Immunization Update New Mexico Family Physicians August 3, 2023

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Conflict of Interest

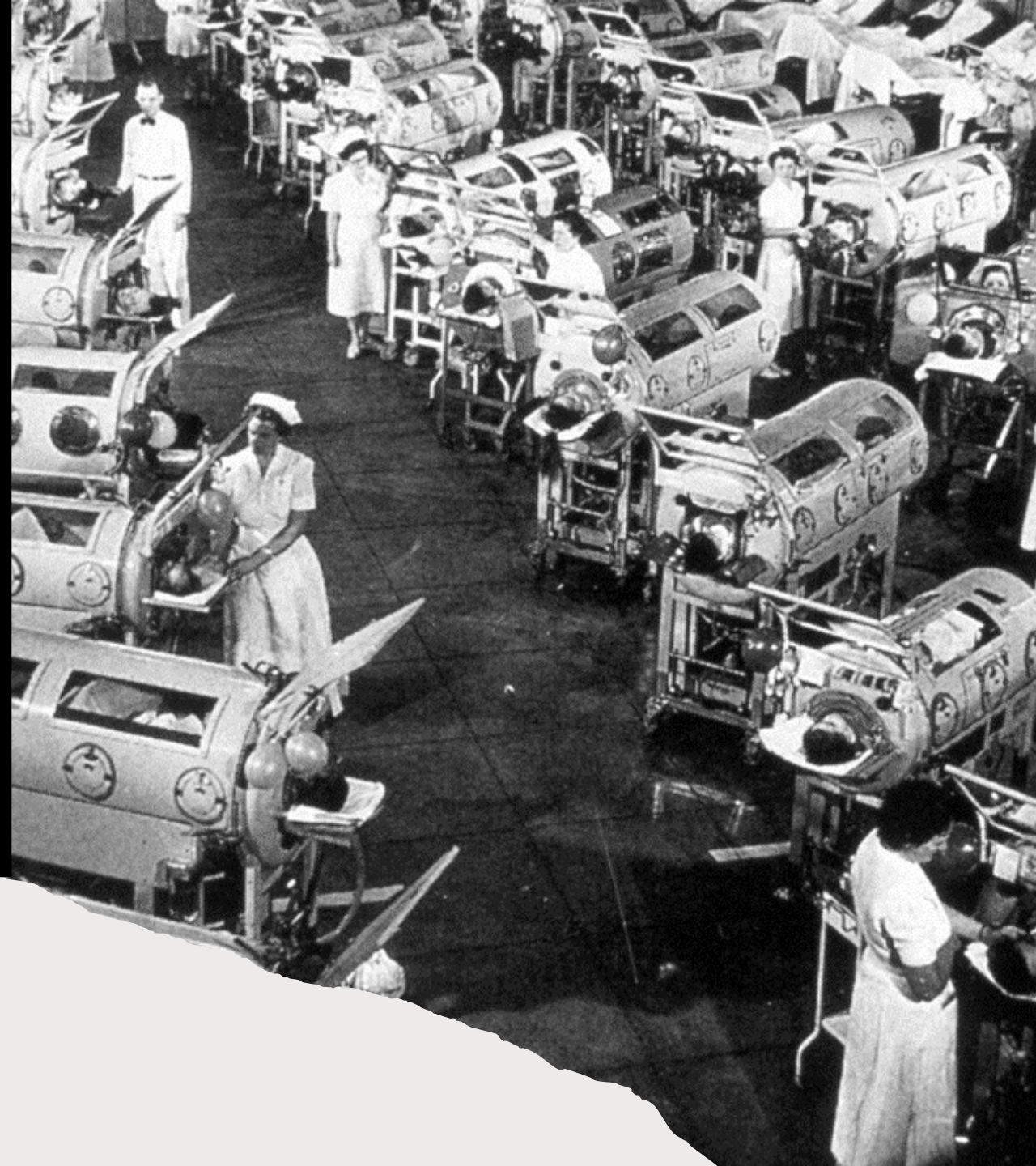
Consultant Seqirus

Objectives

- List approved and soon to be approved RSV Vaccines for adults
- Contrast new and old pneumococcal vaccines
- List changes to Pediatric Vaccine schedule

Vaccines in the news

- Polio Vaccine
- COVID 19
- RSV
- Influenza
- Pneumococcal
  - Adults
  - Children

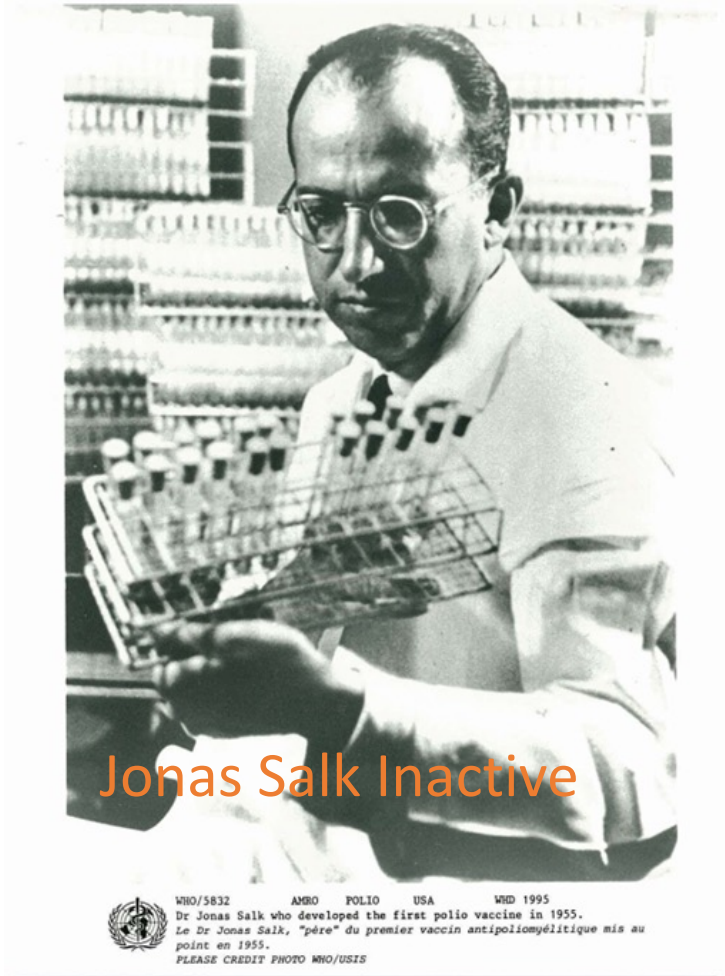


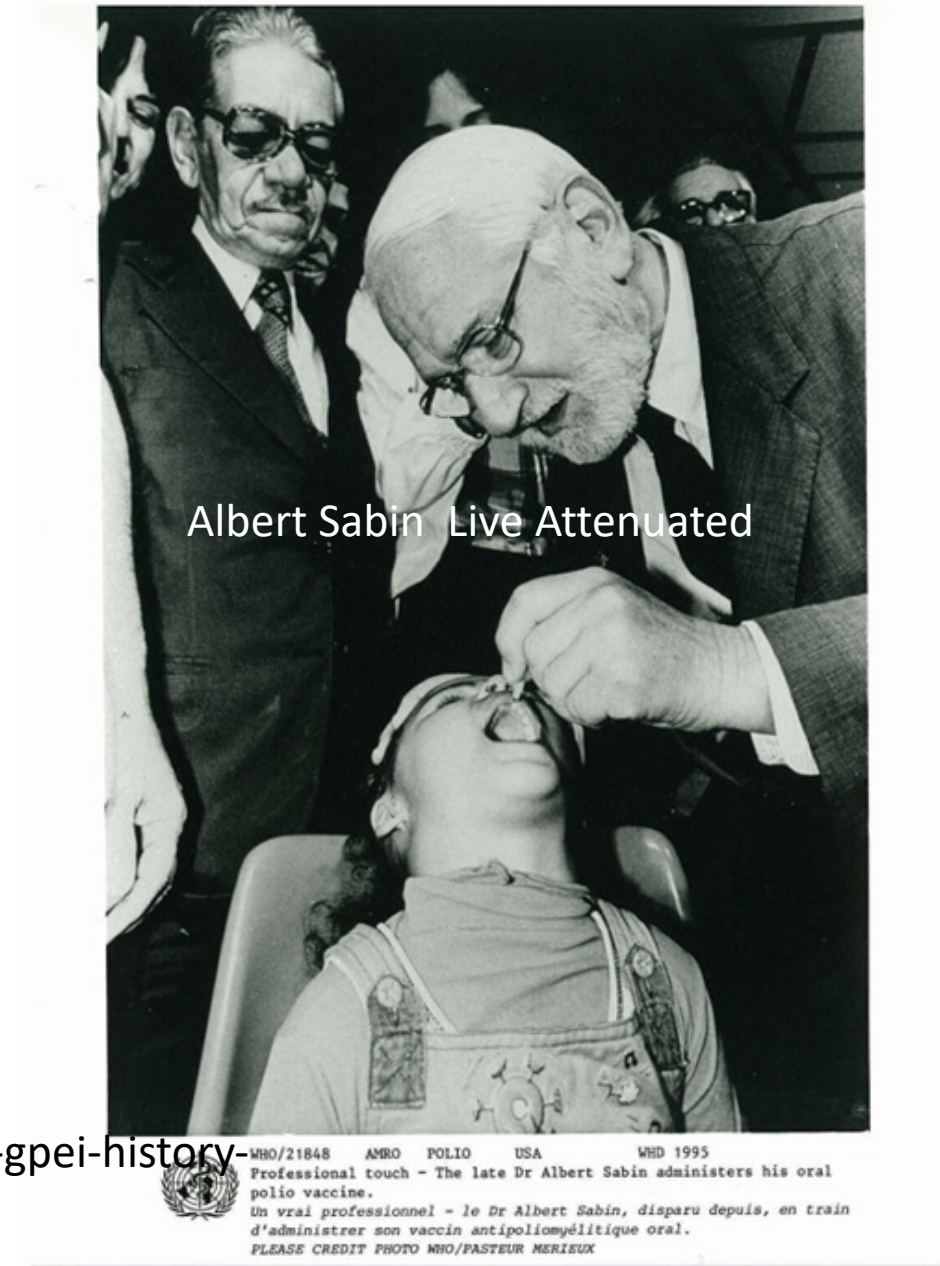
Polio Vaccines

1938

https://www.who.int/news-room/spotlight/history-of-vaccination/history-of-polio-vaccination

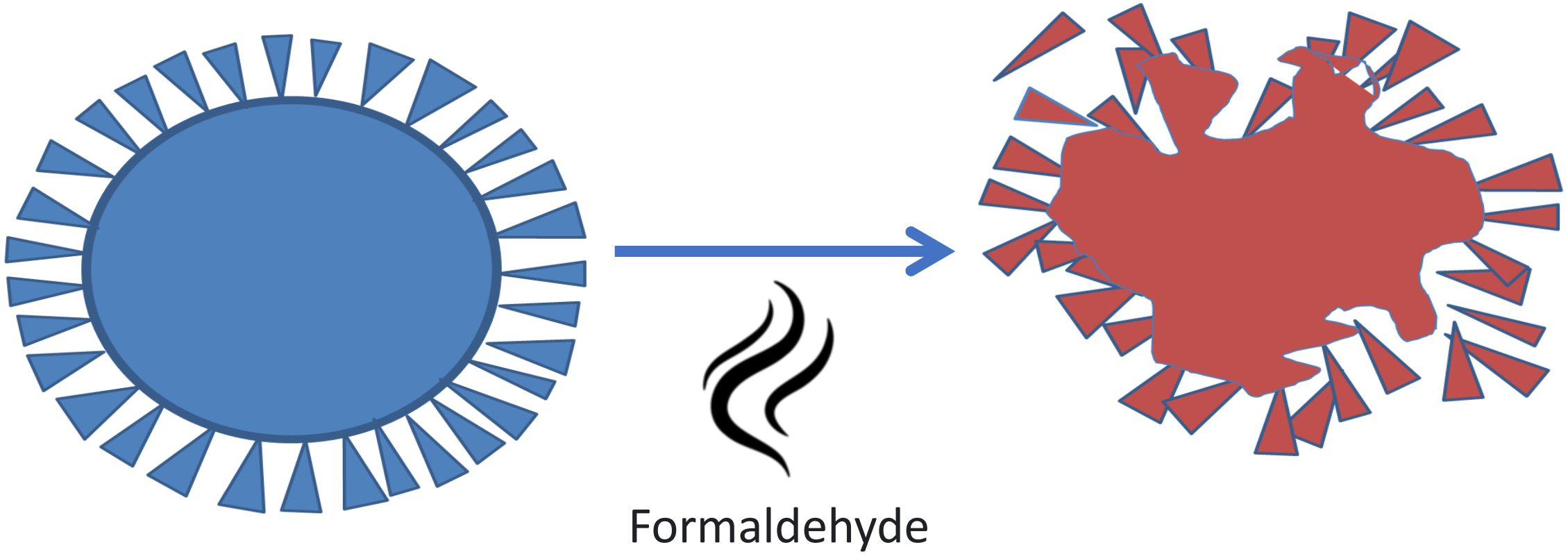
Polio Vaccines



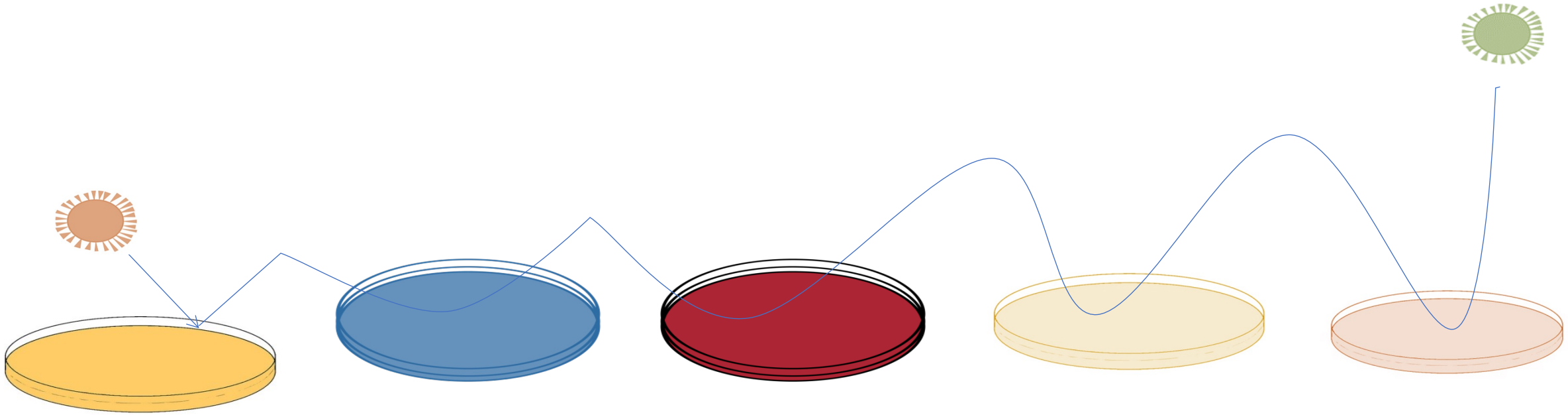


https://polioeradication.org/who-we-are/partners/the-gpei-history-project/

Salk Vaccine



Sabin Vaccine



Salk

- 1954
- Clinical Trial
- 419,000 vaccine
- 330,000 placebo (later unblinded and given vaccine)

