Andrew Bostom, MD, MS: Background

- 40+ year career as an allied health professional (physical therapist & exercise physiologist), then a physician (since 1990), both a clinician (cardiac rehab/CVD prevention), & an academic, incl 24-years as Brown Medical School faculty
- Trained epidemiologist & clinical trialist, who for 10-years ran one of the largest clinical trials ever based in RI, involving kidney transplant recipients from academic centers across the U.S., & also in Canada & Brazil
- 128 scholarly medical publications (113 peer-reviewed), largely focused on epidemiology & clinical trials.
- Has testified as an expert witness in lawsuits pertaining to the Covid-19 pandemic—specifically on vaccine and mask mandates—while researching and writing extensively on those subjects. Recently contributed to an amicus curiae brief to the United States Supreme Court for the covid-19 vaccine mandate case NFIB v. Dept. of Labor, OSHA, et al./Ohio v. Dept. of Labor, OSHA, et al., which was cited by the Washington Post.



Andrew Bostom, MD, MS receives \$19.6 million federal grant
Multi-site trial aims to reduce cardiovascular disease in kidney transplant recipients



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Cochrane Database of Systematic Reviews Review - Intervention

Interventions for lowering plasma homocysteine levels in kidney transplant recipients

Amy Kang, Sagar U Nigwekar, Vlado Perkovic, Satyarth Kulshrestha, Sophia Zoungas, Sankar D Navaneethan, Alan Cass, Martin P Gallagher, Toshiharu Ninomiya, Giovanni FM Strippoli, Meg J Jardine Authors' declarations of interest

Version published: 04 May 2015 Version history

https://doi.org/10.1002/14651858.CD007910.pub2 &

The literature search yielded a total of 359 records (Figure 1). Of these, 44 were reviewed in full text. One study (13 reports) was identified that met our inclusion criteria (FAVORIT Study 2006).







medRxiv preprint doi:

https://doi.org/10.1101/2021.01.26.21250557; this version posted January 29, 2021.

Covid-19 positive test cycle threshold trends predict covid-19 mortality in Rhode Island

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<u>Abstract</u>

The cycle thresholds (Cts) at which reverse transcriptase polymerase chain reaction (rtPCR) tests for covid-19 become positive are intimately associated with both viral load, and covid-19 infectiousness (i.e., ability to culture live virus). Clinical data indicate lower Cts—and hence larger viral loads—independently predict greater covid-19 mortality when patients are hospitalized for symptomatic covid-19 pneumonia. We merged public covid-19 mortality data from the Rhode Island Department of Health with a de-identified dataset of n=5036 positive rtPCR test Cts from the Rhode Island Department of Health State Laboratory to explore the potential relationship between positive covid-19 test Ct distribution trends, and covid-19 mortality in the state of Rhode Island, from March through early to mid-June, 2020. Mean daily covid-19 positive test Ct data were compiled, and 7-day rolling average covid-19 mortality was offset by 21-days, given the lag between infection and death. We divided the Ct data into three strata, >32, 28-32, and <28, which were operationally defined as "not infectious," "maybe infectious," and "infectious," respectively. Between late March and June, mean daily Ct values rose linearly (R-squared=0.789) so that by early June, as the covid-19 pandemic ebbed in severity, all means reached the noninfectious (Ct >32) range. Most notably, this May-June trend for Cts was accompanied by a marked, steady decline in Rhode Island's daily covid-19 mortality. Our results suggest that monitoring, and public reporting of mean population covid-19 test Cts over time is warranted to gauge the vacillations of covid-19 outbreak severity, including covid-19 mortality trends.

"The cycle thresholds (Cts) at which reverse transcriptase polymerase chain reaction (rtPCR) tests for covid-19 become positive are intimately associated with both viral load, and covid-19 infectiousness (i.e., ability to culture live virus). An rtPCR covid-19 assay system developed at the Harvard University/ Massachusetts Institute of Technology Broad Institute, currently determining covid-19 "positivity" at 108 northeastern universities—including Rhode Island's major colleges—described this exponential relationship: '...the Ct values correlated strongly with the logarithm of (covid-19) RNA concentration (R-squared > 0.99), with the observed range from Ct = 12 cycles to Ct = 38 cycles corresponding to viral loads ranging from ~1.9 billion copies/mL to 8 copies/mL, respectively.'"

