

Update on COVID -19 Vaccines for Children 6 months – 17 years

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Views expressed in this presentation are those of the presenter and do not represent those of Indian Health Service

Outline

- Laying the Foundation – is COVID such a big deal for kids?
- What are the benefits of vaccinating children against COVID-19?
- How safe are children's COVID-19 vaccines?

Epidemiology of COVID-19 in Children

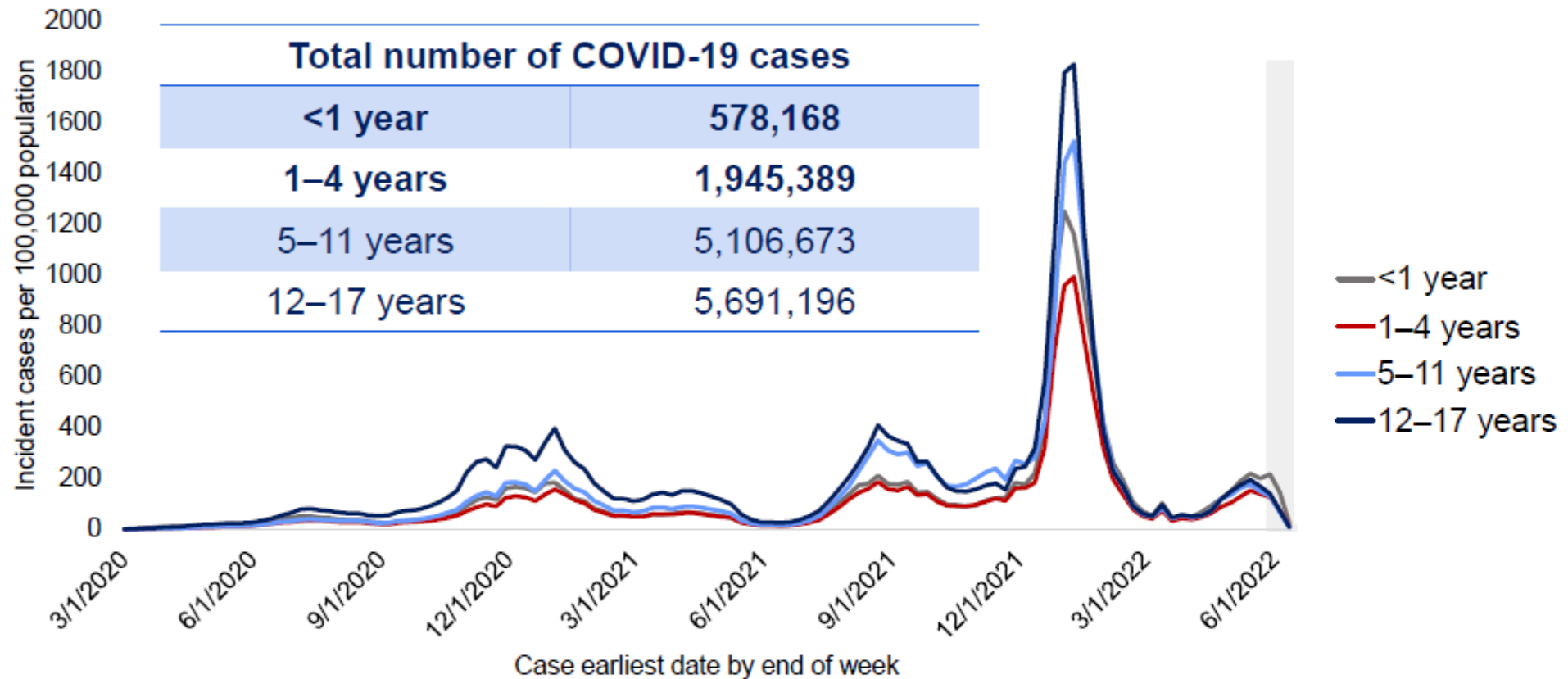
Summary:

- Children ages 6 months – 17 years are at risk for severe illness from COVID-19, including hospitalization and death

	6 months – 4 years	5 – 17 years
Cases	> 2 Million	> 10 Million
Hospitalizations	> 200,000	> 45,000
Deaths	> 200	> 600

- Children can develop long-term complications from COVID-19 infection including headache, respiratory symptoms, fatigue, mental health conditions and metabolic disorders
- 8,525 cases of Multisystem Inflammatory Syndrome in Children (MIS-C) have been documented resulting in 69 deaths (ages 0 – 20 years); 60-70% of cases require ICU care.
- 1,990 cases (9 deaths) occurred in children 6 months – 4 years of age

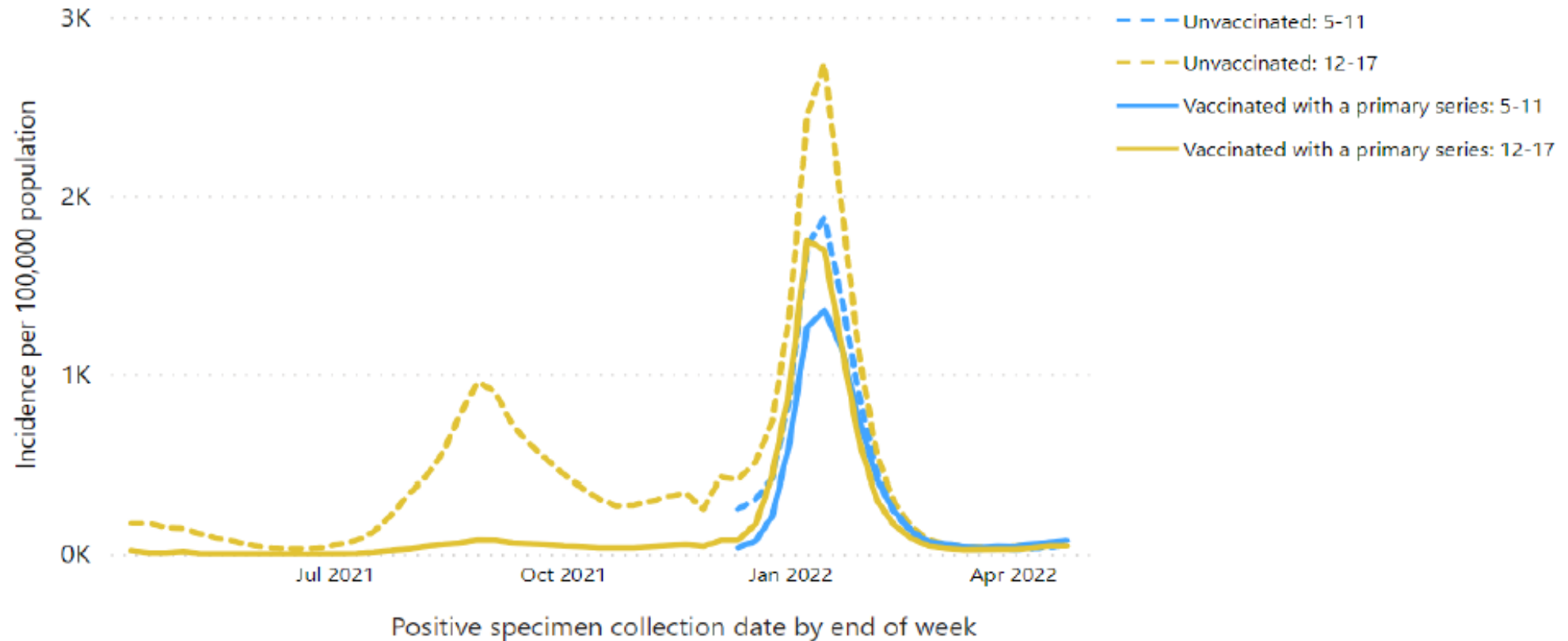
COVID-19 Weekly cases per 100,000 population among children 0–17 years by age group — United States



Reporting may be incomplete for the most recent two weeks of data, denoted by the grey box.

