Analysis of Covid-19 Data

Covid Risks, Vaccines & Kids

October, 2021

https://twitter.com/neverletdatage1

https://neverletdatagetinthewayofagoodstory.com/covid/covid-19-risks-vaccines-children/

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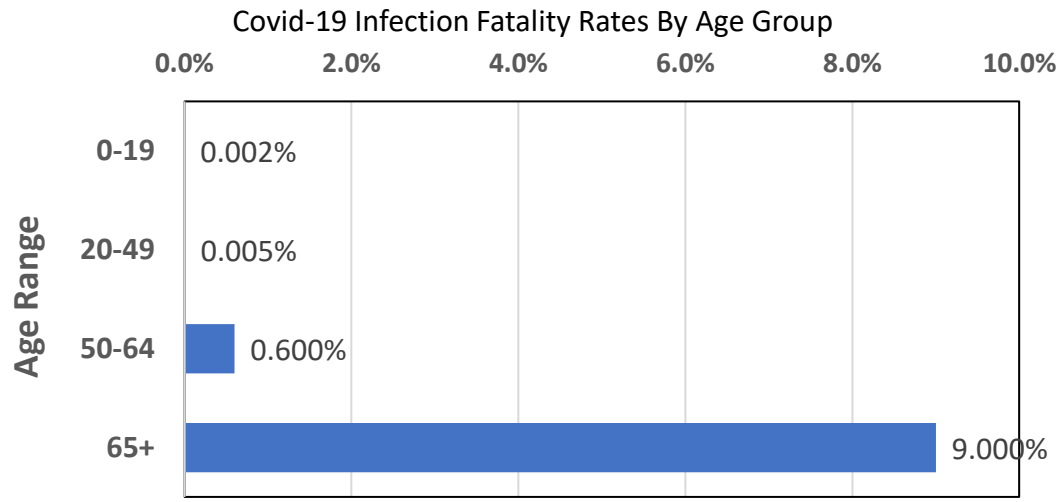
CDC **Planning Scenarios** Make Clear That Covid-19 Risks Are Highly Age Stratified & Very, Very Low for Young People

Covid-19 Infection Fatality Ratios (CDC Planning Scenarios 3/21/2021)

Table 1. Parameter Values that vary among the five COVID-19 Pandemic Planning Scenarios. The scenarios are intended to advance public health preparedness and planning. They are **not** predictions or estimates of the expected impact of COVID-19.

Parameter	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5: Current Best Estimate
R_0*	2.0		4.0		2.5
Infection fatality ratio (Estimated number of deaths per 1,000,000 infections)†	0–17 years old: 6 18–49 years old: 150 50–64 years old: 1,800 65+ years old: 26,000		0–17 years old: 80 18–49 years old: 1,700 50–64 years old: 20,000 65+ years old: 270,000		0–17 years old: 20 18–49 years old: 500 50–64 years old: 6,000 65+ years old: 90,000



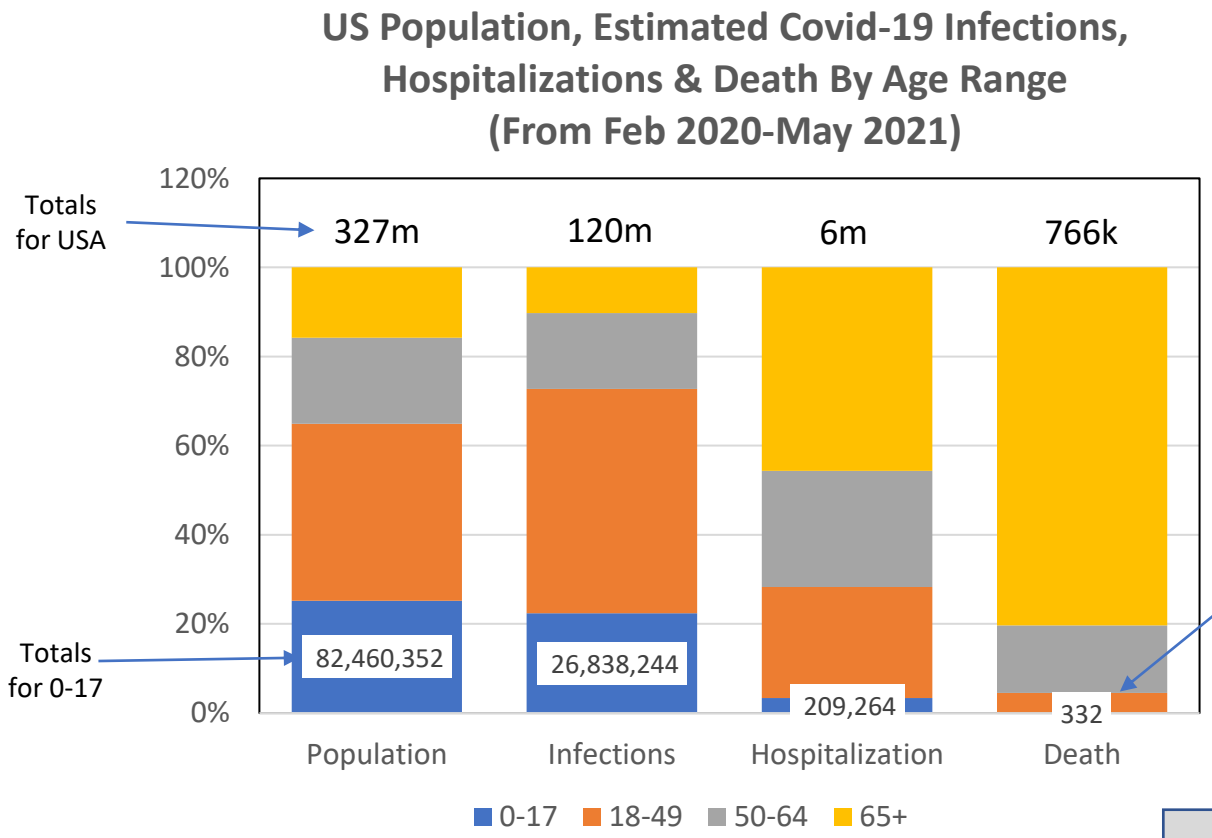
Notes:

- These are **averages** per age group – no segmentation for obesity, other comorbidities
- CDC do not break down risk for the large 18-49 age cohort unlike other countries.

Children have approx. 0.002% (a 20 in a million; 1 in 50,000) chance of dying if they catch Covid-19 (risk will be lower for healthy children)

Note: Another CDC source (Estimated COVID-19 Burden | CDC) estimates chance of death at 1 in 80,000 for children (see next slide).
Source: https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html

CDC Estimate of **Actual Disease Burden** (as at May 29, 2021) Has Lower Risk of Covid-19 Death for Under 18s Than Planning Scenarios

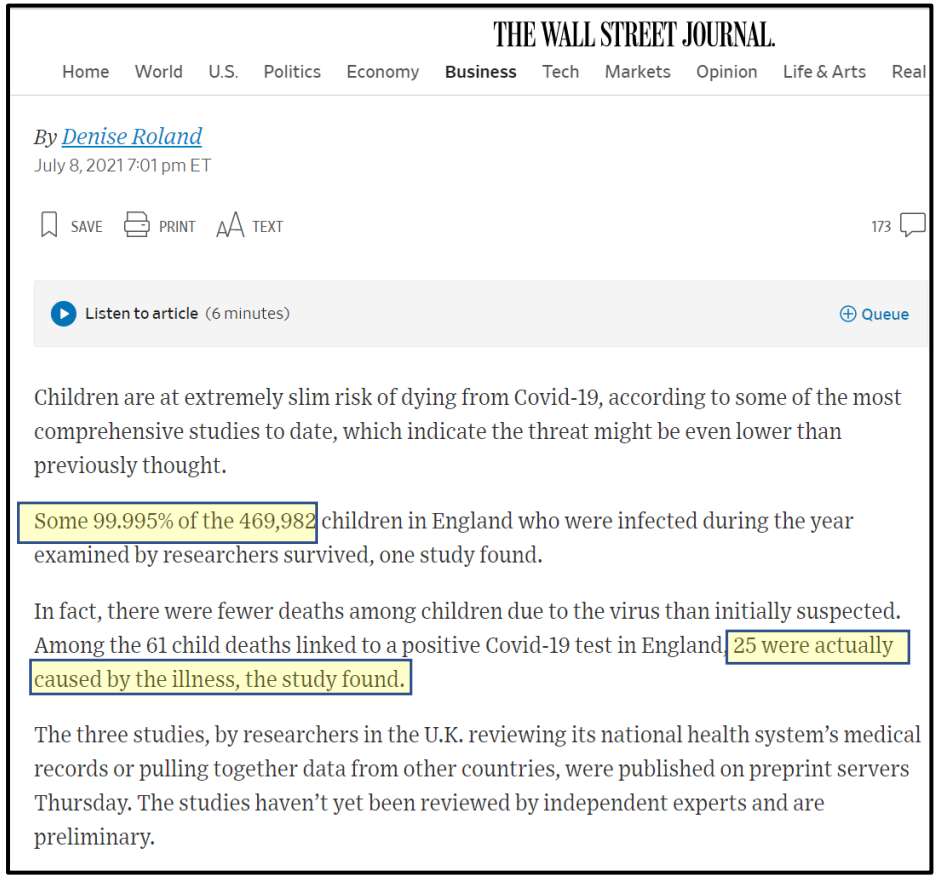


- Covid-19 hospitalizations and deaths heavily concentrated in those aged 65+
- Estimate 332 deaths in 0-17 age group out of 26.8m infections (0.0012%; 1 in 80.8k)
  - Note: CDC estimate over 32% of 0-17 year-olds had already been infected by May 2021

Children 0-17 had approx 0.0012% (332/26.8m) - or 1 in 80,800 - chance of dying if they caught Covid-19 (Note: risk will be much lower for healthy children– see later slides)

Note: Totals only shown in chart for 0-17 age range in order to keep chart more legible. Actual disease burden is less than in CDC planning scenarios – presumably they are being conservative in the planning scenarios.
Source: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

Large UK Study of <18s, Widely Reported in WSJ et al, Showed Covid-19 Death Rate At 2 in 1 Million (1 in 500,000) For This Age Range & Most Had Underlying Comorbidities. Only 6 Individuals With No Identified Comorbidities Died Of Covid-19.



THE WALL STREET JOURNAL.

Home World U.S. Politics Economy **Business** Tech Markets Opinion Life & Arts Real

By Denise Roland
July 8, 2021 7:01 pm ET

SAVE PRINT TEXT 173

Listen to article (6 minutes) Queue

Children are at extremely slim risk of dying from Covid-19, according to some of the most comprehensive studies to date, which indicate the threat might be even lower than previously thought.

Some 99.995% of the 469,982 children in England who were infected during the year examined by researchers survived, one study found.

In fact, there were fewer deaths among children due to the virus than initially suspected. Among the 61 child deaths linked to a positive Covid-19 test in England, 25 were actually caused by the illness, the study found.

The three studies, by researchers in the U.K. reviewing its national health system's medical records or pulling together data from other countries, were published on preprint servers Thursday. The studies haven't yet been reviewed by independent experts and are preliminary.

- WSJ Source: In Children, Risk of Covid-19 Death or Serious Illness Remains Extremely Low, New Studies Find - WSJ
- BBC Source: Covid: Children's extremely low risk confirmed by study - BBC News
- Source: Nature: Deaths from COVID 'incredibly rare' among children (nature.com)

Discussion

- What were the characteristics of the 25 deaths?