Sabin

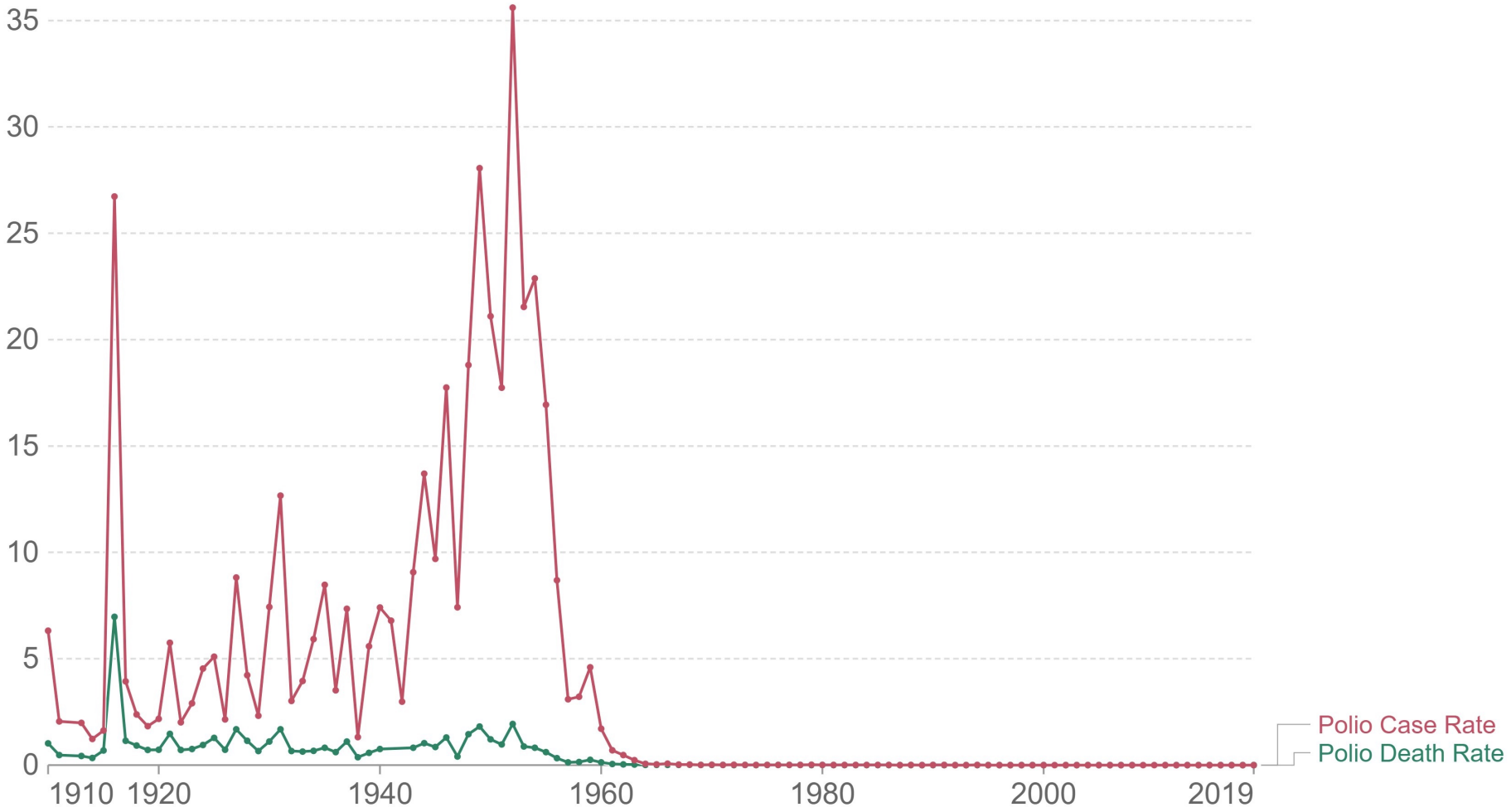
- 1957
- Tested in Mexico and Russa
- 1963 Available in US

- Inexpensive
- Easy to use
- Life-long immunity
- Protects against type 1,2,3

- Adopted as the polio vaccine

Polio case and death rates in the United States

The reported rates are per 100,000 US population and include both wild- and vaccine-derived type polio infections that occurred indigenously and as imported cases.



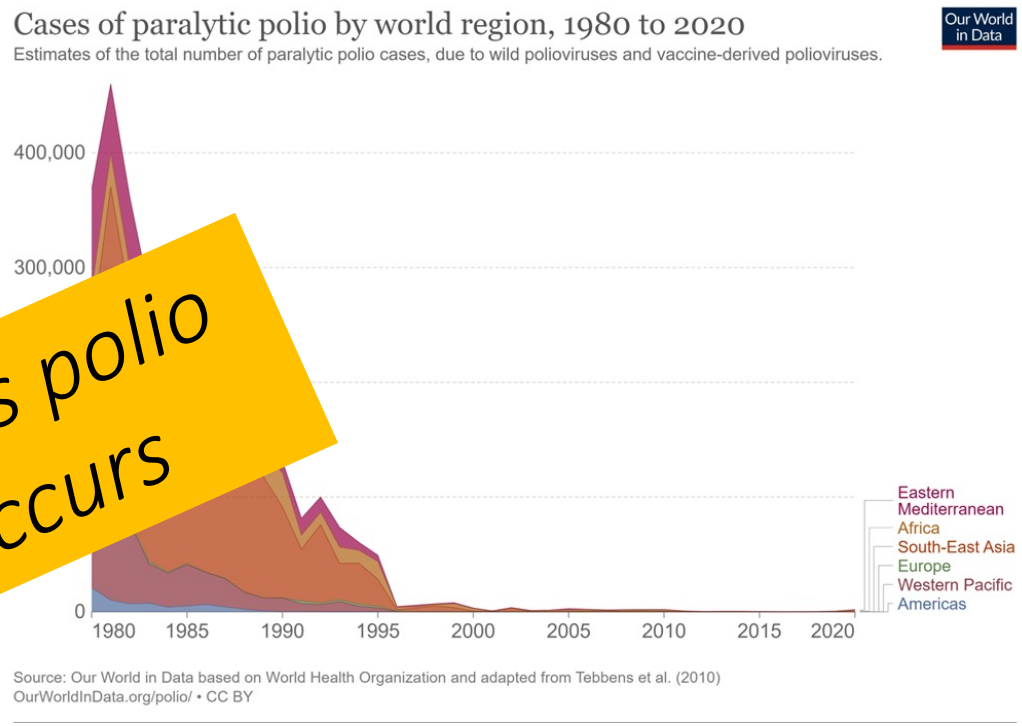
Source: Our World In Data based on US Public Health Service; US Center for Disease Control; and WHO
OurWorldInData.org/polio/ • CC BY

1988 Global Polio Eradication Initiative

- World Health Organization
- Rotary International
- US Centers for Disease Control and Prevention (CDC
- UNICEF
- Bill & Melinda Gates Foundation (later)
- Gavi
- Vaccine Alliance.

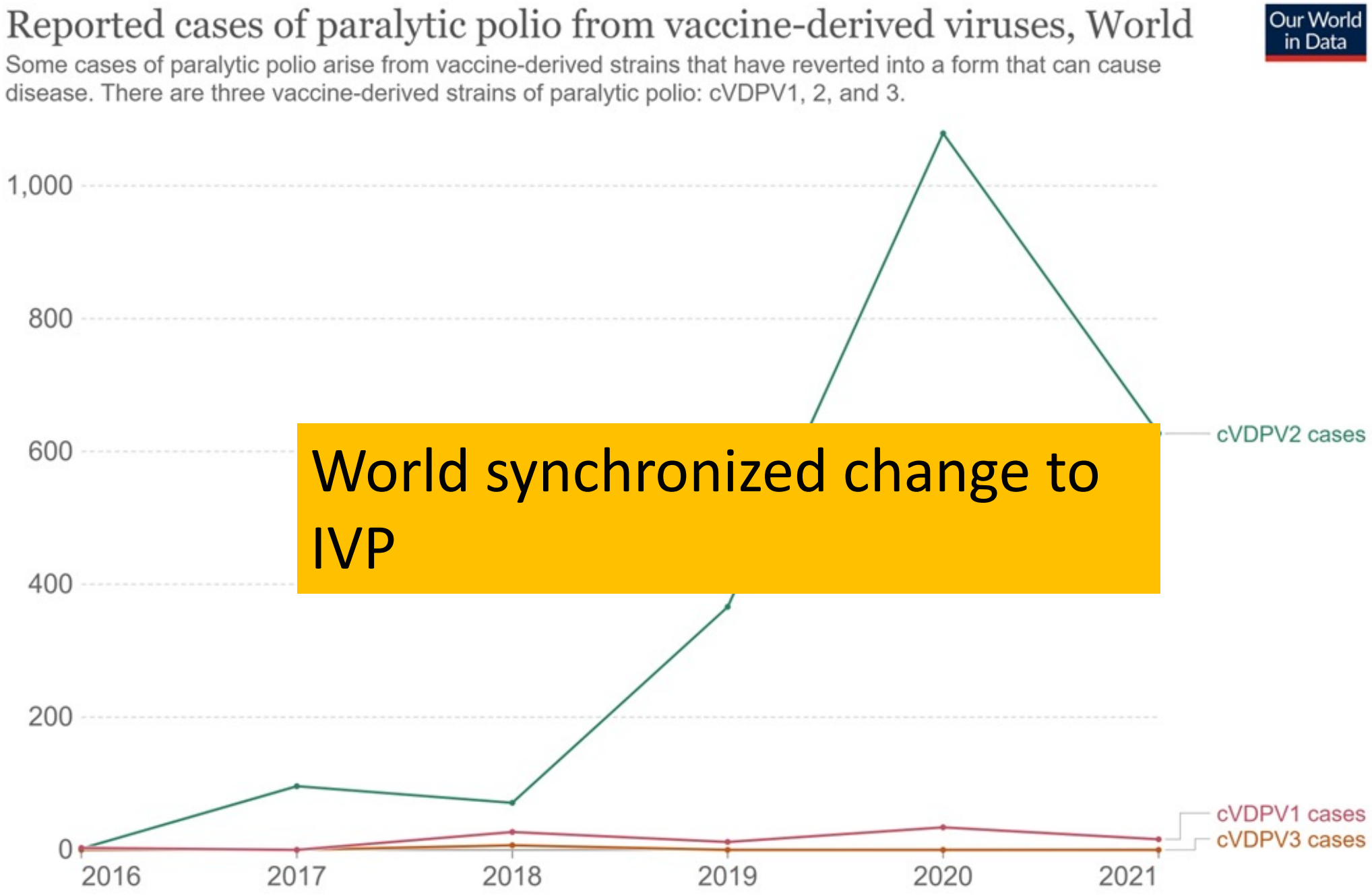
1994 Americas Polio Free
2000 Western Pacific Region Polio Free
2002 European Region Polio Free
2014 South East Asia Polio Free

2003 Nigeria suspends polio vaccines, outbreak occurs



https://ourworldindata.org/polio

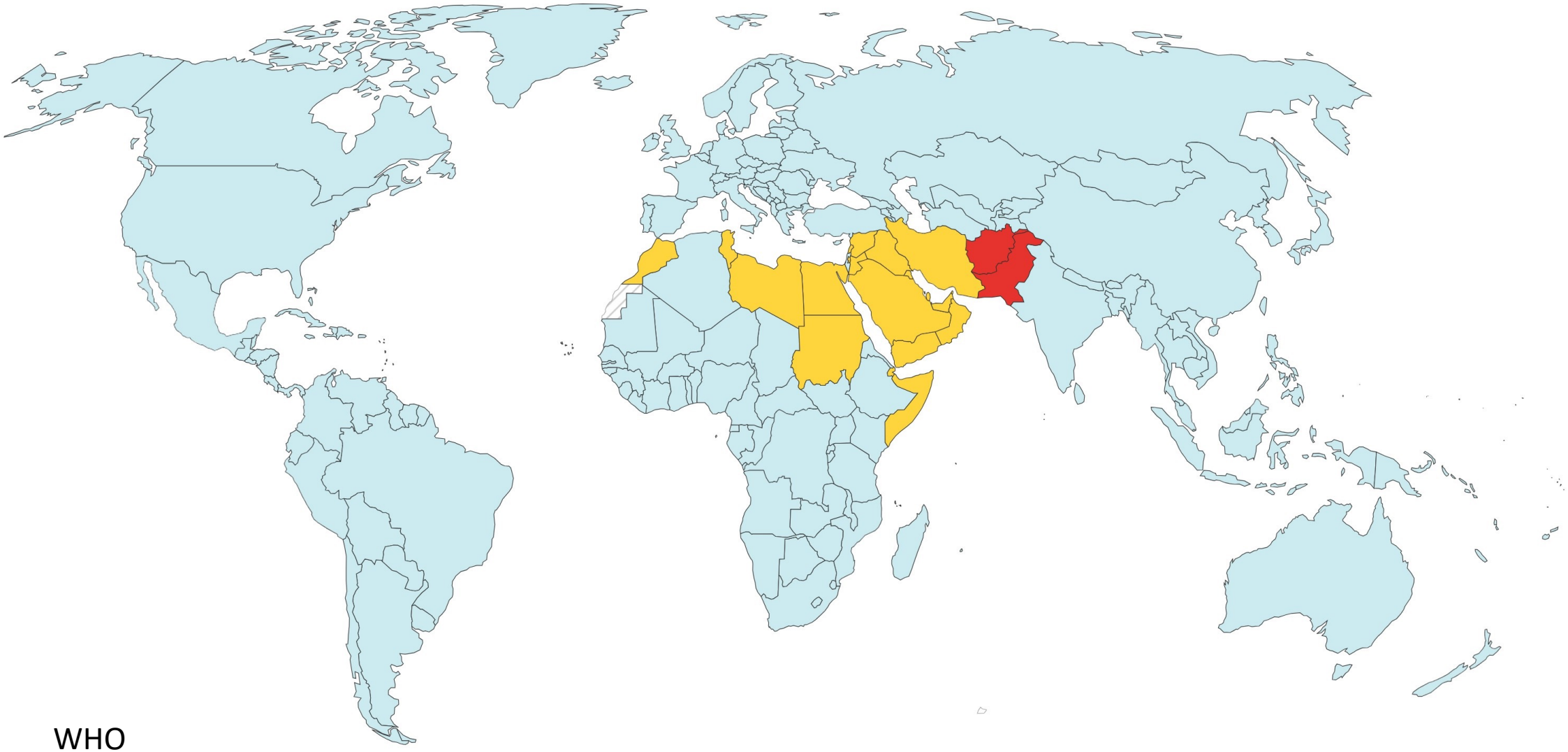
Wild Type 2 Eradicated 2015


Reported cases of paralytic polio from vaccine-derived viruses, World
Some cases of paralytic polio arise from vaccine-derived strains that have reverted into a form that can cause disease. There are three vaccine-derived strains of paralytic polio: cVDPV1, 2, and 3.
Our World in Data
1,000
800
600
400
200
0
2016
2017
2018
2019
2020
2021
cVDPV2 cases
cVDPV1 cases
cVDPV3 cases
World synchronized change to IVP

Progress towards polio eradication, 2020

Countries where there are any cases of paralytic polio from wild polioviruses are considered endemic.