SARS-CoV-2/Covid-19 Infection Fatality Rates (IFR)*: Critical Impact of Age

(*covid-19 deaths/total infected by SARS-CoV-2 antibody seroprevalence data)

Age group (years)	IFR
≥70, overall	4.5%
(incl nursing homes)	
≥70, community dwelling	2.9%
When >85=5%	1.2%
When >85=10%	1.8%
When >85=20%	3.9%
0-69, overall	0.1%
60-69	0.5%
50-59	0.1%
40-49	0.04%
30-39	0.01%
20-29	0.002%
0-19	0.0003%

- ≥ 70, overall, confers 45X the risk of 0-69, overall
- ≥ 70, overall confers 15,000X the risk of 0-19
- *Since omicron IFR for 0-19, esp., is 1/3 of the 0.0003% determined here

Reminders:

 $\rightarrow \rightarrow$ 94% of the world's population is <70

 $\rightarrow \rightarrow$ 86% of the world's population is <60

IFR for all ages, combined, ~0.25-0.30%

References:

Axfors C, **loannidis JPA**. Infection fatality rate of COVID-19 in community-dwelling elderly populations. Eur J Epidemiol. 2022 Mar;37(3):235-249. doi: 10.1007/s10654-022-00853-w. Epub 2022 Mar 20. PMID: 35306604; PMCID: PMC8934243

Pezzullo AM, Axfors C, Contopoulos-Ioannidis DG, Apostolatos A, **Ioannidis JPA**. Age-stratified infection fatality rate of COVID-19 in the non-elderly population. Environ Res. 2023 Jan 1;216(Pt 3):114655. doi: 10.1016/j.envres.2022.114655. Epub 2022 Oct 28. PMID: 36341800; PMCID: PMC9613797.

"Statistical and Numerical Errors Made by the US Centers for Disease Control and Prevention (CDC) During the COVID-19 Pandemic (March 7, 2023)."*

"94% of the errors we identified that pertained to children alone exaggerated their COVID-19 risks. All 13 errors involving COVID-19 mortality risks were exaggerations of pediatric deaths. This is a group that has a COVID-19 infection fatality ratio of at least 1000-fold [at least] less than older groups, and the CDC's errors have likely led the public to believe children's risks are higher than they truly are in non-erroneous data."

Lead author data analyst Kelly Krohnert provided this salient example:

"For months, the CDC reported that an estimated 4.0% of Covid deaths were among children, when the actual percentage based on their initial estimates was 0.04%." (i.e., 100-fold in excess of actual)

References

*Krohnert, Kelley and Haslam, Alyson and Hoeg, Tracy Beth and Prasad, Vinay. "Statistical and Numerical Errors Made by the US Centers for Disease Control and Prevention During the COVID-19 Pandemic (March 7, 2023)." https://srn.com/abstract=4381627 or http://dx.doi.org/10.2139/ssrn.4381627

Kelly Krohnert: https://twitter.com/KelleyKga/status/1638919628494626816?t=V fnR2ytndg7giyR5-NMrQ&s=09

Low Burden of Covid-19 Hospitalizations in Children

- U.S. Pediatric Hospitalizations Were Fraught With Overclassification When Even More Virulent Strains Were Prevalent (in 2020, to early 2021)
- 40-45% of "covid-19" pediatric hospitalizations were incidental (i.e., "+ tests" but admitted for another cause)

The Swedish Pediatric/Primary School Counter-Example, Even During Most Virulent "First Wave," i.e., Spring, 2020, When Primary Schools Remained Open, With In-Class Education, & No Masks:

- —15 children (out of 1,951,905) were hospitalized, 4 of whom had serious, chronic comorbidities
- ZERO deaths in children

