COVID-19 Vaccines:

Safety and Efficacy and Omicron Boosters – Oh My!

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Summary

We are now in the transition phase of the pandemic, but it is not over

mRNA vaccines are safe, effective, and the most likely tool to mitigate morbidity and mortality

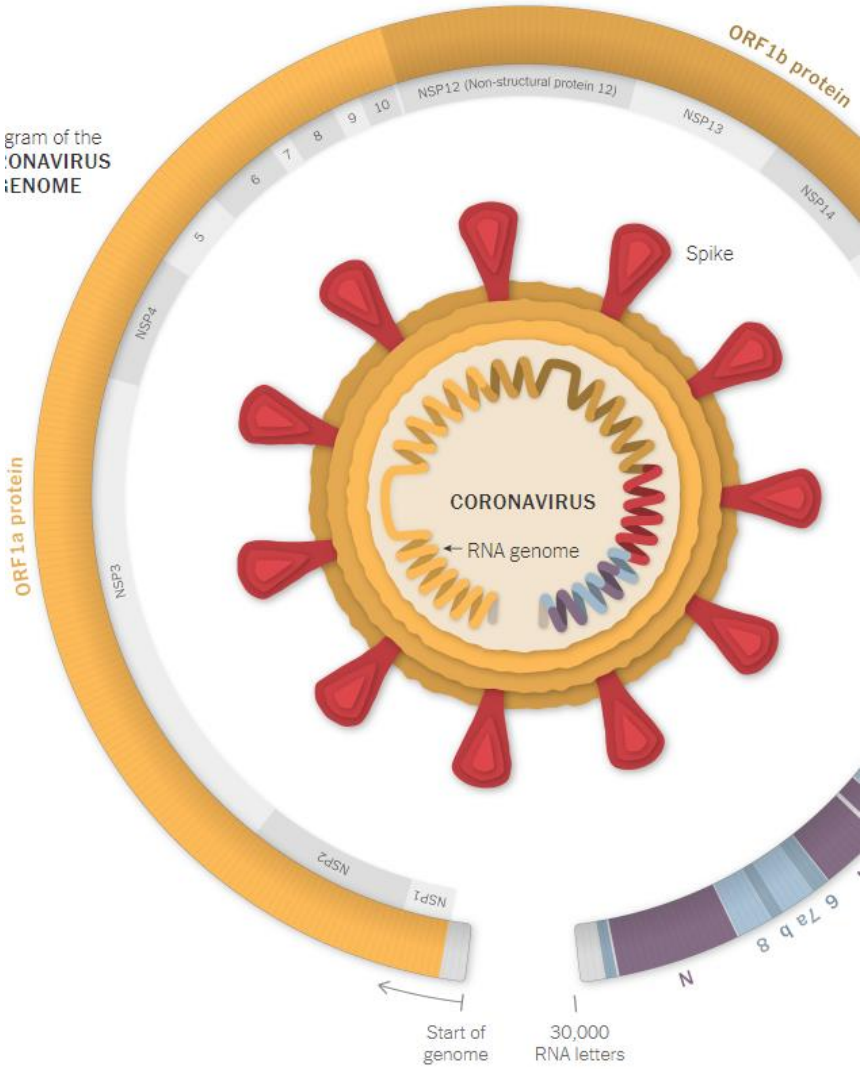
Omicron is uniquely capable of evading immunity

•Bivalent Omicron bivalent boosters show greater neutralizing antibody protection and prevent morbidity and mortality

Vaccine hesitancy continues to be our collective challenge

Current COVID-19 Vaccine Recommendations

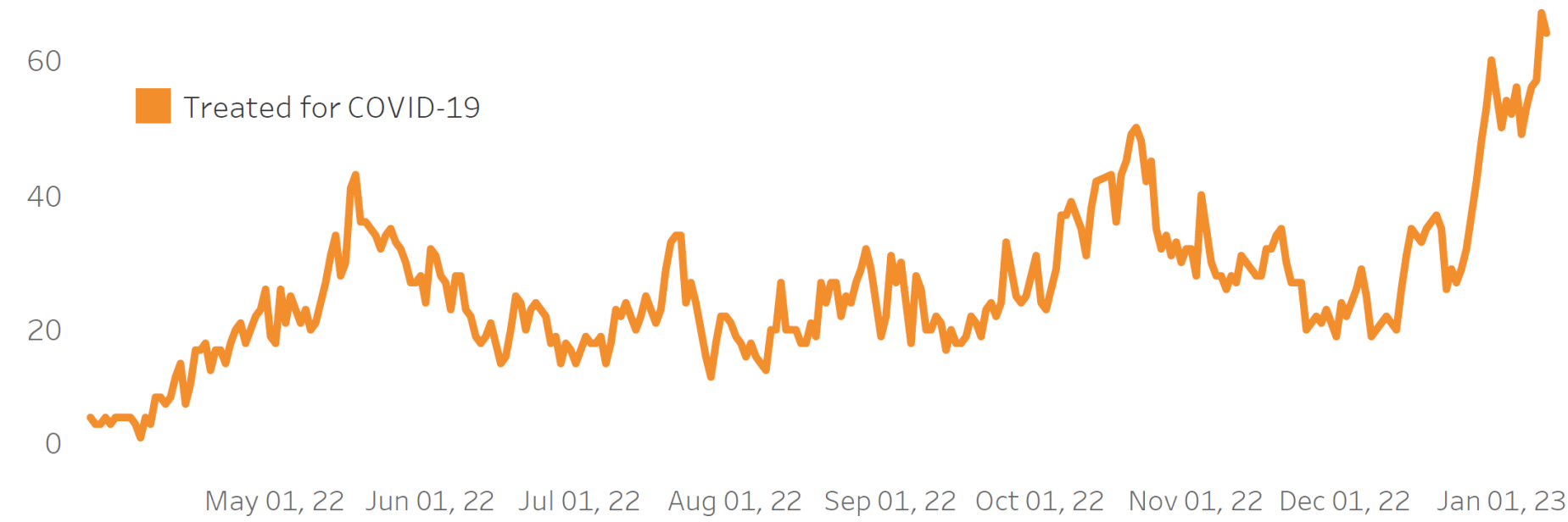
- Everyone ≥6m should complete a COVID-19 vaccine primary series: 2 or 3 doses depending on age, immunocompromised status
  - Pfizer or Moderna mRNA vaccines for persons 6+ months of age
  - Novavax is also available for people 12+ years of age
- Everyone ≥5y who has completed at least a COVID-19 vaccine primary series should receive one bivalent Omicron booster
  - Available for 12+ years since Sept 1st
  - Available for 5-11 years since Oct 12th