Our World in Data



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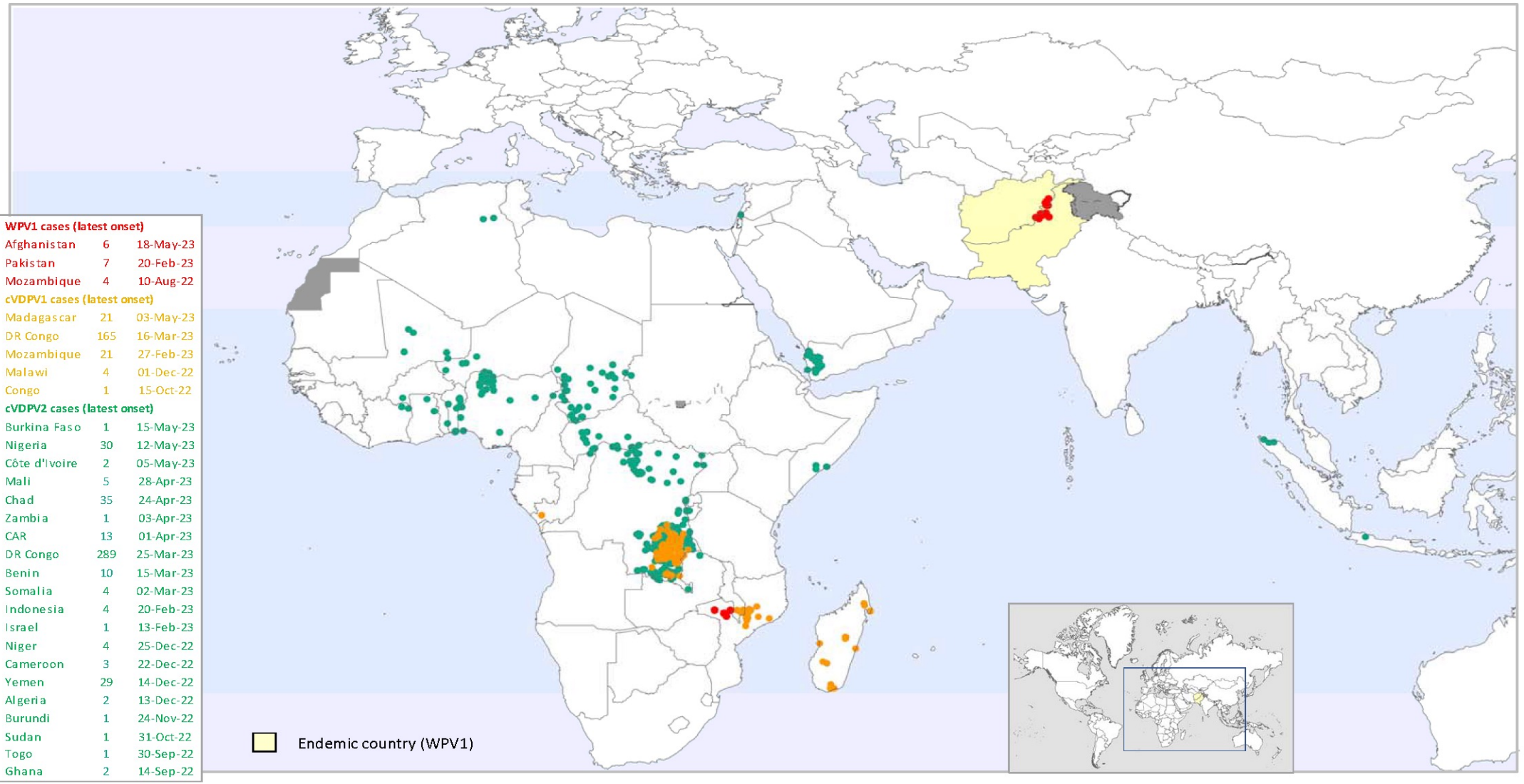
UN condemns brutal killing of eight polio workers in Afghanistan

https://news.un.org/en/story/2022/02/1112612#:~:text=Two%20vaccinators%20and%20a%20social,in%20Kunduz%20and%20Takhar%20provinces.

Global WPV1 & cVDPV Cases[1], Previous 12 Months[2]

World Health Organization

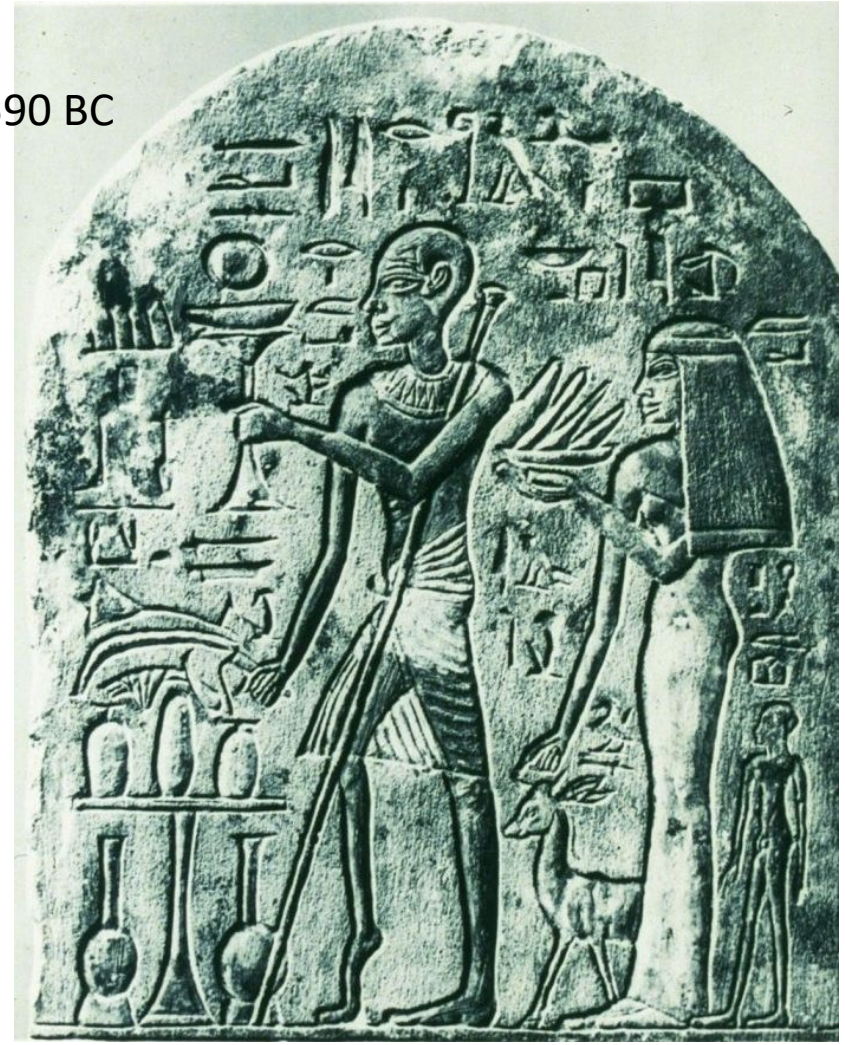


[1]Excludes viruses detected from environmental surveillance; [2]Onset of paralysis: 05 Jul. 2022 to 04 Jul. 2023

Data in WHO HQ as of 04 Jul. 2023

Endemic- Almost Eradicated- Emerging Threat

1590 BC



The New York Times

July 2022

First Polio Case in Nearly a Decade Is Detected in New York State

A man who lives in Rockland County was infected by someone

USA: IPV at

- 2 months old
- 4 months old
- 6 through 18 months old
- 4 through 6 years old.

Adults known/suspected unvaccinated or incompletely vaccinated

Complete a primary vaccination series with inactivated polio vaccine.

A primary series: 3 Doses

ACIP June 2023

Adults at increased risk of poliovirus exposure

May receive another dose of inactivated polio vaccine:

Travelers to countries where polio is epidemic or endemic

Laboratory and healthcare workers who handle specimens that might contain polioviruses.

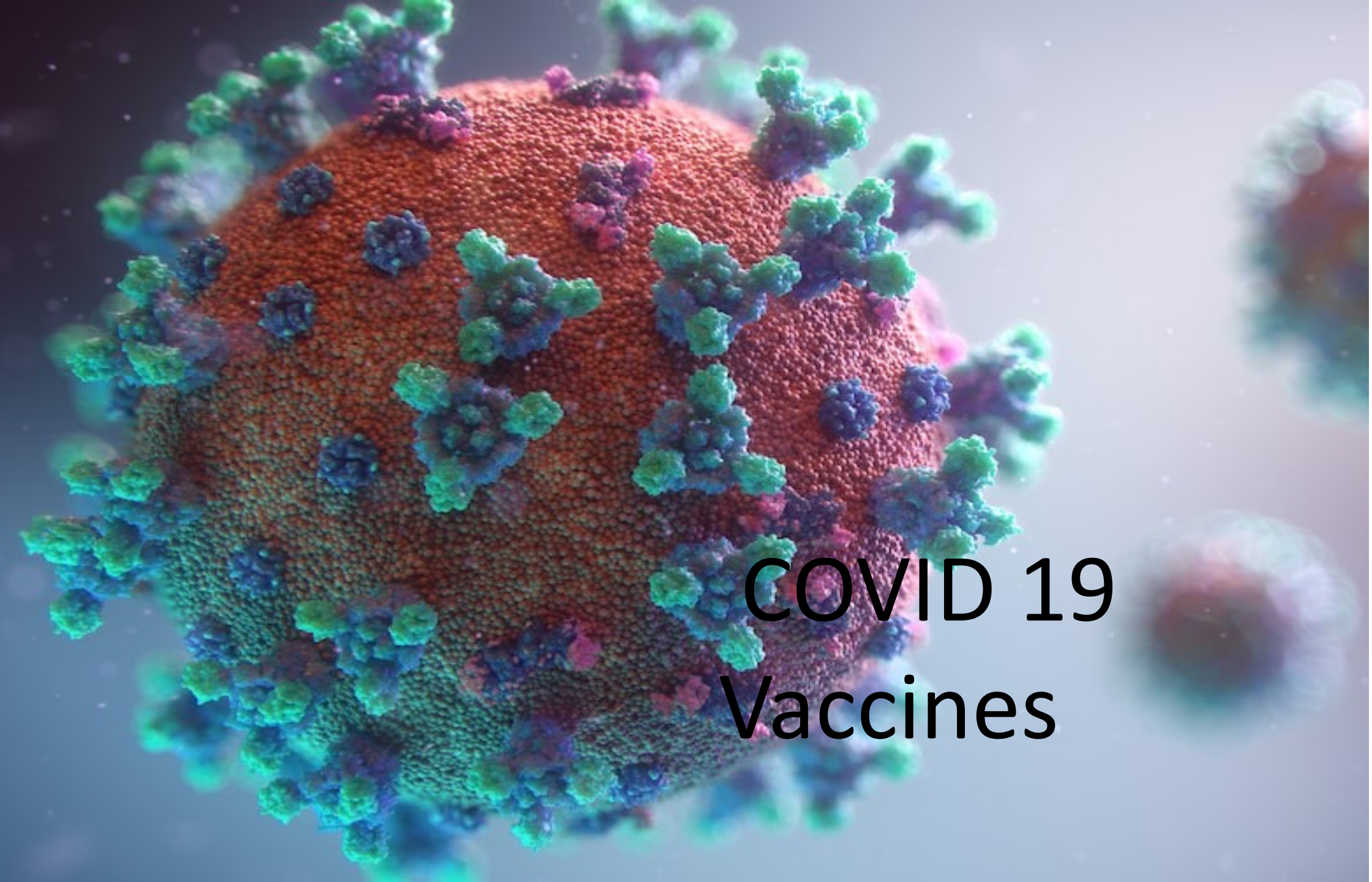
Healthcare workers or other caregivers who have close contact with a person who could be infected with poliovirus.

Unvaccinated or incompletely vaccinated adults whose **children will be receiving oral poliovirus** vaccine(for example, international adoptees or refugees).

Unvaccinated or incompletely vaccinated adults living or **working in a community where poliovirus is** circulating.

- No more than a single lifetime booster dose with inactivated polio virus for adults.

ACIP June 2023

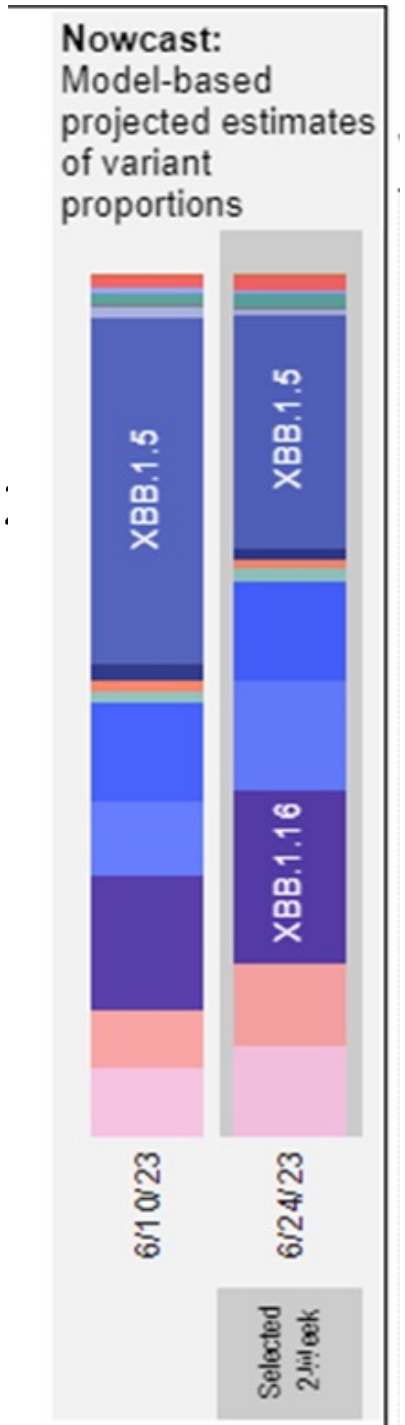


COVID 19 Vaccines

COVID 19 Epidemiology

- XBB sublineages of Omicron
  - > 95% of the circulating virus variants in the U.S. as of early June 20
    XBB.1.5 declining
    XBB.1.16 is on the rise, likely to be dominate in Fall 2023
    XBB.2.3 is slowly increasing in proportion
  - All XBB have similar spike proteins

https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_select_00



COVID Vaccines

FDA to manufacturers:

Develop updated COVID-19 vaccines with a monovalent XBB.1.5 composition

May be mRNA or recombinant

Fall 2023

COVID 19 Vaccines

CURRENTLY

At least 1 Bivalent Vaccine

Last vaccine before Sept 2022

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#:~:text=COVID%2D19%20vaccination%20is%20recommended,younger%20than%20age%206%20months

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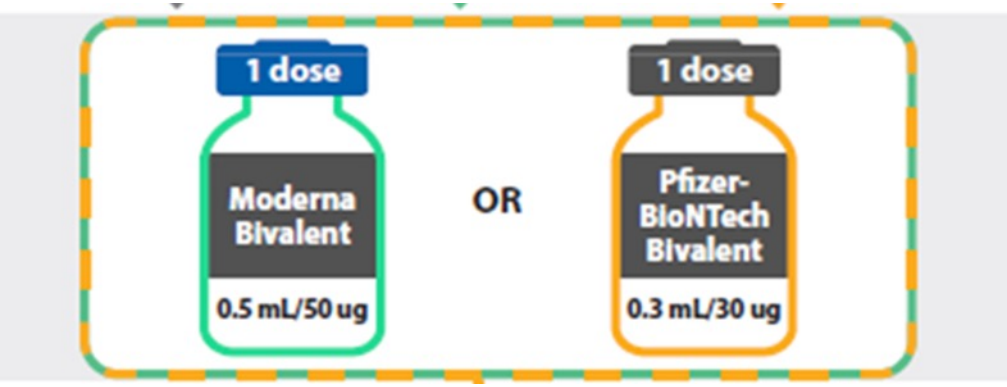
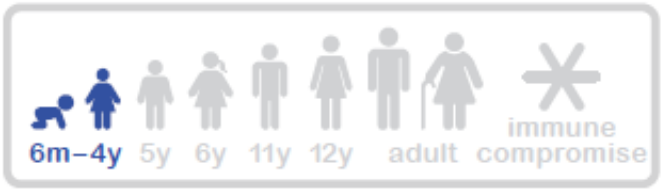
Optional 2nd Bivalent Dose

Age 65+

Immunocompromised



Recommended COVID-19 vaccines for **people without immunocompromise, aged 6 months–4 years**, mRNA vaccines, *with vial icons and dosages*, May 2023*†



COVID-19 vaccination status May 2023

Unvaccinated

Vaccinated

Previously received vaccine(s)

