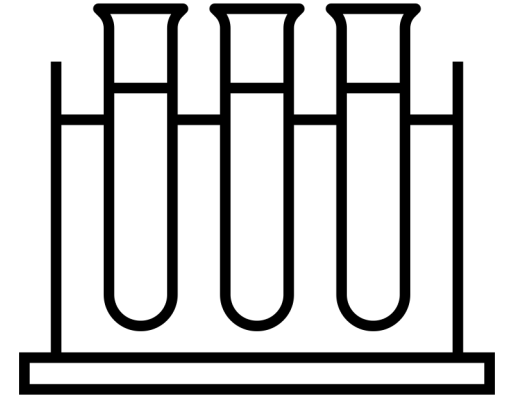
3 dose study

GMT **not inferior** 16–24-year-olds

Vaccine efficacy 80.3% (CI 13.9-97.6)

3/992 vaccine

7/464 placebo



Not powered for effectiveness against severity of disease, hospitalizations or death

Risks



Side Effects

- Redness, pain, swelling
- Fatigue, Drowsiness, fever, headache, chills, vomiting, diarrhea
- most mild ≥ 2 days

Serious Adverse events

- No anaphylaxis
- No pericarditis/no myocarditis
- Pfizer 1.0% Vaccine and 1.5% Placebo – 1 hospitalization for fever and pain
- Moderna 0.5 Vaccine and 0.2 Placebo 1 febrile seizure

Children who are NOT moderately or severely immunocompromised

Pfizer-BioNTech
(6 months–4 years)

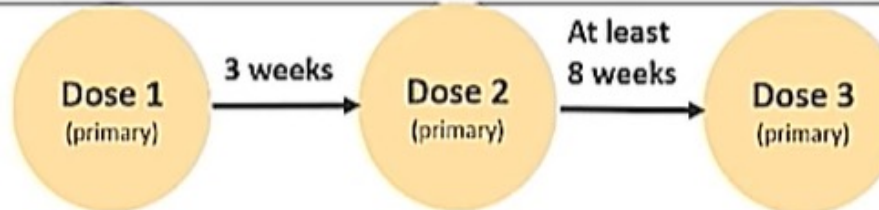


Moderna
(6 months–5 years)

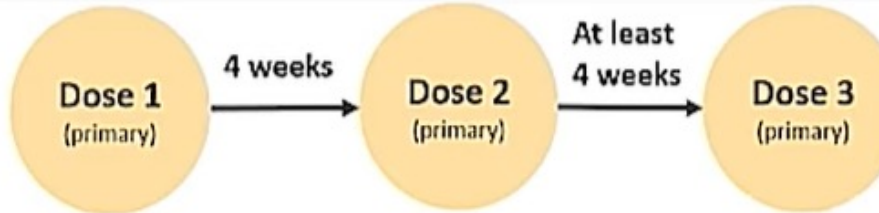


Children who ARE moderately or severely immunocompromised

Pfizer-BioNTech
(6 months–4 years)



Moderna
(6 months–5 years)