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

Number of People Hospitalized & Treated for COVID-19 Each Day in NH

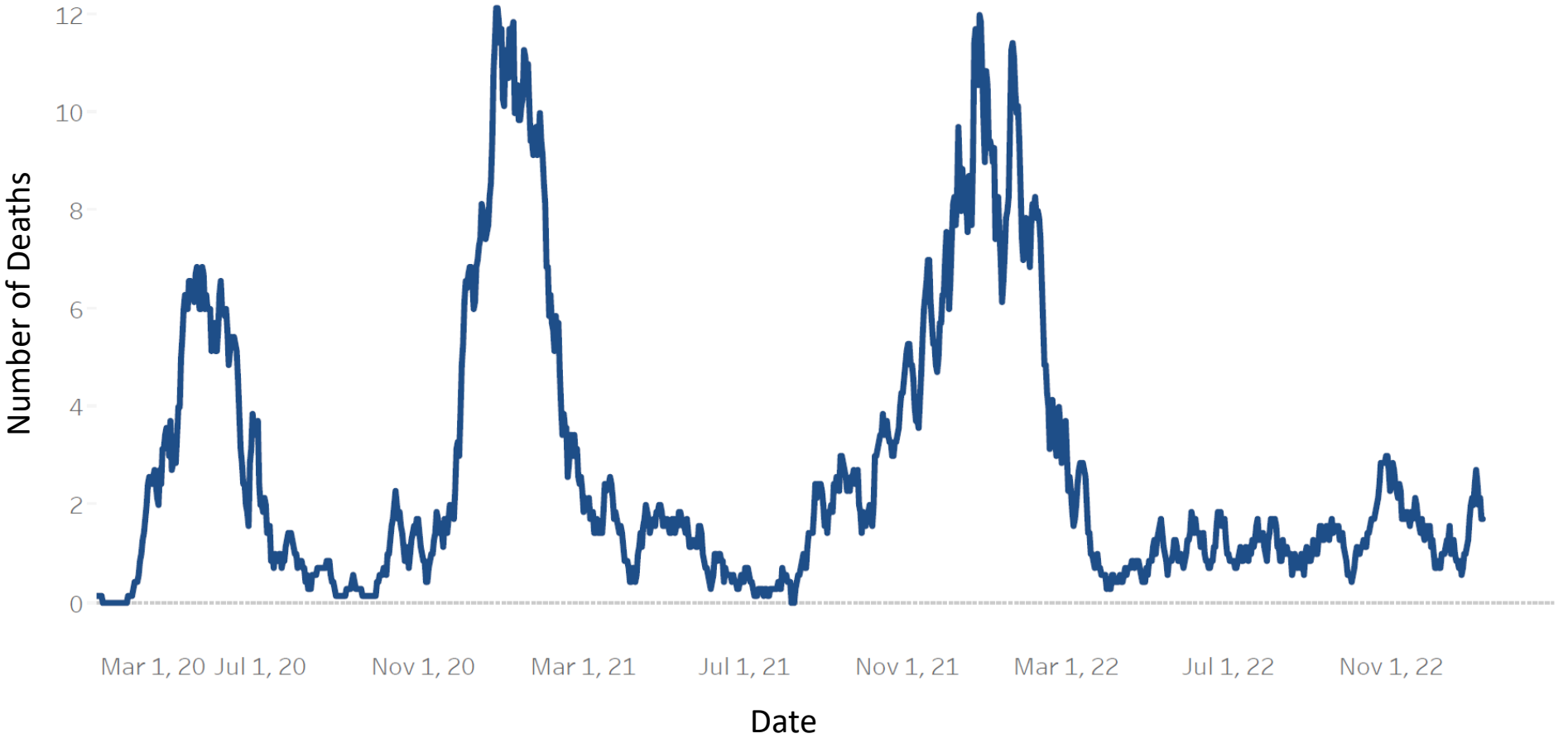
Hospitalized Patients Treated for COVID-19



https://www.covid19.nh.gov/dashboard/hospitals

NH DIVISION OF Public Health Services
Department of Health and Human Services

Average Number of COVID-19 Deaths Each Day in NH (Based on Date of Death)



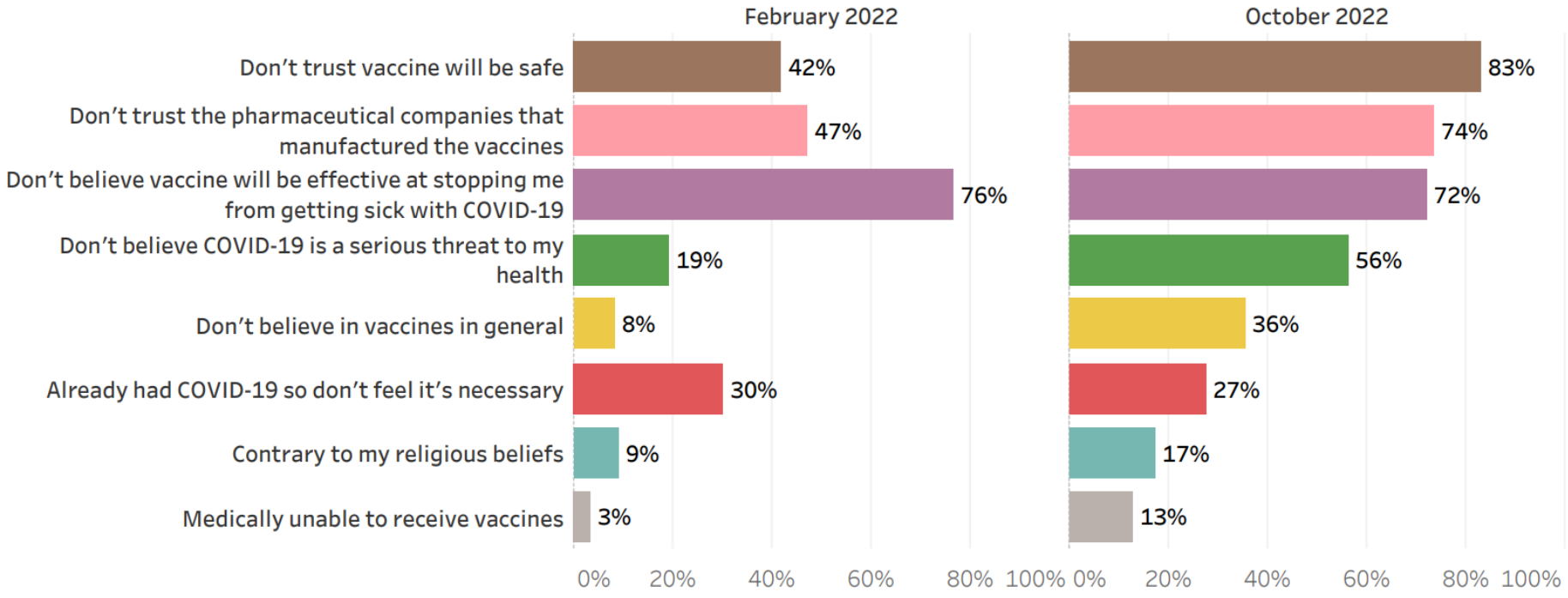
https://www.covid19.nh.gov/dashboard/trends