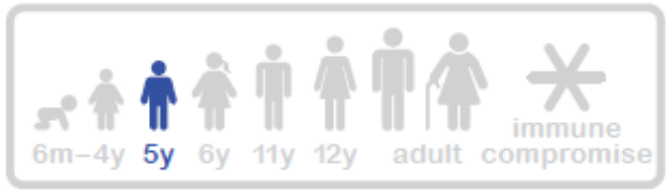
- **1 dose monovalent** Moderna
- **2 doses monovalent** Moderna
- **2 doses monovalent** Moderna and **1 dose bivalent** Moderna
- **1 dose monovalent** Pfizer-BioNTech
- **2 doses monovalent** Pfizer-BioNTech
- **3 doses monovalent** Pfizer-BioNTech
- **2 doses monovalent** Pfizer-BioNTech and **1 dose bivalent** Pfizer-BioNTech

Number of doses indicated, by manufacturer

- **2 doses** Moderna Bivalent 0.25 mL/25 ug **OR** **3 doses** Pfizer-BioNTech Bivalent 0.2 mL/3 ug
- **1 dose** Moderna Bivalent 0.25 mL/25 ug
- **1 dose** Moderna Bivalent 0.2 mL/10 ug
- **2 doses** Pfizer-BioNTech Bivalent 0.2 mL/3 ug
- **1 dose** Pfizer-BioNTech Bivalent 0.2 mL/3 ug

VACCINATION COMPLETE

Recommended COVID-19 vaccines for **people without immunocompromise, aged 5 years,** mRNA vaccines, *with vial icons and dosages*, May 2023*†



COVID-19 vaccination status May 2023

Unvaccinated

Vaccinated

Previously received vaccine(s)

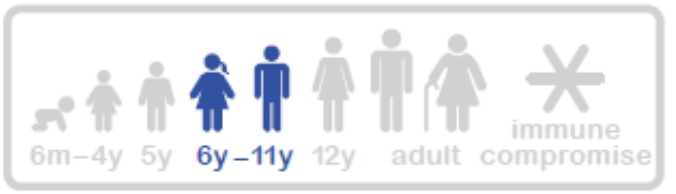
- **1 dose monovalent** Moderna
- **2 doses monovalent** Moderna
- **1 or more doses monovalent** Pfizer-BioNTech
- **2 doses monovalent** Moderna and **1 dose bivalent** mRNA
- **Any doses monovalent** Pfizer-BioNTech and **1 dose bivalent** Pfizer-BioNTech

Number of doses indicated, by manufacturer

- **2 doses** Moderna Bivalent 0.25 mL/25 ug **OR** **1 dose** Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- **1 dose** Moderna Bivalent 0.25 mL/25 ug **OR** **1 dose** Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- **1 dose** Moderna Bivalent 0.2 mL/10 ug **OR** **1 dose** Pfizer-BioNTech Bivalent 0.2 mL/10 ug
- **1 dose** Pfizer-BioNTech Bivalent 0.2 mL/10 ug

VACCINATION COMPLETE

Recommended COVID-19 vaccines for **people without immunocompromise, aged 6–11 years,** mRNA vaccines, *with vial icons and dosages,* May 2023*†



COVID-19 vaccination status May 2023

Unvaccinated

Vaccinated

Previously received vaccine(s)

1 or more doses monovalent Moderna

1 or more doses monovalent Pfizer-BioNTech

2 doses monovalent Moderna and **1 dose bivalent** mRNA

2 doses monovalent Pfizer-BioNTech and **1 dose bivalent** mRNA

Number of doses indicated, by manufacturer

1 dose

Moderna Bivalent

0.25 mL/25 ug

OR

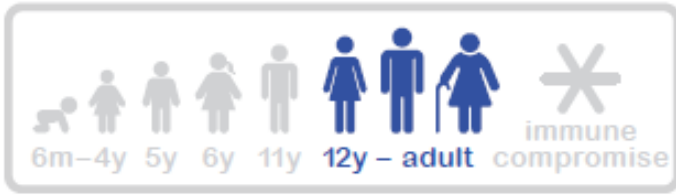
1 dose

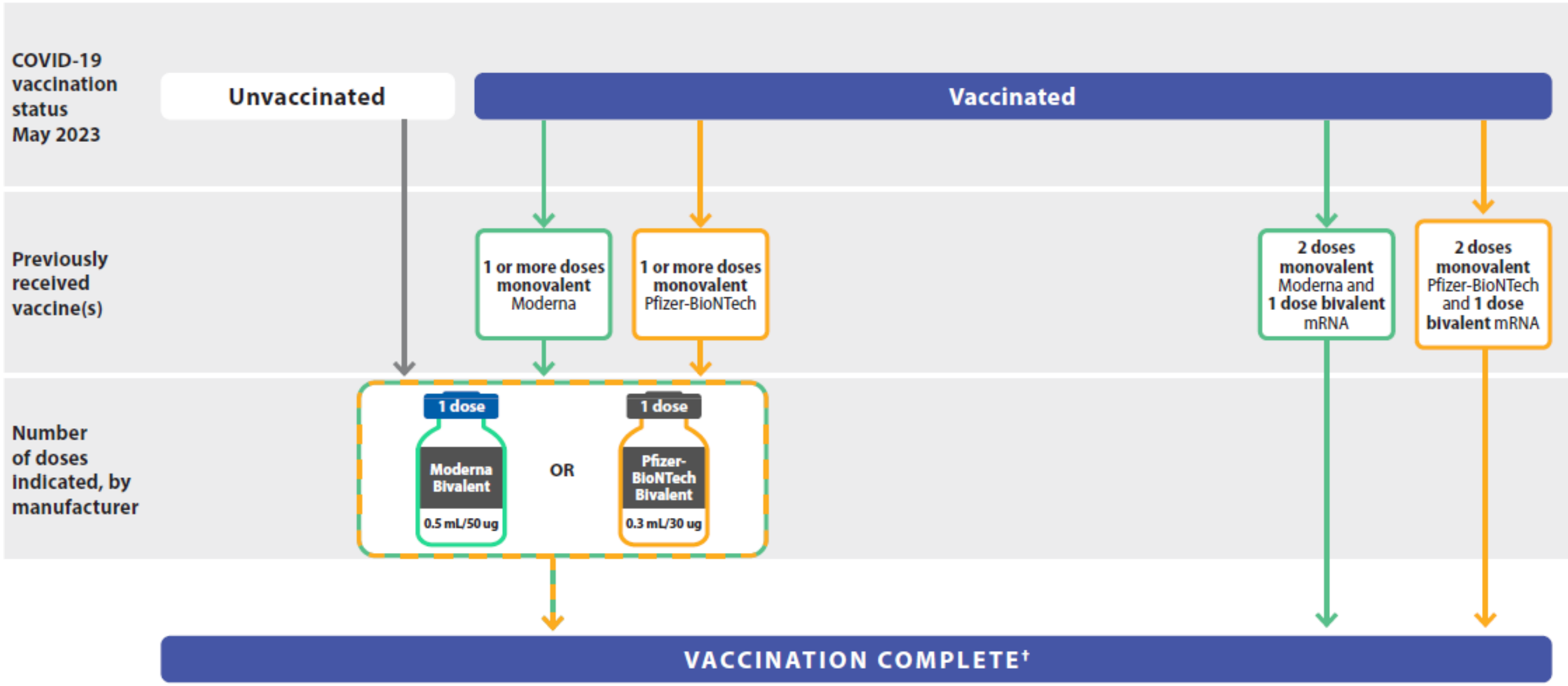
Pfizer-BioNTech Bivalent

0.2 mL/10 ug

VACCINATION COMPLETE

Recommended COVID-19 vaccines for **people without immunocompromise, aged 12 years and older,** mRNA vaccines, *with vial icons and dosages,* May 2023*†

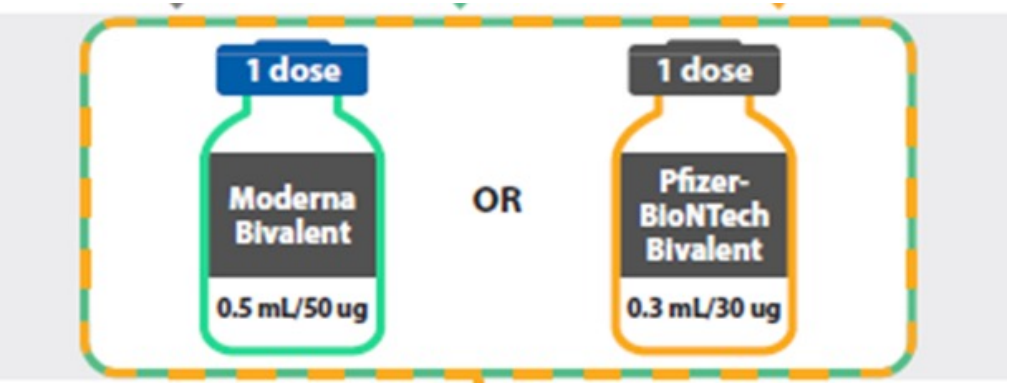




Not mRNA Vaccines

- Novavax age 12+ Monovalent
- Jassen (J&J) No longer recommended

Should be followed by Bivalent RNA booster

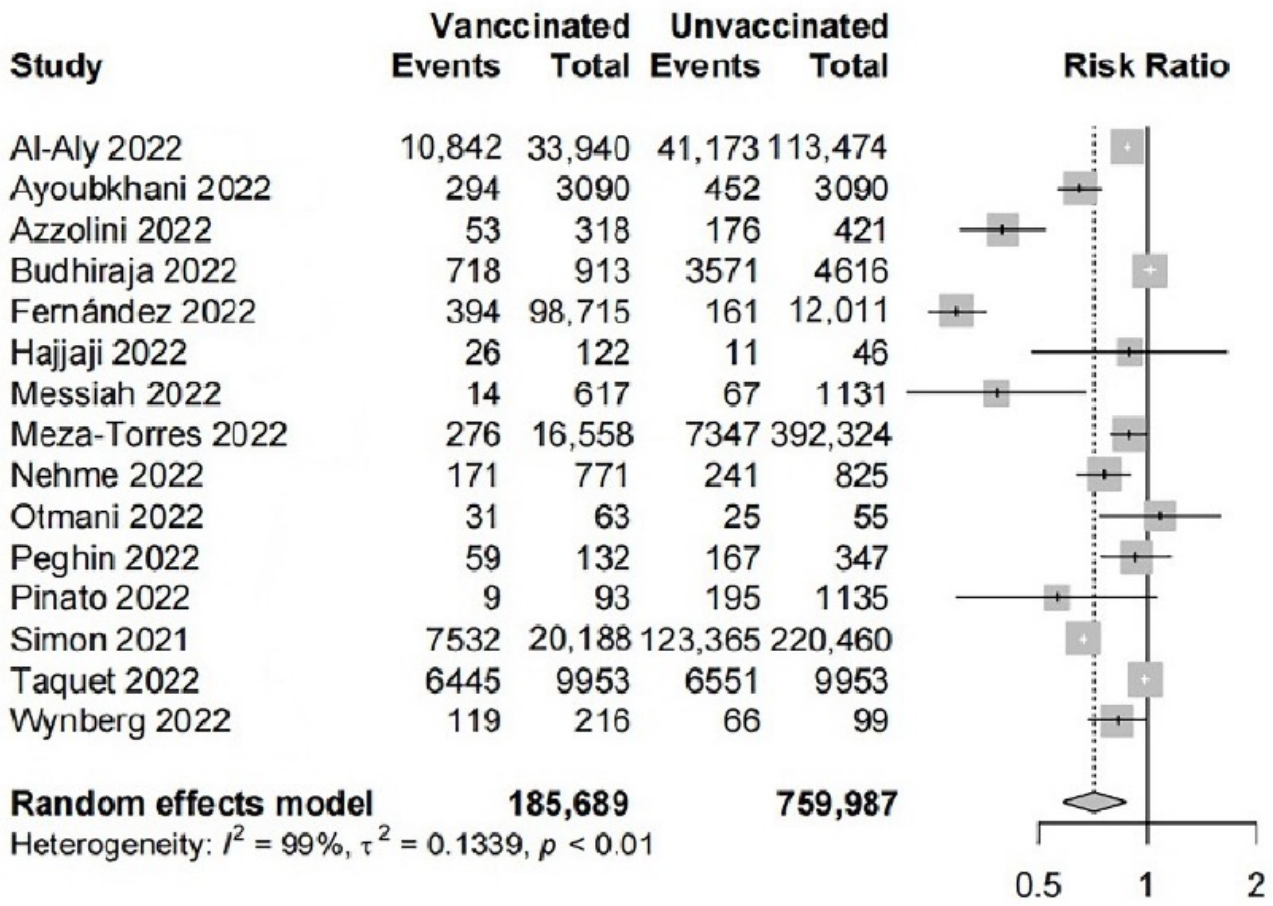


Long COVID

- 1 in 13 (7.5%) of US Adults)
  - symptoms lasting three or more months after first contracting the virus
  - didn’t have prior COVID-19 infection.
- 10-20% of adults who had COVID still experiencing symptoms

CDC
WHO

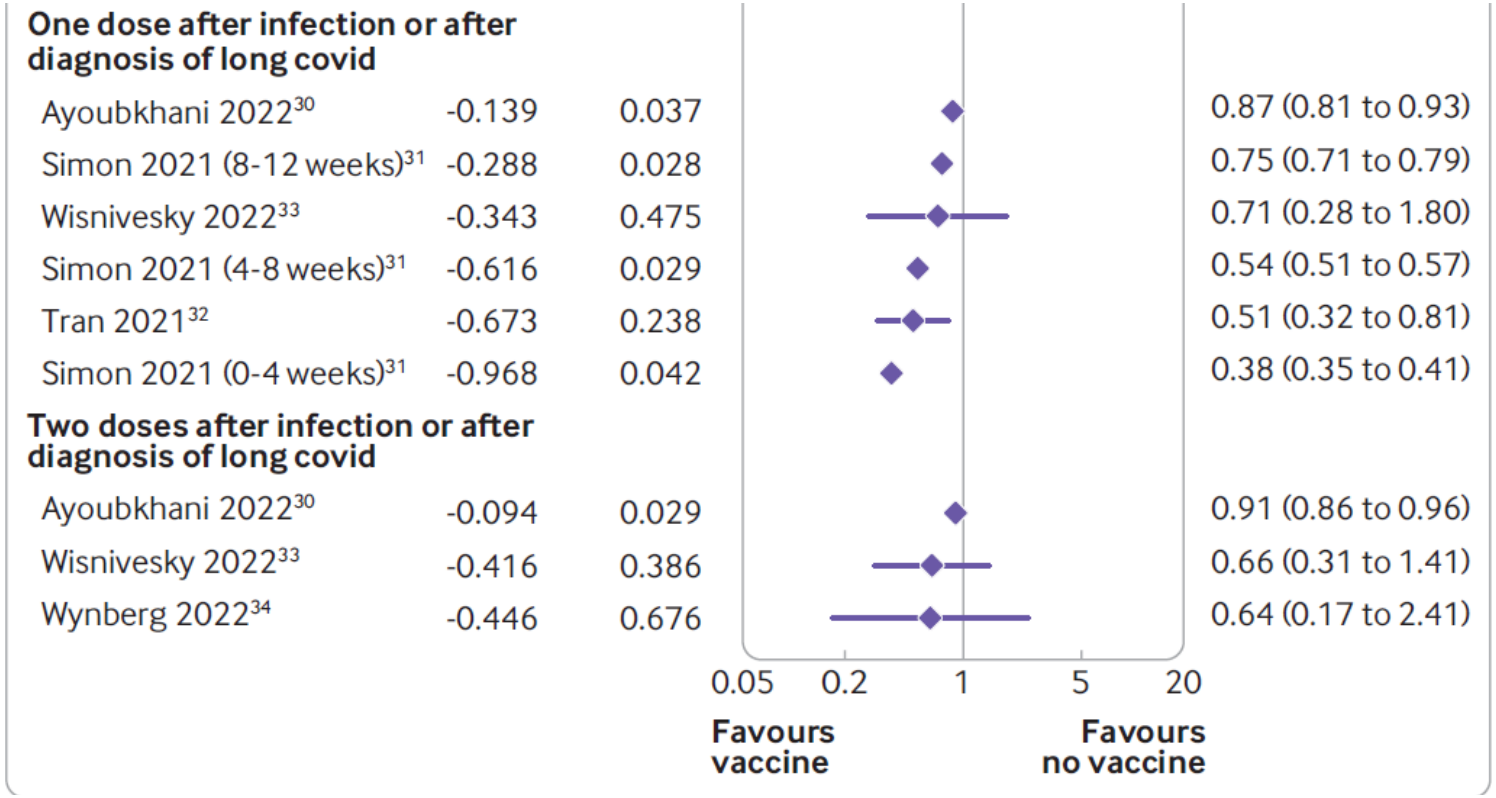
Meta analysis:
Vaccinated 29% lower risk of developing long COVID compared
with unvaccinated group (RR = 0.71, 95% CI: 0.58–0.87, p < 0.01).