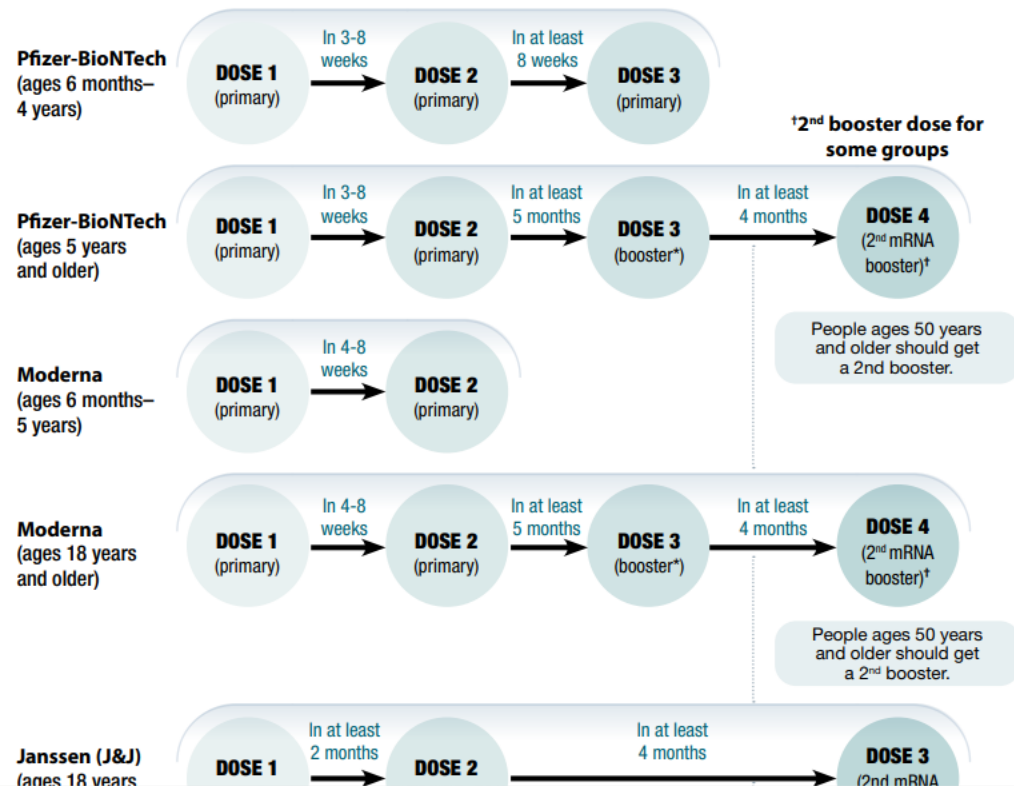
AT-A-GLANCE

COVID-19 Vaccination Schedules

Use the schedules below to determine how many total COVID-19 vaccine doses are recommended based on primary series product, age, and immune status. This schedule does not include clinical details necessary for administering COVID-19 vaccines. For clinical details, see the resources at the end of this document.

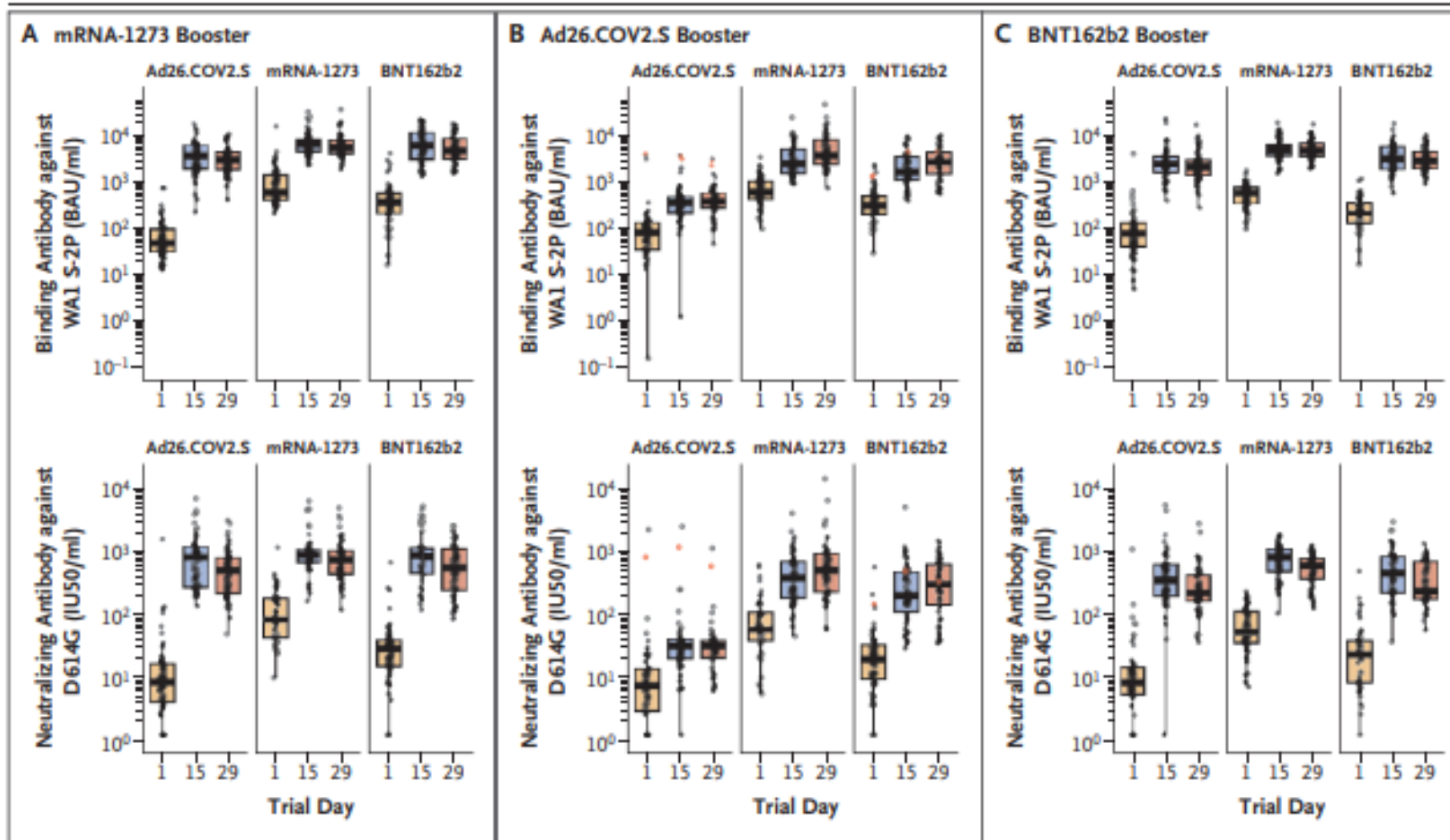
COVID-19 Vaccination Schedule for Most People

