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Attorneys for Plaintiffs
BENJAMIN COLLINS *et al.*

UNITED STATES DISTRICT COURT

DISTRICT OF MARYLAND

BENJAMIN COLLINS, BINGBING YU, and HEALTH FREEDOM DEFENSE FUND, a Wyoming non-profit public benefit corporation,

Plaintiffs,

vs.

UR JADDOU, in his official capacity as Director of U.S. Citizenship and Immigration Services, and MANDY COHEN, in her official capacity as Director of the Centers for Disease Control,

Defendants.

Case No. 1:24-cv-03330-ELH

[Assigned to Hon. Ellen L. Hollander]

DECLARATION OF RAM DURISETI

[Filed concurrently with Declarations of Scott Street, Leslie Manookian, Benjamin Collins, and BingBing Yu]

JW HOWARD/ ATTORNEYS, LTD.
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San Diego, California 92101

DECLARATION OF RAM DURISETI

I, Ram Duriseti, M.D., Ph.D., declare as follows:

1. I am a clinical associate professor at the Stanford Emergency Department. I have been a practicing Board Certified Emergency Physician for over 20 years. My PhD background is in Operations Research with an emphasis computational decision modeling, simulation, and optimization algorithms. I have personal knowledge of the facts set forth below and could testify competently to them if called to do so. A true and correct copy of my curriculum *vitae* is attached to this declaration as **Exhibit "A."**

2. COVID-19 is the disease caused by infection with the SARS-CoV-2 virus. It has been around for at least five years and has been the subject of the most unprecedented public health response I have ever seen.

3. Several vaccines were developed in response to COVID-19. But the current generation of COVID-19 vaccines do not prevent infection. They also do not significantly limit transmission for any sustained period of time. This has been known for several years.

4. We must first acknowledge, in fact, using the Pfizer COVID-19 mRNA vaccine as a canonical example, that the vaccine trials were never designed to test for preventing transmission. Pfizer themselves pointed this out to the FDA. As noted by Dr. Patrick Moore of the University of Pittsburgh Cancer Institute: "One question that addresses these two discussion items, I find is really, really central, and important, is that FDA did not ask in its guidance and Pfizer has presented no evidence in its data today that the vaccine has any effect on virus carriage or shedding, which is the fundamental basis for herd immunity (page 342 of transcription)."[1]

5. As early as Summer 2021, emerging data suggested that vaccinated

[1] https://www.fda.gov/media/144859/download

individuals' net reduction in "viral load" during an infection was no more than 30%.[2] Since that time, between waning efficacy and partial "immune escape" from SARS-CoV-2 variants, it's become clear that even that degree of reduction is not sustained. In a more recent study, researchers used longitudinal sampling of nasal swabs for determination of viral load, sequencing, and viral culture in outpatients with newly diagnosed coronavirus disease 2019 (Covid-19). From July 2021 through January 2022 and concluded that, "we did not find large differences in the median duration of viral shedding among participants who were unvaccinated, those who were vaccinated but not boosted, and those who were vaccinated and boosted."[3]

6. Additional evidence from the real world confirmed this. For example, data published by Walgreen's between 2022 and 2023 regularly showed that people who had taken the COVID-19 vaccine were contracting COVID-19 at roughly the same rate as people who had not taken the vaccine. Attached to this declaration as **Exhibit "B"** is a true and correct copy of a declaration I authored in early 2023 that includes that data and associated analysis.

7. I have provided expert reports regarding these issues in numerous cases since 2021. Attached to this declaration as **Exhibit "C"** is a true and correct copy of the most recent one, which I submitted in April 2024 in a case in California.