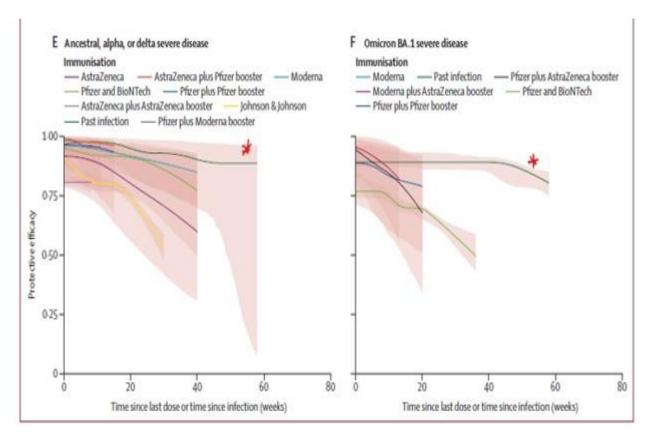
References

Kushner LE, et al. "For COVID" or "With COVID": Classification of SARS-CoV-2 Hospitalizations in Children. *Hosp Pediatr*. 2021; doi: 10.1542/hpeds.2021-006001.; Webb NE and Osburn TS. Characteristics of Hospitalized Children Positive for SARS-CoV-2: Experience of a Large Center. *Hosp Pediatr*. 2021; doi: 10.1542/hpeds.2021-005919.; https://ridoh-covid-19-response-hospital-data-rihealth.hub.arcgis.com/; https://www.andrewbostom.org/wp-content/uploads/2022/08/APRA-request-Only-15-Peds-Hosps-Feb-13-to-June-4.pdf; https://www.andrewbostom.org/2022/12/rsv-accounted-for-90-of-rhode-island-pediatric-tripledemic-hospitalizations-in-october-and-november/; Ludvigsson JF, Engerström L, Nordenhäll C, Larsson E. Open Schools, Covid-19, and Child and Teacher Morbidity in Sweden. N Engl J Med. 2021 Feb 18;384(7):669-671. doi: 10.1056/NEJMc2026670. Epub 2021 Jan 6. PMID: 33406327; PMCID: PMC7821981.

Naturally-Acquired Immunity to SARS-CoV-2 is More Robust & Enduring Than Covid-19 Vaccine-Acquired Immunity, in Both Adults & Children

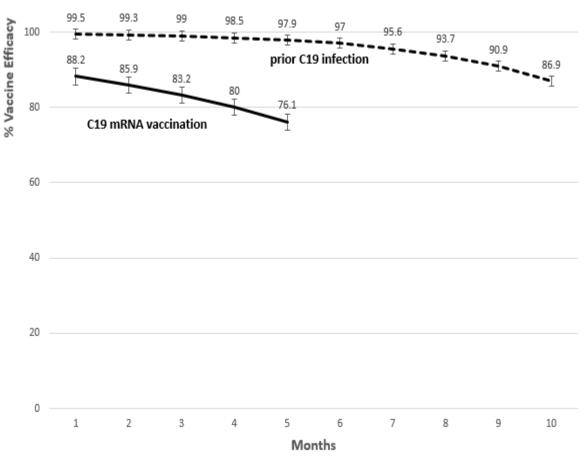
12 pooled studies from adults in *The Lancet,* severe covid-19 disease* data

(*covid-19 hospitalization & death)



COVID-19 Forecasting Team. Past SARS-CoV-2 infection protection against re-infection: a systematic review and meta-analysis. Lancet. 2023 Mar 11;401(10379):833-842.

Study of ~900K N Carolina children aged 5-11 yo, covid-19 hospitalization data



Suppl to: Lin D-Y, Gu Y, Xu Y, et al. Effects of vaccination and previous infection on omicron infections in children. N Engl J Med. DOI: 10.1056/NEJMc2209371, plot of data from Tables S5 & S6

Generic Failures of the Covid-19 Vaccine Trials: No Evaluation of SARS-CoV-2 Transmission*, & Underpowered for Clinical Outcomes, i.e., Covid-19 Hospitalizations & Deaths

"80 years of vaccine development for inhaled viral infections, failed to develop one sterilizing vaccine capable of inducing herd immunity*...[N]o vaccine induces stronger immunity than that following the disease, yet it took a recent *Lancet* meta-analysis to confirm that post Covid-19 trumps vaccine immunity."

—Emeritus Professor Robert Clancy, Foundation Professor of Pathology in the Medical School, University of Newcastle. He is a clinical immunologist.