Number and intervals of COVID-19 vaccine doses



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

Mix boosters?



No clinical data

Antibodies titers

Vaccines in other countries

No harm in mixing

NEJM March 2022

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July 2022	Novavax EUA

Novavax Covid Vaccine

Operation Warp Speed

1.6 Billion Dollar Loan from US
More from International Funds

Internationally 740,000+ doses



World Health Organization



European Union



UK



India*



Switzerland



Japan†



South Korea



United Arab Emirates



Bangladesh



Australia



The Philippines



Thailand*



Canada



New Zealand



Indonesia

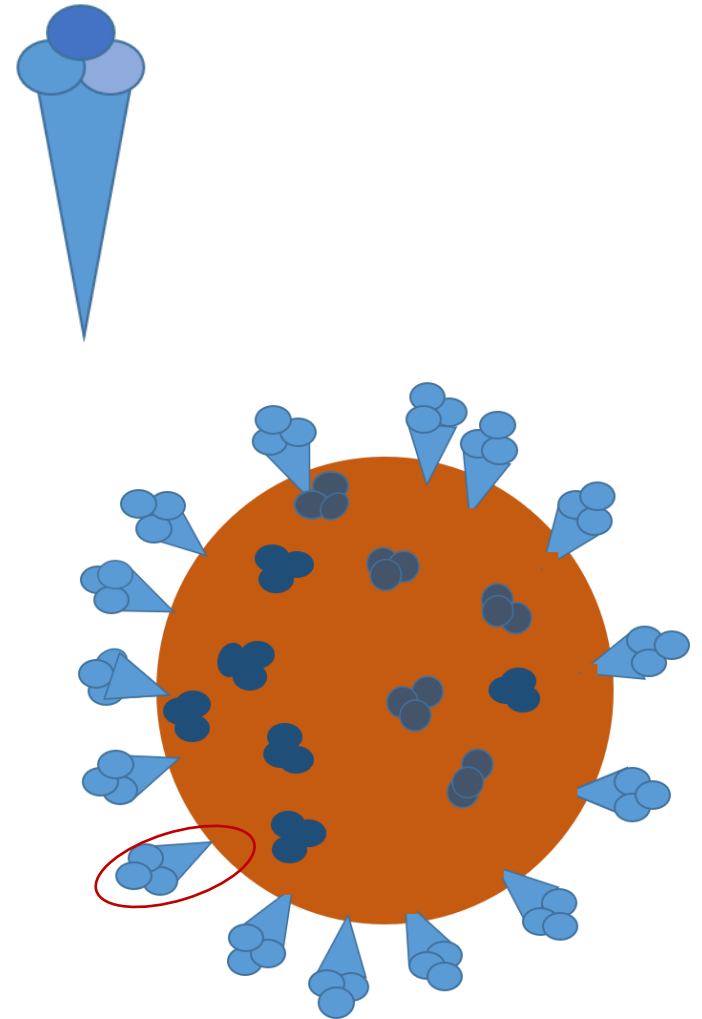


Singapore

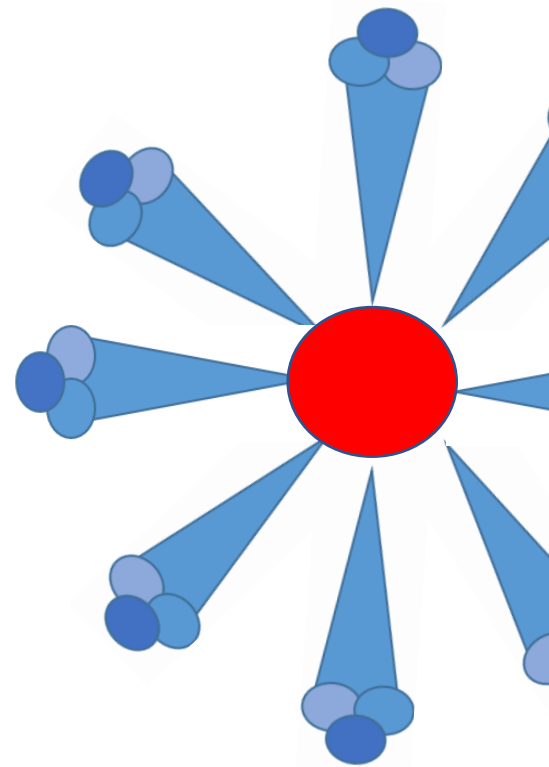
S Proteins

Binds to angiotensin-converting enzyme 2 (ACE2),
expressed many cells—lungs

Antigen for most vaccines



NVX CoV2373



Spike Protein

Other Adjuvanted Vaccines

HPV

Hep B (new)

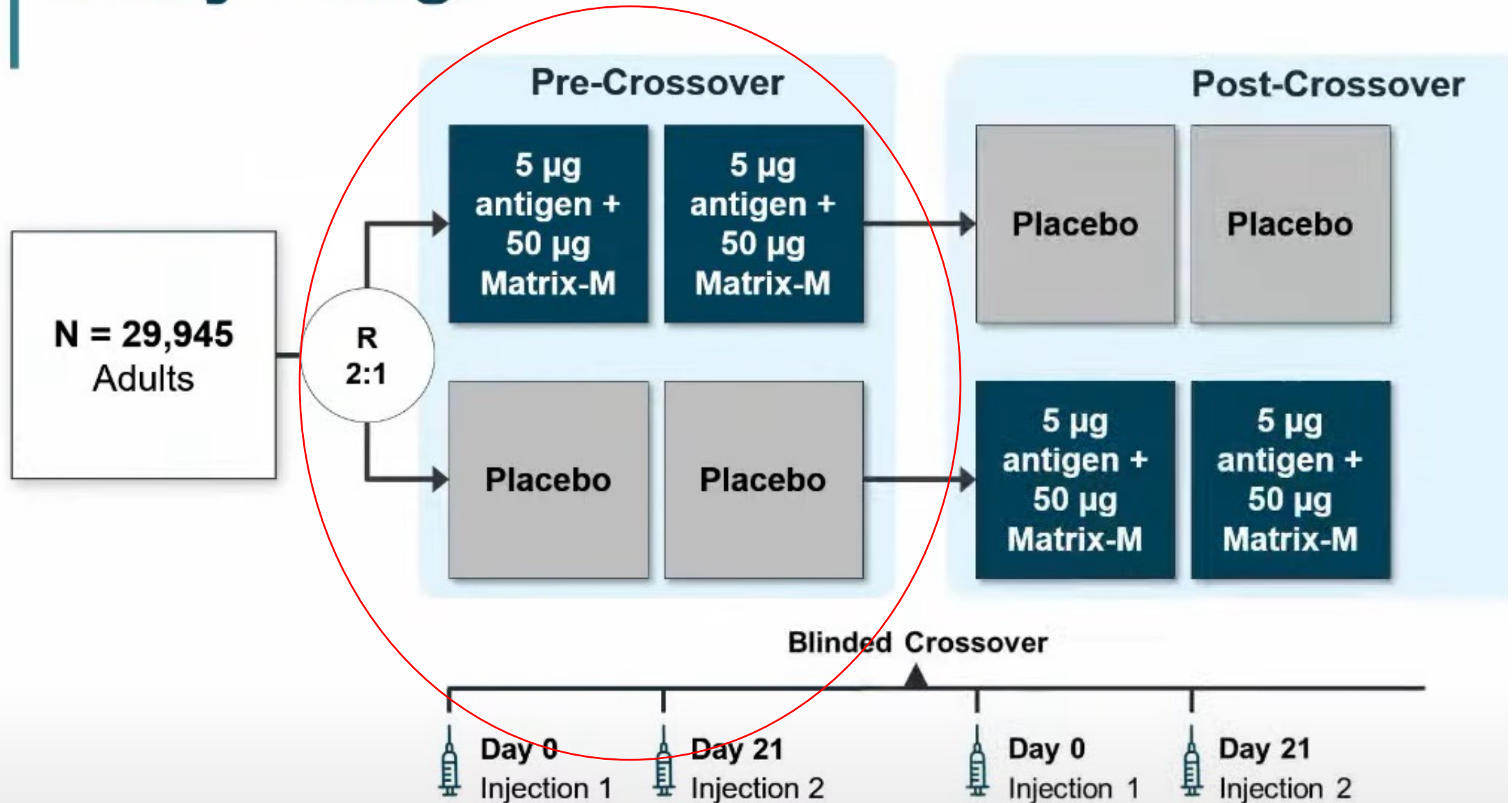
Influenza (adjuvanted)