8. At this point, the evidence is clear. COVID-19 is not a "vaccine-preventable disease." It is not in the process of being eradicated. By Spring of 2021, it was obvious that it was not an eradicable disease. The entire medical community (of which I am part) and the public health community (of which I am also part) recognize this. There may be some benefit to the COVID-19 vaccines. But currently, these benefits are, at best, limited to specific high risk cohorts. Medical and public health officials are still debating those questions. But there is no debate about the issue in

[2] https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1.full-text
[3] https://www.nejm.org/doi/full/10.1056/NEJMc2202092

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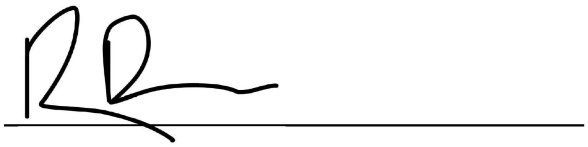
this case: COVID-19 is not a vaccine-preventable disease.

Under penalty of perjury, under the laws of the United States of America, I declare that the foregoing is true and correct. Executed this 10th day of January 2025, at Sebastopol, California.



Ram Duriseti, M.D., Ph.D.

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EXHIBIT A

Ram Duriseti, M.D., Ph.D.
(650) 521-4517
ramduriseti@gmail.com

Educational Background:

Engineering:

•9/01-5/07: Doctoral degree from the Stanford University School of Engineering with a concentration in Decision/Risk Analysis, Machine Learning, and Clinical Decision Support. Coursework included Decision and Risk Analysis, Probability and Statistical Inference, Bayesian Networks, Machine Learning, Computer Science, and Clinical Informatics. Funded through a VA Medical Informatics Fellowship.

- Computing Background: C++, Java, Matlab, C, Ruby On Rails, Javascript and HTML with Ajax, Drools (JBoss Rules Engine), controlled medical terminology deployment (IMO services, SNOMED-CT, RxNorm, and other UMLS resources), Apelon server deployment, LISP, PostGreSQL, MySQL, JBoss application server, UNIX environment, Visual Basic (Excel Modules), Git, Subversion and Mercurial version control, R including visualization tools, Python

Medical and Undergraduate:

•11/97-11/2001: Residency training in Emergency Medicine at Stanford Medical Center.
•5/96: M.D. with highest honors, University of Michigan Medical School
•6/92: B.S. in Biology, and B.A in Political Economy, with distinction Stanford University.

Select Relevant Employment Experience:

11/00 – Present: Clinical Associate Professor, Stanford Emergency Department. Contacts: Dr. Bernard Dannenberg and Dr. Matthew Strehlow. Numbers available upon request.

3/01- Present: Mills Peninsula Emergency Medical Associates shareholder. President and CEO until 6/2017

6/08 – Present: Founder, CEO, and Product Engineer (principle algorithm and product design architect) for ShiftRx, L.L.C. ShiftRx provides the ShiftGen service that provides a cloud-based enterprise workforce management tool. Key elements: machine learning algorithms, schedule optimization, workforce management, revenue cycle management with payroll integration, Java, Ruby on Rails, MySQL, SaaS on ec2.

10/08 – Present: Special consultant and subject matter expert to Sutter Health for Epic EHR implementation. Provided technical design for the billing extracts to migrate clinical information into a file sharing framework for billing companies supporting Sutter Emergency Medicine groups. Contacts: Multiple. Numbers available upon request.

4/15 – 3/2017: CEO and subsequently CTO and CMO of LifeQode Inc. which provides the Lifesquare product. Helped craft and secure 4 different patents, with continuations, around the central business processes for the product. Contacts: Larry Leisure and Steve Shulman. Numbers available upon request.

7/09 – 10/09: Technical consultant to Rise Health, Inc. Contacts: Eric Langshur, Forrest Claypool, and Inder-Jeet Gujral. Numbers available upon request.