  "They checked England's public health data and found most of the young people who had died of Covid-19 had underlying health conditions:
  - *Around 15 had life-limiting or underlying conditions, including 13 living with complex neuro-disabilities*
  - *Six had no underlying conditions recorded in the last five years - though researchers caution some illnesses may have been missed"*

- What was implied fatality rate[1]? (NB. This is not Infection Fatality Rate)

  "Of 3,105 deaths from all causes among the 12 million or so people under 18 in England between March 2020 and February 2021, 25 were attributable to COVID-19 — a rate of about 2 for every million people in this age range. "

Caveats:

- The study was based on confirmed cases, and will thus undercount the true number of cases in this age group (i.e. no testing of asymptomatic patients).
- Delta?

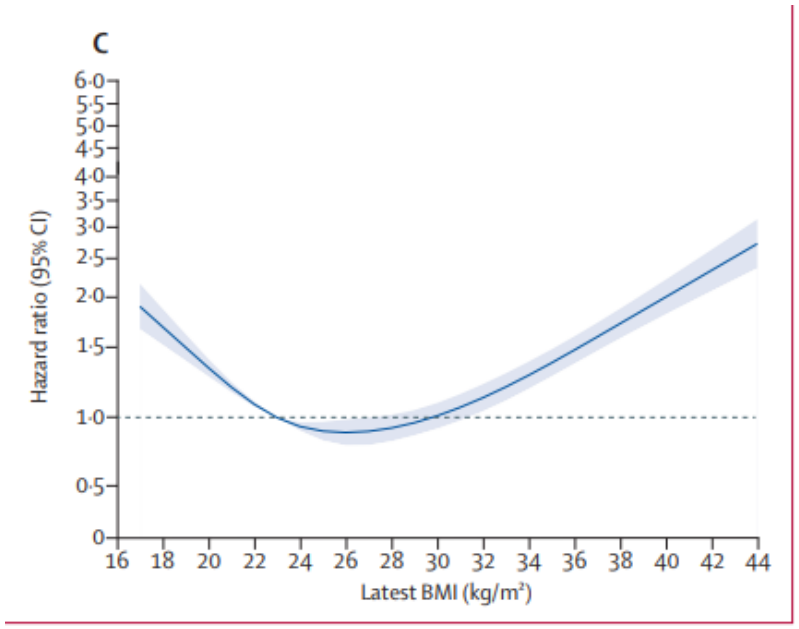
  Dr Elizabeth Whittaker, from the Royal College of Paediatrics and Child Health and Imperial College London, said it was encouraging they were seeing very few seriously unwell children in hospital.

  She added: "Although this data covers up to February 2021, this hasn't changed recently with the Delta variant. We hope this data will be reassuring for children and young people and their families."

- Note: [1]a high percentage of the UK population will have had Covid-19 by Feb 21 – likely several million of the 12 million in the study cohort. The infection fatality rate would be 3,105 divided by the number of people who had been infected.

Massive UK Study of 6.9m People Over Age 20, Showed Risks of Covid-19 Highly Associated With Obesity

Hazard Ratio vs BMI for Death (all ages)



		Attributable risks per 10,000 person-year				Attributable fractions % per 10,000 person-year			
COVID-19 Hospital admission	Incidence rate per 10,000 population	BMI 23 kg/m²	BMI 30 kg/m²	BMI 35 kg/m²	BMI 40 kg/m²	BMI 23 kg/m²	BMI 30 kg/m²	BMI 35 kg/m²	BMI 40 kg/m²
20-39 years	0.040	0	21	46	85	0	45	64	77
40-59 years	0.120	0	49	105	187	0	42	60	73
60-79 years	0.316	0	59	113	178	0	24	38	49
80+ years	1.141	0	29	50	73	0	7	11	16
COVID-19 ICU admission									
20-39 years	0.005	0	2	6	12	0	57	77	87
40-59 years	0.025	0	3	8	16	0	52	71	83
60-79 years	0.049	0	2	5	8	0	29	44	56
80+ years	0.025	0	5	10	16	0	33	50	63
COVID-19 Death									
20-39 years	0.001	0	3	9	21	0	67	85	93
40-59 years	0.016	0	14	35	73	0	57	77	87
60-79 years	0.121	0	16	30	46	0	19	30	39
80+ years	0.765	0	0	0	0	0	0	0	0

Low absolute risk for 20-39 year old cohort

Obesity explains large part of risk

Source: [Associations between body-mass index and COVID-19 severity in 6.9 million people in England: a prospective, community-based, cohort study (thelancet.com)]

This General Pattern Of Very Low Risk For Young, And Those Without Comorbidities, Is Consistent Across Multiple Countries & Multiple Studies (& Has Been Known Since Mid 2020)

Netherlands Antibody Study, April 2020

Covid-19 Risks By Age Group

Age	Chance of Hospitalization	Chance of ICU Admission	Chance of Death
0-19	0.20%	0.02%	0.003%
20-29	0.17%	0.03%	0.003%
30-39	0.29%	0.06%	0.008%
40-49	0.69%	0.18%	0.017%
50-54	1.28%	0.39%	0.058%
55-59	1.98%	0.69%	0.145%
60-64	2.70%	0.99%	0.290%
65-69	3.52%	1.37%	0.757%
70-75	5.30%	1.82%	1.668%
75-80	8.14%	1.70%	4.433%
80-85	9.11%	0.50%	7.836%

Source: Economisch Statistische Berichten (ESB) based on data from RIVM, Pienter Research, CBS, Stitching Nice

<60 0.03%

Over 60 2.99%

Overall Average[1]: 0.78%

100-fold higher risk for over vs under 60s.

Stockholm University Study

Chance of Surviving Covid-19 by Age and Sex

Age	FEMALE		MALE	
	No Underlying Conditions	One or Greater Underlying Conditions	No Underlying Conditions	One or Greater Underlying Conditions
0-9	99.99996	99.9639	99.99996	99.9603
10-19	99.99996	99.9639	99.99996	99.9603
20-29	99.9998	99.9466	99.9997	99.9037
30-39	99.9991	99.8636	99.9986	99.79
40-49	99.998	99.8153	99.9965	99.6943
50-59	99.9888	99.3647	99.9815	99.2135
60-69	99.9562	98.7605	99.8895	97.9992
70-79	99.8251	97.6094	99.5245	95.6517
80+	98.9087	92.8152	96.3318	79.9154

"Predicted COVID-19 Fatality Artes Based on Age, Sex, Comorbidities, and Health System Capacity" Stockholm University, June 2020

- Study findings: a healthy 10-19 year old with no underlying conditions has a 0.00004% (1 in 2,500,000) chance of dying from Covid-19
- Study results seem consistent with later data (e.g. UK study)

Note: Sample: 2800 people. Infection rate at April 1st and course of disease to April 27
[1]Weighted average based on population pyramid for Netherlands & estimated 12% case fatality rate for 85+
Source: https://esb.nu/blog/20059695/we-kunnen-nu-gaan-rekenen-aan-corona; https://www.populationpyramid.net/netherlands/2018/

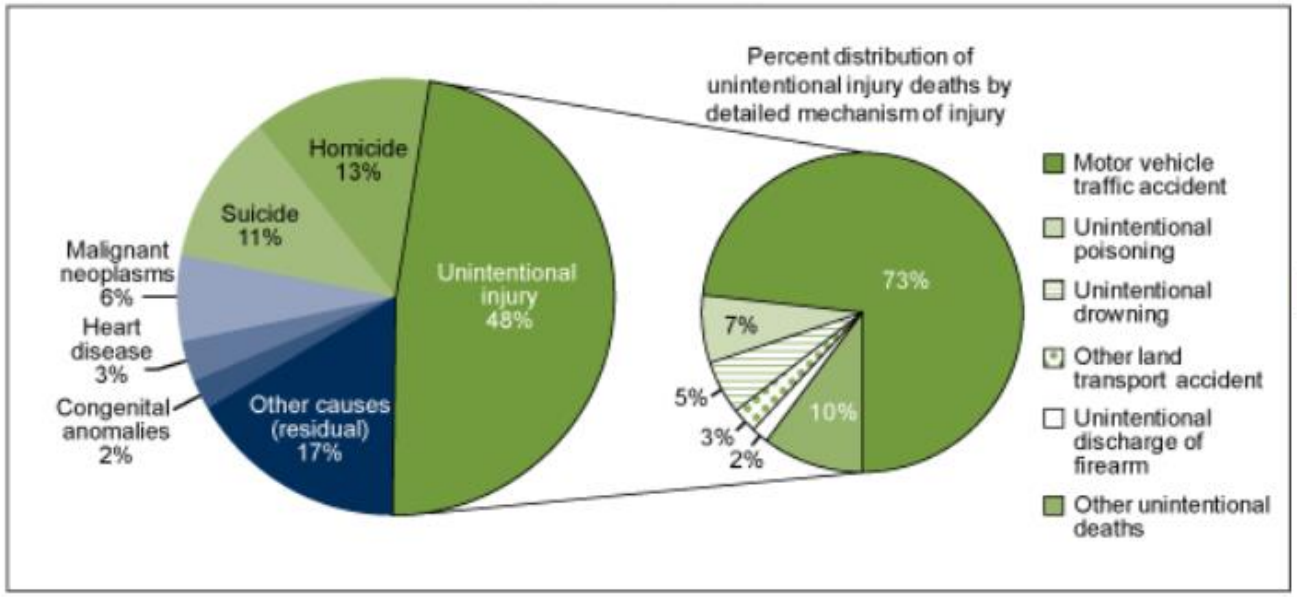
Source: Predicted COVID-19 Fatality Rates Based on Age, Sex, Comorbidities, and Health System Capacity (cgdev.org)

For 12-19 Year Olds, Covid-19 Accounts for Less Than 1% of All Deaths Per Year; Suicide Risk is Over Ten Times Greater

- Pre Covid, 16,375 teenagers 12-19 died every year in the US from 1999-2006 (CDC Health Statistics),
  - ~7,860 injuries per year
  - ~1,800 suicides per year

Note: in 20/21, "CDC Reports 51% Increase in Suicide Attempts Among Teenage Girls" (Source: CDC)

Figure 2. Percent distribution of all deaths to teenagers 12–19 years, by cause of death: United States, 1999–2006