Gua *Int J Environ Res Public Health*. 2022

Vaccination for Long COVID treatment

30-40% improve after vaccination



Byambasuren *BMJ Med 2023*

COVID Vaccine Coverage

- Public Health Emergency Ended May 2023
- VFC for children 6-m to 18 years
- Bridge Access Program –DOH and Pharmacies through 2024

Proposed: Vaccines for Adults in 2024

Medicare

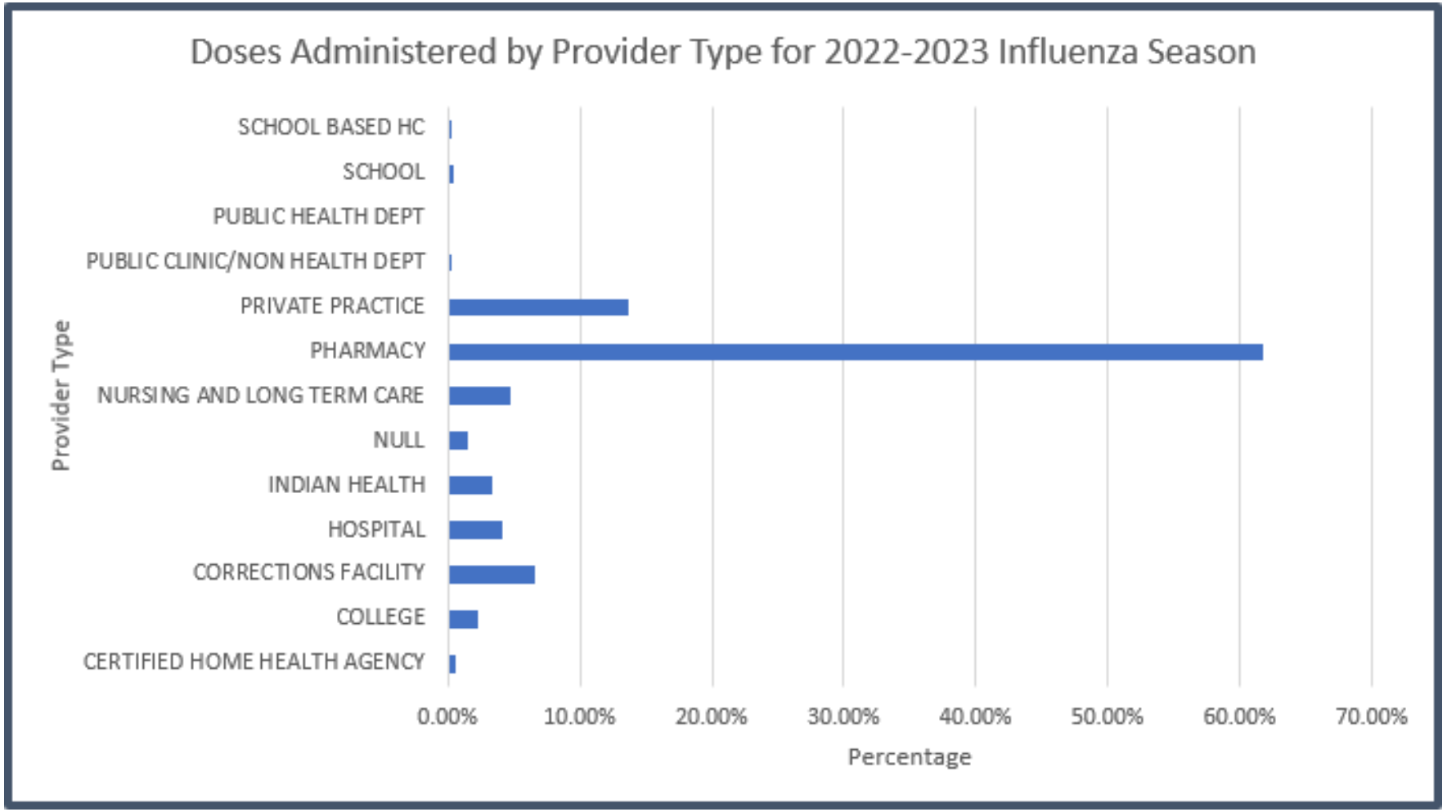
- Part B Covers
  - COVID
  - Influenza
  - Pneumococcal
  - Hep B (high risk)
  - Td (in case of injury)

Part D
- Shingles
- RSV?
- Tdap

Covered with No Copay

Inflation Reduction Act

Medicaid -Covered with no copays



Katie Cruz NMDOH

Vaccines for Children

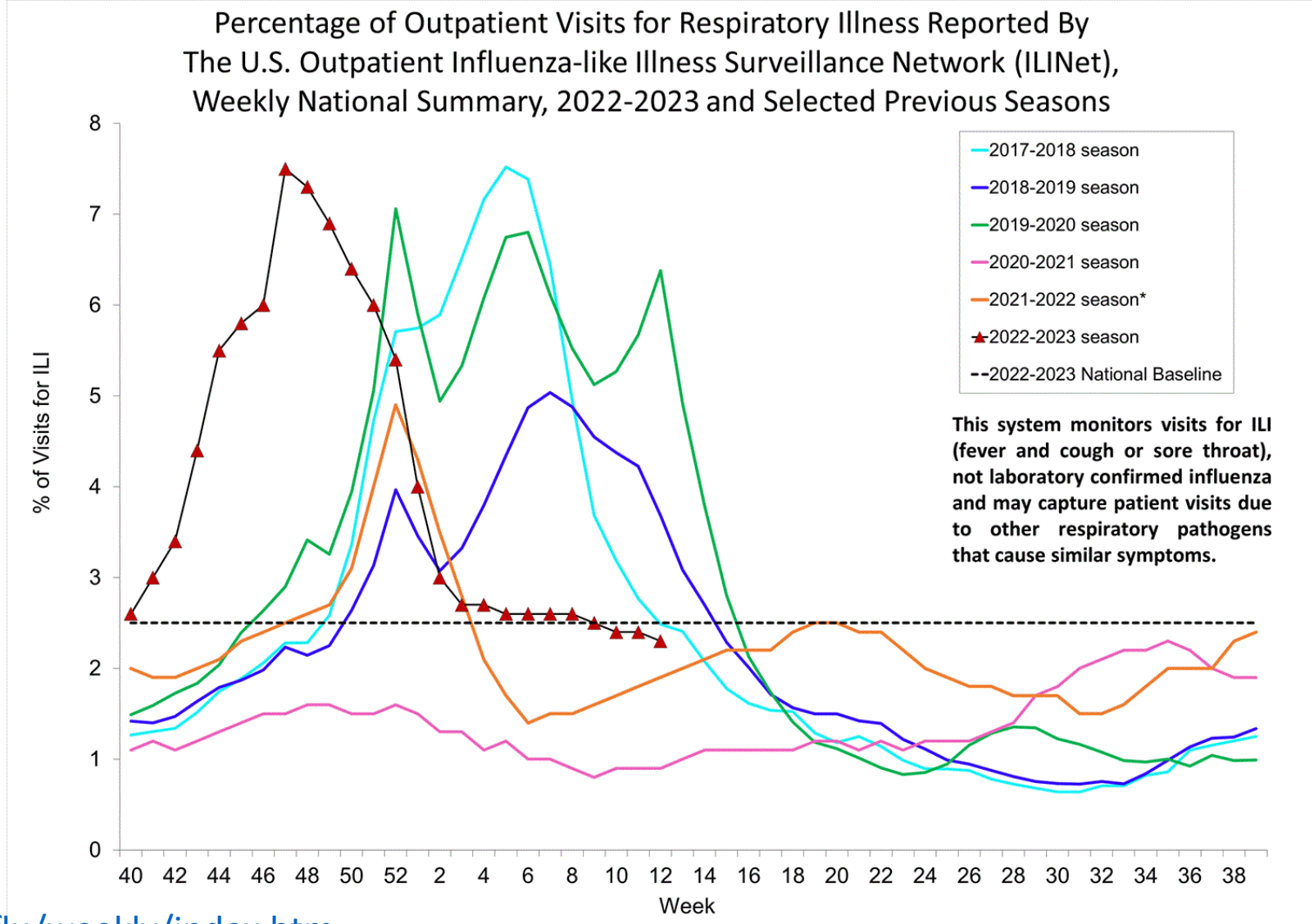
- Simplified Schedules
- Single dose vials
- No additional COVID era reporting

New Mexico
Vaccines for Children

https://www.nmhealth.org/about/phd/idb/imp/vfc/

Influenza Vaccines

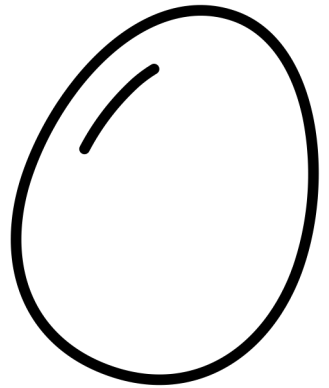
Influenza



https://www.cdc.gov/flu/weekly/index.htm

Influenza Vaccine

Persons with egg allergy should receive influenza vaccine unless a contraindication exists.
Any influenza vaccine (egg based or non-egg based).



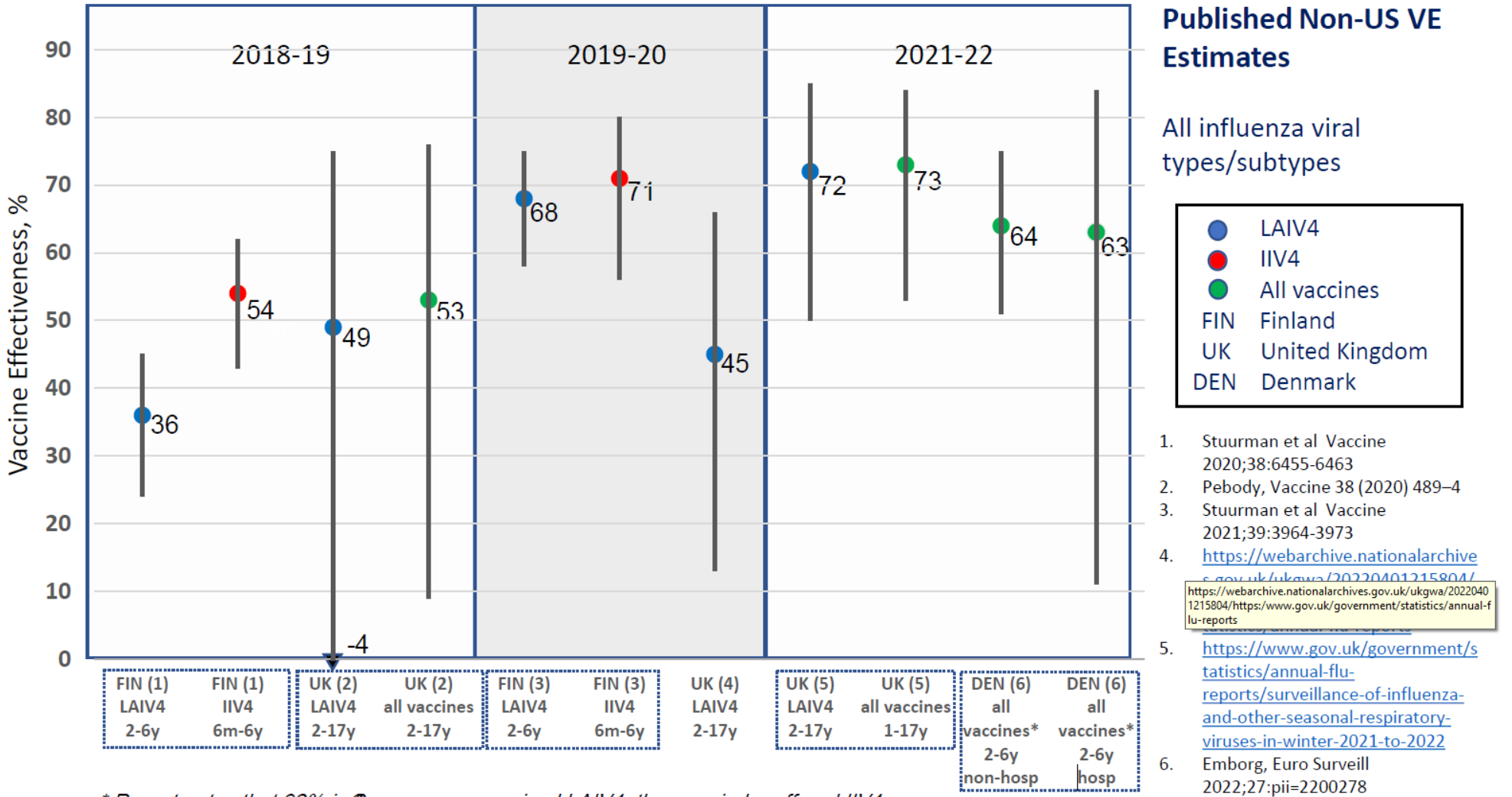
Life-threatening reactions to vaccines can rarely occur with any vaccine.

All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available.