NH DIVISION OF Public Health Services
Department of Health and Human Services

Uptake in NH

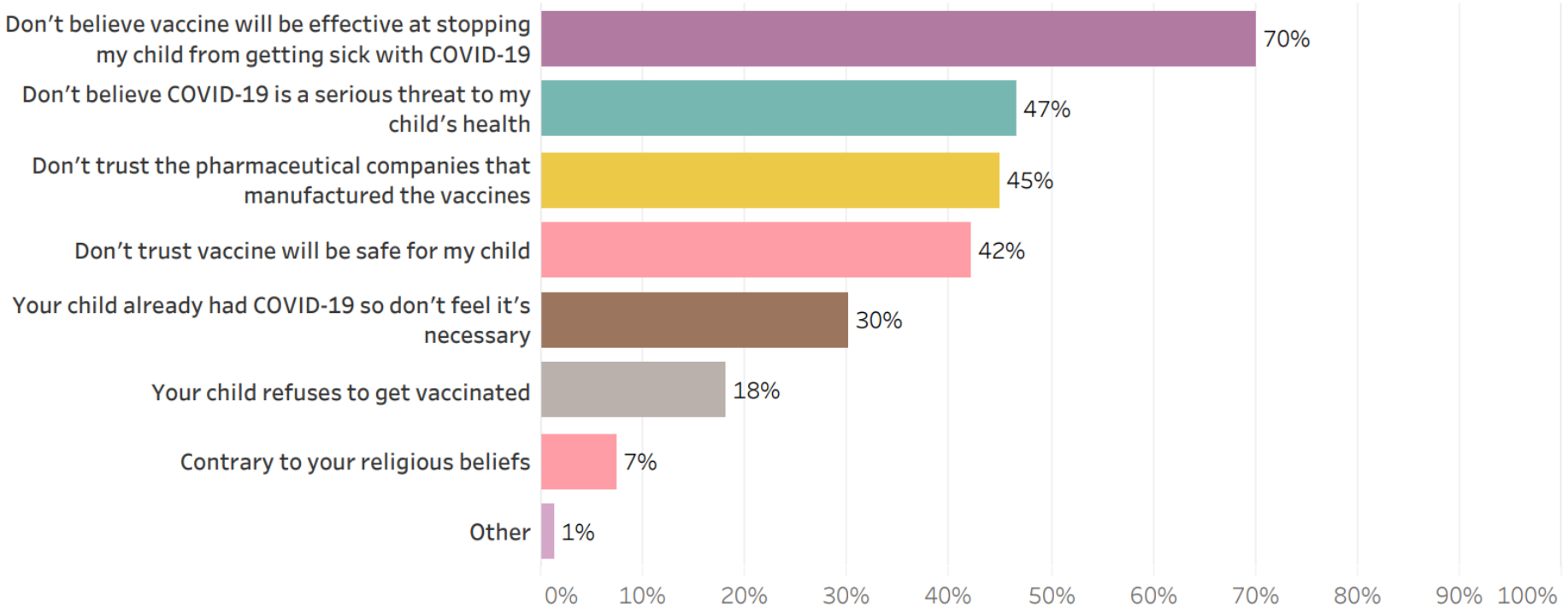
Age Group	Completed COVID-19 Vaccine Primary Series No. (% of population)	Received COVID-19 Bivalent Omicron Booster No. (% of population)
6 months – 4 years	3,654 (6%)	56 (<1%)
5 – 11 years	30,420 (31%)	4,710 (5%)
12 – 17 years	54,295 (58%)	9,317 (10%)
18-64 years	628,406 (74%)	137,092 (16%)
65+ years	255,440 (>99%)	131,817 (52%)

UNH Survey Center: Reasons Adults Don't Get COVID-19 Vaccine, October 2022



https://scholars.unh.edu/cgi/viewcontent.cgi?article=1714&context=survey_center_polls

UNH Survey Center: Parental Reasons for Not Vaccinating Children, February 2022



https://scholars.unh.edu/cgi/viewcontent.cgi?article=1689&context=survey_center_polls

mRNA Safety

Critical knowledge to support uptake

U.S. Safety Monitoring Systems

VAERS: Providers are required report all serious adverse events (including deaths) that occur after vaccination, regardless of whether or not they are plausibly associated with vaccination

- Designed as an early warning system to detect potential safety signals
- Cannot establish causality

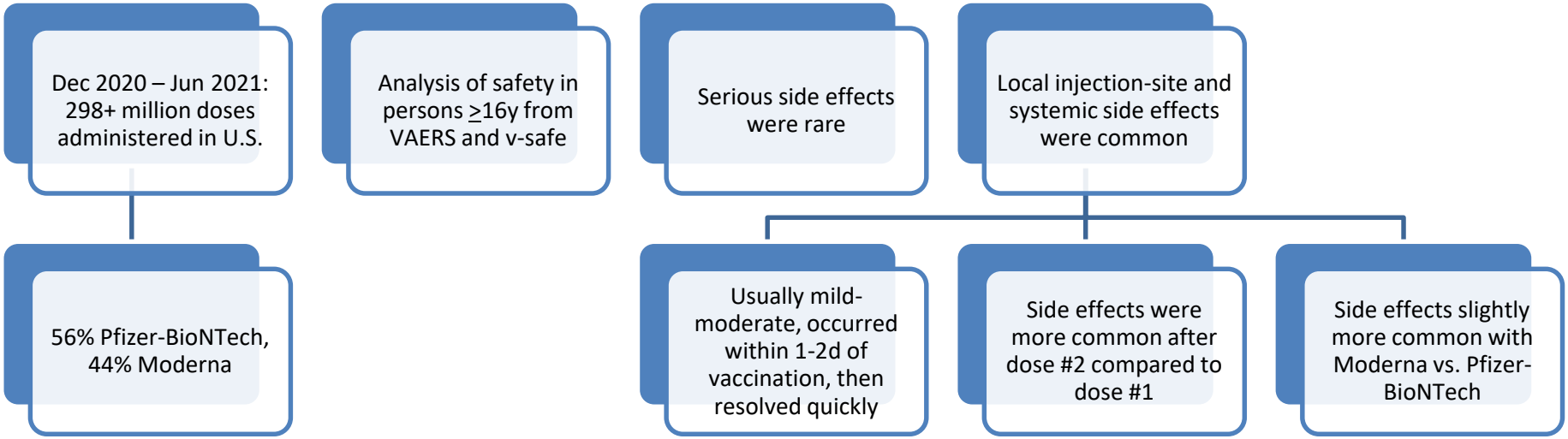
V-safe: Voluntary smartphone-based system that uses text messaging and web-based surveys to monitor for COVID-19 vaccine side effects

- Expected overrepresentation from those with side effects

https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00054-8/fulltext

THE LANCET
Infectious Diseases

Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe



https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00054-8/fulltext

VAERS Reports Summary

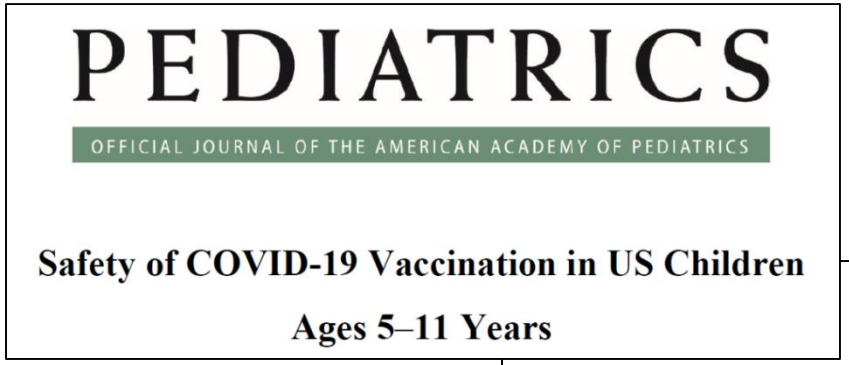
340,522 reports

- 92% were non-serious (e.g., headache, fatigue, fever/chills, pain)
- 7% serious (e.g., dyspnea, fever, fatigue, headache, chest pain)
- 1% deaths