New Shingles

Meningococcal B

Adjuvant

Study Design



3 Month follow up

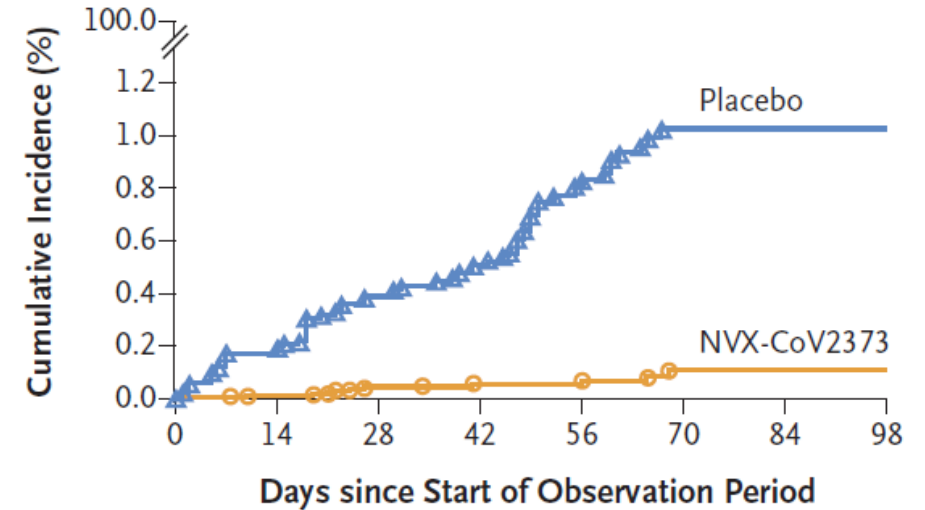
77 Cases

Vaccine 14

Placebo

Before Omicron

**B Analysis with Surveillance Starting 7 Days after Second Dose
(Per-Protocol Efficacy Analysis Population)**



No. at Risk

Placebo	8,140	7,619	6,989	6,349	4,627	2803	1055	220
NVX-CoV2373	17,312	16,782	16,166	15,330	11,458	6951	2447	379
		16	30	38	56	63	63	63
		2	7	10	11	14	14	14

Vaccine efficacy, 90.4%; 95% confidence interval [CI], 82.9 to 94.6; $P < 0.001$).

100% for protection against moderate to severe

NXV CoV2373 Summary

2 doses 21 days apart

Booster doses unknown but likely will be needed

Able to store in refrigerator and short-term room temp (ease of use)

Used worldwide

High efficacy but no clinical data on Omicron

Seems to have low reactivity

Some cases of myo/pericarditis but no clear cause/effect

Duration of immunity unknown

Public response to more typical vaccine type

Approval Process

Vaccines and Related Biological Products Advisory Committee
Recommended approval for ages 18+

FDA

Advisory Committee on Immunization Practices

CDC Recommendations

FDA to review variant formulations for COVID
vaccines

Recent Changes in COVID Vaccine Recommendations

October 2021	Three Primary doses for immunoprobed Additional Primary Booster for immunocompromised
October 2021	Booster 12 and up
November 2021	Pfizer age 5-12
January 2022	mRNA preferred over DNA Based Vaccines
March 2022	1 st and 2 nd dose extended to 8 weeks
March 2022	2 nd booster option for age 50+ and immunocompromised
May 2022	Booster dose for ages 5-11
June 2022	Pfizer and Moderna for under 5 years old
Pending	Novavax EUA
Omicron Specific Antigen Pending Fall or winter 2022	



Influenza aged 65
and up

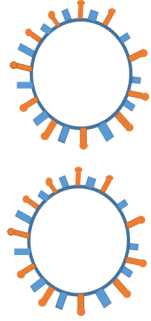
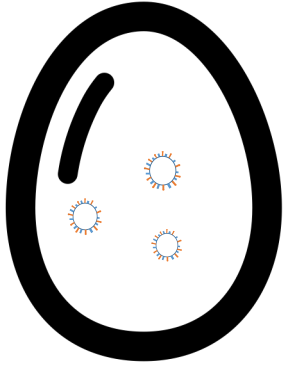
Influenza and Older Adults (Aged ≥65 Years)