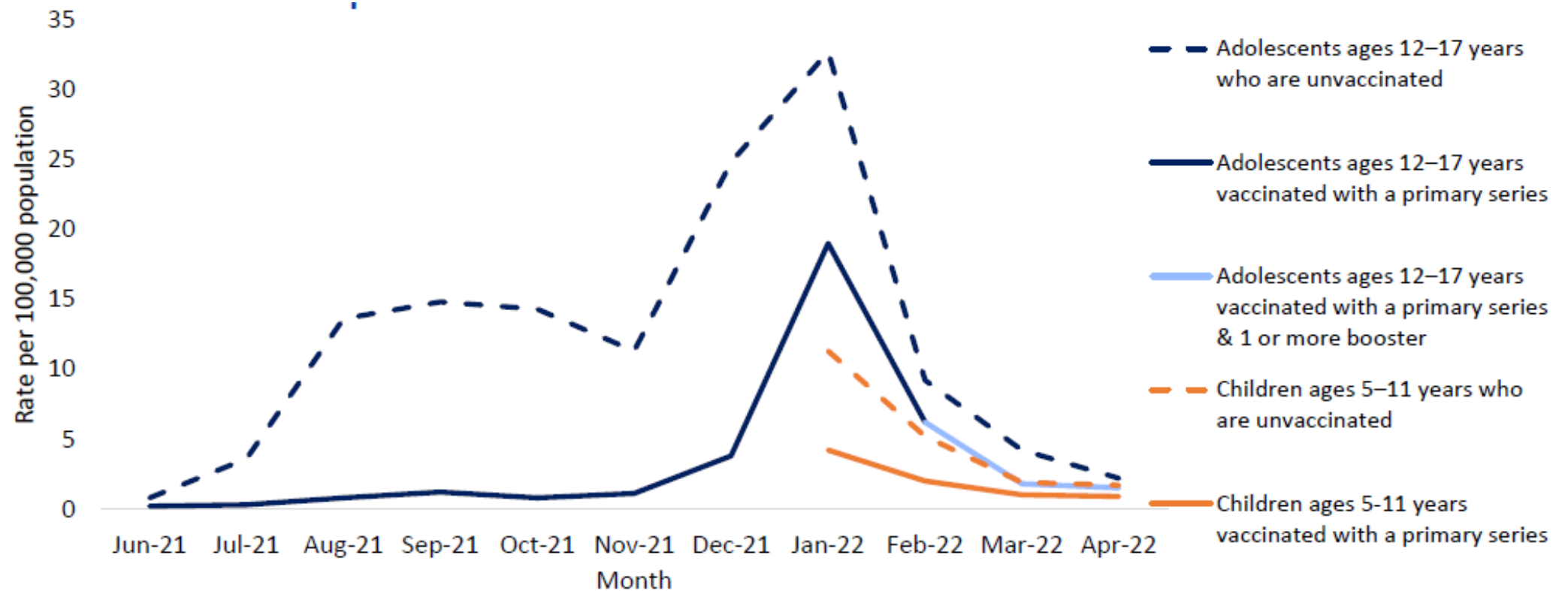
Source: COVID Data Tracker, <https://covid.cdc.gov/covid-data-tracker/#demographicsovertime>. Accessed June 16, 2022

Rates of COVID-19 cases by vaccination status and age group (April 4, 2021–April 23, 2022)



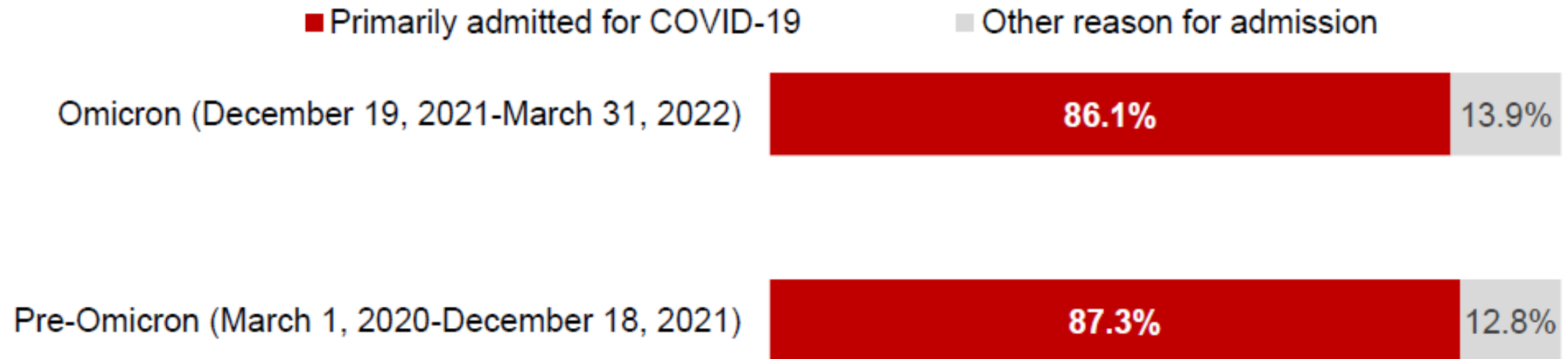
CDC COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status> Accessed May 20, 2022

Rates of monthly COVID-19-associated hospitalizations by vaccination status and age group, COVID-NET (June, 2021–April, 2022)



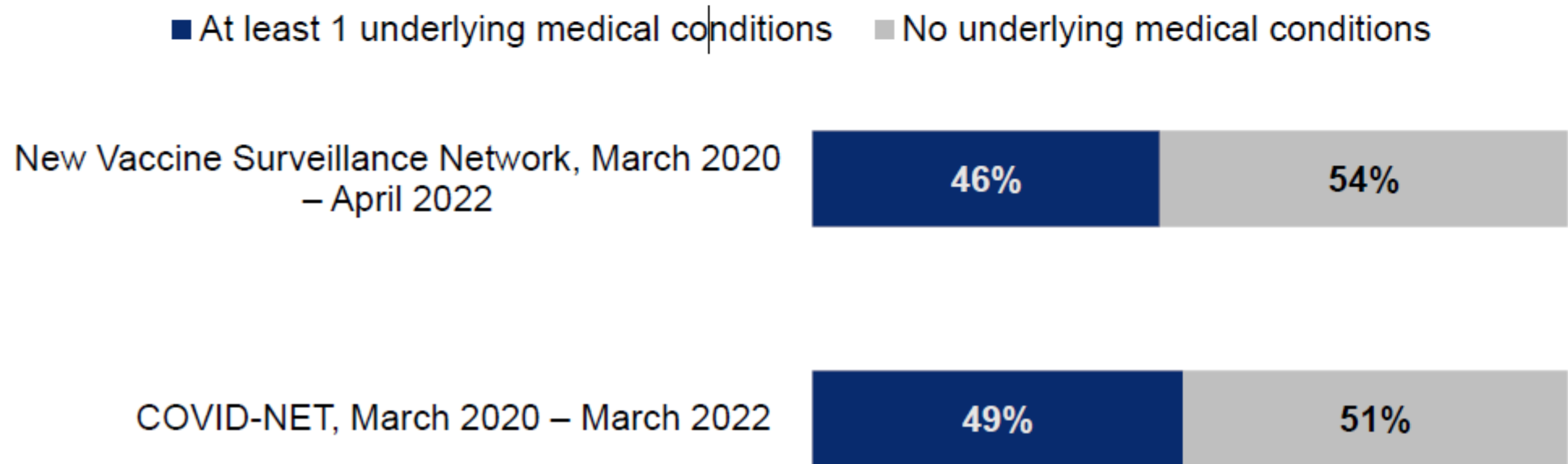
Source: [CDC COVID Data Tracker: COVID-NET Hospitalizations by Vaccination Status](#). Accessed June 20, 2022.

Proportion of children ages 6 months–4 years with COVID-19 associated hospitalization primarily admitted for COVID-19, COVID-NET March 2020 – March 2022



All children in COVID-NET had a positive SARS-CoV-2 test within 14 days of or during hospital admission. “Primarily admitted for COVID-19” was defined based on the “Reason for admission” field from the case report form. If the chief complaint or history of present illness in the medical chart documents fever/respiratory illness, COVID-19-like illness, or a suspicion for COVID-19, a case is categorized as having COVID-19 as the primary reason for admission. Examples of other non-COVID-19-related reasons for admission seen in this age group include admissions for trauma or inpatient surgeries. Source: COVID-NET data, Accessed May 21, 2022.

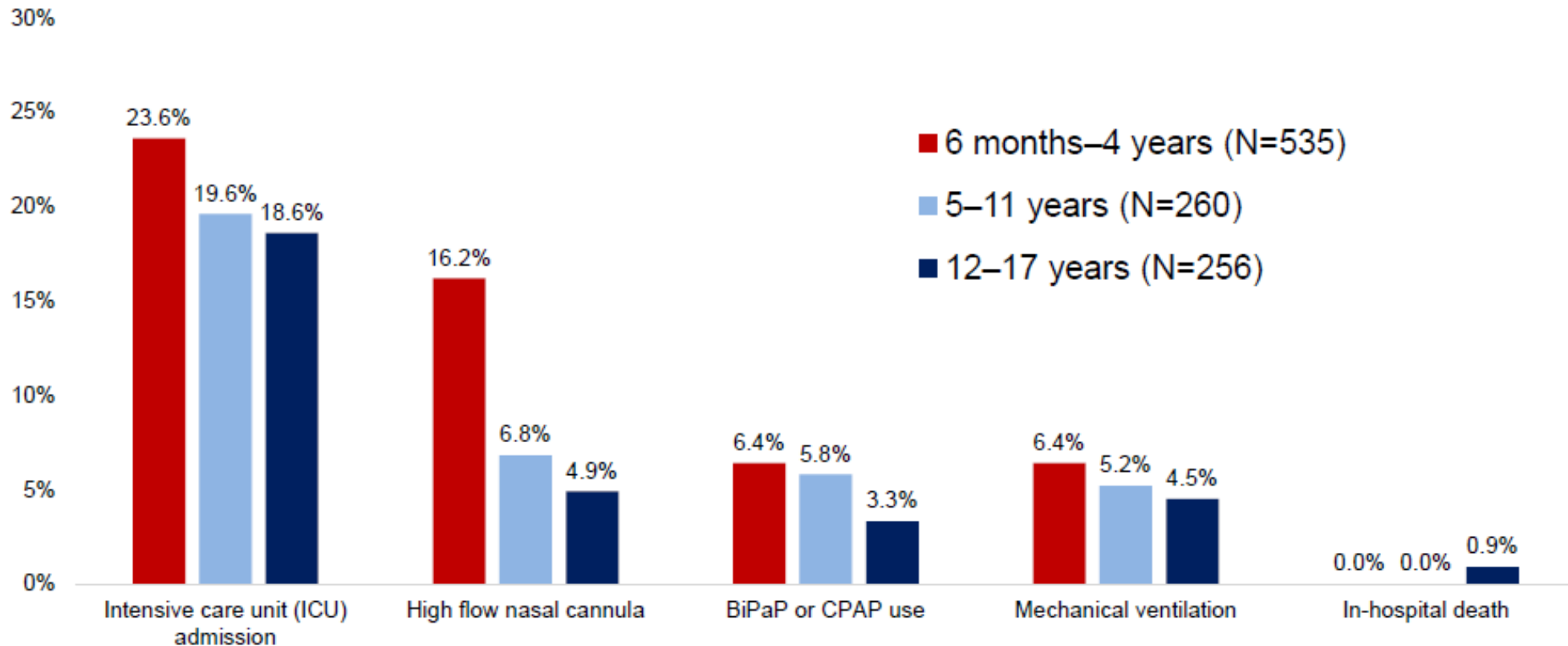
Percent of children ages 6 months–4 years with COVID-19 associated hospitalization with underlying health conditions