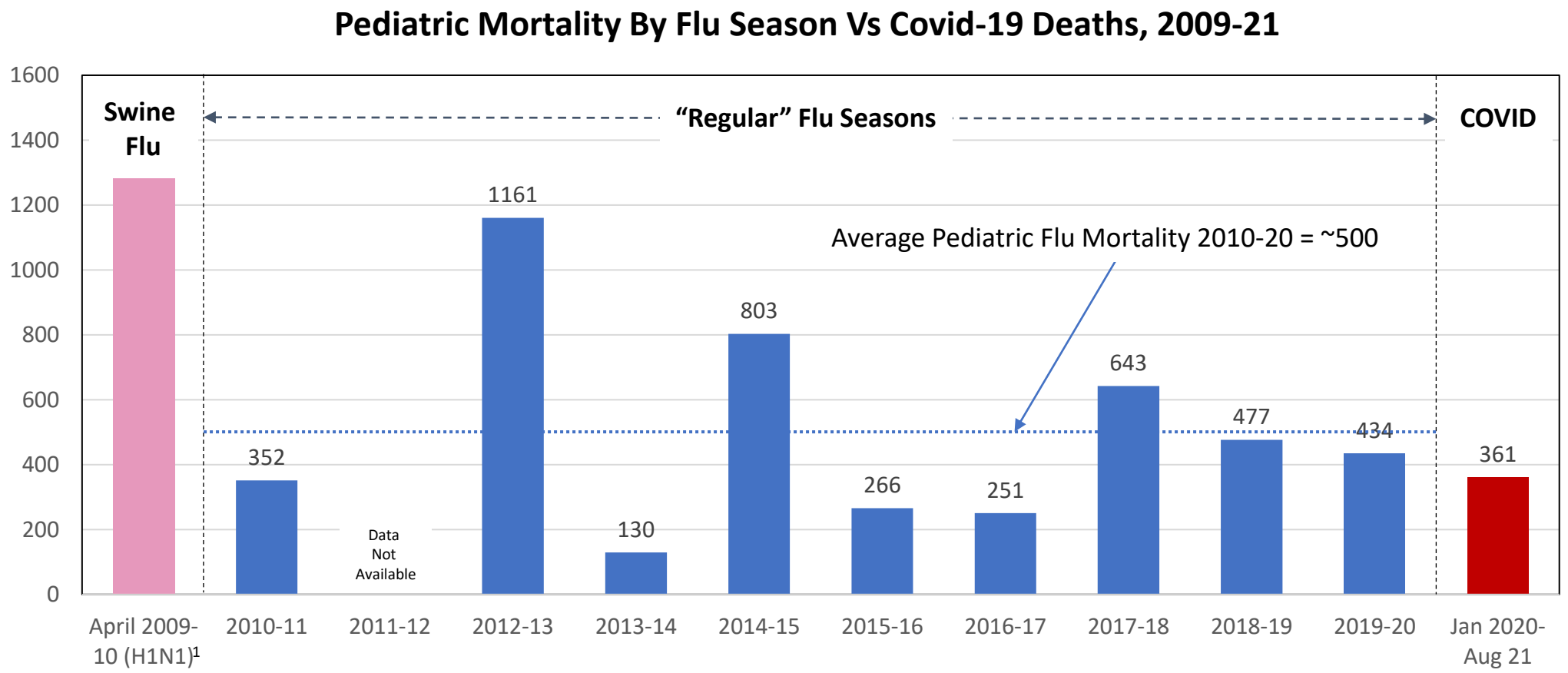
SOURCE: National Vital Statistics System, Mortality.

- Reminder (slide 4): 2020/21 Covid-19 deaths for 0-17 years: 332 across 15 months ➔ 156[1] in 12-19 age group ➔ **125 over 12 months**

For high schoolers, Covid-19 deaths account for ~0.8% of all deaths (125 / 16,375)[2]
Suicide risk is over 10 times higher (1,800 vs 125)

Notes: [1]Assumes deaths are equally weighted by age; [2]does not account for population growth since 2006.

Covid-19 Mortality for Age <18 Is Lower Than In Five Of The Last 10 Flu Seasons, Well Below 2010-20 Average, & Substantially Lower Than In the H1N1 (Swine Flu) Season

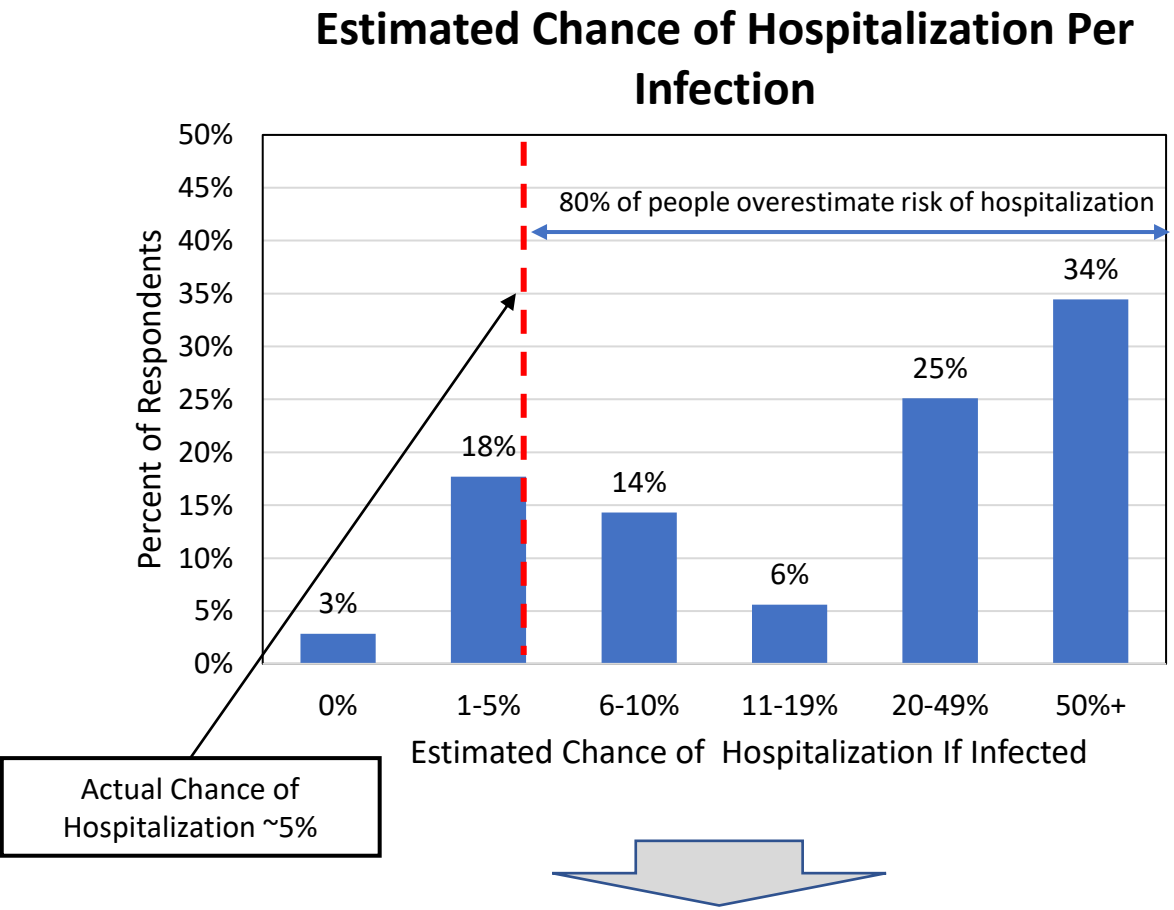


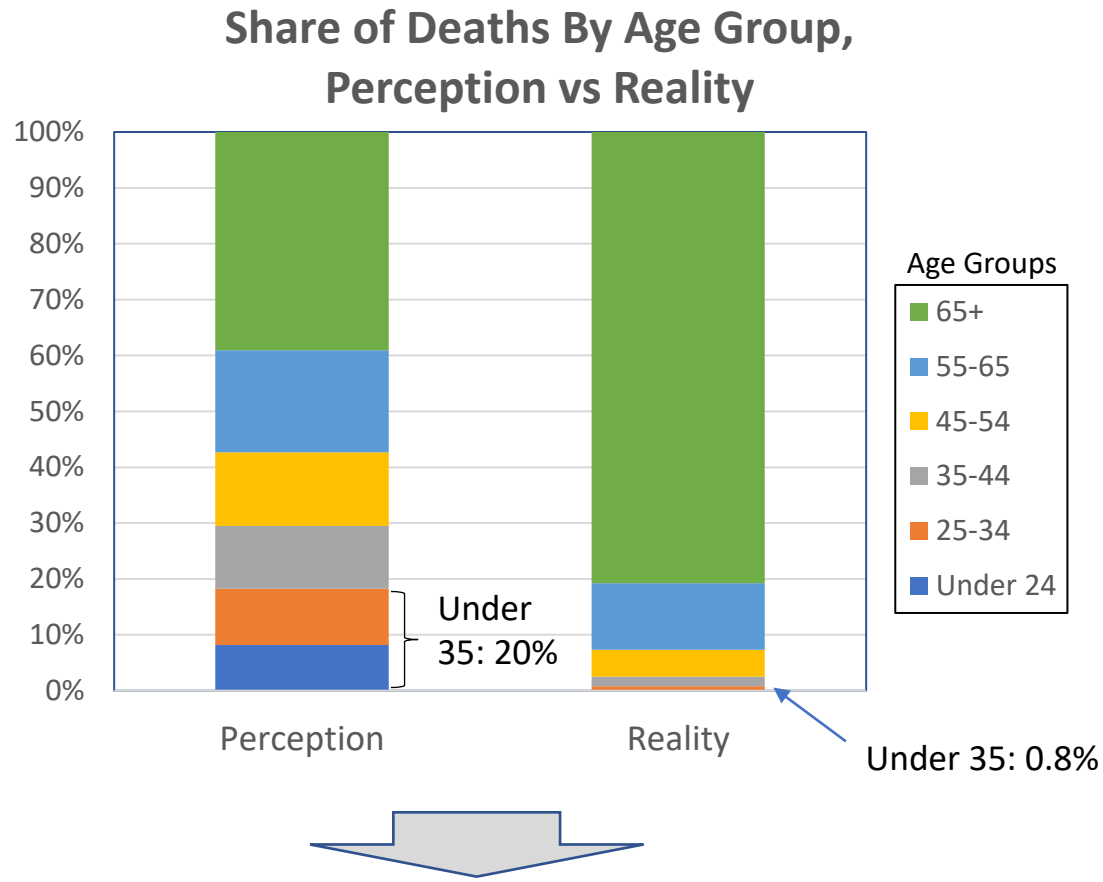
Note: time period is more than 12 months

Sources:

- [1] https://academic.oup.com/cid/article/52/suppl_1/S75/499147
- Others: https://www.cdc.gov/flu/about/burden/past-seasons.html

Risk Perception vs Reality: Most People Vastly Over-Estimate The Risks From Covid-19, And Believe More Young People Are Impacted Than Is Actually The Case





80% of people greatly overestimate the risk of hospitalization from Covid-19; 34% believe there is a greater than 50% chance of hospitalization vs reality of 5%

People believe 20% of Covid-19 deaths have been in the under 35s, when the real number is 0.8%

Note: Chance of hospitalization from Covid-19 varies very substantially with age: over 65 - 22%, under 18 – 0.8% (Source: CDC Disease Burden)
Source: Franklin Templeton-Gallup Economics of Recovery Study n=35,000), December 2020

Covid-19 Risks - Summary

- Most people vastly over-estimate the risks from Covid-19, and believe more young people are impacted than is actually the case.
- Overall Covid-19 risk is very strongly driven by age and comorbidities, notably obesity.
- Any analysis of risks / benefits that is not structured by a) relatively small age cohorts (e.g. age ranges of 5-10 years[1]) and b) people with vs without relevant comorbidities, is potentially very misleading.
- Risks of serious illness or death from Covid-19 for healthy <18 y.o. are very, very small - absolute risk of death for healthy child/young adult is **maybe 1 in 300-500k[2]**.
- Covid-19 has accounted for less than 1% of deaths of 12-19 year-olds in US.
- Risk of suicide ~10 times greater than risk of Covid-19 for 12-19 year-olds in US.