Season	Overall VE, % (all ages, viruses, and vaccine types)	≥65 yrs (all viruses and vaccine types)
2019-20	39 (32, 44)	39 (9, 59)
2018-19	29 (21, 35)	12 (-31, 40)
2017-18	38 (31, 43)	17 (-14, 39)
2016-17	40 (32, 46)	20 (-11, 43)
2015-16	48 (41, 55)	42 (6, 64)
2014-15	19 (10, 27)	32 (3, 52)
2013-14	52 (44, 59)	50 (16, 71)
2012-13	49 (43, 55)	26 (-10, 50)
2011-12	47 (36, 56)	43 (-18, 72)

- Persons aged ≥65 years are at increased risk of severe illness, hospitalization, and death due to influenza.
- Target population for annual influenza vaccination since the early 1960s.
- Influenza vaccines are often less effective compared with younger populations.

CDC, U.S. Flu VE Network,

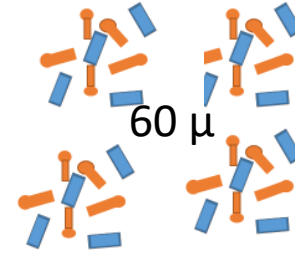
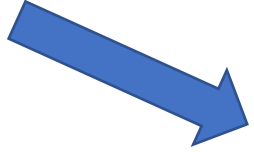
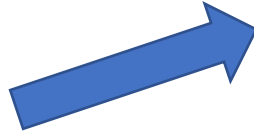
<https://www.cdc.gov/flu/vaccines-work/past-seasons-estimates.html>