Source: 1. New Vaccine Surveillance Network. Preliminary data as of May 25, 2022, reflecting data from March 2020–April 2022

2. COVID-NET data. Accessed May 21, 2022, reflecting data from March 2020–March 2022

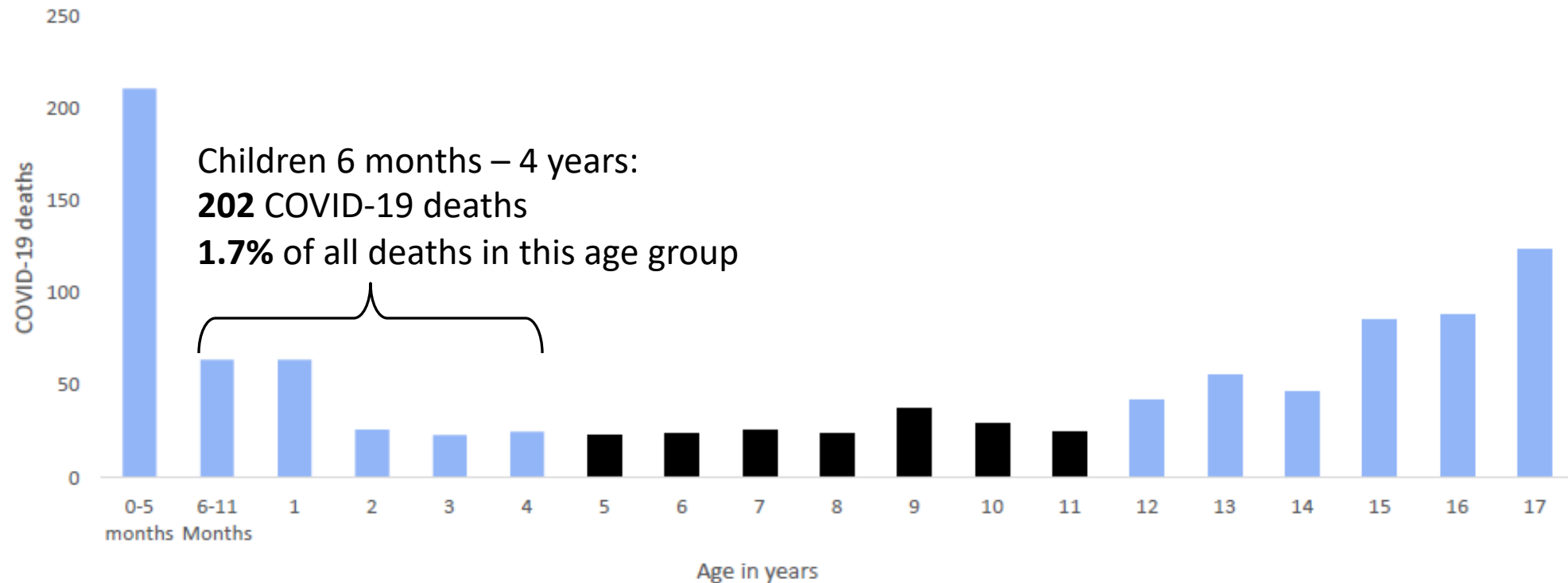
Severity of COVID-19-associated hospitalizations among children 6 months–17 years, COVID-NET, December 19, 2021 – March 31, 2022 (Omicron period)



BiPaP: bilevel positive pressure, CPAP: continuous positive pressure

Source: COVID-NET data. Accessed May 21, 2022.

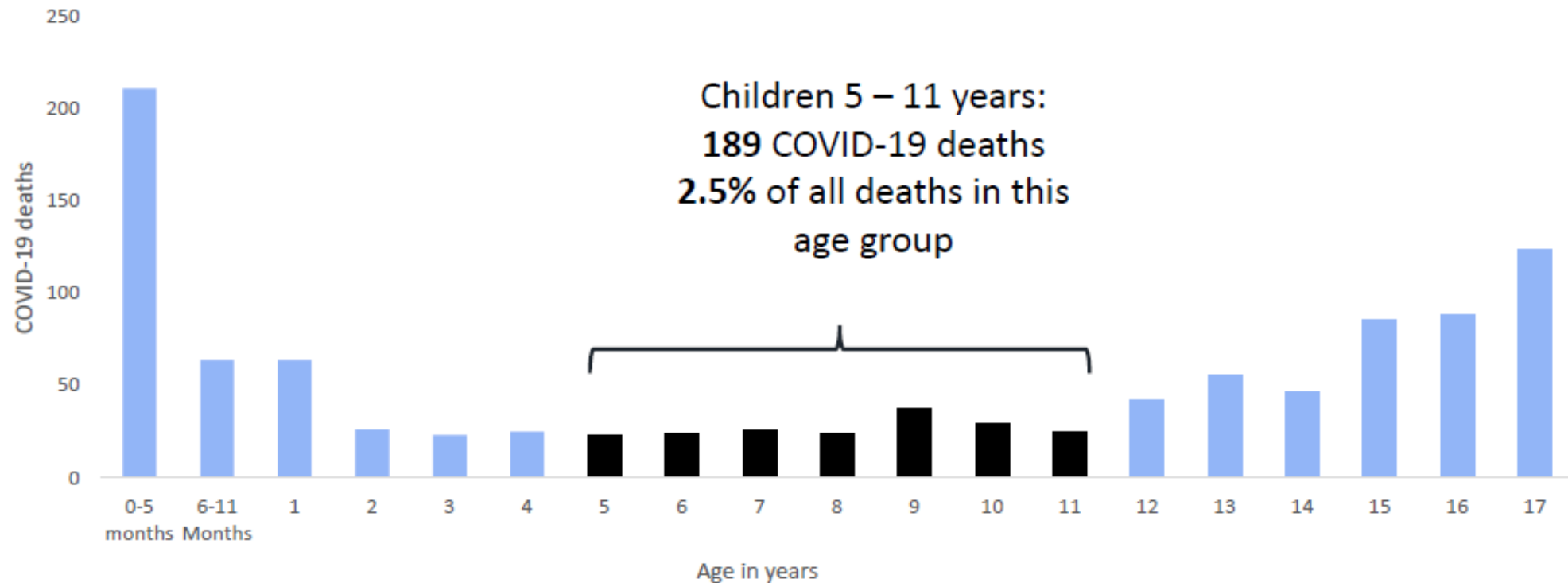
COVID-19 deaths in children and adolescents by age based on death certificate data, National Center for Health Statistics, January 1, 2020–May 11, 2022



<https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Counts-by-Age-in-Years/3apk-4u4f/data>. Accessed 5/14/22

The provisional counts for coronavirus disease 2019 (COVID-19) deaths are based on a current flow of mortality data in the National Vital Statistics System. National provisional counts include deaths occurring within the 50 states and the District of Columbia that have been received and coded as of the date specified. It is important to note that it can take several weeks for death records to be submitted to National Center for Health Statistics (NCHS), processed, coded, and tabulated. Therefore, the data shown on this page may be incomplete, and will likely not include all deaths that occurred during a given time period, especially for the more recent time periods.