ACIP June 2023

LAIV Effectives Estimates

LAIV Ages 2-49 years



ACIP April 2023

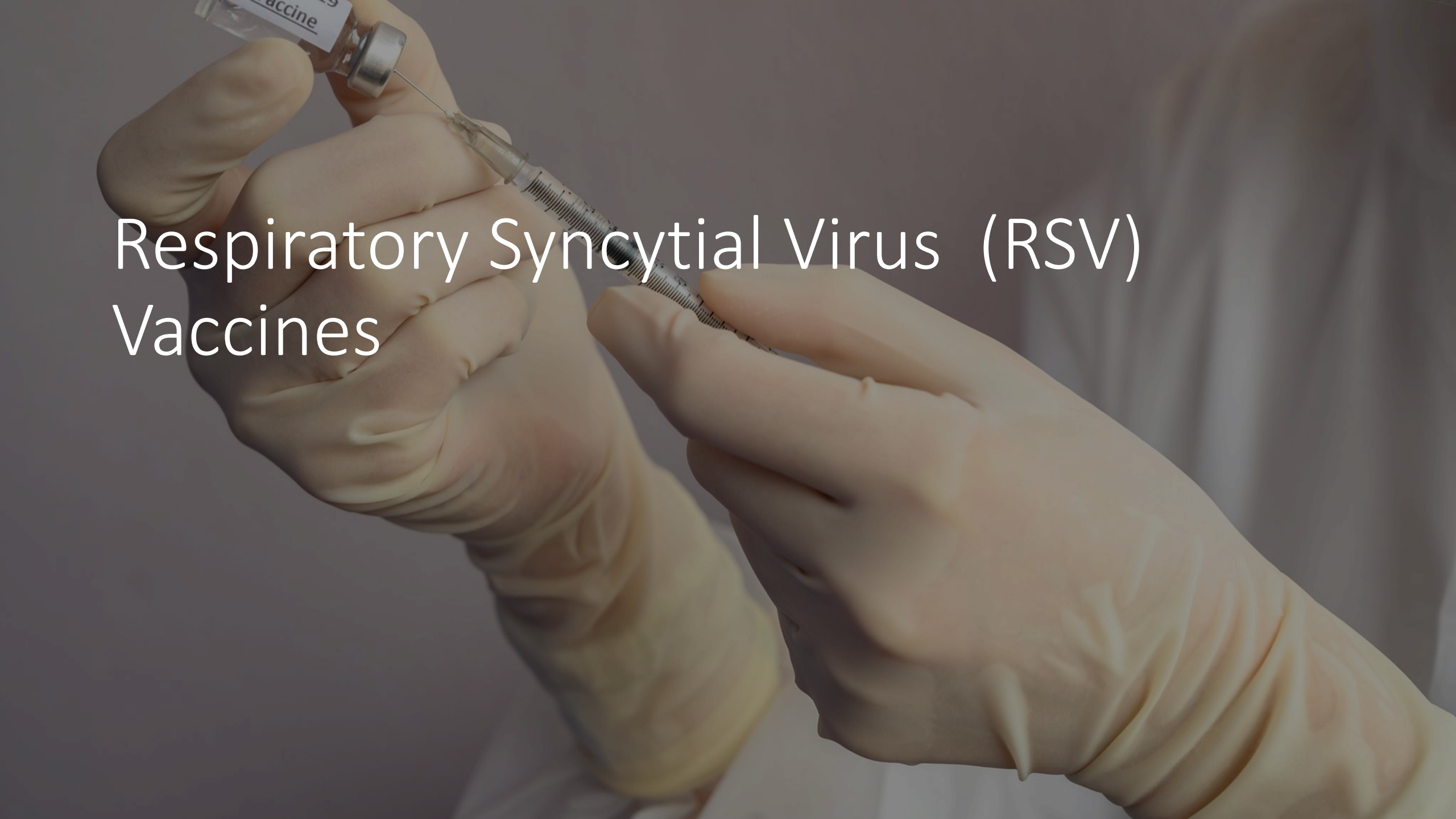
Adults aged ≥65 years preference

High-dose (Fluzone)inactivated influenza vaccine (HD4IV)
Recombinant (Flublock) influenza vaccine (RIV4)
Adjuvanted (Fluad) inactivated influenza vaccine (aIIV4).
No preference for which of the three

Medicare Part B

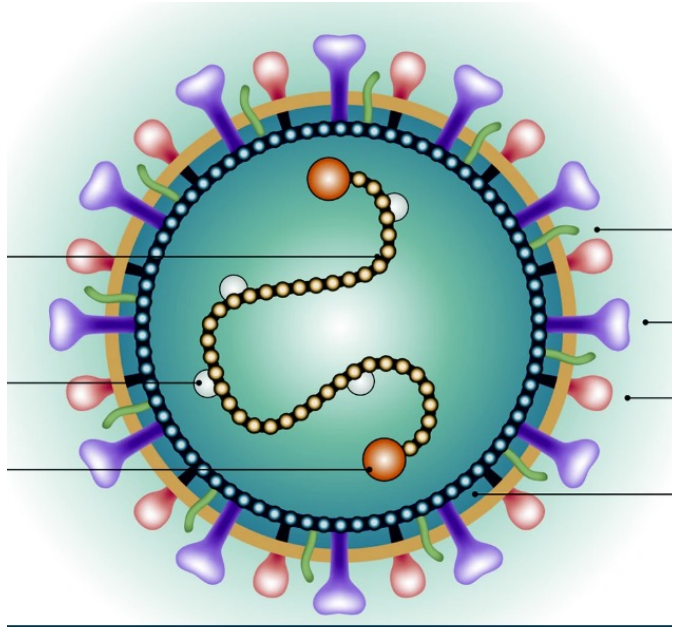
If none of these three vaccines is available, then any other age-appropriate influenza vaccine should be used.

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



Respiratory Syncytial Virus (RSV) Vaccines

Respiratory Syncytial Virus



Leading cause of hospitalization of infants in US

Common cause respiratory infection in adults

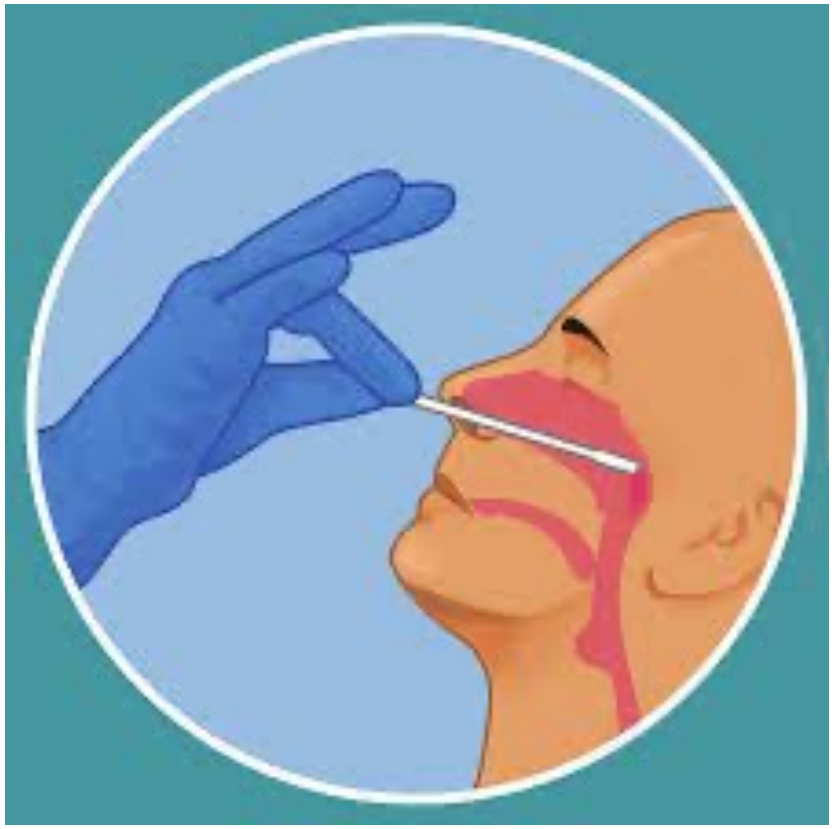
Reinfections occur

Mazua Lancet Infections Disease 2022

RSV Symptoms in Adults

- Runny nose
- Decrease in appetite
- Coughing
- Sneezing
- Fever
- Wheezing

Diagnosis

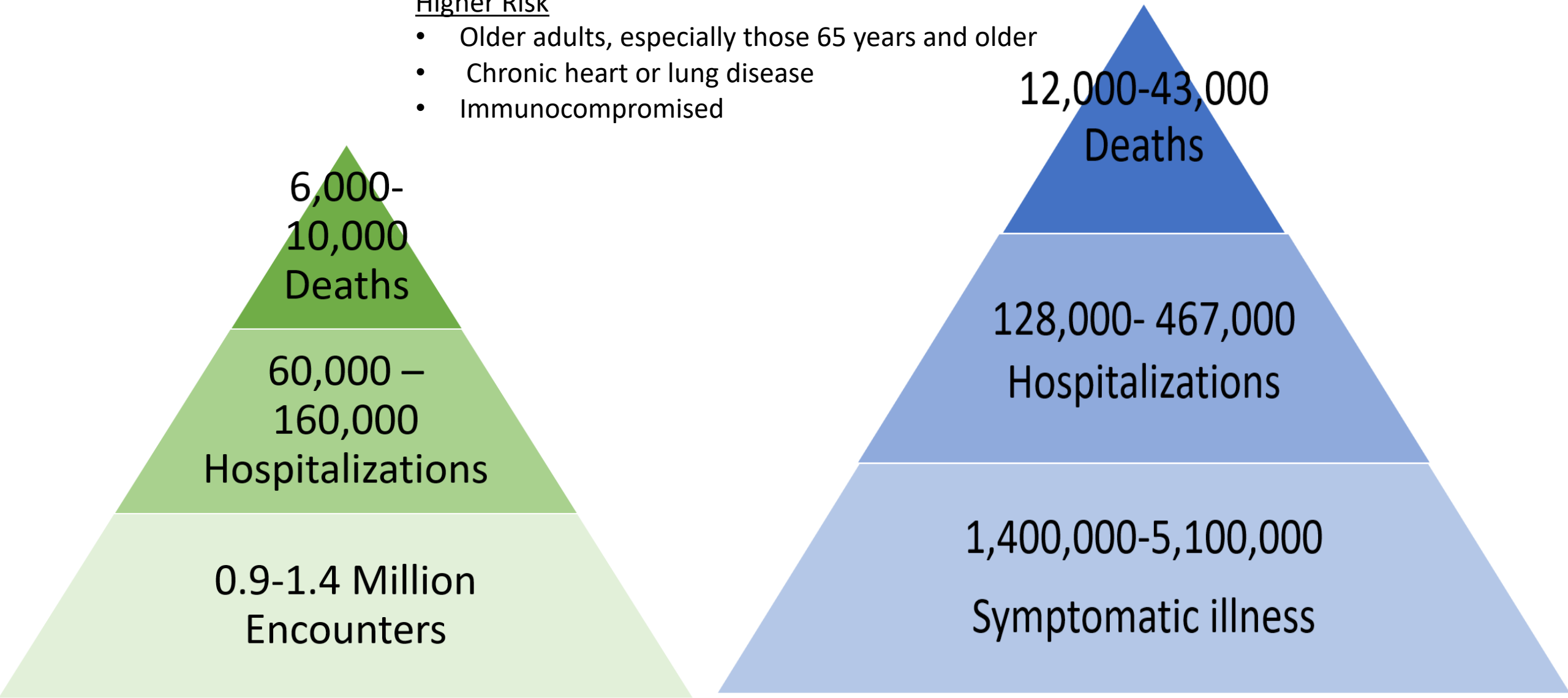


- RT-PCR is the gold standard
  - Sensitivity 84-100%
  - RESPAN at TRICOR Labs
- Serology
  - Not helpful for adults because all adult cases are reinfections
  - Need 2 serum samples showing 4 X increase in antibodies to identify acute infection

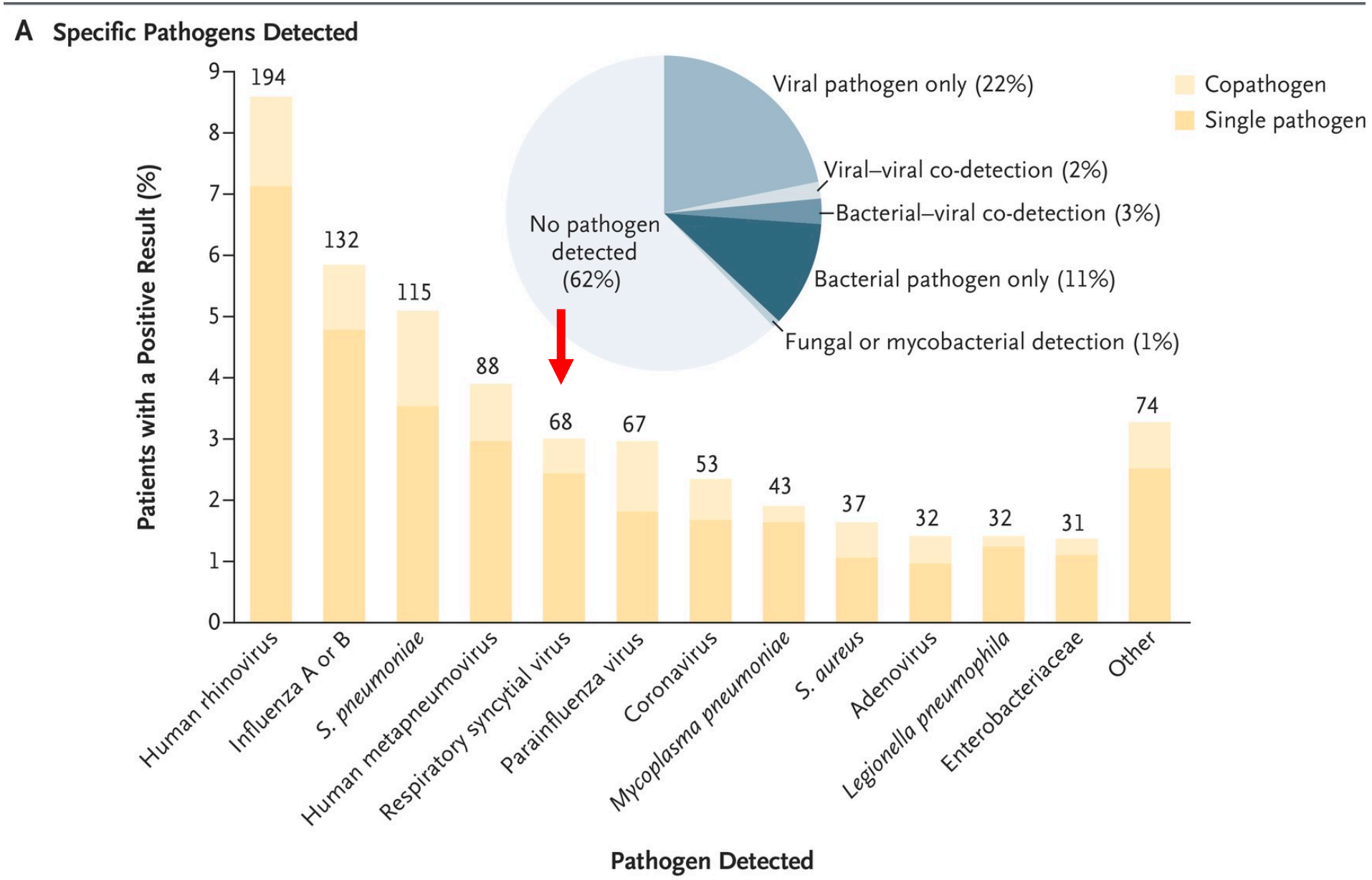
Burden of RSV Disease in Adults 60 and/or 65+

<u>Higher Risk</u>

- Older adults, especially those 65 years and older
- Chronic heart or lung disease
- Immunocompromised