Standard
dose



15 μ



60 μ

High
dose



15 μ

Adjuvanted



RNA

45 μ



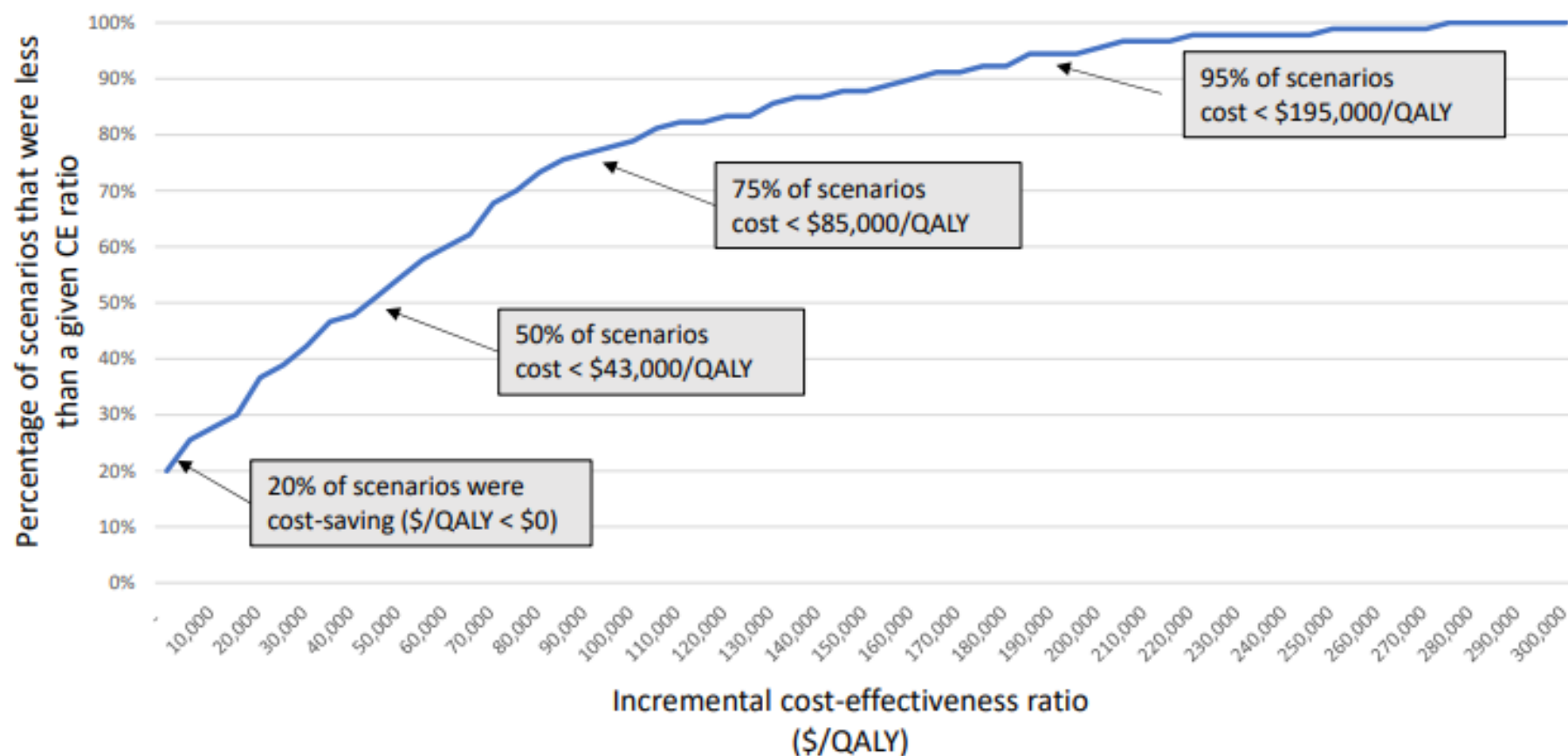
Recombinant

Evidence Summary: EIVs vs SD-IIVs

Outcome	Importance	HD-IIV3 vs SD-IIV	allIV3 vs SD-IIV	RIV vs SD-IIV
Benefits				
Influenza illnesses	Critical	Level 1 (High) Favors HD-IIV3	Level 2 (Moderate)	Level 2 (Moderate)
Influenza outpatient/ER visits	Critical	Level 2 (Moderate) Favors HD-IIV3	Level 2 (Moderate)	
Influenza hospitalizations	Critical	Level 2 (Moderate) Favors HD-IIV3	Level 2 (Moderate) Favors allIV3	Level 2 (Moderate) Favors RIV4
Influenza deaths	Critical	Level 2 (Moderate) Favors HD-IIV3		

Very limited evidence for RIV over HD-IIV3 and allIV3

Incremental Cost-effectiveness Curve



ACIP June 22, 2022

Adults aged ≥ 65 years should receive

- quadrivalent high-dose inactivated influenza vaccine (HD4IV)
- quadrivalent recombinant influenza vaccine (RIV4)
- quadrivalent adjuvanted inactivated influenza vaccine (aIIV4).

No preference for which of the three

If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.

<https://khn.org/news/article/why-black-and-hispanic-seniors-are-left-with-a-less-powerful-flu-vaccine/>

Streptococcal Pneumoniae

- AKA Pneumococcus
 - Ear infections
 - Sinusitis
 - Pneumonia (36% CAP)
 - **Invasive Pneumococcal Disease (IPD)**
 - Bacteremia
 - Meningitis
 - 92 Sub types
 - 10 Subtypes cause 62% of all Invasive Pneumococcal Disease (IPD)



Pneumococcal Vaccines



Pneumococcal Bacteria



PCV13, 15,
or 20

Current Recommendations

No Previous Conjugate Vaccine

Age $\geq$ 65

Age 19-64 with high-risk conditions

Age 19-64 with immunocompromising conditions

PCV20

Or

PCV15 + PPSV23

12 months or if high
risk, 8 weeks later

ACIP January 12, 2022

PCV in Children

- Either PCV13 or PCV15 is recommended as a 4-dose series at ages 2, 4, 6, and 12–15 months.
- PCV13 and PCV15 can be used interchangeably.
- Interruption of the vaccination schedule does not require reinstitution of the entire series or the addition of extra doses.

PCV20 Licensure for children anticipated in 2023



2-6 Months

- 3 doses of PCV (either PCV13 or PCV15).
- Infants receiving their first dose at age ≤ 6 months should receive 3 doses of PCV at intervals of approximately 8 weeks (the minimum interval is 4 weeks).
- The fourth (booster) dose is recommended at age 12--15 months and at least 8 weeks after the third dose.
- Newborns should begin the schedule at age 2 months, although the first dose can be administered as early as 6 weeks.

Aged 7–11 Months: Catch up

- Three doses of PCV (either PCV13 or PCV15)
- First 2 doses at least 4 weeks between doses.
- The third dose should be administered at age 12--15 months, at least 8 weeks after the second PCV dose

Aged 12-23 Months Catch up

- Two doses of PCV (either PCV13 or PCV15) are recommended, with an interval of at least 8 weeks between doses.