From: Robert Clancy, "Strange times: Covid, immunology and medicine," The Spectator (Australia), March 11, 2023 https://www.spectator.com.au/2023/03/strange-times/

*certainly by the summer of 2021, self-evident clinical/observational data emerged, such as the Barnstable County, MA covid-19 delta variant outbreak in primarily (74%) fully vaccinated persons, to demonstrate the covid-19 vaccines did *NOT* prevent SARS-CoV-2 transmission

(reported by CDC itself in MMWR: https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm)

Early Brown University Nursing Home Patient* Data (2/15/21-3/31/21) Among those Receiving Covid-19 mRNA Vaccines, Before "Vaccine Waning" [*Highest Covid-19 Risk Group]

- 1240/18,242 = 6.8% with ANY incident SARS-CoV-2 infections among the vaccinated, & 270/3,990 also=6.8% incident SARS-COV-2 infections among the unvaccinated <u>by</u> <u>including</u> infections which accrue days 0-14 in each group
- Vaccinated with at least one dose=335/18,242=0.0184 → (1.84%) with SYMPTOMATIC incident SARS-CoV-2 infections among the vaccinated, & 90/3,990=0.0223 = (2.23%), a mere 0.39% absolute reduction, & a Number Needed to Vaccinate of 256 to prevent 1 SYMPTOMATIC SARS-CoV-2 infection

"Incident SARS-CoV-2 Infection among mRNA-Vaccinated and Unvaccinated Nursing Home Residents" July 29, 2021 N Engl J Med 2021; 385:474-476 DOI: 10.1056/NEJMc2104849

Benn et al., i*Science* 26, 106733 May 19, 2023. https://doi.org/10.1016/j.isci.2023.106733 (online 5/9/23)

"In the RCTs with the longest possible blinded follow-up," mRNA vaccines \rightarrow no \downarrow in total mortality (31 deaths vaxxed/30 deaths unvaxxed), possible slight \uparrow in CVD mortality (16 deaths vaxxed/11 deaths unvaxxed), & possible small \downarrow in covid mortality (2 deaths vaxxed/5 deaths unvaxxed)

	Vaccine group (deaths/N)	Placebo group (deaths/N)	Relative risk (95% CI)
Combined for Pfizer and Moderna vs. placebo ^d			
Overall mortality	31/37110	30/37083	1.03 (0.63–1.71)
COVID-19 mortality	2/37110	5/37083	0.40 (0.08–2.06)
Cardiovascular mortality	16/37110	11/37083	1.45 (0.67–3.13)
Other non-COVID-19 mortality	11/37110	12/37083	0.92 (0.40-2.08)
occidents	2/37110	2/37083	1.00 (0.14–7.09)
Ion-accident, non-COVID-19 mortality	27/37110	23/37083	1.17 (0.67–2.05)

For each covid-19 death prevented by mRNA vaccination (NNV=12,346), there will be 1.65 CVD (cardiovascular disease) deaths caused (NNV=7,463)

Polio and Polio Vaccination, Vs. Covid-19 and Covid-19 Vaccination, in Young Children

Polio vs. Covid-19 Mortality in Children

- —US polio mortality in children, 1915-1954, averaged 5.7%
- The U.S. pediatric covid-19 IFR is ≤ 0.0003%
- —In RI, during the 1st 10 months of 1953 (thru 10/31), there were 289 polio cases & 15 polio deaths, a 5.2% mortality
- —Despite thousands of pediatric "covid-19 cases" (& 95-100% of the pediatric population infected), there have been ZERO pediatric covid-19 deaths in 3-years in RI

Polio vs. Covid-19 RCT Data

- —The 1954 polio RCT (& field trial) enrolled 1.8 million children, and polio vaccination prevented 374 cases of crippling polio (vs. placebo).
- —The 2021 Pfizer mRNA RCT in 5-11-year-olds enrolled ~2300, & covid 19 mRNA vaccination "prevented" 13 cases of mild C19 (i.e., sniffles)
- There were ZERO covid-19 hospitalizations in EITHER the placebo or active C19 vaccine groups
- None of the subgroup of children with prior infection history (natural immunity) even developed sniffles regardless of active C19 or placebo vaccination

These blogs contain the primary sources: https://www.andrewbostom.org/2021/12/pediatric-polio-in-rhode-island-reported-by-the-newport-daily-news-december-16-1953-289-cases-treated-15-deaths-reported-through-october-31-1953-a-5-2-fatality-rate/

Formal Risk-Benefit Analyses of Covid-19 mRNA Vaccines Based Upon RCT & Observational Data

Adult Risk/Benefit Data:

"In the Moderna trial, the excess risk of serious Adverse Events of Special Interest* (AESIs; 15.1 per 10,000 participants) was (8.7/10,000) higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (6.4 per 10,000 participants). In the Pfizer trial, the excess risk of serious AESIs (10.1 per 10,000) was (7.8/10,000) higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (2.3 per 10,000 participants).