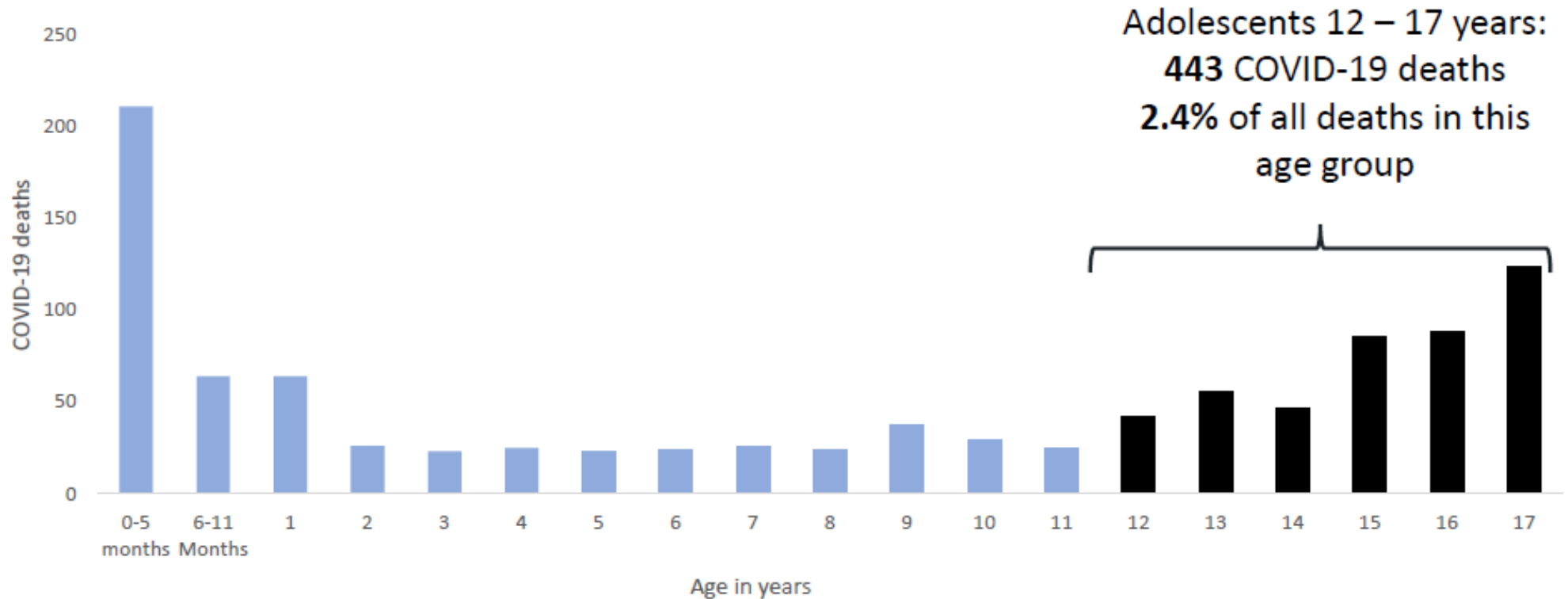
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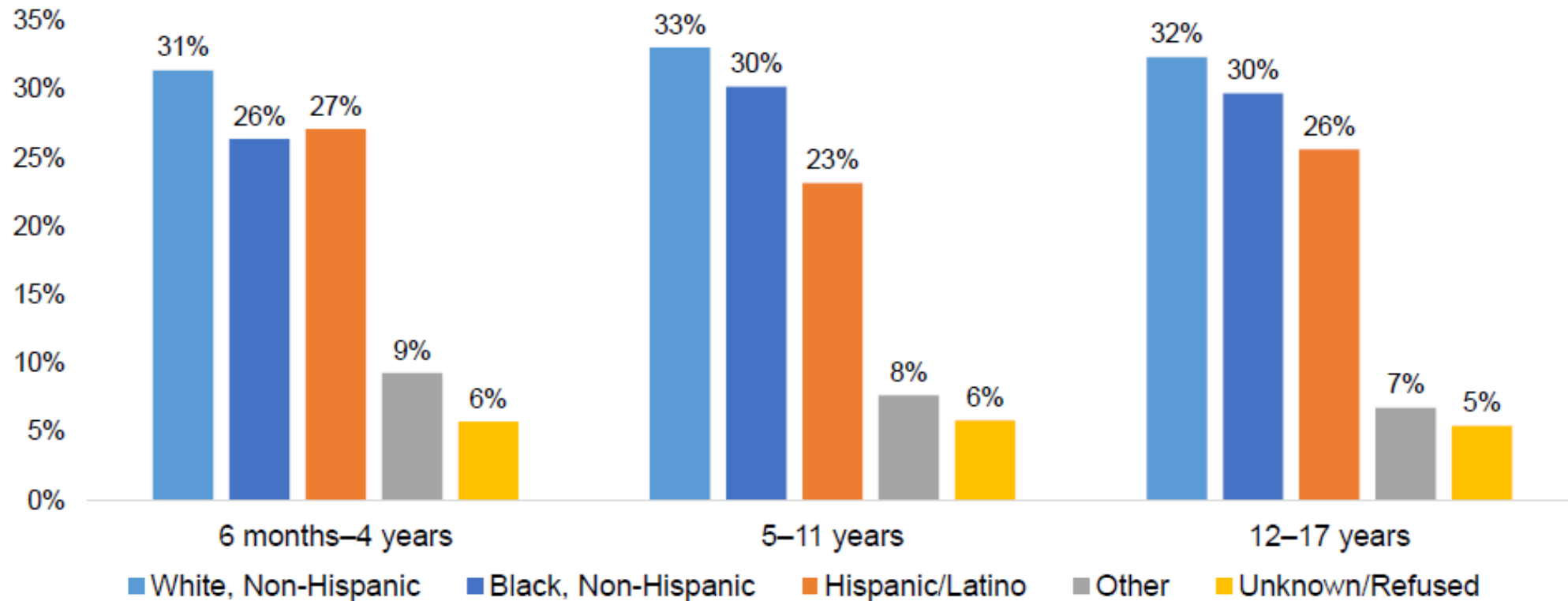
COVID-19 is a leading cause of death among children ages 0–19 years March 1, 2020–April 30, 2022

Age group	Rank of COVID-19 among causes of death
<1 year	4
1–4 years	5
5–9 years	5
10–14 years	4
15–19 years	4

Based on death certificate data from the National Center for Health Statistics. COVID-19 based on cumulative total incidence of COVID-19 deaths from March 1, 2020-April 30, 2022.

Source: Flaxman S, Whittaker C, Semenova E et al. Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States. medRxiv 2022.05.23.22275458; [Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States | medRxiv](#)

MIS-C patients by race & ethnicity for children and adolescents ages 6 months–17 years by age group February 1, 2020 – May 31, 2022

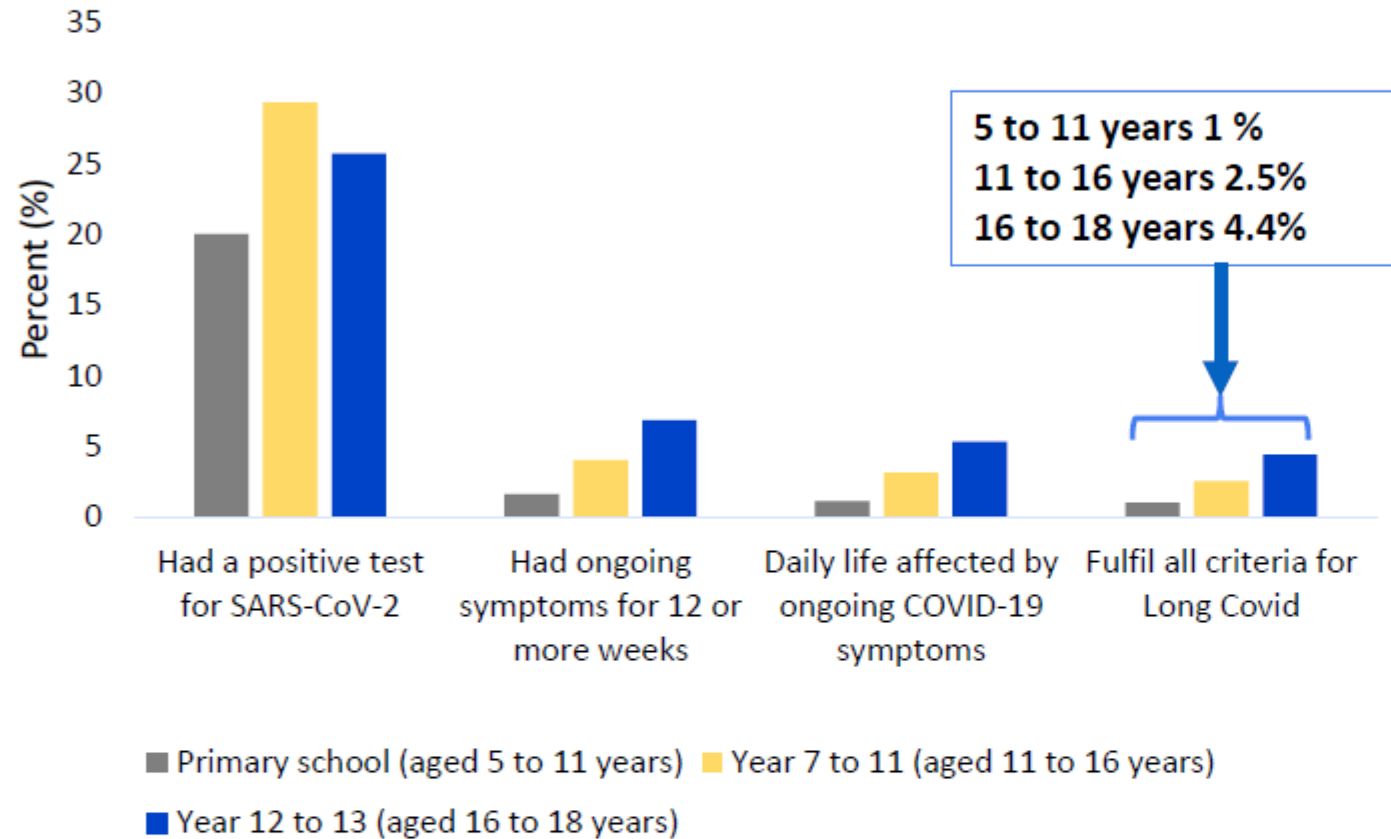


Age is missing for 1 case.