1/07 – 9/08: Chief Medical Officer and Director of Medical Informatics for Enfold, Inc. Responsibilities include design and implementation of intelligent medical functionality and a

taxonomy engine as well as oversight of medical content driving the system. Implementation details: Java, Ruby on Rails, Drools, Apelon Server, Oracle 10g Database, MySQL. Contacts: Inder-jeet Gujral, Kimberly Higgins-Mays. Numbers are available upon request.
10/06 – 3/08: Medical Informatics Director Working Group Stanford University Hospitals and Clinics CIS Initiative. Particular emphasis on handheld technology integration into the Epic Initiative and organizing patient encounter level reportable data on clinical documentation events. Contacts: Kevin Tabb, President, and CEO Beth Israel Deaconess Medical Center. Contact information is available upon request.
6/05 –12/06: Design and implementation of an attribute matching expert system in Java as a consultant to Wellnet Inc. Implemented in a Java environment with Hibernate DBMS and MySQL. Contacts: Kimberly Higgins-Mays. Number available upon request.

Select Research Experience:
7/11-Present: Design and implementation of a computational model for stochastic stimulation of the cost-effectiveness of various strategies to diagnose pediatric appendicitis (manuscript in progress).
10/05-Present: Design and implementation of an asymmetric cost Support Vector Machine to evaluate a large clinical database on chest pain patients presenting to the University of Pennsylvania Hospital Emergency Department (manuscript in progress).
09/02-9/04: Medical Informatics Fellow, Palo Alto Veteran's Administration Hospital.
04/03-Present: Development of Bayesian decision network for evaluation of the clinical utility of the quantitative Vidas ELISA Ddimer Assay. Published work listed.
02/04-Present: Bayesian decision network implementation modeling reasoning in the clinical domain of chest pain and associated pathology in the Emergency Department.
6/05-3/06: Using portable digital devices to generate a standard electronic medical record that can be downloaded directly to a relational database to facilitate data mining for prospective clinical research.
11/99 – 4/00: Retrospective chart review to examine the incidence of electrolyte and cardiac enzyme abnormalities in patients presenting to the Stanford Emergency Department with Supraventricular Tachycardia.

Select Administrative Experience:
6/09 – Present: CEO and Founder of ShiftRx, LLC
6/09 – Present: Regional Information Services Steering Committee for Sutter Health
6/08 – 6/18: President of CEO of Mills Peninsula Emergency Medical Associates
9/12 – 3/17: Acting CMO and CEO of Lifesquare, Inc.
6/07 – 9/08: Chief Medical Officer and Director of Medical Informatics at Enfold, Inc.
5/05-9/08: Member of Medical Informatics Director Working Group and RFP phase of evaluation for the Epic initiative at Stanford University Hospitals and Clinics
4/05-6/06: Served on the Mills-Peninsula Health Information Management and Medical Records Committee.

Current Volunteer Activities

3/22 – Present: Board of Director of Restore Childhood which is a non-profit focused on research initiatives quantifying risks to children in schools in the 'COVID Era". The goals are

both legal and scientific. The scientific goal is to generate novel research and support mitigation measures that are both effective and maintain in person education.
12/21 – Present: Co-author of Urgency of Normal. We are a group of physicians focused on collating and presenting data as it pertains to children and COVID. We help facilitate safe school openings.
7/22 – 1/2023: Co-author for Norfolk Group documents to assess COVID-19 pandemic policy and response to guide COVID-19 Commissions: https://www.norfolkgroup.org/
Guest Lecturer at the Wharton School of Business (University of Pennsylvania) 2007/2008/2009 for health economics and information technology course

Select Honors and Distinctions:

- Guest Lecturer at the Wharton School of Business (University of Pennsylvania) 2007/2008/2009 for health economics and information technology course
- VA Medical Informatics Fellowship
- Alpha Omega Alpha Medical Honor Society
- Graduation with Distinction from the University of Michigan Medical School (top 5%)
- Recommended for Graduation with Distinction from Stanford University
- National Merit Scholarship Recipient
- Telluride Foundation Fellow

Select Papers and Publications (Manuscripts in Progress marked as such):

Bourdon, P.S., Duriseti. R., Gromoll, HC, Dalton, DK, Bardosh K., Krug, A.E. "A Reanalysis of the FDA's Benefit-Risk Assessment of Moderna's mRNA-1273 COVID Vaccine: For 18-25-Year-Old Males, Risks Exceeded Benefits Relative to Hospitalizations"; Preprint with submission in progress. October 2024