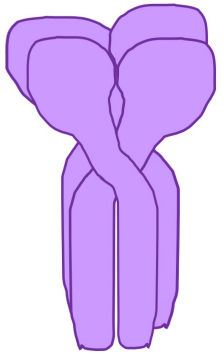


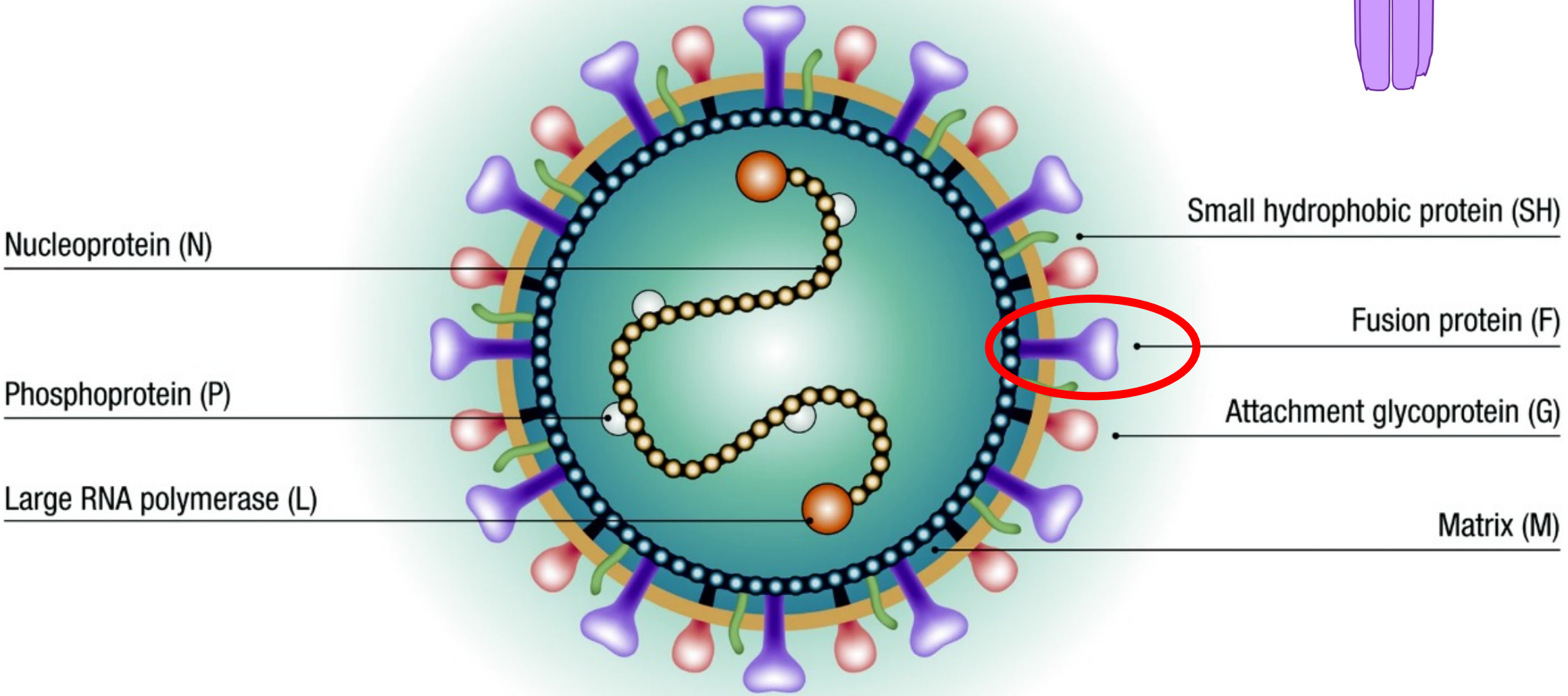
Community Acquired Pneumonia in Adults



Jain NEJM 2015

1960‘s
Live Attenuated Vaccine
Caused Disease Enhancement



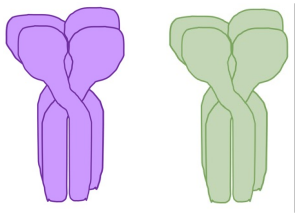


Mazur Lancet ID 2023

Subunit Vaccines

Pfizer **RSVpreF ABRYSVO®**

Prefusion F proteins from A and B strains



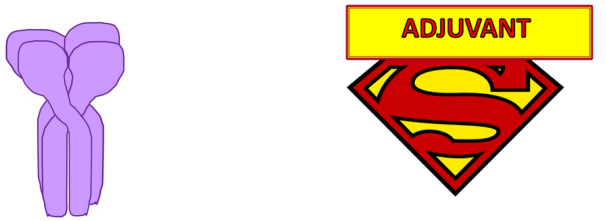
Age 60 or 65+

Pregnant women (FDA to Review in August)

GSK **RSVPreF3 AREXVY®**

Prefusion F proteins

Adjuvant

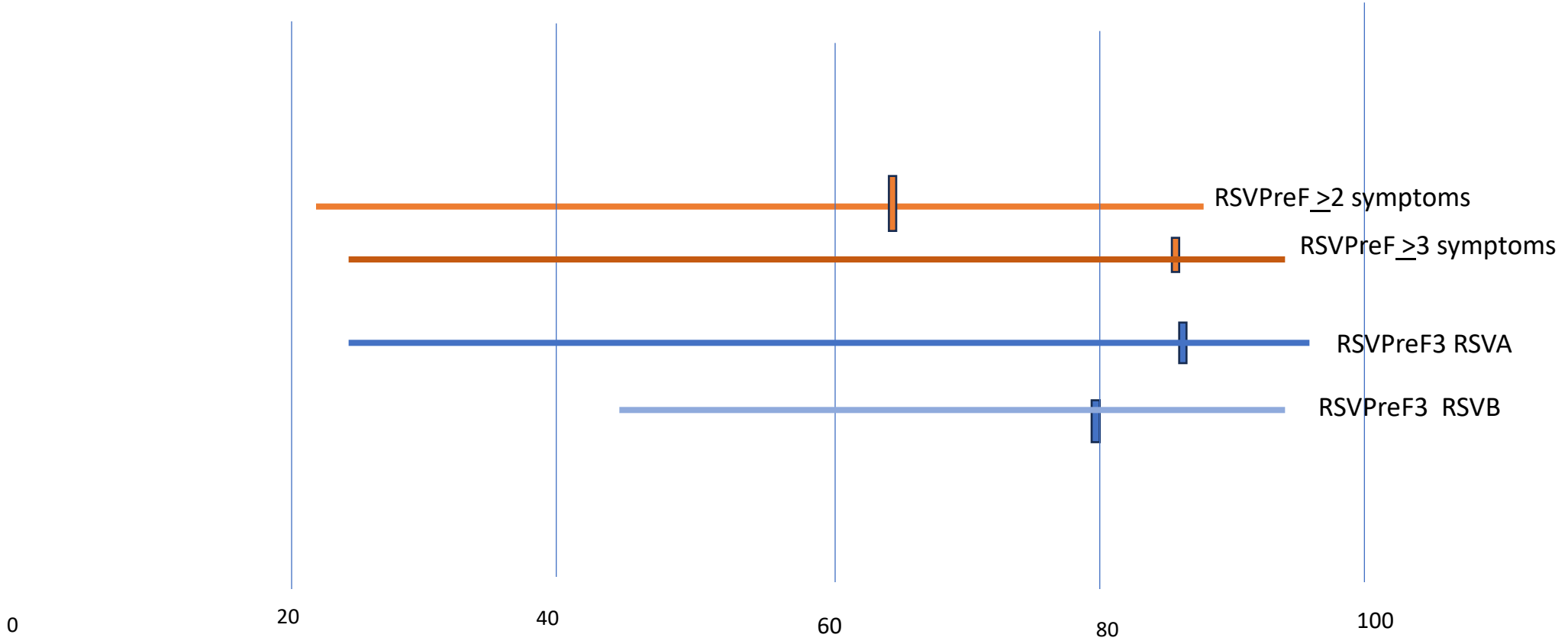


AS01E=same adjuvant in shingles vaccine

Age 60 or 65+

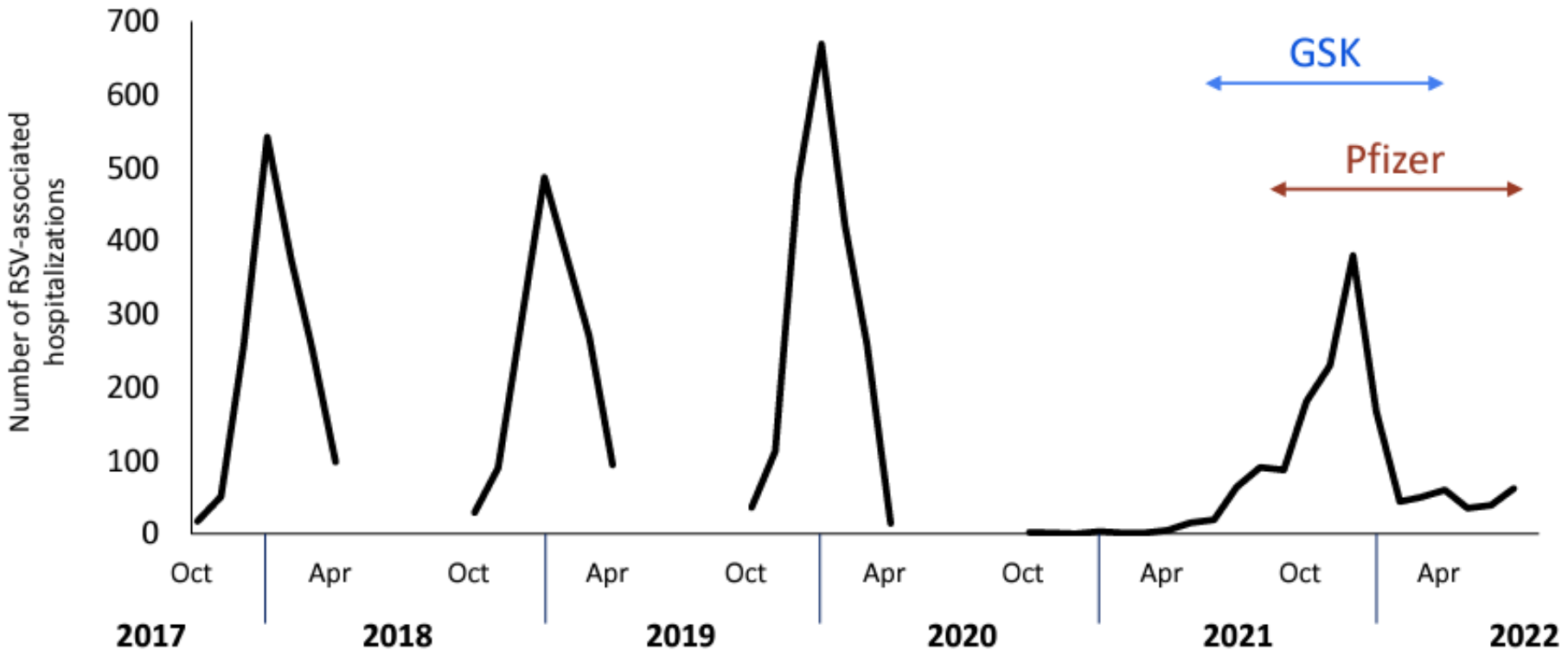
ACIP Oct 2022
Marura Lancet ID 2023
Qiu Growth Factor Reviews 2022

Wide Confidence Intervals for VE



FDA approval data

Monthly RSV-associated hospitalizations among adults aged ≥65 years reported to RSV-NET, 2017–2022



RSV-NET: unpublished data. Data are preliminary and subject to change.

Melgar ACIP Oct 2022

RSVpreF

	Events Vaccine	Events Placebo	Efficacy
Season 1 (N 36,127)			
RSV>3 symptoms	2	18	88.9%
RSV >2 Symptoms	15	43	61.5%
Midseason 2 (N20,019)			
RSV>3	3	14	78.6%
RSV>2	23	45	48.9%

ACIP June 2023

RSVPreF3

	Events Vaccine	Events Placebo	Efficacy
Season 1 (N24,954)			
RSV>2 Symptoms	7	40	82.6%
Midseason 2			
RSV>2	14	85	80.9%
2 Doses (12 m apart)	30	139	75.4%

Efficacy

70-80 ish%

Imprecise

Unclear on adults 75+ and those with conidiations that put them at risk

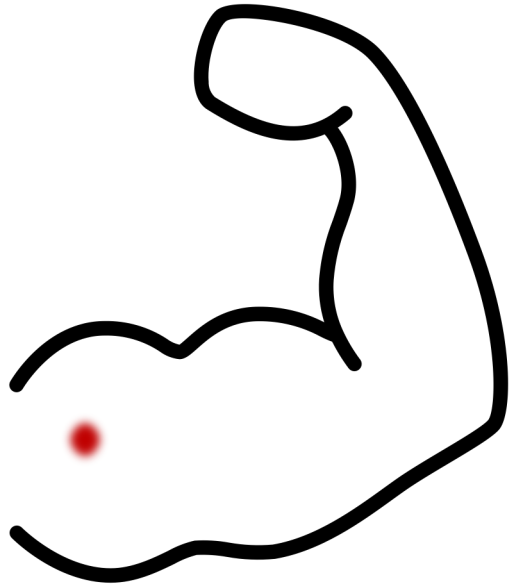
Only assessed in 1 ½ seasons

Impact on death and hospitalization: not able to evaluate

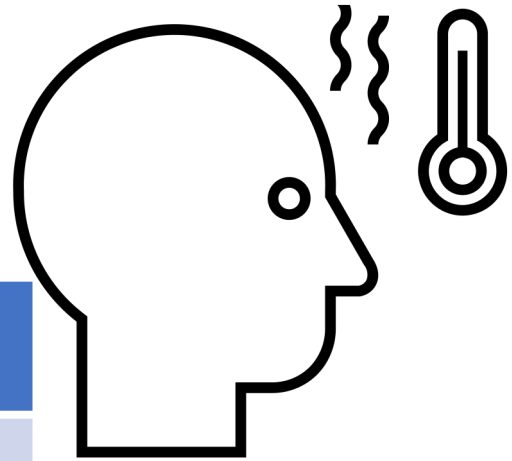
Likely to decline with time

Local Reactions

	RSVpre	RSVpre3
Pain	10.5%	60%
Redness	2.7%	5.5%
Swelling	2.4%	7.5%



Systemic Reactions



	RSVPreF	RSVPreF3
Fever	1.4%(>38.9°C <0.1%)	2%(>39°C 0.1%)
Fatigue	15.5% (Severe 0.3%)	33% (*Grade 3* 1.7%)
Headache	12.8% (Severe 0.1%)	27.2%(*Grade 3* 1.3%)
Muscle aches	10.1% (Severe 0.2%)	28.9%(*Grade 3* 1.4%)
Joint pain	7.5% (Severe<0.1%)	18.1%(*Grade 3* 1.3%)
Nausea	3.4%	Not reported
Vomiting	0.9%	Not reported
Diarrhea	%.9%	Not reported

Package inserts

Serous Adverse Events

RSVpre	RSVpre3
Guillain-Barré Syndrome 7 days after vaccination **Miller Fisher Syndrome** reported 8 days after vaccination **Hypersensitivity** reported 8 hours after vaccination.	**Guillain-Barré Syndrome** 9 days after vaccination **Acute disseminated encephalomyelitis X2** 7 and 22 days after vaccination (both also had Flu Shots)

Background rate Guillain-Barré Syndrome 1.5-3 per 100,000

Comparison of GSK and *Pfizer* vaccines: Update base case & scenario $/QALY results using UM-CDC model

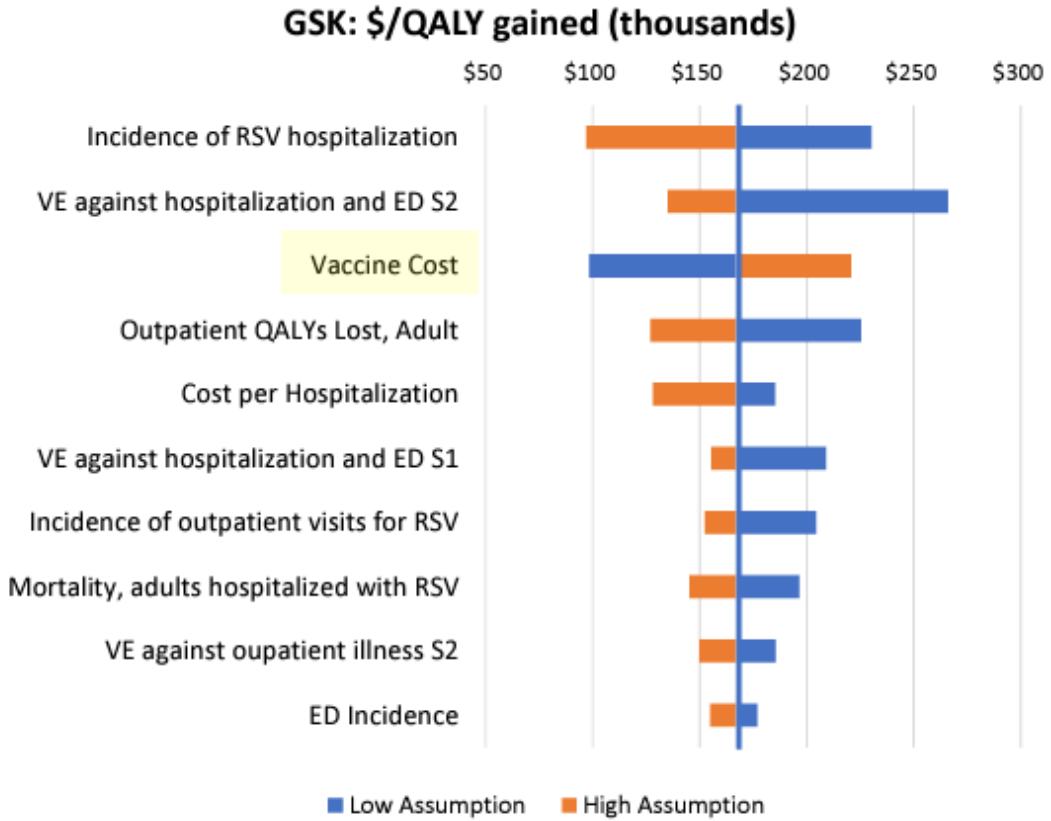
Scenario	GSK	*Pfizer*
Vaccinating adults aged 60 to <65 years only	$372,656	$218,250
Lower incidence of RSV[a] in adults ≥65 years	$276,393	$161,487
Vaccine cost $340 per dose	$220,864	$187,865
Vaccinating adults ≥60 years,	$205,638	$118,735
Residual vaccine protection = 0% at 18 (GSK) or 14 (Pfizer) months	$170,022	$135,886
Base case[b] (Vacc price $270 GSK, $200 *Pfizer*, adults ≥65yrs)	**$167,301**	**$94,673**
Vaccine cost $180 per dose	$98,485	$81,358
Higher incidence of RSV[b] in adults ≥65 years	$84,736	$40,467