Note: [1]Why the CDC continues to aggregate data for large age ranges (e.g. 18-49 age group in planning scenarios) is a mystery to the author
[2]Assumes 15-25% of deaths in this age range are attributed to people without known co-morbidities (i.e. assumed healthy)

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  - Hospital Admissions In Younger Age Groups
  - Long Covid

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  - Pediatric Vaccine Trial Design – Brief Observations
  - Risk/Benefit For Children / Young Adults

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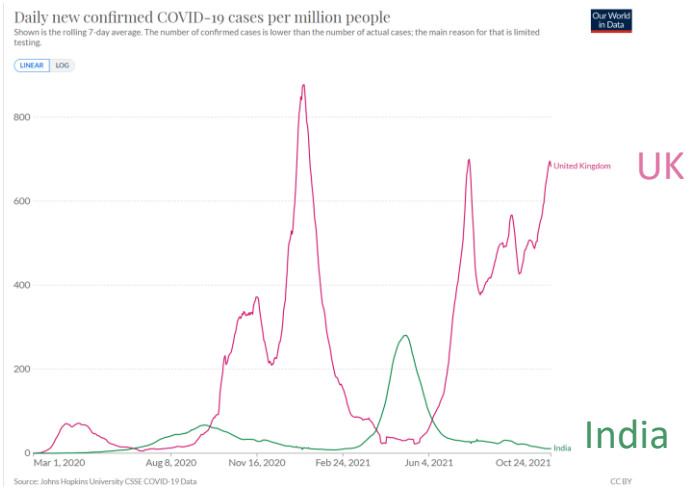
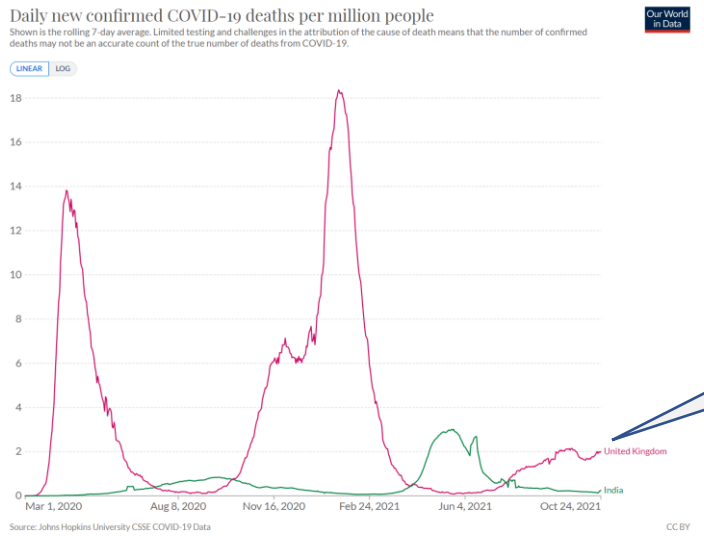
Have Things Changed With Delta? UK Data Suggests Not Much; Likely More Transmissible, But Case Fatality Is Potentially Lower

Delta came and went in India pretty quickly. UK cases remain high (but testing is higher than last year)



UK

India



Deaths in UK are not following Q1 pattern (NB possible impact of vaccines)

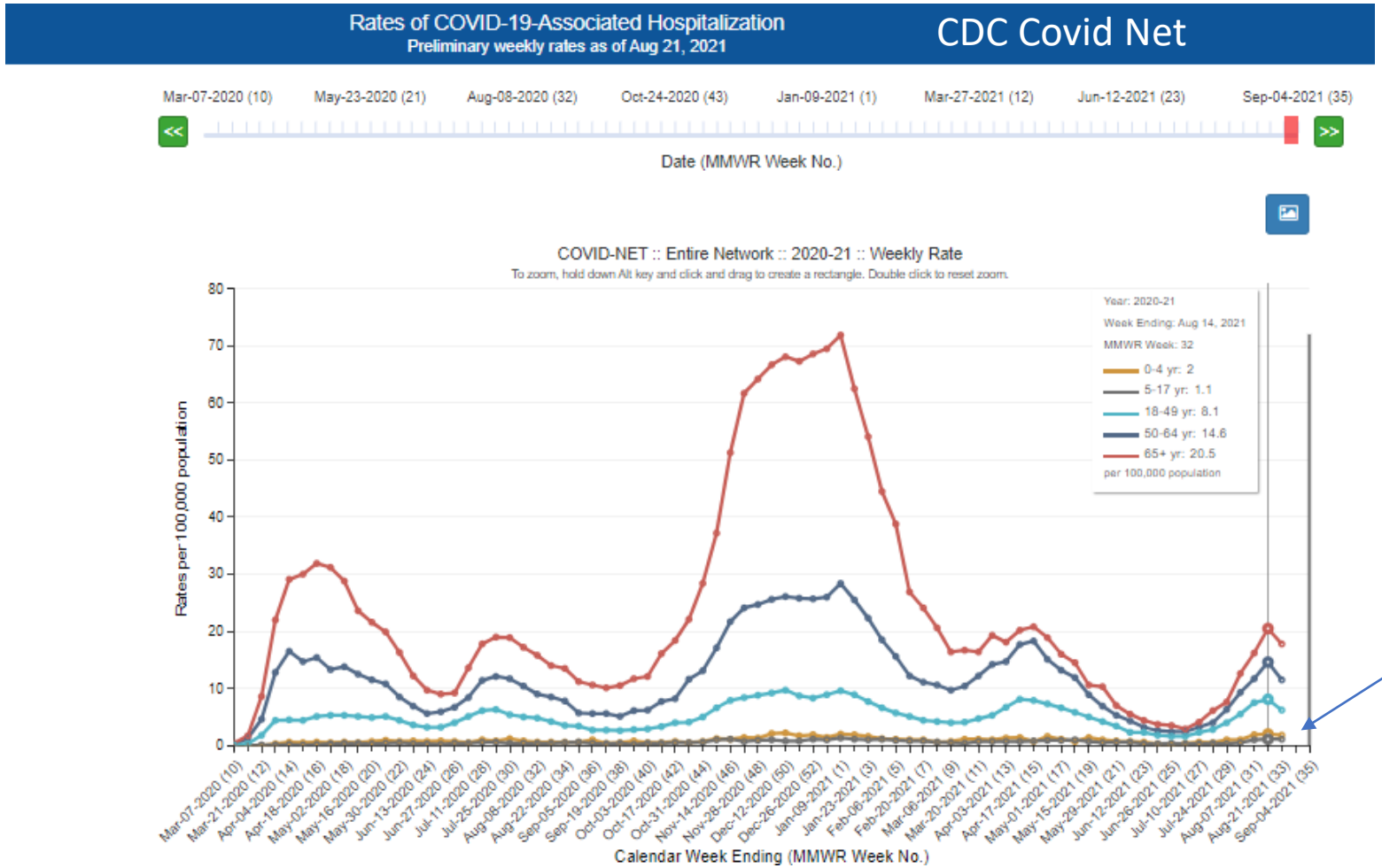
Public Health England Data on Delta Shows Low/Similar Case Fatality

Case Fatality (for patients with ER visit or hospitalization)

- Overall case fatality:
  - Alpha: 1.1%
  - Delta: 0.5%[2]
- Delta case fatality under 50s:
  - Vaccinated: 0.026%
  - Unvaccinated: 0.028%
- Note: different testing policies for vaxx vs unvaxx, time series effects may confound data

Sources: Public Health England Technical Briefing, July 21, 2021
[2]Public Health England Technical Briefing 26, Oct 22, 2021
Note: Case Fatality Rate is NOT the same as infection fatality rate.

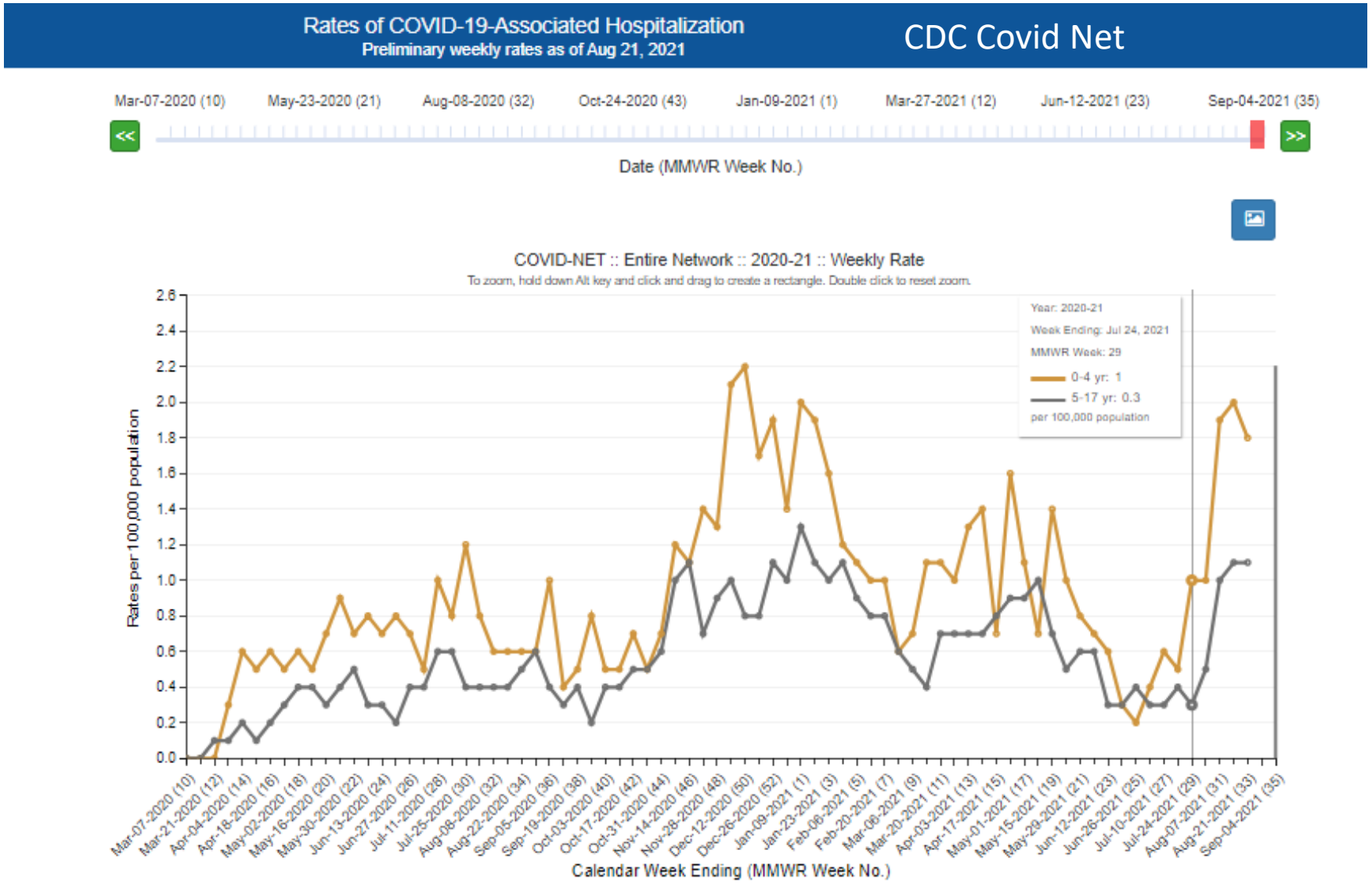
News Reports of Major Increases in Hospitalizations In The Young With Delta Are Not Supported By The Data. Hospitalizations Are Rising Overall With The Seasonal Covid-19 Outbreak But…