*esp. myopericarditis, coagulation disorders, cholecystitis

Fraiman J et al. "Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults." *Vaccine*. 2022 Sep 22;40(40):5798-5805.

Risk/Benefit Data for 18-29 Year Olds*:

"To prevent one COVID-19 hospitalization over a 6-month period, we estimate that 31 207–42 836 young adults aged 18–29 years must receive a third mRNA vaccine. Booster mandates in young adults are expected to cause a net harm: per COVID-19 hospitalization prevented, we anticipate at least 18.5 serious adverse events from mRNA vaccines, including 1.5–4.6 booster-associated myopericarditis cases in males (typically requiring hospitalization). We also anticipate 1430–4626 cases of grade ≥3 reactogenicity interfering with daily activities (although typically not requiring hospitalisation)."

"It is even harder to justify a two-dose primary vaccine mandate in late 2022 than when such policies began in mid-2021**. This rationale is weak at best and wrong at worst. Consistent with our argument above, the now high prevalence of prior infection, data regarding the lack of sustained transmission reduction by current vaccines and the age at peak risk for myo/pericarditis being young adults aged 16–17 years"

Bardosh K et al. COVID-19 vaccine boosters for young adults: a risk benefit assessment and ethical analysis of mandate policies at universities. *J Med Ethics*. 2022 Dec 5:medethics-2022-108449.

^{*}In ≤18-year-olds, Fraiman estimated for each covid-19 hospitalization prevented by mRNA vaccination, there would be 700 cases of vaccine-associated myocarditis; for each ICU hospitalization prevented, that # rises to 2000!

^{**} The monovalent 2-dose regimen had its EUA termionated in April is no longer available!!

12/7/23: Pooled analysis* of pediatric Covid-19 mRNA vaccine RCT data suggests ↑ed risk for both Resp Syncytial Virus (RSV) & Lower Resp Tract infections, & severe adverse events, <u>among vaccinated children</u>

• The analyses included 25,549 children and adolescents below 18 years of age (17,538 mRNA vaccine recipients and 8,011 placebo recipients).

"Among the older children, the vaccines were associated with a 3.5-fold higher risk of Severe AEs. Among children younger than 5 years of age, the mRNA vaccines were associated with a 3-fold higher risk of LRTI and a 2-fold higher risk of RSV. Given the low risk of severe COVID-19 infections in children, the RCTs call for a renewed assessment of the value of COVID-19 vaccination of children and adolescents."

^{*}Stine S. Hoffmann, Sebastian Nielsen, Sanne M. Thysen, Ram Duriseti, **Christine S. Benn.** "Overall Health Effects of mRNA COVID-19 Vaccines in Children and Adolescents: A Systematic Review and Meta-Analysis" **medRxiv** 2023.12.07.23298573; doi: https://doi.org/10.1101/2023.12.07.23298573

VAERS* cases of myopericarditis in Tennessee among 6 to 17-year-old males comparing <3-years of covid mRNA vaccination (since mid-2021), to 10-years of influenza vaccination (2012-2022)

Vaccine type	Time period	# Myopericarditis cases
Influenza	2012-2022	0
	(10-years)	
Covid-19 (mRNA)	Mid-2021-Present	7
	(< 3-years)	(5 hospitalized)

^{*}CDC's Vaccine Adverse Event Reporting System (https://wonder.cdc.gov/vaers.html)

There is NO "Post-Covid-19 condition (PCC)" in mildly afflicted adolescents & young adults

Data from 509 Norwegian adolescents and young adults:

- (1) "the prevalence of PCC 6 months after acute COVID-19 was approximately 50%, but was equally high in a control group of comparable SARS-CoV-2-negative individuals";
- (2) "acute COVID-19 was not an independent risk factor for PCC";
- (3) "the severity of clinical symptoms at baseline, <u>irrespective of SARS-CoV-2 status</u>, was the main risk factor of persistent symptoms 6 months later."

CONCLUSION:

"persistent symptoms & disability that characterize PCC are associated with factors other than SARS-CoV-2 infection, <u>including psychosocial factors</u>"

Selvakumar J et al. "Prevalence and Characteristics Associated With Post-COVID-19 Condition Among Nonhospitalized Adolescents and Young Adults" JAMA Netw Open. 2023 Mar 1;6(3):e235763.