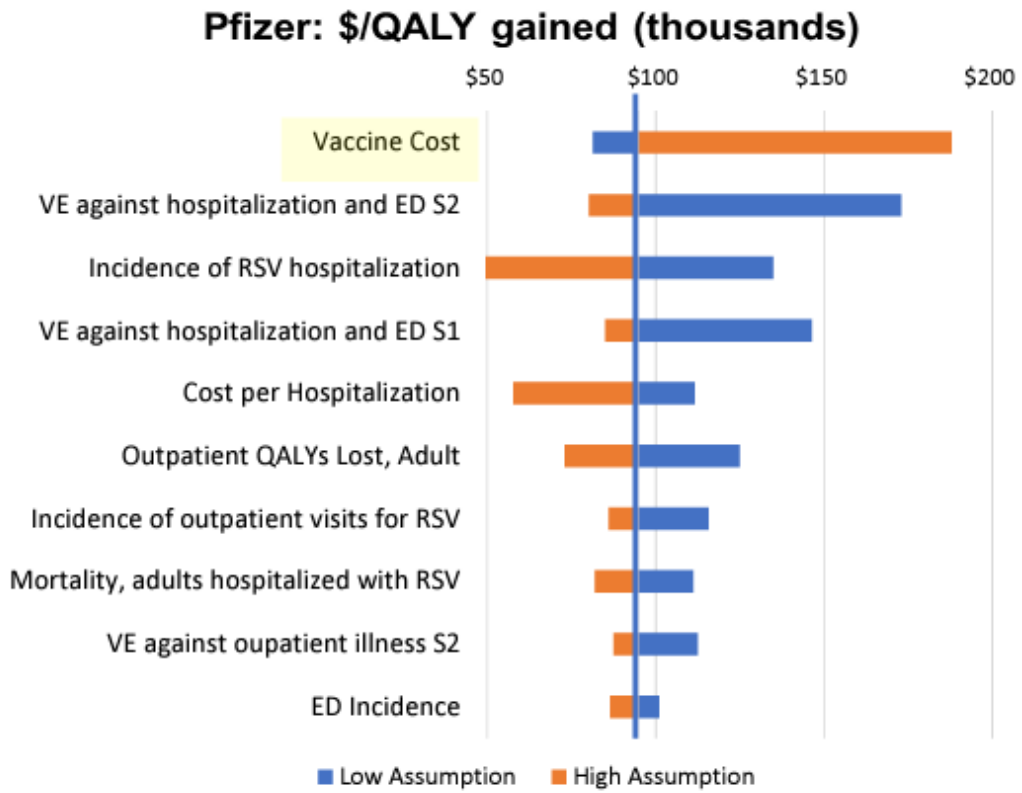
a Incidence rates: Lower incidence assumes 95% RT-PCR test sensitivity, Higher rate incorporates the upper limit of the 95% CI around the base case incidence rate estimate.

b Recommendation = vaccination at age ≥65 years; incidence rates of RSV outcomes upwardly adjust 1.5x to account for incomplete RT-PCR sensitivity on a respiratory specimen (McLaughlin et al; Open Forum Infect Dis 2022); vaccine efficacy only considered for two years post-vaccination

UM-CDC model: Updated One-way Sensitivity Analyses

Base case: Age ≥65yrs; $167,301/QALY (GSK), $94,673/QALY (Pfizer)





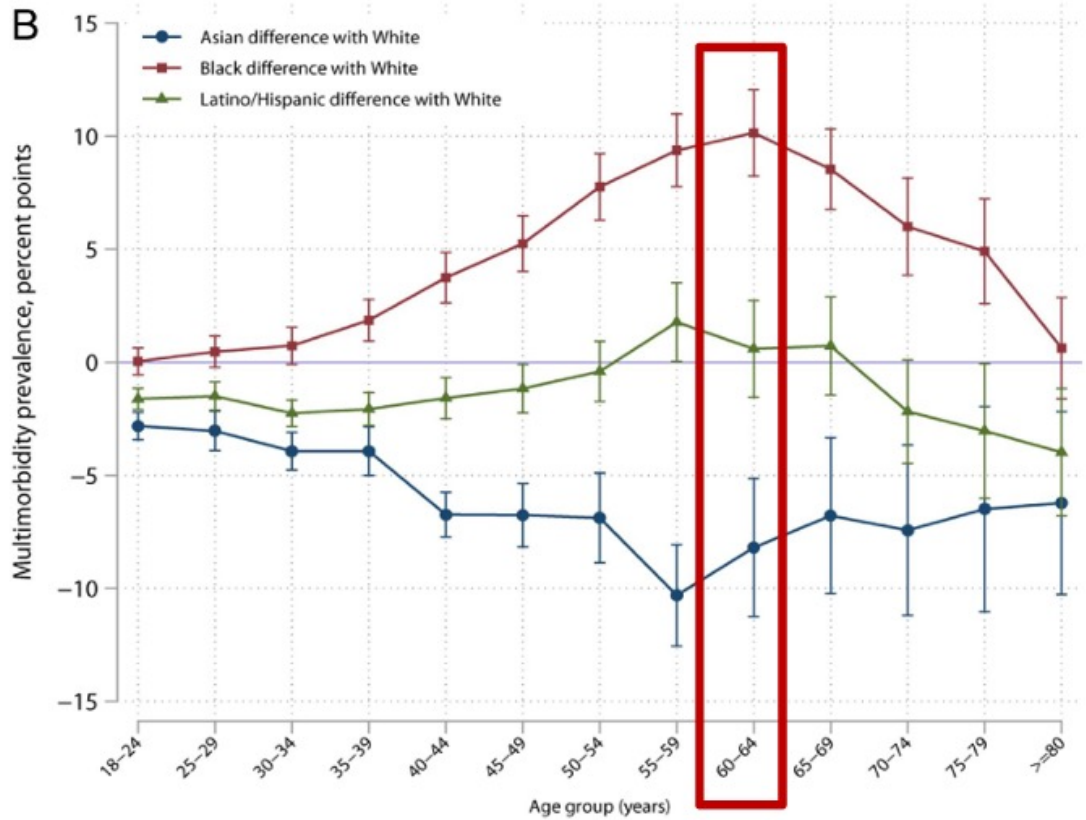
Vaccine cost per dose $270/dose (GSK), $200/dose (Pfizer)

Two-year time frame

Age-based vaccination recommendation: ≥65 years, VE=Vaccine Efficacy LRTD= Lower Respiratory Tract Disease, S1=Season 1, S2=Season 2.

Equity

Difference in prevalence of multiple chronic conditions by age and race/ethnicity, National Health Interview Survey, 1999 to 2018



- Prevalence of multimorbidity (≥2 concurrent conditions) diverged between Black individuals and White individuals
- Reached maximum difference of 10% among those aged 60-64 years

Source: Caraballo C, Herrin J, Mahajan S, et al. Temporal Trends in Racial and Ethnic Disparities in Multimorbidity Prevalence in the United States, 1999-2018. *Am J Med.* 2022;135(9):1083-1092.e14. doi:10.1016/j.amjmed.2022.04.010

RSV Vaccine for Age 60+
Shared Decision Making

Yes

No

ACIP June 2023

RSV Vaccine for Age 60+
Shared Decision Making

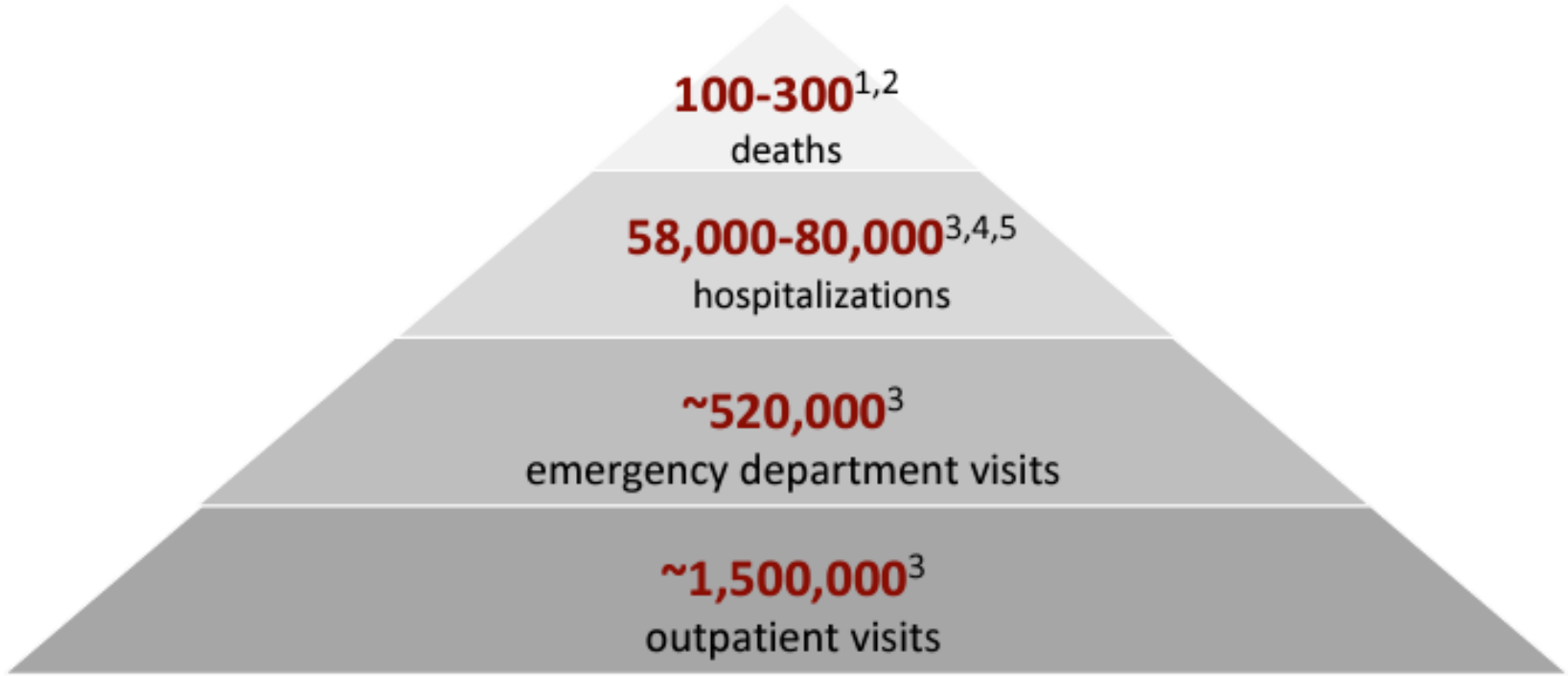
Yes

Some protection against reparatory illness
Tolerable side effects
Probably protects against death and hospitalizations
Can be given with Flu shot

No

Cost (Medicare part D) ? Private Insurance
We don’t know how well this works or how long it lasts
Rare cases of Guillen Barre

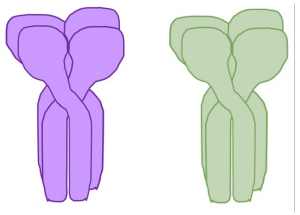
Each year among U.S. children aged less than 5 years, RSV is associated with…



Subunit Vaccines

Pfizer **RSVpreF ABRYSVO®**

Prefusion F proteins from A and B strains

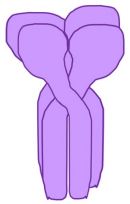


Intended for60 or 65+ and pregnant women

GSK **RSVPreF3 AREXVY®**

Prefusion F proteins

Adjuvant



AS01E=same adjuvant in shingles vaccine

FDA to Review in August

ACIP Oct 2022
Qiu Growth Factor Reviews 2022
Mazua Lancet Infections Disease 2022

Monoclonal Antibodies for infants and young children

CURRENT:

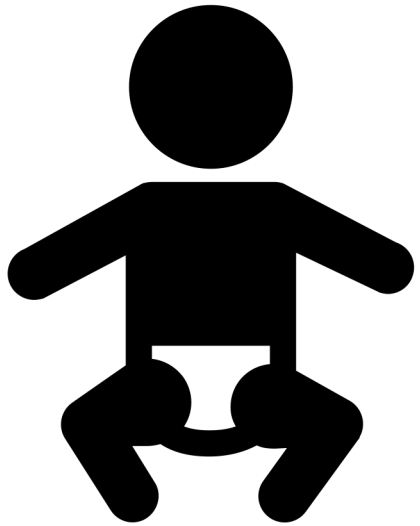
Palivizumab SYNAGIS®

- monoclonal antibody
- Targets RSV F glycoprotein

FDA Committee Recommended Approval June 2023

Nirsevimab (MEDI-8897)

- Monoclonal antibody
- Targets site Ø of the F protein



Mazur Lancet ID 2023
ACIP Oct 2022

Pneumococcal Vaccines

Medicare Part B

Pneumococcal in Adults ≥65 Years Old

Prior Vaccine			
None	PCV20	**Or**	PCV15 → PPSV23 (≥1 year)
PPSV23	PCV20 (≥1 year after PPCV23)	**Or**	PCV15(≥1 year after PPSV23)
PCV13	PCV20 (≥1 year after PCV13)	**Or**	PPSV 23 (≥1 year after PCV13)
PCV13 and PPSV23(before age 65)	PCV20(5 years after last pneumo vax)	**Or**	PPSV23 (5 years after last pneumo vax)

PCV20 for Age 65 with Previous PCV13 and PPSV23
5 years after last pneumococcal vaccine
Shared Decision Making

Yes

No

ACIP April 2023

Children 2-23 Months

PCV15 or PCV20

- 2 Months
- 4 Months
- 6 Months
- 12-18 Months

ACIP June 2023

24-59 months and incomplete pneumococcal vaccination

Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3
No further doses needed healthy children, first dose at 24 months or older. **4 weeks** if first dose before 1st birthday. **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after.	**No further doses needed** for healthy children if previous dose age 24 months or older. **4 weeks** if current age is younger than 12 months and previous dose given at <7 months old. **8 weeks (as final dose for healthy children)** if previous 7-11 months (wait until at least 12 months old); OR if current 12 months or older and at least 1 dose before age 12 months.	**8 weeks (as final dose)** only necessary for children aged 12 through 59 months regardless of risk, or age 60 through 71 months with any risk, who received 3 doses before age 12 months.

Children ages 2 to 18 years with a risk condition

Previously received PCV vaccines before Age 6 **and** 1 or more doses of PCV20

Done

Received 13-valent PCV (PCV13; Prevnar 13).

Give: PCV20 **or** PPSV23

Summary

- Polio Vaccine for un- or under- vaccinated and high-risk adults
- Bivalent COVID 19 vaccine for everyone now
- Anticipate new Monovalent COVID 19 vaccines for fall 2023
- Live Attenuated Influenza(oral) Vaccine now okay, age 2-49 years
- High dose, Adjuvanted or Recombinant preferred in $\geq$65
- Flu Vax okay in egg allergic
- RSV vaccine shared decision-making age 60+
- PCV20 or PCV15 for children
- PCV20 or PCV15 plus PPSV23 for 65+ and certain conditions

Thank You

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