0-4, and 5-17 year olds

Source: https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html

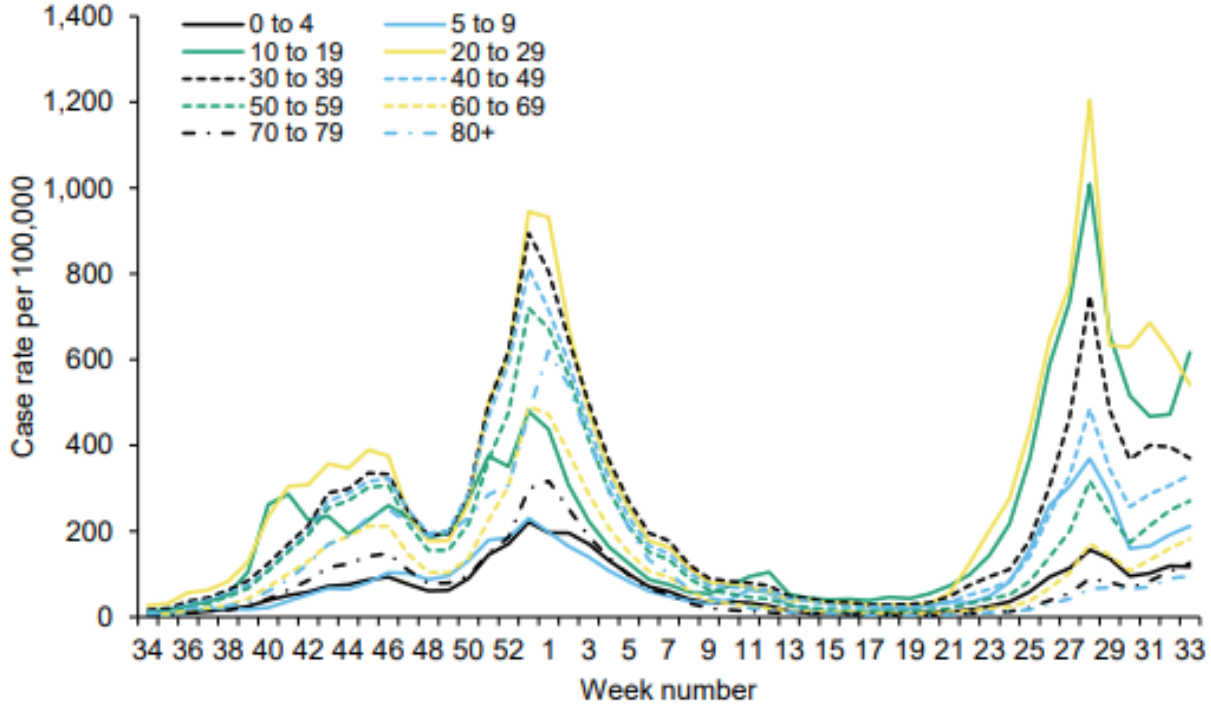
Zooming In, For 0-4 and 5-17, Rates of Hospitalization Are No Higher Than 2020/21 Winter Season

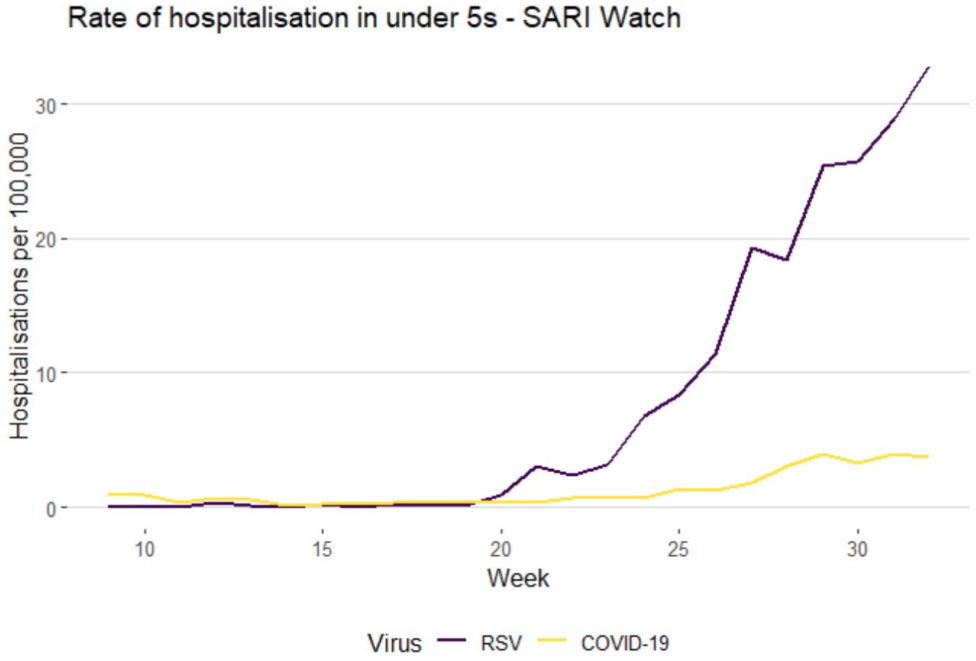


Source: https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html

In UK, Where Delta Dominates, Confirmed Covid-19 Cases Are At Similar Levels to Winter, While Hospitalization in Under 5s is Low For Covid-19, But Soaring For RSV Which Is Impacting Hospital Capacity

Figure 5: Weekly confirmed COVID-19 case rates per 100,000, tested under Pillar 1 and Pillar 2, by age group





US data re RSV appears similar, but robust datasets and trends are harder to find than for UK.

Andrew Bostom, MD, MS @andrewbostom · Aug 31

STOP the unwarranted pediatric delta hysteria in New England: As of HHS update 8/31/21, 8am, there are ZERO confirmed pediatric C19 hospitalizations in CT,RI,VT, & NH, & only 4 in NE region. MA=3; ME=1 beta.healthdata.gov/dataset/COVID-...

Note: UK Data is generally more complete and robust than US where the healthcare system is more fragmented by state and across insurers.

Source: National flu and COVID-19 surveillance reports: 2021 to 2022 season - GOV.UK (www.gov.uk)

Long Covid: CDC Admits “Knowledge Is Still Limited”

- CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/post-covid-conditions.html
- July 9th 2021: CDC: “scientific knowledge is still limited about these effects…”

Background

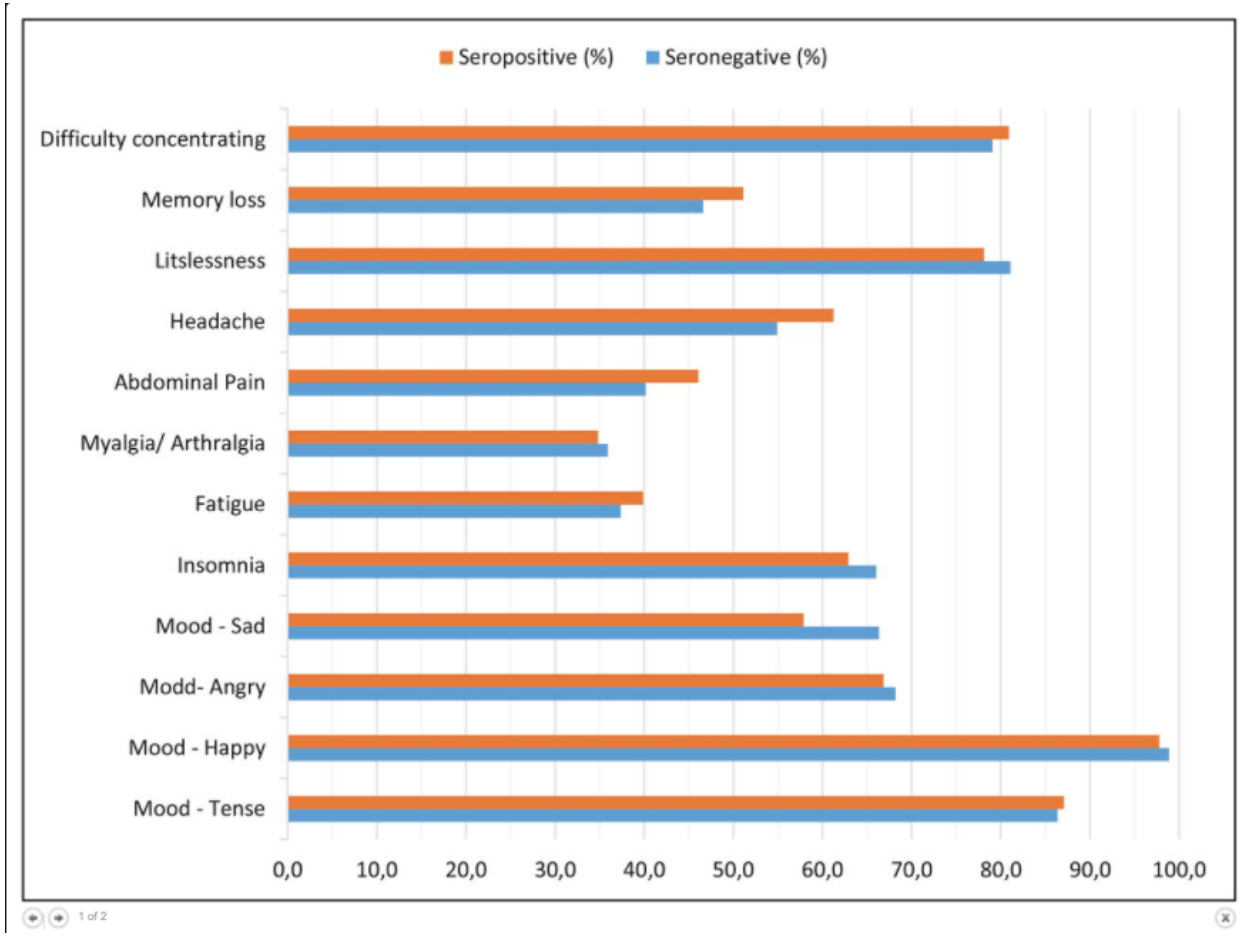
Some patients who have been infected with SARS-CoV-2, the virus that causes COVID-19, have new, recurring, or ongoing symptoms and clinical findings four or more weeks after infection, sometimes after initial symptom recovery. Post-COVID conditions can occur in patients who have had varying degrees of illness during acute infection, including those who had mild or asymptomatic infections. Medical and research communities are still learning about these post-acute symptoms and clinical findings.

Post-COVID conditions are being referred to by a wide range of names, including long COVID, post-acute COVID-19, long-term effects of COVID, post-acute COVID syndrome, chronic COVID, long-haul COVID, late sequelae, and others, as well as the research term post-acute sequalae of SARS-COV-2 infection (PASC). Although standardized case definitions are still being developed, in the broadest sense, post-COVID conditions can be considered a lack of return to a usual state of health following acute COVID-19 illness. Post-COVID conditions might also include development of new or recurrent symptoms that occur after the symptoms of acute illness have resolved.

Scientific knowledge is still limited about these effects, including what causes them and how often they occur. Interim terminology will be updated as more information becomes available.