Source: CDC data. Accessed June 7, 2022

Non-hospitalized children also experience post-COVID conditions

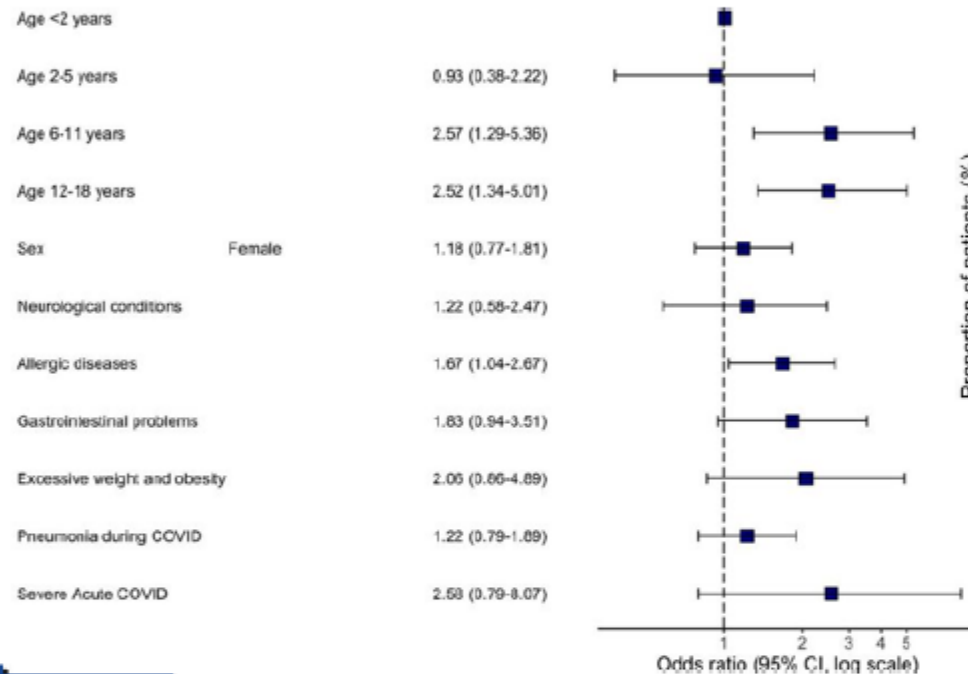
- Survey of school age children and parents in the UK (n = 4,530)
 - Weighted to ages 5 - 18 years, UK population
- Occurrence higher among adolescents 16-18 years



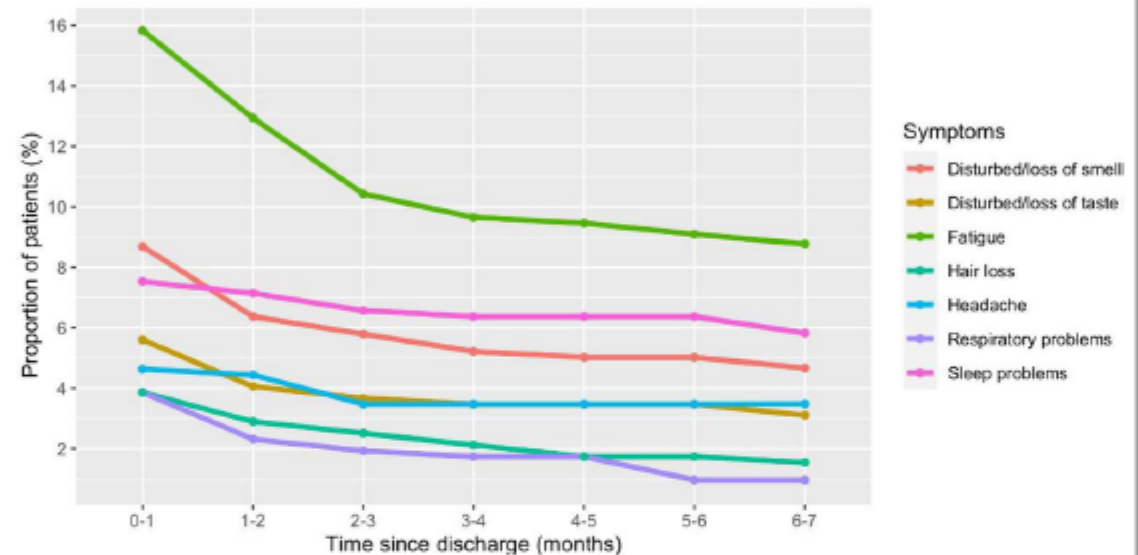
[COVID-19 Schools Infection Survey, England - Office for National Statistics](#), accessed March 2022

Risk factors of post-COVID conditions in children previously hospitalized for COVID-19

- Risk factors include older age and allergic disease



- Symptoms decrease over time

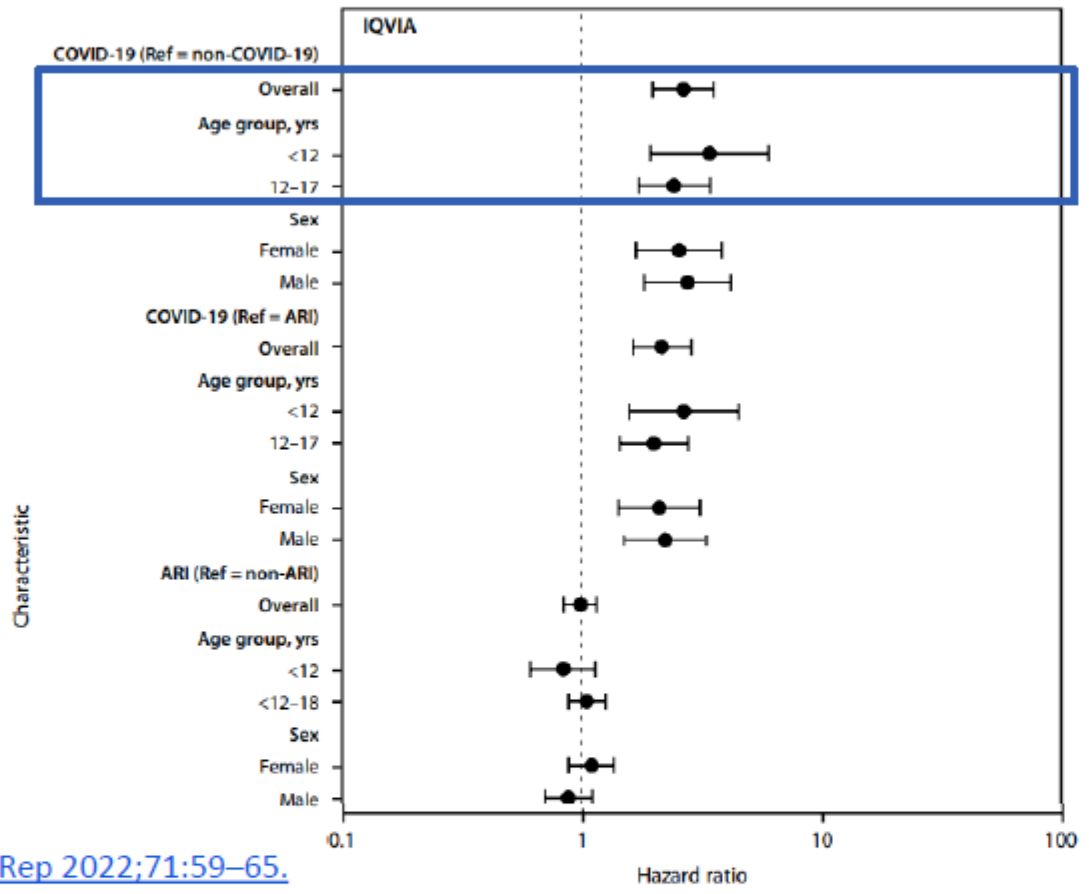


Osmanov et al. Risk factors for long COVID in previously hospitalized children. *European Respiratory Journal* 2021

Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 Years — United States, March 1, 2020–June 28, 2021