4,471 deaths reported after vaccination

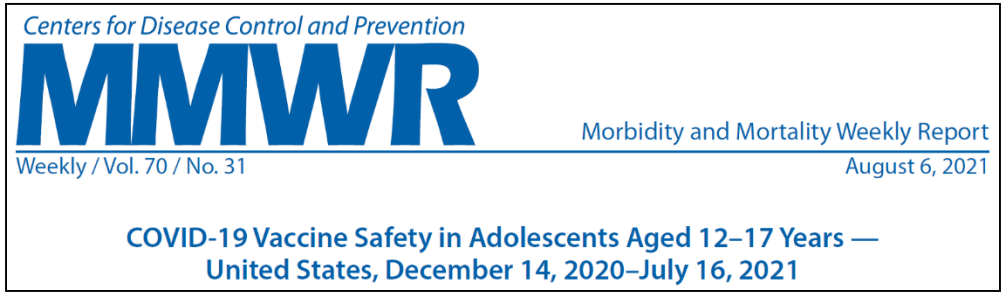
- “No unusual patterns in cause of death among the death reports”
- Median age of persons who died: 76 years (IQR 66-86 years)
- Deaths with a death certificate or autopsy report (18%)
  - Heart diseases: 47%
  - COVID-19: 13%

Safety Monitoring in Children and Adolescents Also Show mRNA Vaccines are Safe


PEDIATRICS

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Safety of COVID-19 Vaccination in US Children Ages 5–11 Years

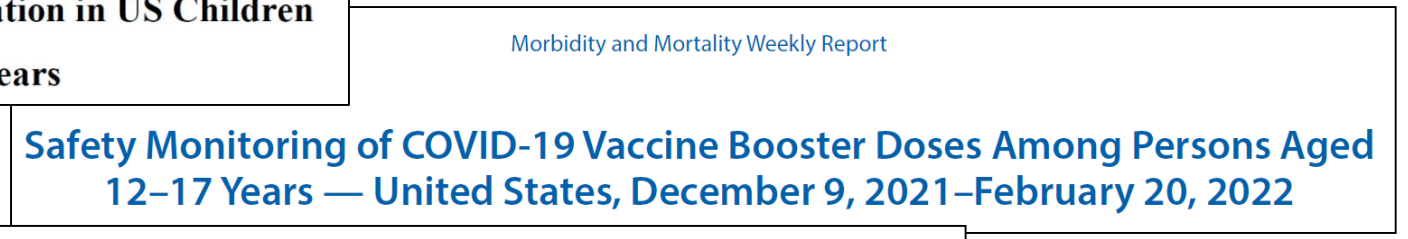

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Weekly / Vol. 70 / No. 31 August 6, 2021

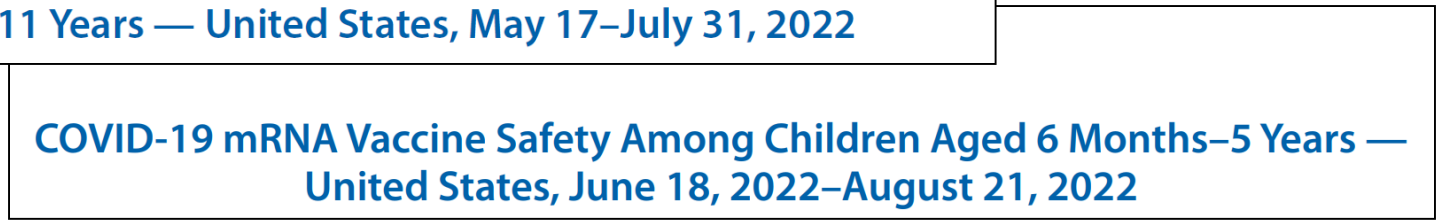
COVID-19 Vaccine Safety in Adolescents Aged 12–17 Years — United States, December 14, 2020–July 16, 2021


Morbidity and Mortality Weekly Report

Safety Monitoring of COVID-19 Vaccine Booster Doses Among Persons Aged 12–17 Years — United States, December 9, 2021–February 20, 2022


Morbidity and Mortality Weekly Report

Safety Monitoring of Pfizer-BioNTech COVID-19 Vaccine Booster Doses Among Children Aged 5–11 Years — United States, May 17–July 31, 2022


COVID-19 mRNA Vaccine Safety Among Children Aged 6 Months–5 Years — United States, June 18, 2022–August 21, 2022

https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm
https://www.cdc.gov/mmwr/volumes/71/wr/mm7109e2.htm
https://pubmed.ncbi.nlm.nih.gov/35581698/
https://www.cdc.gov/mmwr/volumes/71/wr/mm7133a3.htm?s_cid=mm7133a3_x
https://www.cdc.gov/mmwr/volumes/71/wr/mm7135a3.htm?s_cid=mm7135a3_w