On The Other Hand, German Study of Teenagers (n=1560) Showed No Difference In Typical "Long Covid" Symptoms Between Seropositive (IE Previously Infected) and Seronegative (IE Never Infected), Suggesting Much of Long Covid Is Psychological

Prevalence of neurocognitive, pain and mood symptoms in seronegative and seropositive study participants (Fisher's exact test: n = 1553, * significant at level 0·05)



- Source: Mental health of Adolescents in the Pandemic: Long-COVID-19 or Long-Pandemic Syndrome (n=1560); https://www.medrxiv.org/content/10.1101/2021.05.11.21257037v1

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The Ground Continues to Move On Vaccine Adverse Events (AEs)

The Early Days

- The vaccines are totally safe and effective
- Nuisance side effects only

September 2021

- Clear data that vaccines are not benign. Issues include:
  - VITT
  - Myocarditis, pericarditis
  - Guillain-Barre
  - VTE/PE
  - Troubling signals on heart attacks/ACS in 20-29 age group in Israel and elsewhere

Note: It is also now clear that vaccines do not prevent infection or transmission (see UK Public Health Data – October 2021)

Are We Sure The Spike Protein Is Benign / Harmless?

Circulation Research

RESEARCH LETTER

SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2

Yuyang Lei,* Jiao Zhang,* Cara R. Schiavon, Ming He, Lili Chen, Hui Shen, Yichi Zhang, Qian Yin, Yoshitake Cho, Leonardo Andrade, Gerald S. Shadel, Mark Hepokoski, Ting Lei, Hongliang Wang, Jin Zhang, Jason X.-J. Yuan, Atul Malhotra, Uri Manor,† Shengpeng Wang,† Zu-Yi Yuan,† John Y-J. Shyy†

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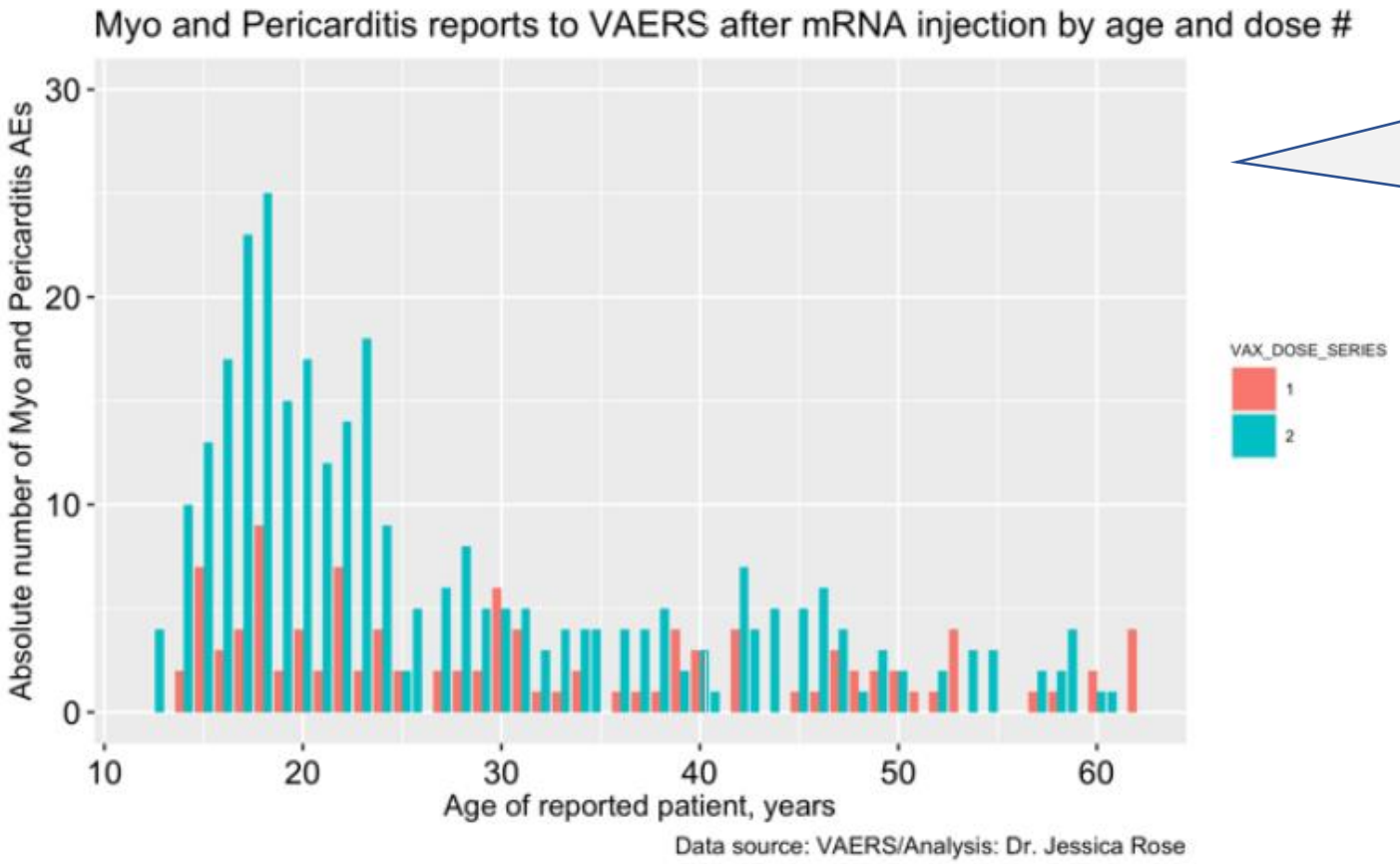
For Sources of Funding and Disclosures, see page 1324.

Circulation Research is available at www.ahajournals.org/journal/res

Evidence of Dose Dependent AEs From Analysis of VAERS Reports. Example: Myocarditis & Pericarditis

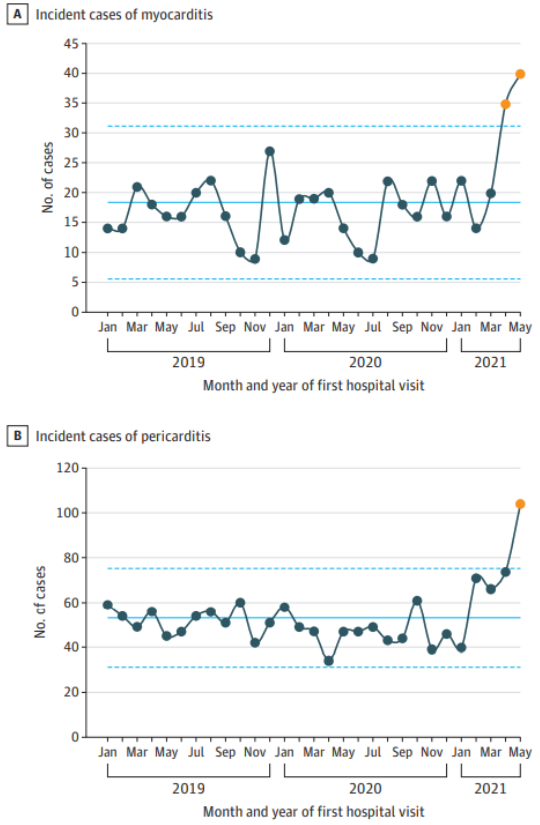


- Higher rates of reported Myocarditis & Pericarditis following second dose and concentrated in young people
- Data is consistent with CDC discussion on myocarditis

Note: I have validated this pattern with my own analysis of VAERS Wonder Data (see later slides)

US Study From 40 Large Hospitals Confirms Spike in Myocarditis & Pericarditis Cases Coincident With Vaccine Rollout

Figure. Monthly Number of Inpatient and Emergency Department Cases of Myocarditis and Pericarditis at 40 Hospitals in the Western US



- Spike in cases at time of vaccine rollout
- Note: NO trend in 2020 from Covid-19 infections

Table. Characteristics of Post–COVID-19 Vaccination Myocarditis and Pericarditis Cases[a] (continued)

Characteristics	Myocarditis (n = 20)	Pericarditis without myocarditis (n = 37)
Laboratory findings (highest value during hospital visit)		
ALT ≥50 U/L	1 (5)	2 (5.4)
AST ≥50 U/L	6 (30)	1 (2.7)
Creatinine ≥1.2 mg/dL	1 (5)	4 (10.8)
Hemoglobin <9 g/dL	0	0
White blood cell count ≥12 000/μL	3 (15)	8 (21.6)
Absolute neutrophils, median (IQR), $\times 10^9$/L	5 (3.5-7.5)	7 (5-8)
Absolute lymphocytes, median (IQR), $\times 10^9$/L	2 (1.5-2)	2 (1-2)
Platelets $<100\times10^3$/μL	0	0
Platelets $\geq400\times10^3$/μL	0	2 (5.4)
ESR ≥30 mm/h	0	5 (13.5)
Elevated troponin level	19 (95)	0
Temperature ≥38 °C	0	0
Bundle branch block	1 (5)	2 (5.4)
ST elevation	9 (45)	14 (37.8)
PR depression	0	7 (18.9)
Corrected QT interval, median (IQR), ms	444 (425-467)	425 (413-457)
Ejection fraction <50%	5 (25)	3 (8.1)

- 25% of myocarditis cases have ejection fraction of less than 50% - which is associated with an increase in long term cardiac complications

Source: jamanetwork.com Research Letter: Myocarditis and Pericarditis After Vaccination for COVID-19 - George A. Diaz, MD Guilford T. Parsons, MD, MS Sara K. Gering, BS, BSN Audrey R. Meier, MPH Ian V. Hutchinson, PhD, DSc Ari Robicsek, MD

Israel: Myocarditis Linked To Vaccine & New Evidence Shows Increase in Cardiac Arrest & ACS In Young People Associated With Vaccine Rollout

- In Israel, post vaccine myocarditis reported at rate of 1 in 3000-6000

Source: [Israel's Health Ministry confirms probable link between myocarditis, Pfizer vaccine | All Israel News]

- Increased Incidence of Heart Attacks & ACS In Young People Aligning With Vaccine Rollout

Israel 2021 (Prof. Retsef Levi – MIT Sloan): MDA Emergency calls:

- 35% increase in Cardiac arrests (20-29).
- 83.6% increase in Heart attacks (Women 20-29).

According to the study, this increase was correlated with mass vaccination.