Sandlund, J., Duriseti, R., Ladhani, S., Stuart, K., Noble, J., Beth-Hoeg, T. "Face Masks and Protection Against COVID-19 and Other Viral Respiratory Tract Infections: Assessment of Benefits and Harms in Children", Paediatric Respiratory Reviews 2024

- Hoffman S., Nielsen S., Thyssen S., Duriseti R., Stabell Benn C. "Overall Health Effects of mRNA COVID-19 Vaccines in Children and Adolescents: A Systematic Review and Meta-Analysis"; https://doi.org/10.1101/2023.12.07.23298573

- Beth-Hoeg T., Duriseti, R., Prasad VP. "Evidence of Healthy Vaccinee Bias in a Clalit Health Pfizer BNT-162b2 Study"; New England Journal of Medicine, July 20th, 2023; 389: 284-286 (https://www.nejm.org/doi/full/10.1056/NEJMc2306683)

- Beth-Hoeg T., Duriseti, R., Prasad VP. "Residual Confounding and Falsification Endpoints in Observational Studies of Vaccine Effectiveness: A Case Study of the Clalit Health Services in Israel" (submission in progress)

- Chandra, A., Beth-Hoeg T., Duriseti, R., Ladhani, S., Prasad VP. "School mask mandates and COVID-19: A Re-analysis and methodological critique of a retrospective observational study

from Massachusetts, USA", Annals of Internal Medicine 2024. Pre-print: https://arxiv.org/abs/2307.11974

• Haltigan, JD, Colvys, Kim, Duriseti, R. "Reanalysis of the Bangladesh Mask RCT with Generalizability Theory and Monte Carlo Simulation" (manuscript in progress)

• "Impact of Pre-Omicron COVID-19 Infection Burden on Disease Burden During Omicron Dominant Variants" (manuscript in progress – multiple authors and a county health authority)

• Pieris, S., Leung R., Peterson, S., Yarusevych, S., Duriseti, R. "Efficacy of Surgical Masks and N95 masks on Filtration of Sub-Micron Aerosols" (submitted for publication)

• Sandlund, J., Duriseti, R., Ladhani, S., Stuart, K., Noble, J., Beth-Hoeg, T. "Child mask mandates for SARS-CoV-2: a systematic review"; Archives of Disease in Childhood 02 December 2023. doi: 10.1136/archdischild-2023-326215

• Bhattacharya, J, Beinin, L, Duriseti, R., Beth-Hoeg, T., Makary, M., Kuldorff, M., Smelkinson, M., Templeton, S. "Questions for a COVID-19 Commission": https://www.norfolkgroup.org/

• "Analysis of Economic Support Measures by Industry During COVID-19 Mitigation Measures, Economic Research Institute of University of Ljubljiana, Slovenia, Senior author Velimir Bole, PhD (manuscript in progress – multiple authors)

• Vidal, C., Holland, E, Duriseti, R. "School closures: The trigger point in the decline in pediatric mental health outcomes during the COVID-19 pandemic". Journal of the Canadian Academy of Child and Adolescent Psychiatry; 2023; 32:2

• Lowe, T., Brown, I., Duriseti, R. "Emergency Department Access During COVID-19: Dis parities in Utilization by Race/Ethnicity, Insurance, and Income", Western Journal of Emergency Medicine; April, 2021

• Menon, A. S., Greenwald, S., Ma, T. J., Kooshesh, S., Duriseti, R. "Patient and Physician Willingness to Use Personal Health Records in the Emergency Department". Western Journal of Emergency medicine; 2012; 13 (2): 172–75

• Duriseti, R., Brandeau M. "Cost-Effectiveness of Strategies for Diagnosing Pulmonary Embolism Among Emergency Department Patients Presenting with Undifferentiated Symptoms", Annals of Emergency Medicine; October, 2010

• Duriseti, R., Wu, T. "Gastrointestinal introduction and abdominal pain – Pediatric Abdominal Pain in the Emergency Department", A Practical Guide to Pediatric Emergency Medicine, Cambridge University Press, Cambridge, 2010