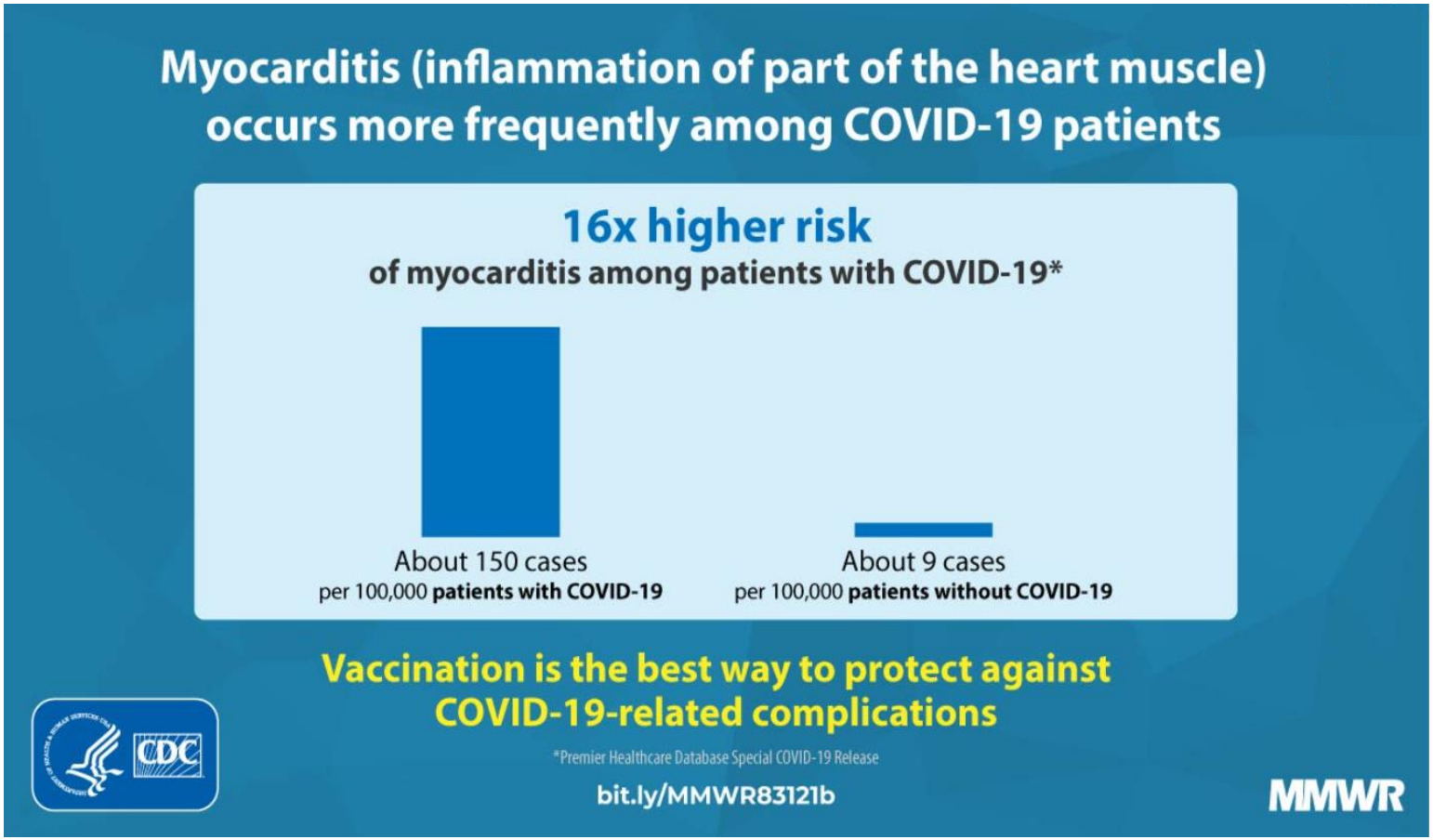
Myocarditis and Pericarditis

- Myocarditis/pericarditis have multiple causes including infection, inflammatory response, toxins, autoimmune, etc.
  - COVID-19 itself can cause myocarditis/pericarditis
- mRNA COVID-19 vaccines associated with development of myocarditis/pericarditis
  - Highest risk is in adolescent and young adult males
  - Usually after dose #2, in first 7 days after vaccination
- Nearly all persons who develop myocarditis/pericarditis after COVID-19 vaccination recover

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-07-19/03-COVID-Shimabukuro-508.pdf

Morbidity and Mortality Weekly Report

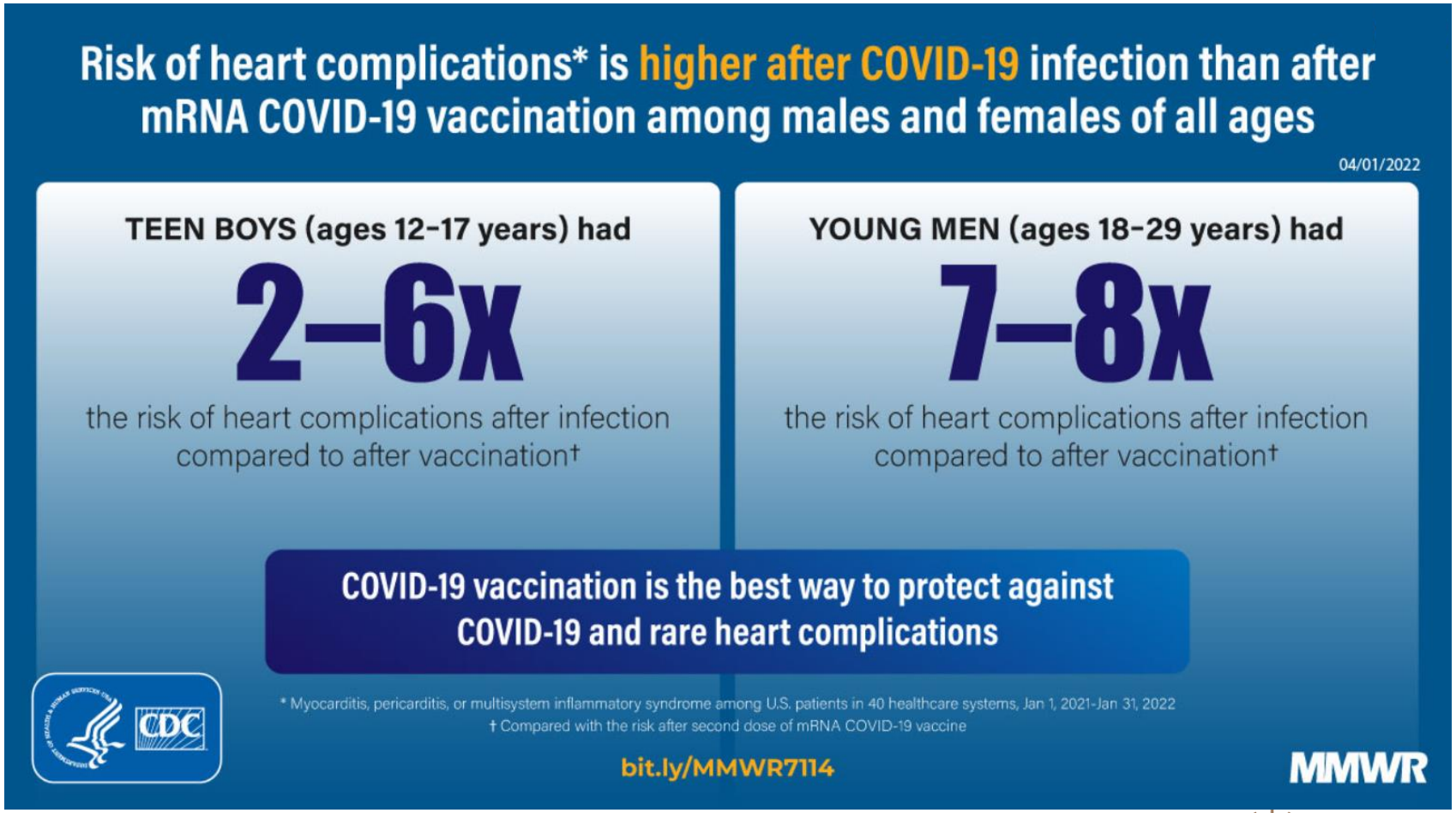
Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021



https://www.cdc.gov/mmwr/volumes/70/wr/mm7035e5.htm

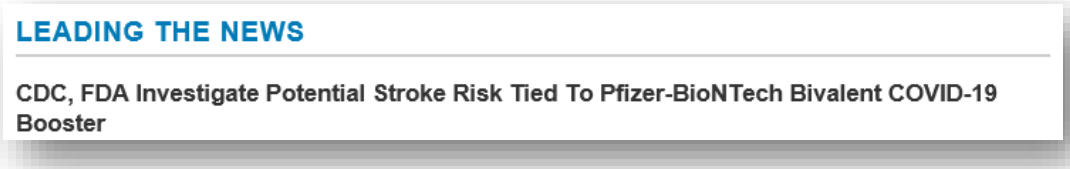
Morbidity and Mortality Weekly Report

Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination — PCORnet, United States, January 2021–January 2022



https://www.cdc.gov/mmwr/volumes/71/wr/mm7114e1.htm

Ongoing Surveillance


LEADING THE NEWS

CDC, FDA Investigate Potential Stroke Risk Tied To Pfizer-BioNTech Bivalent COVID-19 Booster

- Jan 13 2023 FDA/CDC announced preliminary signal in Vaccine Safety Datalink system prompted an investigation about whether people ≥ 65y were more likely to have an ischemic stroke in 3w following Pfizer bivalent booster compared to 22-44d after vaccination
- Not seen in
  - 3 other federal vaccine safety tracking databases
  - Pfizer's global safety database
  - Other countries' monitoring systems
  - With Moderna bivalent booster
- All data to be reviewed at FDA Jan 26 meeting

Safety Summary

Local and systemic side effects are common

Patients should be counseled to expect to not feel well for 1-2 days after vaccination, but symptoms will usually subside quickly

Serious vaccine side effects are rare

Myocarditis/pericarditis have been rarely associated with mRNA COVID-19 vaccination, usually in the 7d after dose #2 in male adolescents and young adults

- Risk is greater after COVID-19 compared with vaccination in **all age groups**
- Most will fully recover