Cardiac Arrest:

Sex	Age Group	Jan. 1st to May 31st: 2019 and 2020, average count	Jan. 1st to May 31st: 2021, count	Percent increase in incidence rate from "2019 and 2020" to "2021" (P-value)	Absolute change from "2019 and 2020" to "2021", n
Male	20-29	35	53	51.4 (P<0.05)	18
Male	30-39	64	84	31.3 (P=0.052)	20
Male	40-49	123	143	16.3 (P=0.152)	20
Female	20-29	13.5	13	-3.7 (P=0.917)	-0.5
Female	30-39	21	29	38.1 (P=0.181)	8
Female	40-49	56.5	75	32.7 (P=0.056)	18.5
All*	20-29	49	66	34.7 (P=0.061)	17
All*	30-39	85	113	32.9 (P<0.05)	28
All*	40-49	179.5	218	21.5 (P<0.05)	38.5

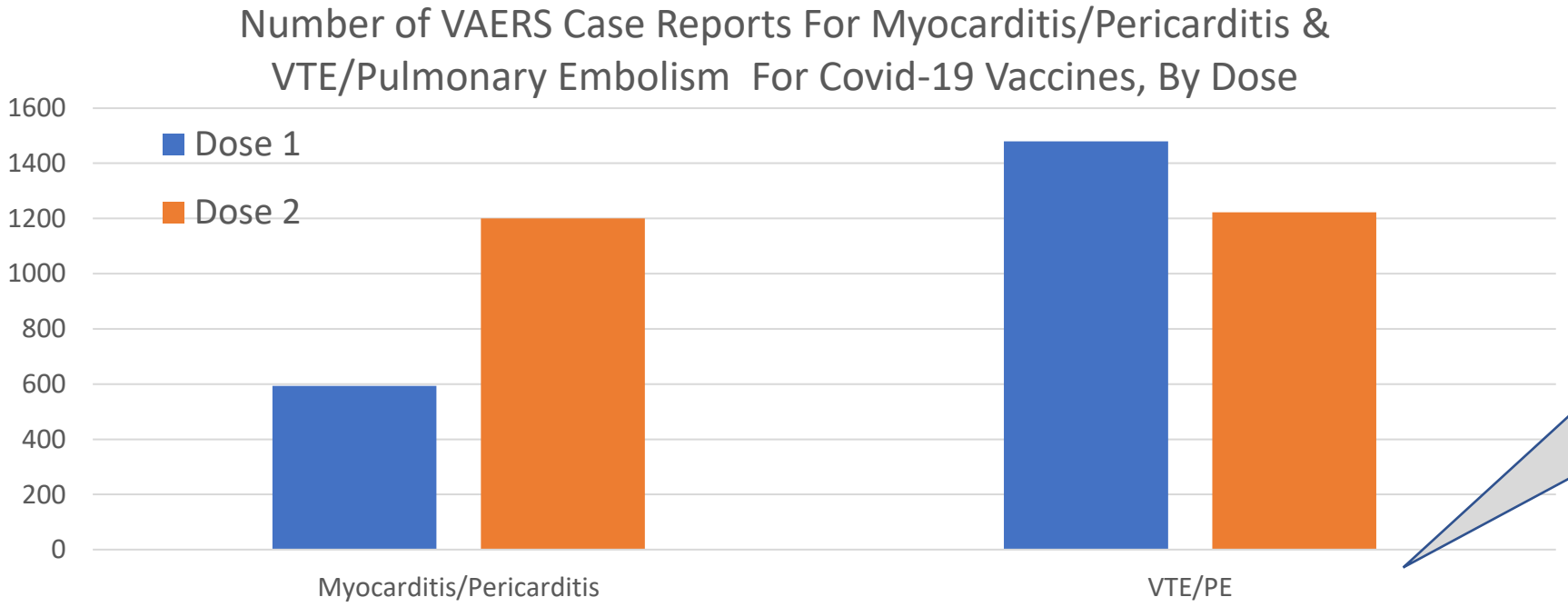
*Counts in the "All gender" category includes calls with missing gender variable values.

Acute Coronary Syndrome:

Sex	Age Group	Jan. 1st to May 31st: 2019 and 2020, average count	Jan. 1st to May 31st: 2021, count	Percent increase in incidence rate from "2019 and 2020" to "2021" (P-value)	Absolute change from "2019 and 2020" to "2021", n
Male	16-19	12	23	91.7 (P<0.05)	11
Male	20-29	104.5	137	31.1 (P<0.05)	32.5
Male	30-39	336	416	23.8 (P<0.001)	80
Male	40-49	911.5	1066	17.0 (P<0.001)	154.5
Female	16-19	2.5	6	140.0 (P=0.143)	3.5
Female	20-29	30.5	56	83.6 (P<0.001)	25.5
Female	30-39	99	152	53.5 (P<0.001)	53
Female	40-49	263.5	403	52.9 (P<0.001)	139.5
All*	16-19	14.5	29	100.0 (P<0.01)	14.5
All*	20-29	135	193	43.0 (P<0.001)	58
All*	30-39	436.5	568	30.1 (P<0.001)	131.5
All*	40-49	1181.5	1469	24.3 (P<0.001)	287.5

Source: [Levi Study - Google Drive]

Incidence of VTE & PE Are Higher Than Myocarditis/Pericarditis According To VAERS



Note: incidence rate of PE and thrombosis in VAERS for covid is reported to be 250-470 times higher than for VAERS reporting for other vaccines (data still unpublished).

Note: VAERS is well known to be an under-report of suspected AE. Estimates of under-report factor vary from 25-100. Best estimate of under-report factor from my/others review of data, and to align with Israeli data is ~30

Source: VAERS Wonder Search on 8/12/2021

Feb 21 Study Suggested Thrombocytopenia Following Vaccination Was Similar to Background Rates, **However**, It Was Based On VAERS Reports As At End of January, Which is a Huge Problem

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COMMENTARY

AJH WILEY

Thrombocytopenia following Pfizer and Moderna SARS-CoV-2 vaccination

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Cases of apparent secondary immune thrombocytopenia (ITP) after SARS-CoV-2 vaccination with both the Pfizer and Moderna versions have been reported and reached public attention. Public alarm was heightened following the death of the first identified patient from an intracranial hemorrhage, which was reported on the Internet, then in USA Today[1] and then in The New York Times.[2] Described below, we have collected a series of cases of very low platelet counts occurring within 2 weeks of vaccination in order to enhance our understanding of the possible relationship, if any, between SARS-CoV-2 vaccination and development of ITP with implications for surveillance and management.

Twenty case reports of patients with thrombocytopenia following vaccination, 17 without pre-existing thrombocytopenia and 14 with reported bleeding symptoms prior to hospitalization were identified upon review of data available from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), agencies of the U.S. Department of Health and Human Services (HHS) Vaccine Adverse Events Reporting System (VAERS), published reports,[3,4] and via direct communication with patients and treating providers. These cases were investigated as suspicious for new onset, post-vaccination secondary ITP; we could not exclude exacerbation of clinically undetected ITP. Search terms relating to "decreased platelet count", "immune thrombocytopenia", "hemorrhage", "petechiae", and "contusion" were utilized to identify cases reported in VAERS.

The reports describing 19 of 20 patients included age (range 22–73 years old; median 41 years) and gender (11 females and 8 males). Nine received the Pfizer vaccine and 11 received the Moderna vaccine. All 20 patients were hospitalized and most patients presented with petechiae, bruising or mucosal bleeding (gingival, vaginal, epistaxis) with onset of symptoms between 1–23 days (median 5 days) post vaccination. Platelet counts at presentation were available for all 20 cases with the majority being at or below 10×10^9/L (range $1–36 \times 10^9$/L; median 2×10^9/L).

One patient had known ITP in remission; another had mild–moderate thrombocytopenia in 2019 with note of positive anti-platelet antibodies, a third had previous mild thrombocytopenia (145×10^9/L) while a fourth had inherited thrombocytopenia with baseline platelet counts of $40–60 \times 10^9$/L. Three other patients had known autoimmune conditions including hypothyroidism, Crohns disease, or positive tests for anti-thyroglobulin antibodies. Treatment for suspected ITP was described in 15 of the cases, including corticosteroids n = 14, intravenous immune globulin (IVIG) n = 12, platelet transfusions n = 8, rituximab n = 2, romiplostim = 1, vincristine = 1, and aminocaproic acid (Amicar) n = 1; combination therapy was used in

Authors searched on 5 terms and identified 20 patients In VAERS as at End of January:

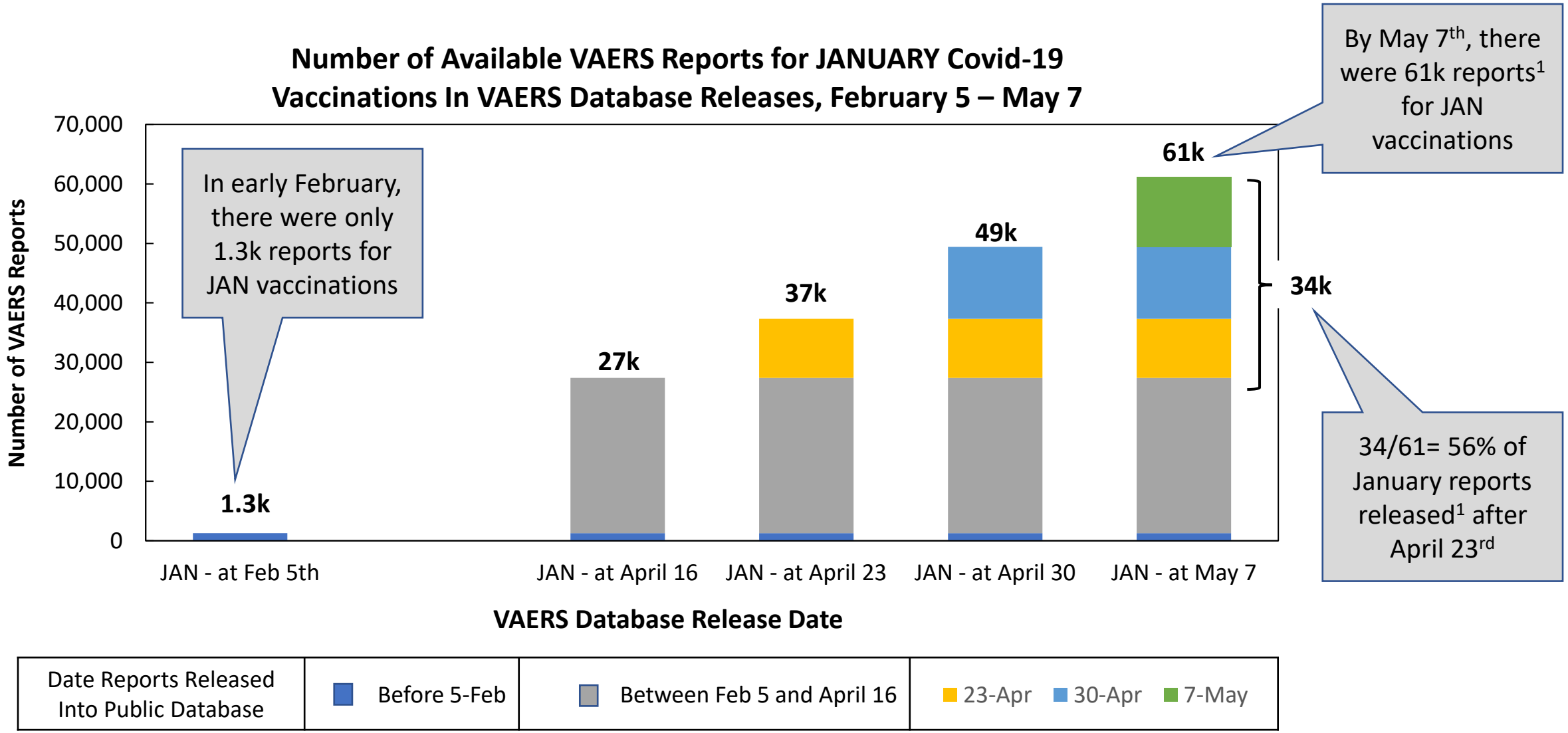
- Decreased platelet count
- Immune thrombocytopenia
- Hemorrhage
- Petechiae
- Contusion

Authors then related these cases to the 22m people vaccinated in January … "1 in 1 million…" and "similar to background rates"

Major Issues With This Study

1) VAERS was massively backlogged at end January – see next slide
2) They did not examine age stratification of covid risks
3) They did not account for VAERS under-reporting