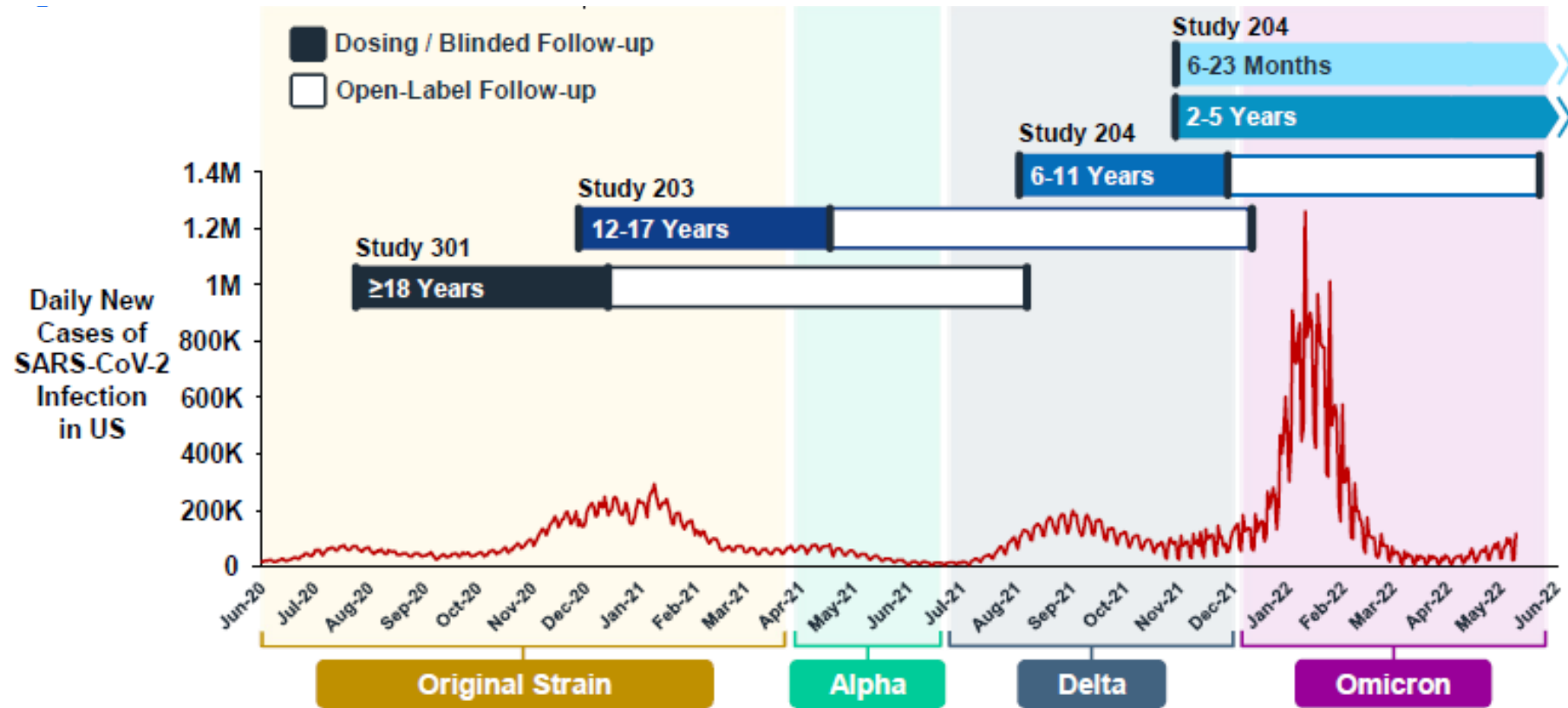
- Retrospective cohorts constructed using IQVIA healthcare claims data from March 1, 2020, through February 26, 2021
- Incidence of new diabetes diagnosis among COVID-19 patients, matched by age and sex, was higher compared to no COVID-19 diagnosis and to pre-pandemic non-COVID acute respiratory infection (ARI)
- Hazard ratio of **2.66** overall



Barrett CE, et al. MMWR Morb Mortal Wkly Rep 2022;71:59–65.

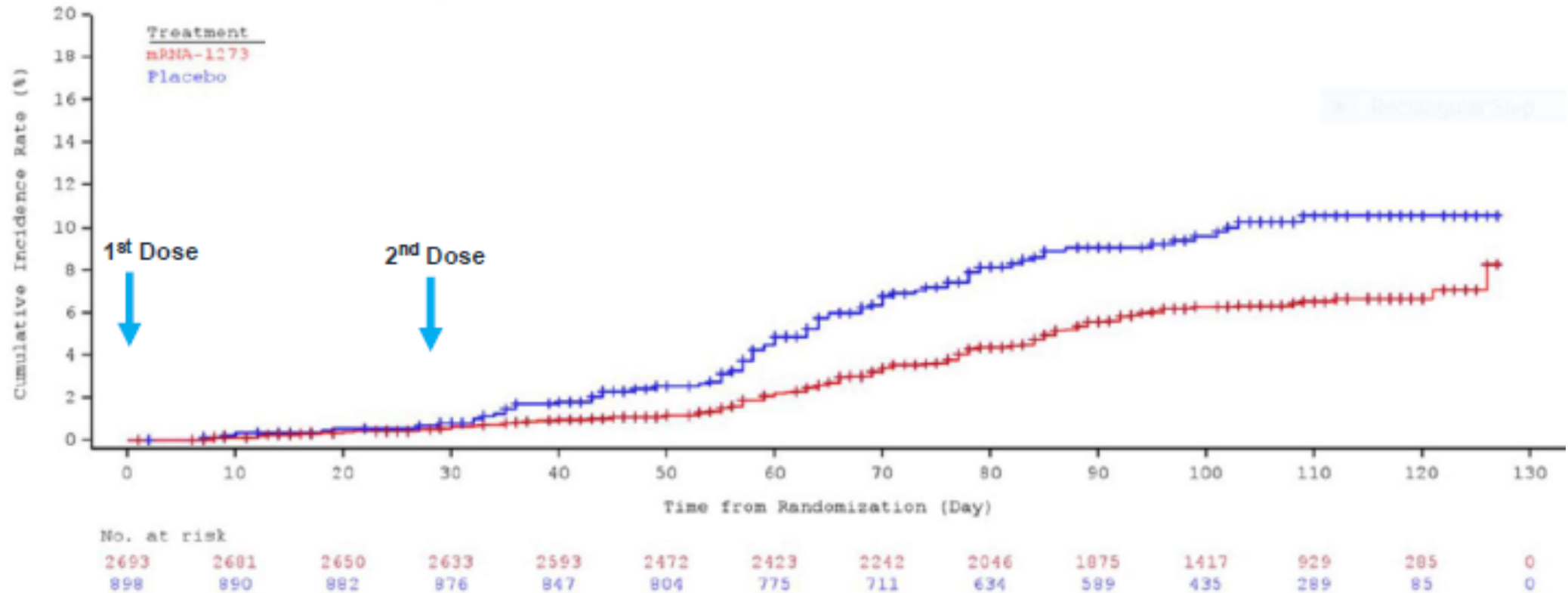
Vaccine Efficacy

Clinical Studies Conducted During Different Periods of COVID-19 Pandemic



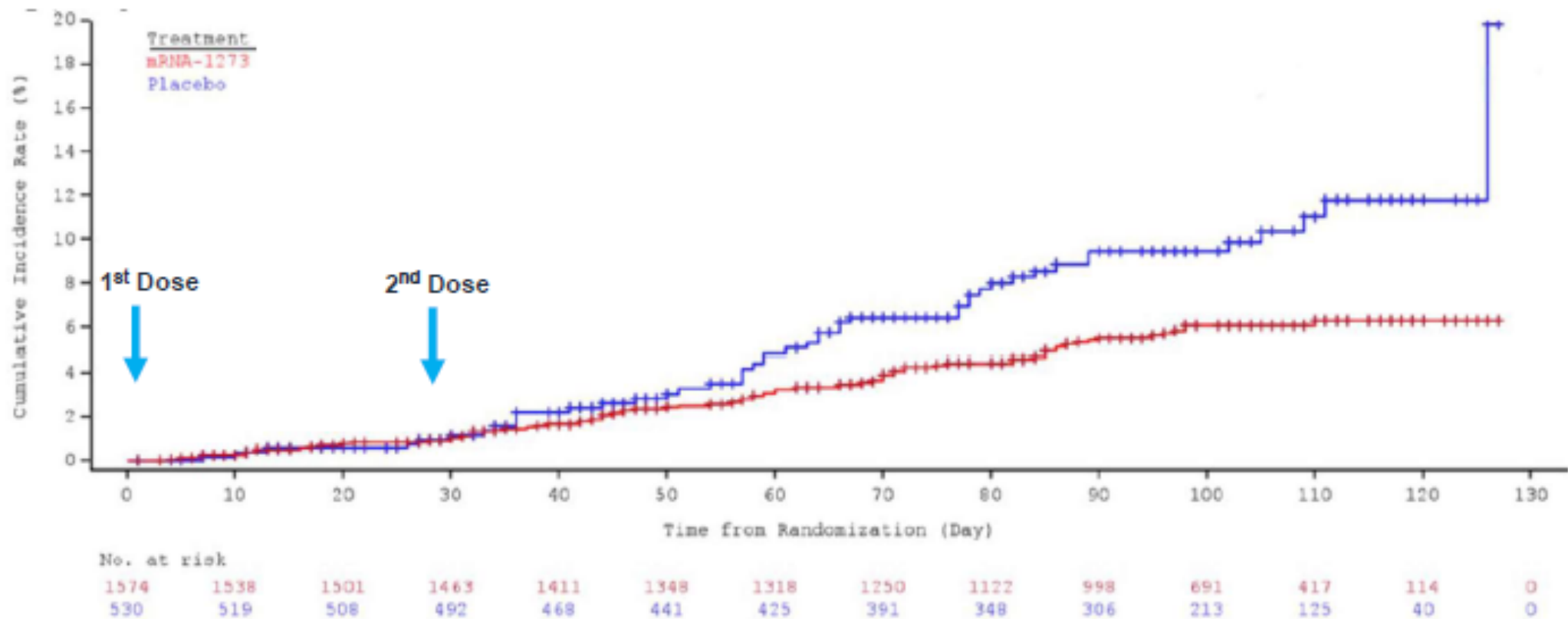
Cumulative Incidence Curve of COVID-19 Starting after Dose 1 (CDC Case Definition)