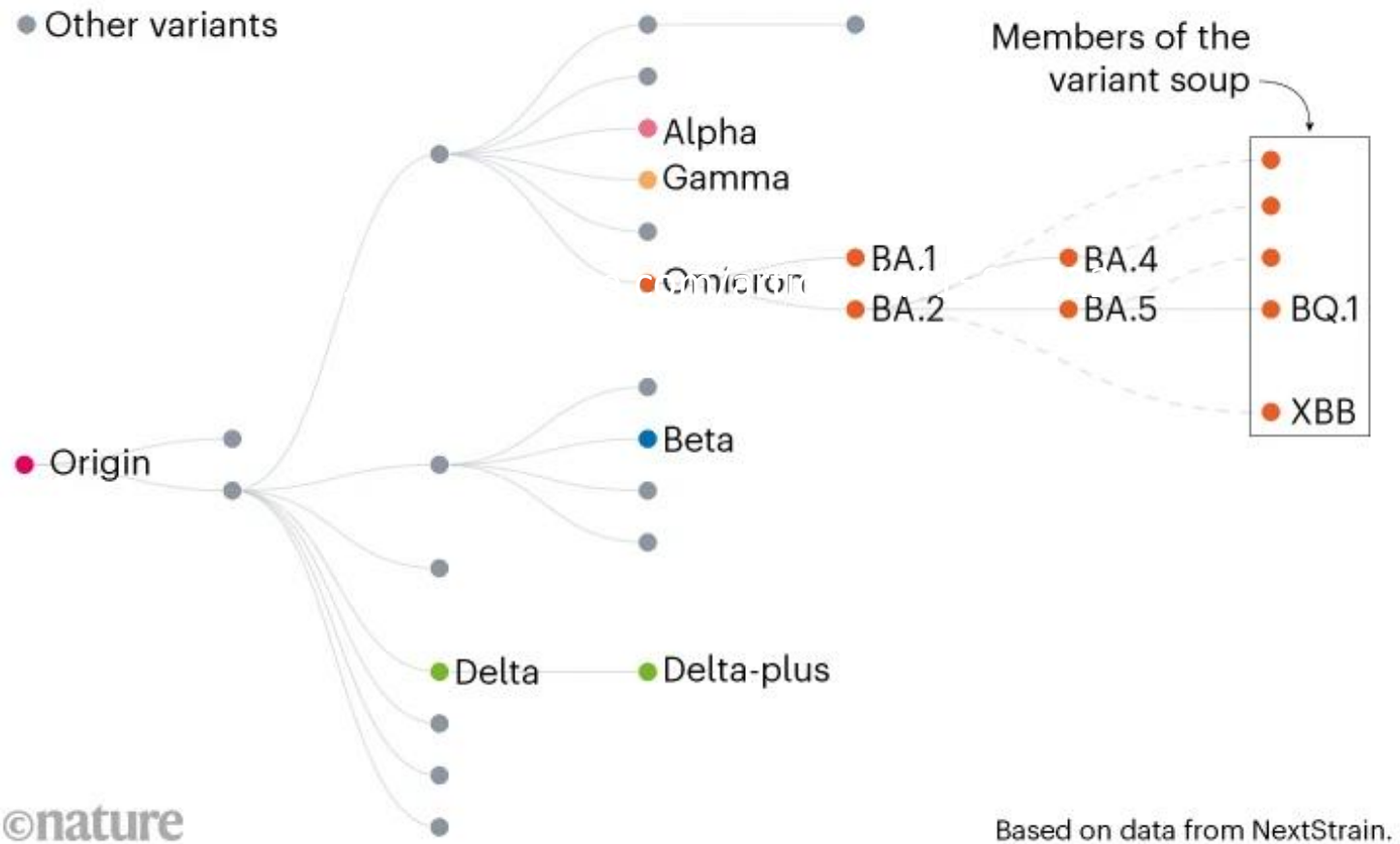
Multiple safety surveillance systems ongoing to detect any signal

Omicron Variants

Evading immunity from original vaccines and disease

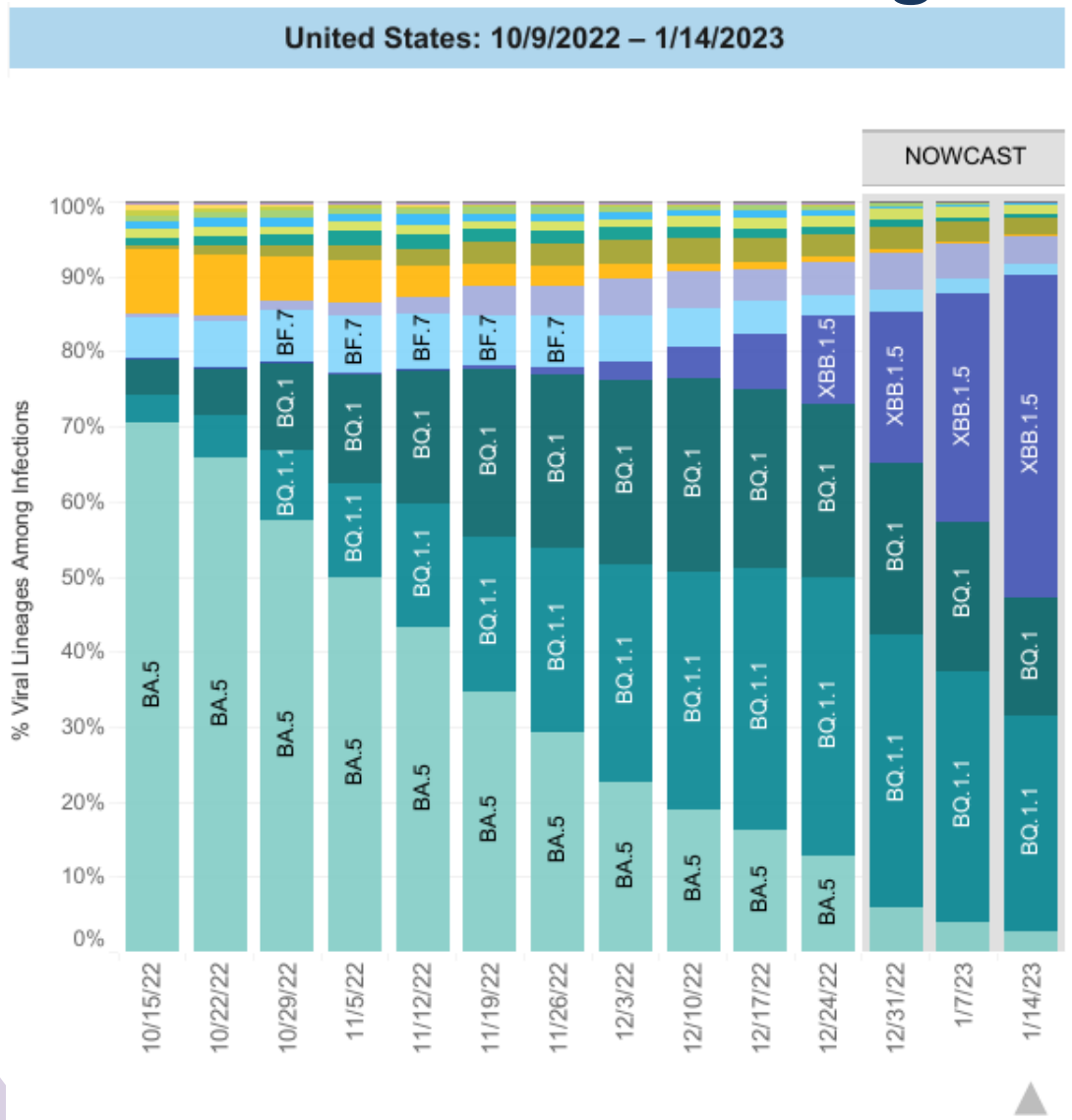
GROWING FAMILY

Omicron sublineages come from a single part of the SARS-CoV-2 family tree, unlike earlier variants of concern such as Alpha and Delta.



https://www.nature.com/articles/d41586-022-03533-7

Omicron Variant Lineages



43.0%

15.9%

28.8%

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Bivalent Omicron Boosters

Coming amidst tremendous pandemic fatigue

Omicron Variants Substantially Impact Vaccine Effectiveness and Durability of Immunity

- Antibody neutralization is lower against Omicron variants
- This translates into lower VE at preventing infection and symptomatic disease
- VE against serious outcomes like hospitalization and death is greater and more durable, but protection still shows declines over time, particularly against Omicron variants
- The updated bivalent Omicron booster increases protection

“Do I Need the Bivalent Vaccine?”