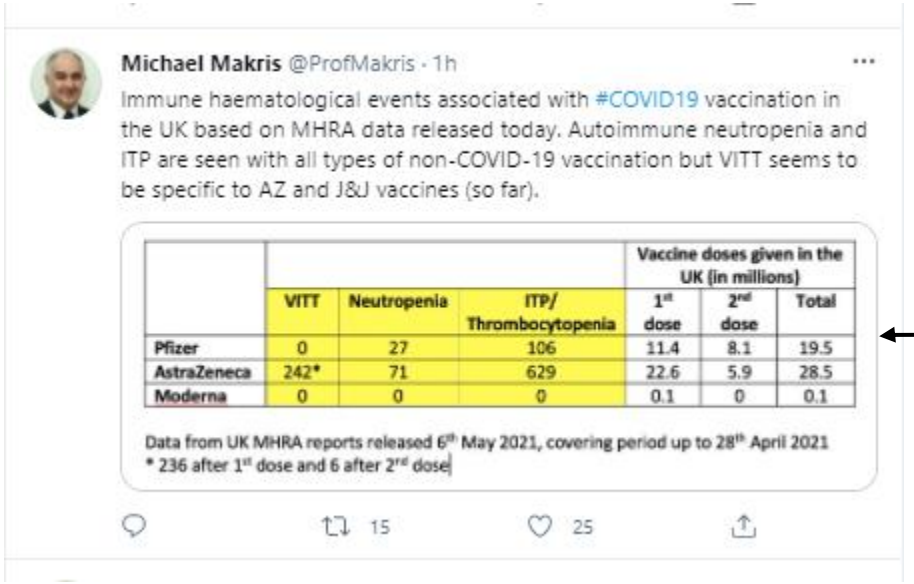
VAERS Was Massively Backlogged When They Did Their Study. At End January, There Were Only 1.3k Cases In VAERS for January Vaccinations, On May 7th There Were 61k for January Vaccinations (Most Reports Received In Jan and Not Processed Until Later)



Note: [1]45k of these 61k reports were received by VAERS in January - they just took months to process.
Source: VAERS databases downloaded each week from https://vaers.hhs.gov/data.html

VAERS Wonder Database Search At May 6th, Revealed **At Least** 10 Times As Many Cases With Same Search Terms As Feb Study – A Level More In Line With UK Case Reporting – And Well Above Baseline Levels

	Number of Cases in 2021, April 30th VAERS Dataset (Wonder Search)	
Search Terms	Dec Vaxx Date	Jan Vaxx Date
Decreased Platelet Count	20	103
Immune Thrombocytopenia	5	22
Hemorrhage	10	36
petechiae	I did not search on petechiae or contusion due to time constraints as other 3 search terms already showed many more cases than paper	
contusion		
Total	35	161
	Overall Total	196



~10 times as many cases as February paper => 1 in 100k, which is similar to UK data

What if?		
If VAERS underports by factor of…	10	50
Number of cases	1960	9800
Odds of event: 1 in …	11,224	2,245

Allowing for VAERS under-reporting, cases could be quite common (and a significant concern for groups at low covid risk)

Note: It is well recognized that VAERS does not capture all potential events, with some estimating it only captures 1% of potential cases.
Source: VAERS Wonder databases searches. https://vaers.hhs.gov/data.html

Oxford Study Suggested mRNA & AZ-Oxford Vaccines Had Similar Risks of Blood Clotting

Risk of rare blood clotting higher for COVID-19 than for vaccines

RESEARCH | HEALTH | CORONAVIRUS | COVID-19 VACCINE

COVID-19 leads to a several-times higher risk of cerebral venous thrombosis (CVT) blood clots than current COVID-19 vaccines.

Researchers at the University of Oxford have today reported that the risk of the rare blood clotting known as cerebral venous thrombosis (CVT) following COVID-19 infection is around 100 times greater than normal, several times higher than it is post-vaccination or following influenza.

The study authors, led by Professor Paul Harrison and Dr Maxime Taquet from Oxford University's Department of Psychiatry and the NIHR Oxford Health Biomedical Research Centre, counted the number of CVT cases diagnosed in the two weeks following diagnosis of COVID-19, or after the first dose of a vaccine. The then compared these to calculated incidences of CVT following influenza, and the background level in the general population.

They report that CVT is more common after COVID-19 than in any of the comparison groups, with 30% of these cases occurring in the under 30s. Compared to the current COVID-19 vaccines, this risk is between 8-10 times higher, and compared to the baseline, approximately 100 times higher.

The breakdown comparison for reported cases of CVT in COVID-19 patients in comparison to CVT cases in those who received a COVID-19 vaccine is:

- In this study of over 500,000 COVID-19 patients, CVT occurred in 39 in a million patients.
- In over 480,000 people receiving a COVID-19 mRNA vaccine (Pfizer or Moderna), CVT occurred in 4 in a million.
- CVT has been reported to occur in about 5 in a million people after first dose of the AZ-Oxford COVID-19 vaccine.
- Compared to the mRNA vaccines, the risk of a CVT from COVID-19 is about 10 times greater.
- Compared to the AZ-Oxford vaccine, the risk of a CVT from COVID-19 is about 8 times greater.

However, all comparisons must be interpreted cautiously since data are still accruing.

Caution: covid-19 patients in this study were hospitalized and so this VASTLY OVERSTATES covid-19 risks relative to general population, and in particular relative to younger populations

"mRNA & AZ-Oxford vaccines have similar risk levels" (+/-20%) – stated as lower than covid infection in populations examined (but see caution above)

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  - **Pediatric Vaccine Trial Design – Brief Observations**
  - Risk/Benefit For High School Age
- Conclusion

Pediatric Covid-19 Vaccine Trial Is Small & Would Not Pick Up Low Frequency Adverse Events/Safety Issues

EUA Amendment Request includes data from ~3.1k vaccinated 5-11 years olds, with 2+ months of safety data available for 1,518 children and median of 2.4 weeks of safety data for another 1,519 patients

5 EUA AMENDMENT REQUEST FOR THE PFIZER-BIONTECH COVID-19 VACCINE FOR USE IN CHILDREN 5-11 YEARS OF AGE

On October 6, 2021, Pfizer and BioNTech submitted a request to amend this EUA to include use of a 2-dose primary series of the Pfizer-BioNTech COVID-19 Vaccine (10 µg each dose, administered 3 weeks apart) in individuals 5-11 years of age for active immunization to prevent COVID-19 caused by severe acute coronavirus 2 (SARS-CoV-2).

The request is accompanied by safety data from 1,518 BNT162b2 and 750 placebo (saline) Phase 2/3 participants 5-11 years of age in ongoing clinical study, C4591007, of which a total of 1,444 (95.1%) had safety follow-up ≥2 months after Dose 2 at the time of a September 6, 2021 data cutoff, and data from an additional 1,591 BNT162b2 and 788 placebo participants with a median duration of follow-up of 2.4 weeks post-Dose 2 at the time of an October 8, 2021 data cutoff. Vaccine effectiveness in children 5-11 years of age was inferred by immunobridging SARS-CoV-2 50% neutralizing antibody titers (NT50, as assessed by SARS-CoV-2 mNG microneutralization assay) among C4591007 study participants 5-11 years of age following completion of a primary series to antibody titers of those of young adults 16-25 years of age who received two doses of 30 µg BNT162b2 in study C4591001. Efficacy against COVID-19 disease was assessed descriptively in study C4591007 participants 5-11 years of age.

Source: FDA Briefing Document, Vaccines and Related Biological Products Advisory Committee Meeting October 26, 2021
https://www.fda.gov/media/153447/download

Modelling In EUA Amendment Request Estimates That If 1 Million Children Are Vaccinated It Will Save 1-3 Lives, But Does Not Assess Benefits vs Risks In Higher Risk vs Lower Risk Children

Table 14. Model-Predicted Benefit-Risk Outcomes of Scenarios 1-6 per One Million Fully Vaccinated Children 5-11 Years Old

	Benefits				Risks			
Sex	**Prevented COVID-19 Cases**	**Prevented COVID-19 Hospitalizations**	**Prevented COVID-19 ICU Admissions**	**Prevented COVID-19 Deaths**	**Excess Myocarditis Cases**	**Excess Myocarditis Hospitalizations**	**Excess Myocarditis ICU Admissions**	**Excess Myocarditis Deaths**
Males & Females								
Scenario 1	45,773	192	62	1	106	58	34	0
Scenario 2	54,345	250	80	1	106	58	34	0
Scenario 3	2,639	21	7	0	106	58	34	0
Scenario 4	58,851	241	77	1	106	58	34	0
Scenario 5	45,773	192	62	1	106	58	34	0
Scenario 6	45,773	192	62	1	53	29	17	0

Assuming the modeling is right…….

It is not unreasonable to think that prevented hospitalizations, ICU admissions and deaths will be in high-risk groups with comorbidities (e.g. obese, immuno-compromised etc)

However, risks are relevant for all children, including the healthy. (Note: myocarditis is the only risk modeled & included in table)

Source: FDA Briefing Document, Vaccines and Related Biological Products Advisory Committee Meeting October 26, 2021
https://www.fda.gov/media/153447/download

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Risk Benefit For A Healthy Child / Young Adult Does Not Support Taking A Covid-19 Vaccine At This Point

Assessment of Benefits vs Risk for Healthy Child / Young Adult

	From Covid-19 (if infected)	From Vaccine

Benefits	• Best to avoid, but will obtain natural immunity which is at least as good as vaccines and longer lasting	• Potential absolute risk reduction is tiny:
		  • Improving chance of survival from 99.999% to 99.999%
		  • Severe disease, hospitalization and death: some reduction in risk expected (but not proven by trials), but absolute risk is very small
		• Reduced risk of infection/transmission: likely lower for a while (though not proven by trials), but vaccine efficacy against infection/transmission wanes over a few months

Risks	• 1 in 300,000/500,000 risk of death[1] • Some risk of hospitalization[2] • Long term complications: possible but generally associated with severe disease and quality of evidence is low	Short Term • Risk of myocarditis (esp. males): 1 in 3000-6000 (Israel, VAERS) • VTE/PE: higher than myocarditis (VAERS) • Potentially increased risk of heart attacks or ACS (Israel) • Thrombocytopenia: 1 in 2,500-5,000 (VAERS, EU reporting) • Others…data still emerging. • Nuisance side effects: 18% of recipients have grade 3 or 4 AE (fatigue, myalgia) that interferes with daily life Long Term Risks • From spike protein: unknown • From lipid nanoparticles, other adjuvants: unknown

Note: [1]Even at 1 in 100,000 for healthy young adult, the risk benefit calculus is similar
[2]Have not seen good data on hospitalization that accounts for age and comorbidities

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Conclusions

- Society has lost its sense of perspective with respect to Covid-19 in general, and in particular with respect to Covid-19 in kids.
- The kids will be all right (from Covid-19) and they should not be living in fear.
- We should be more concerned about childrens' mental health than about Covid-19.
- The balance of benefits vs risks does NOT support vaccinating healthy children.
  - Vaccine benefits will heavily be concentrated in the obese / otherwise co-morbid.
  - Vaccine risks are relevant for all children, including the healthy.

Consider Vaccinating Children At Significant Risk (I.E. Those With Relevant Comorbidities), Leave Healthy Children Alone