Study 204 (Part 2): Young Children (2 - 5 Years), mITT1 Set



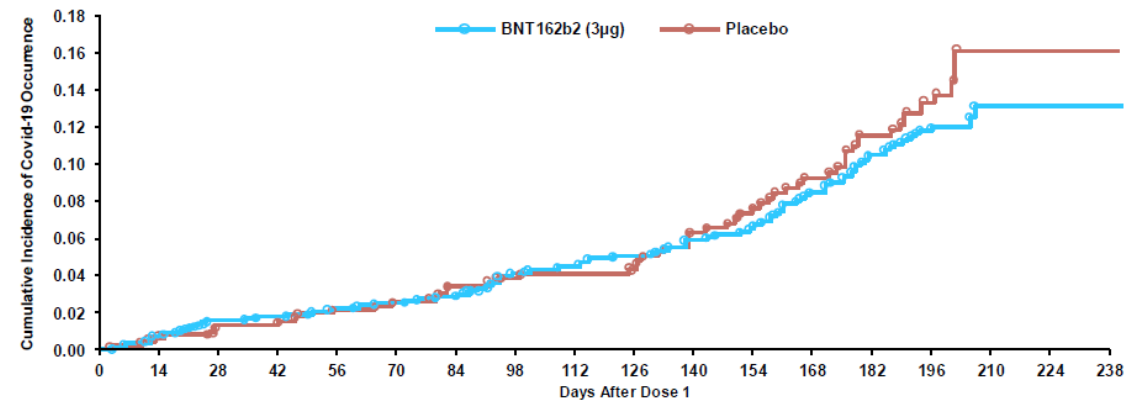
Cumulative Incidence Curve of COVID-19 Starting after Dose 1 (CDC Case Definition)

Study 204 (Part 2): Infants & Toddlers (6-23 Months), miTT1 Set

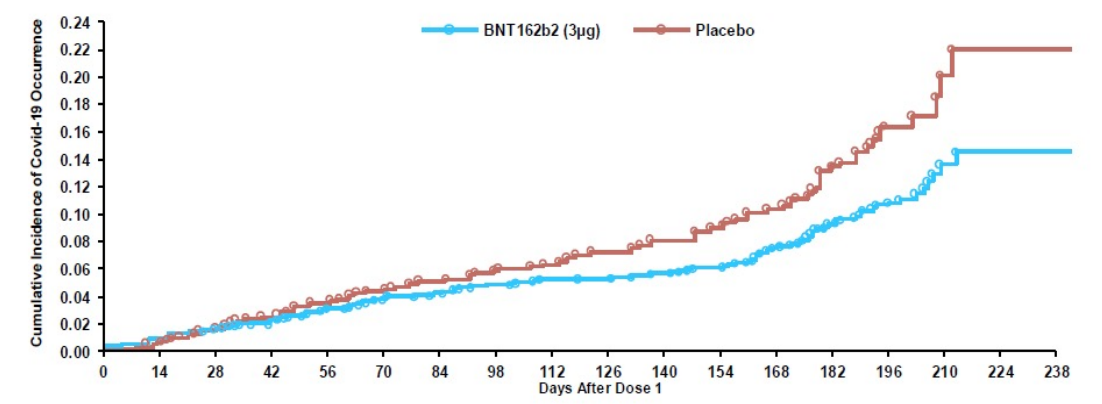


Cumulative Incidence Curves for Pfizer/BioNTech Vaccine

AGE 6 mo. to <2
Cumulative Incidence Curves Show Increasing Separation at Later Timepoints
Dose 1 All Available Population



AGE 2 to <5
Cumulative Incidence Curves Show Increasing Separation at Later Timepoints
Dose 1 All Available Population



Neutralizing antibody response

Moderna	6 – 23 months	2 – 5 years	6 – 11 years	12 –17 years
GMT	1781 (1601,1974)	1410 (1274, 1561)	1610 (1457, 1780)	1401 (1276, 1539)
GMT ratio*	1.28 (1.12, 1.47)	1.01 (0.88, 1.17)	1.2 (1.1, 1.4)	1.1 (0.9, 1.2)

*Compared with young adults 18–25 years (not shown)

Success criteria point estimate ≥ 0.8 , lower 95% confidence interval ≥ 0.67

Pfizer/BioNTech	6 –23 months (3 μ g)	2 < 5 years (3 μ g)
GMT	1407 (1211,1633)	1535 (1388, 1698)
GMT ratio [†]	1.19 (1.00, 1.42)	1.30 (1.13, 1.50)

[†]Post dose 3 compared to post dose 2 for ages 16–25 years (not shown)

Success criteria point estimate ≥ 0.8 , lower 95% confidence interval ≥ 0.67

Vaccine efficacy against symptomatic COVID-19 infection

Moderna	6 – 23 months	2 – 5 years	6 – 11 years	12 –17 years
CDC definition	50.6% (21.4, 68.6)	36.8% (12.5, 54.0)	88.0% (70.0,95.8)	93.3% (47.9, 99.9)
Study definition	31.5% (-27.7, 62.0)	46.4% (19.8, 63.8)	91.8% (74.2, 98.0)	100% (28.9, NE)

CDC case definition: 1 systemic symptom or 1 respiratory symptom and positive RT-PCR

Study case definition: 2 systemic symptoms or 1 respiratory symptom and positive RT-PCR

Pfizer/BioNTech	6 –23 months	2 < 5 years	6 months < 5 years
Study definition	75.5 (-370.1, 99.6)	82.3 (-8.0, 98.3)	80.3 (13.9, 96.7)

Vaccine Safety

Safety Evaluations

Data Sources

- Clinical Trials – verified from solicited and unsolicited patient reports
- VAERS – Can rapidly detect potential safety problems and can detect rare events, but is a passive reporting system and **generally cannot determine cause and effect**
- Vaccine Safety Datalink – Collaboration between CDC and 9 integrated healthcare organizations using rapid cycle analysis of healthcare data to measure pre-specified outcomes of interest

Types of adverse events

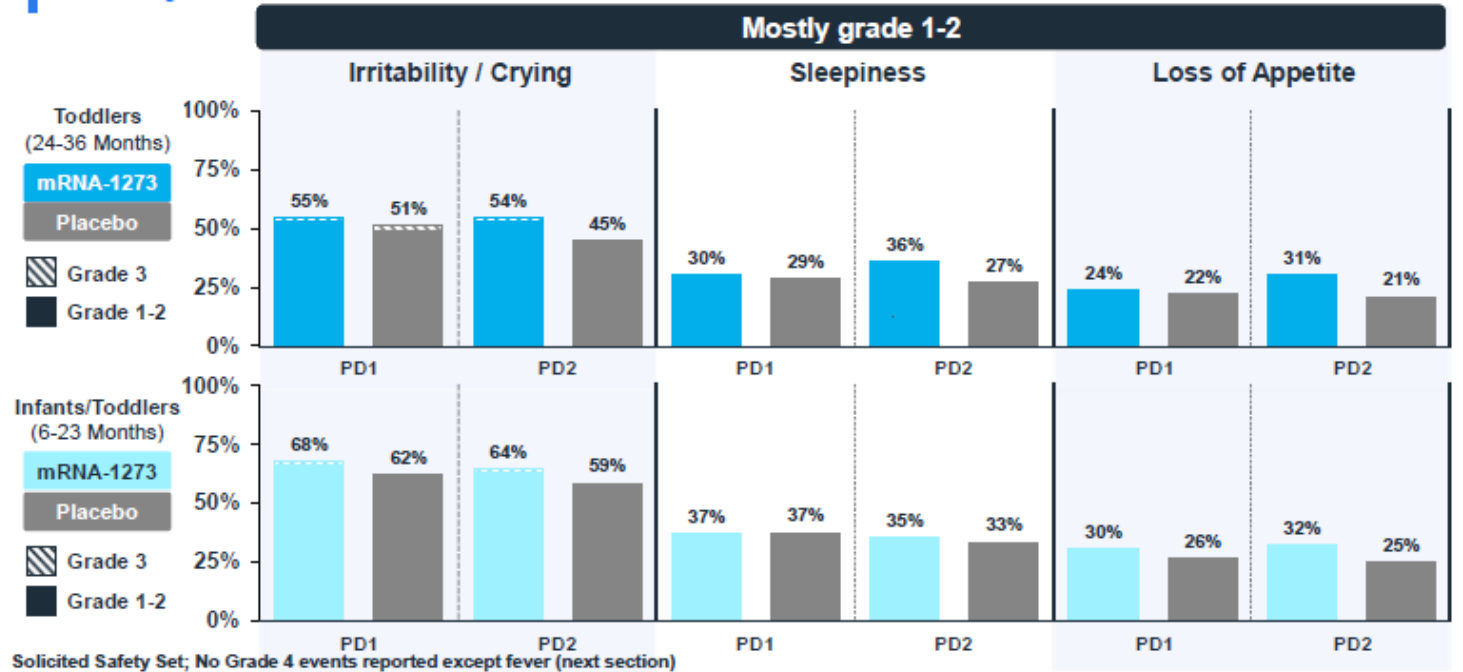
- Local Reactions
- Systemic reactions
- Pre-specified conditions, including myocarditis



Vaccine safety

Clinical trials – for mRNA vaccine administered to children, reactions were similar as seen in other age groups (adolescents, adults). Systemic reactions such as irritability, crying, poor feeding and sleepiness were seen more commonly in those vaccinated compared to placebo in the 6–36 months age group, but the differences between groups were small.