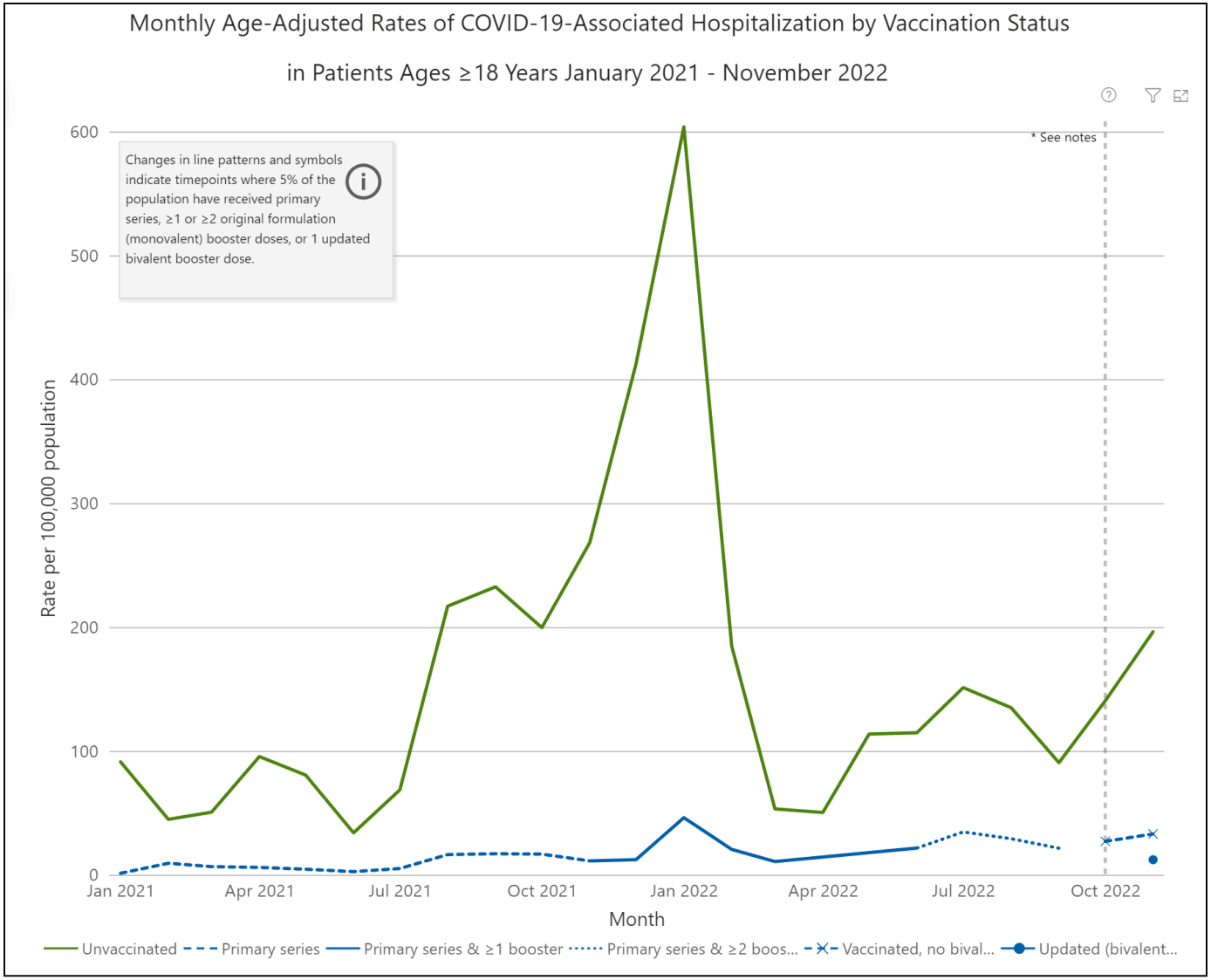
- 8 lab-based studies suggest the bivalent vaccine boosters targeting the Omicron BA.4/BA.5 subvariants provide broad and better protection than original boosters against severe COVID-19 outcomes
- Real-world data is coming in with consistent findings that the bivalent booster protects against hospitalization and death

Real-World

- US CDC's *MMWR [r20.rs6.net]* showed bivalent booster provided 73% additional protection against COVID-19 hospitalization among immunocompetent adults ≥65y, compared to past monovalent
- Newer CDC data [r20.rs6.net] show that during November 2022, there was a 90% reduction of hospitalizations for people ≥65y who had the bivalent booster compared to those who were unvaccinated, a 13.5-fold increased risk of hospitalization for unvaccinated individuals, and a 2.5-fold risk among those who were vaccinated but not a bivalent booster
- An Israeli study [r20.rs6.net] found in 70d follow up after Omicron-adapted booster, 81% reduction in hospitalization among people ≥65y