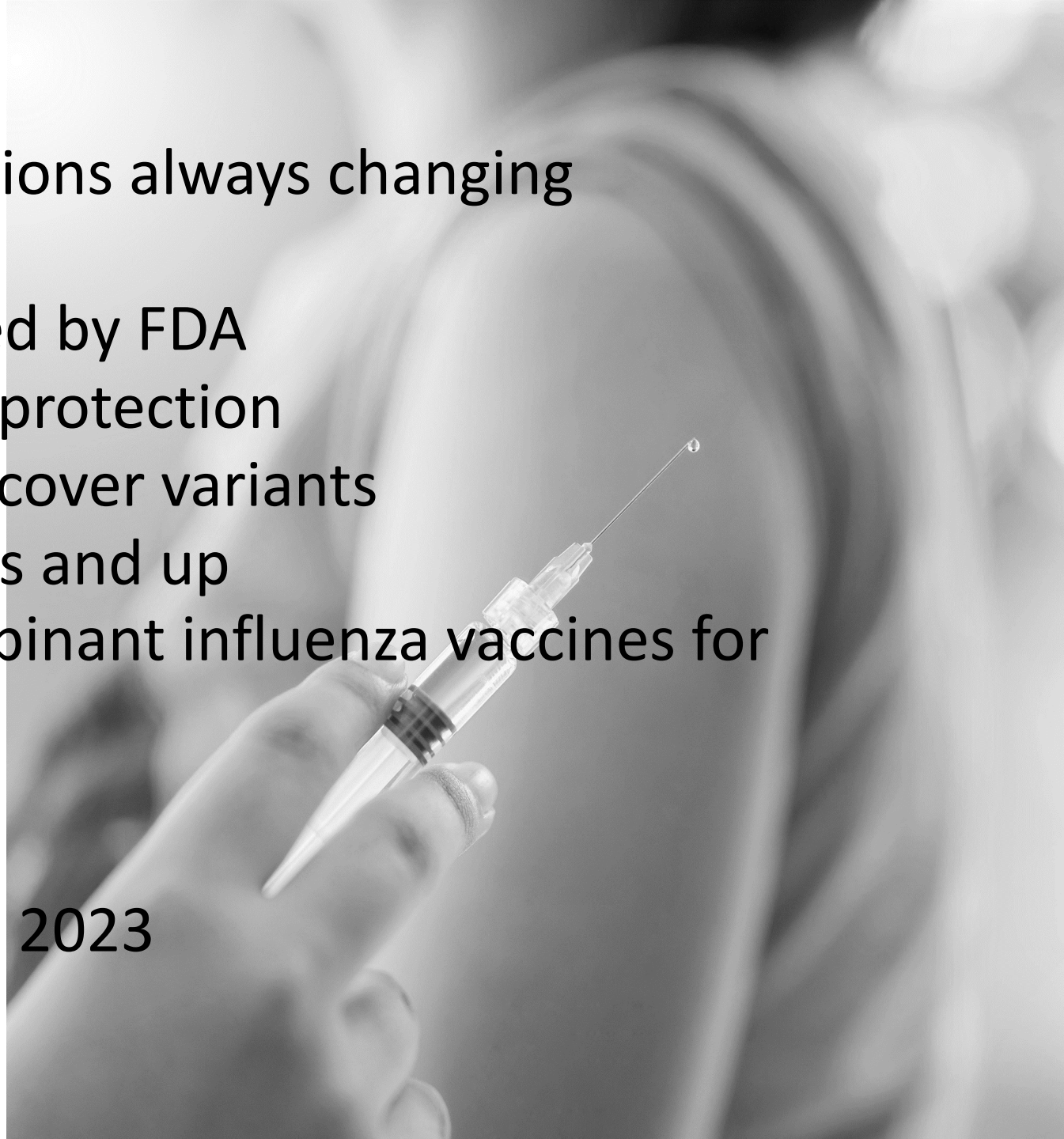
Unvaccinated age 24 months and up

- 24--59 months with out medical conditions should receive a single dose of PCV (either PCV13 or PCV15).
- 24--71 months with underlying medical conditions should receive 2 doses of PCV with an interval of at least 8 weeks between doses.
- Healty ≥ 5 years PCV is not recommended



Summary

- COVID 19 Vaccine recommendations always changing
 - mRNA over DNA
 - Adjuvanted subunit approved by FDA
 - Boosters provide additional protection
 - Formulation may change to cover variants
 - Now available ages 6 months and up
- High dose, adjuvanted or recombinant influenza vaccines for 65+
- PCV15 or PCV20 certain adults
- PCV13 or PCV15 children
 - PCV20 expected for children 2023



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