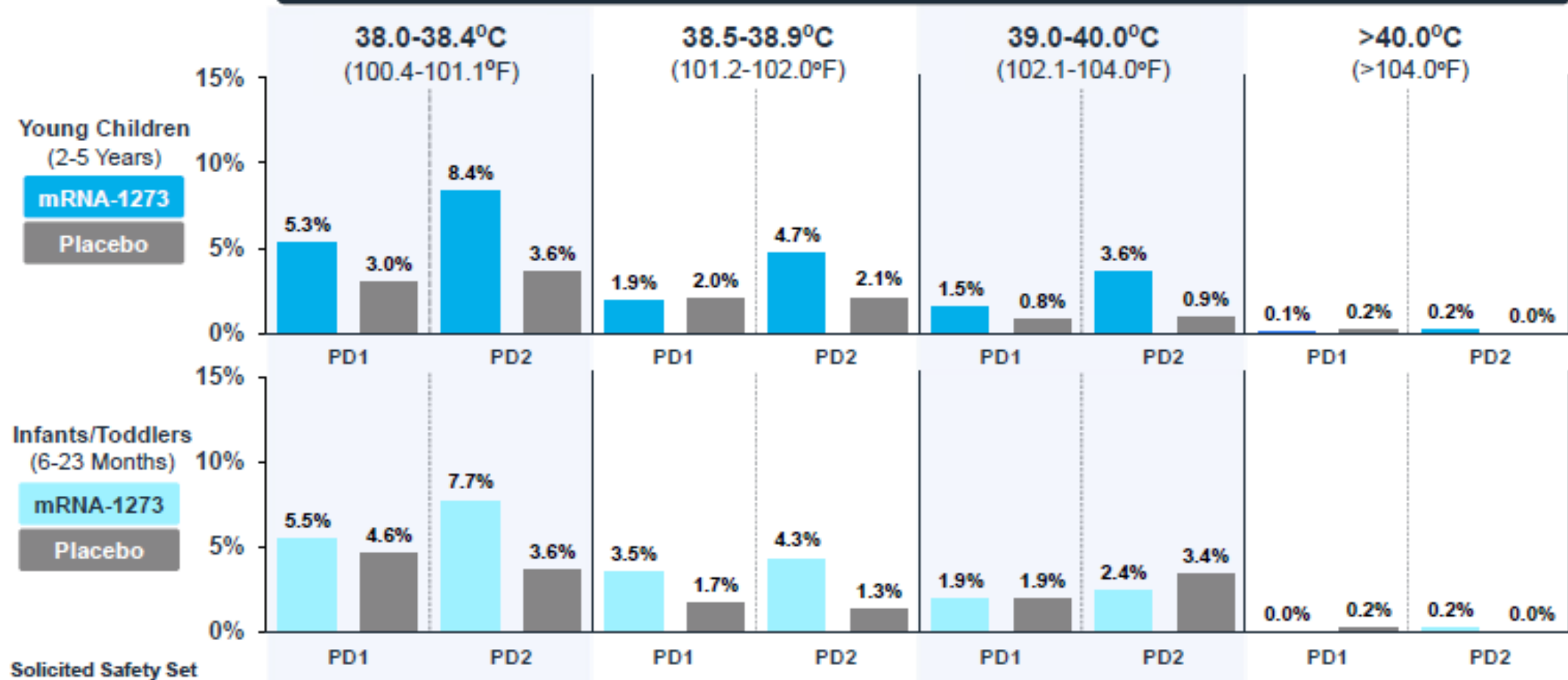
Solicited Systemic Reactions within 7 Days After Dose 1 & 2
Study 204: Infants/Toddlers (6-23 Months) & Toddlers (24-36 Months), Infant/Toddler Toxicity Scale



Maximum Temperatures within 7 Days After Dose 1 & 2

Study 204 (Part 2): Infants/Toddlers (6-23 Months) and Young Children (2-5 Years)

Fever more common after vaccine than placebo & after dose 2



VAERS and enhanced follow-up: myocarditis following Pfizer-BioNTech vaccination in 5–17-year-olds

54.8 million Pfizer-BioNTech doses administered to children ages 5–17 yrs

- 27.7 million dose 1, 23.3 million dose 2, 3.8 million 1st booster dose (ages 12–17 years)

VAERS: 635 myocarditis case reports that met the CDC case definition

- Symptom onset clusters within several days of vaccination, most within 0–7 days
- Reporting rates generally higher for males than females, especially for age groups 16–17 and 12–15 years; differences by sex in children ages 5–11 years less pronounced
- Reporting rate of myocarditis in male children ages 5–11 years after dose 2 of the primary series slightly elevated when compared to background incidence; otherwise, reporting rates for both sexes similar to background incidence

Enhanced follow-up of myocarditis cases

- Most patients reached reported no impact on quality of life, missing school or work
- Most (80%) healthcare providers indicated patient fully recovered or probably fully recovered

Shimabukuro, ACIP presentation, June 23, 2022

Characteristic	Myocarditis associated with mRNA COVID-19 vaccination ^{*,†}	Viral myocarditis [‡]
Inciting exposure	mRNA COVID-19 vaccination • Dose 2 > Dose 1	Viral illness • 30–60% with asymptomatic viral course
Demographics	Most cases in adolescents and young adults, males > females	Males > females, male incidence peaks in adolescence and gradually declines
Symptom onset	A few days after vaccination, most within a week	1–4 weeks after viral illness
Fulminant course	Rare [¶]	23%
ICU level support	~2%	~50%
Mortality/transplant	Rare [¶]	11–22%
Cardiac dysfunction	12%	60%
Recovery of cardiac function	Nearly all	~75%
Time to recovery of cardiac function (ejection fraction on cardiac echo), if initially poor	Hours to days	Days to weeks to months



* <https://www.cdc.gov/vaccines/acip/meetings/index.html>, <https://www.cdc.gov/vaccinesafety/research/publications/index.html>

† Oster et al. JAMA. 2022;327:331-340.

‡ Law et al. Circulation. 2021;144:e123-e135. Ghelani et al. Circ Cardiovasc Qual Outcomes. 2012;5:622-7. Kim et al. Korean Circ J. 2020;50:1013-1022. Messroghli et al. Am Heart J. 2017;187:133-144. Patel et al. J Am Heart Assoc. 2022;11:e024393.

¶ There are rare reports in the literature, especially from other countries, but it is unclear to what extent such cases were investigated

Conclusions

COVID-19 can be a serious illness for children and adolescents

- At present, we are unable to predict which children will develop serious illness resulting in hospitalization or death

COVID-19 vaccines have proven real-world effectiveness to prevent hospitalization and death in adolescents and adults, even during the Omicron variant period

- Vaccine trials in children showed neutralizing antibody responses similar to those seen in older ages
- Efficacy against symptomatic infection during the Omicron period was low and had wide confidence intervals, but was similar to vaccine effectiveness estimates seen in older age groups at this time

COVID-19 vaccine safety in older children and adults as monitored through VAERS and VSD continue to show a strong safety profile

- Myocarditis is seen at higher rates, but the clinical course of vaccine-associated myocarditis is generally much milder than in COVID-19 infection associated myocarditis

COVID Vaccine Updates

On 6/23/22, CDC's Advisory Committee on Immunization Practices (ACIP) expanded the recommendations for the use of Moderna COVID-19 vaccines:

- Children ages 6 through 17 years - 2-dose primary series for children ages 6 through 17 years; and
- Immunocompromised children, ages 6 through 17 years - 3-dose primary series for children ages 6 through 17 years who are moderately or severely immunocompromised.

Other resources and upcoming informational activities related to the recommendations:

Updated [Interim Clinical Considerations](#)

Updated web pages for the public including:

- [Moderna COVID-19 Vaccine Overview and Safety](#)
- [Stay Up to Date with Your COVID-19 Vaccines](#)
- [COVID-19 Vaccines for People who are Moderately or Severely Immunocompromised](#)

[Post-ACIP Partner call](#)– June 27 materials can be shared

[CDC COVID-19 All-STLT Update Call](#)– July 18, 2022

Information Sources

Slides and graphs included in this presentation were downloaded from CDC ACIP Meeting Materials for June 17-18 and June 22-23 meetings. The slides were reformatted to fit this presentation and do NOT represent the presenter's own research or original conceptualization.



Thank you!

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