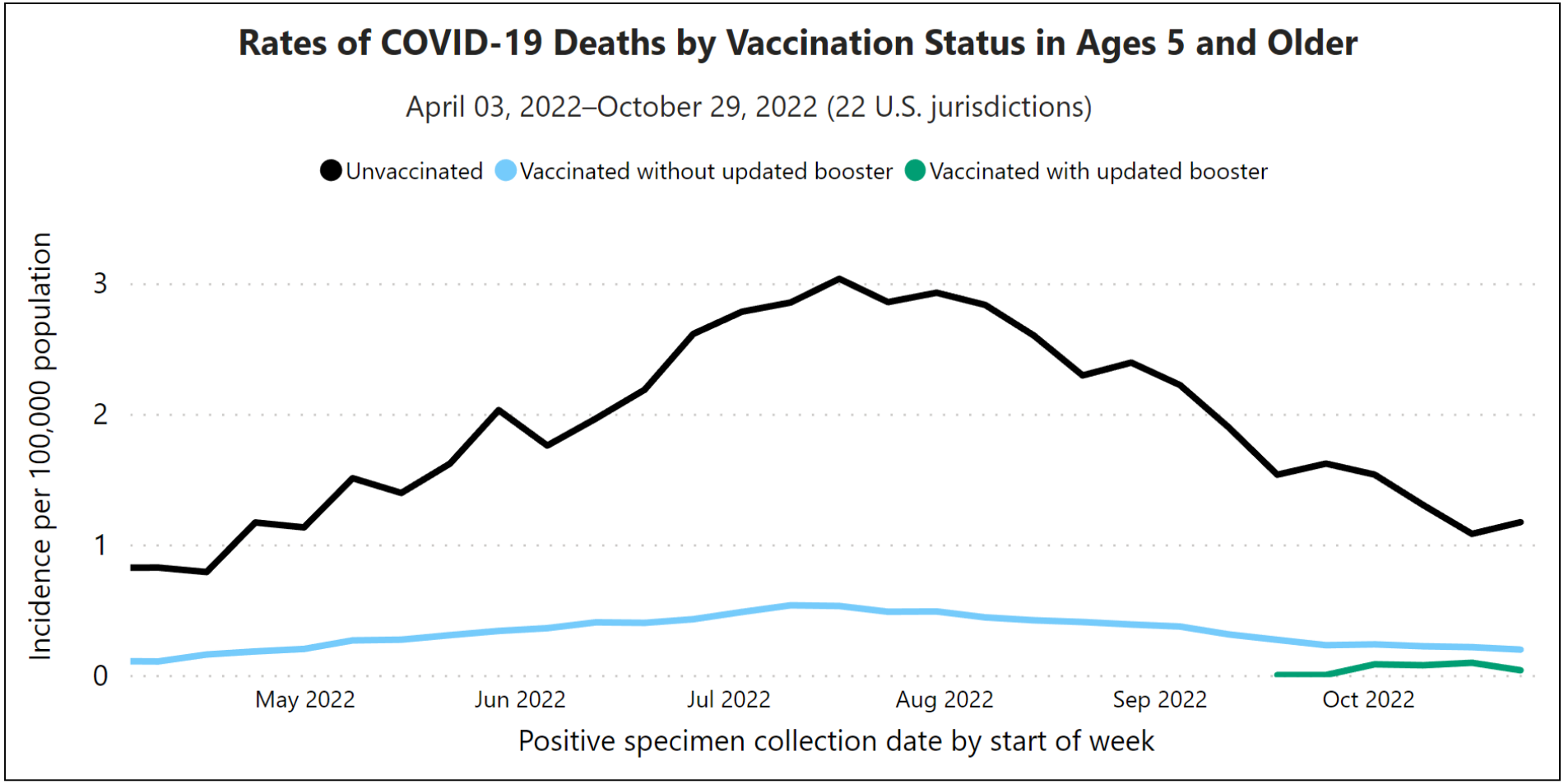
“What if I am Younger?”

- *MMWR [r20.rs6.net]* study of adults ≥18y found the bivalent booster was 38-57% effective against hospitalization, consistent with, but at a lower magnitude, than protection among older adults
  - Among 18-49yo, monthly rates of COVID-19-associated hospitalizations were 29.9 times higher in unvaccinated individuals and 3.2 times higher in vaccinated individuals



In November 2022, compared to adults ages 18 years and older who received an updated COVID-19 bivalent booster dose, monthly rates of COVID-19-associated hospitalizations were **16.0x Higher in Unvaccinated** and **2.7x Higher in Vaccinated Adults without an updated booster.***

https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination



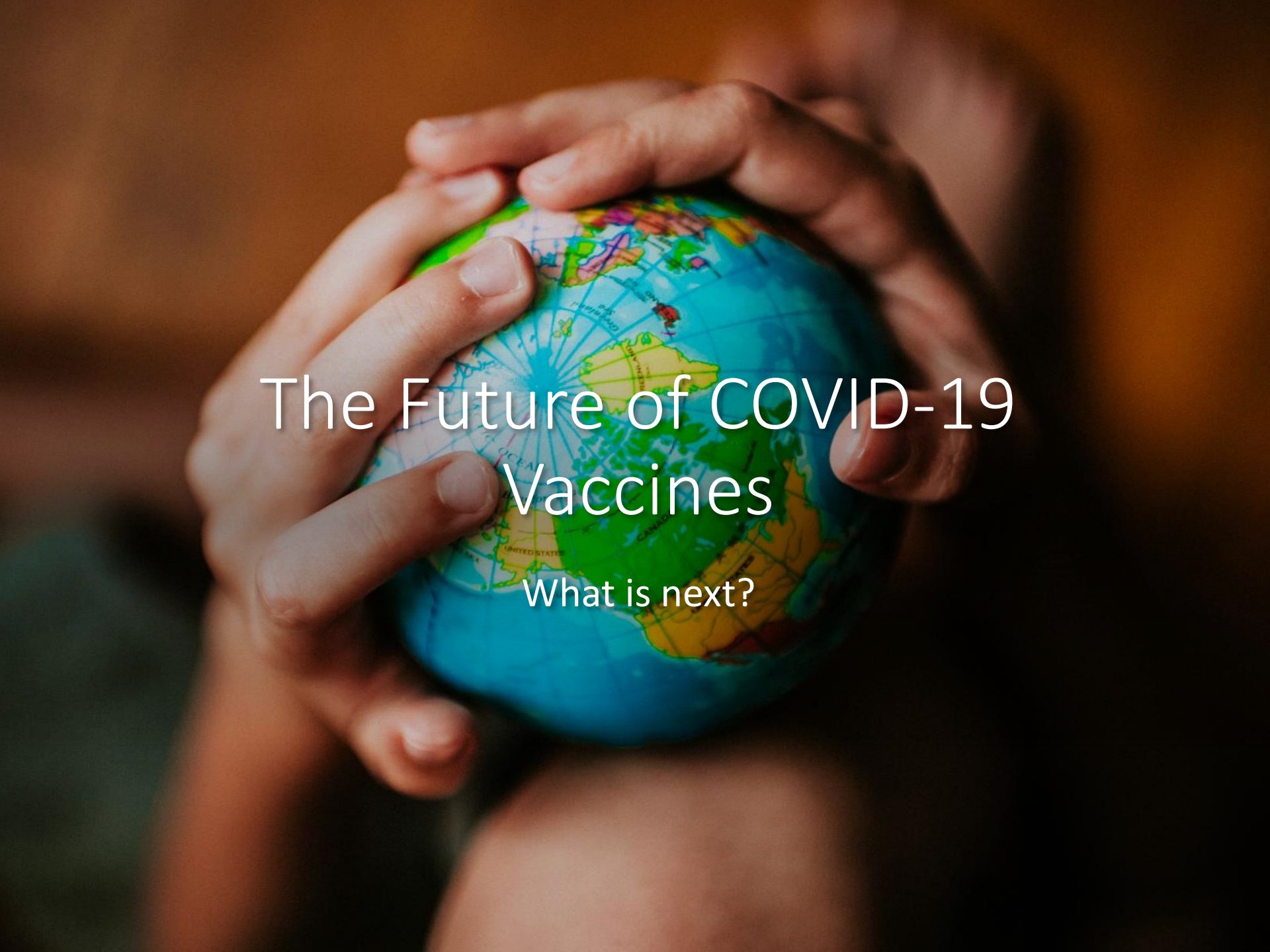
People aged 5 and older vaccinated with an updated (bivalent) booster had:

18.6X

lower risk of dying from COVID-19

in October 2022, compared to unvaccinated people.

https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status



The Future of COVID-19 Vaccines

What is next?

Predictions

COVID-19 will continue to circulate and evolve to new variants – people will continue to be exposed and infected

Yearly routine boosting is likely to be important, particularly to protect against severe disease

Combination vaccines (e.g., influenza + COVID-19) are being developed

Incorporate COVID-19 vaccination into routine well-child and primary care appointments

Summary

We are now in the transition phase of the pandemic, but it is not over

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Thanks