• Duriseti, R. "Musculoskeletal Trauma: fractures", A Practical Guide to Pediatric Emergency Medicine, Cambridge University Press, Cambridge, 2010

• Duriseti, R. "Using Influence Diagrams in Cost Effectiveness Analysis for Medical Decisions", Optimization in Biology and Medicine, Auerbach Press, New York, 2008

• Duriseti, R. "Non-Bayesian Classification to Obtain High Quality Clinical Decisions", Optimization in Biology and Medicine, Auerbach Press, New York, 2008

• Duriseti, R., Shachter R., Brandeau M. "Implications of a Sequential Decision Model on the Use of Quantitative D-Dimer Assays in the Diagnosis of Pulmonary Embolism", Academic Emergency Medicine; July, 2006

•Duriseti R, VanderVlugt T. Paroxysmal supraventricular tachycardia is not associated with clinically significant coronary ischemia. ACEP Abstracts. ACEP Scientific Assembly 10/2001

•VanderVlugt T., Duriseti R. Electrolyte findings in patients with paroxysmal supraventricular tachycardia. ACEP Abstracts. ACEP Scientific Assembly 10/2001

•Contributing Editor for Trauma Reports for the topic, "Trauma in Pregnancy"; published 2/2001

•Duriseti R. Cost Effective Management of Common Infections in the Emergency Department. Resident Reporter. Wyeth Ayerst Resident Scholars Program. March, 2000

Select Professional Lectures and Expert Engagements:

• Commonly Encountered Statistical Concepts in the Emergency Medicine Literature
• Medical Decision Making, Clinical Information Systems, and Cost Control: Complexity Collides with Uncertainty
• Elijah Brown, et al. v. Mills-Peninsula, et al., No. CIV536321 (Cal. Super. Ct. County of San Mateo 2015)
• Julia Sullivan v. The Superior Court of Santa Clara, No. 18FL001837 (Cal. Super. Ct. County of Santa Clara 2018)
• UNIFYSCC, et al. v. Sara H. Cody, et al., No. 22-cv-01019-BLF (N.D. Cal. 2022)
• Vincent Tsai, et al. v. County of Los Angeles, No. 21STCV36298 (Cal. Super. Ct. Los Angeles County 2021)
• Jennifer Guilfoyle et al. v. Austin Beutner et al., No. 2:2021-cv-05009-VAP (C.D. Cal. 2021)
• State of Missouri and Eric Schmitt vs. Columbia Public Schools January 2022
• Montana Nurses Association vs. Austin Knudsen September 2022
• Toro v. the City of San Diego October 2022
• Calvary Church of San Jose v. Gavin Newsom, Santa Clara County, Cindy Chavez, Sara H. Cody, MD, Joe Simitian, Santa Clara Board of Supervisors November 2022
• Barbara Andreas, Stephen J Cribb, and Adam Pajer vs The Walt Disney Company and Disney Parks, Experiences, And Products, Inc. January 2023
• United States v. Keith Lawrence Middlebrook, 20-cr-00229-DSF May 2024
• Unify v. Santa Clara County June 2024
• Rock Dunbar v Twentieth Century Fox November 2024

EXHIBIT B

Tab 43

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Attorneys for Plaintiff Ingo Rademacher

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

INGO RADEMACHER, an individual,

Plaintiff,

vs.

AMERICAN BROADCASTING COMPANIES, INC., a Delaware corporation; and DOES 1 through 10, inclusive,

Defendants.

Case No.: 21STCV45383

Assigned for All Purposes to:
Hon. Stephen Goorvitch, Dept. 39

DECLARATION OF RAM DURISETI

Reservation ID No. 823526443264

Date: March 13, 2023
Time: 9:00 a.m.
Dept.: 39
Judge: Hon. Stephen Goorvitch

Complaint filed: December 13, 2021
Trial Date: May 1, 2023

Declaration of Ram Duriseti MD, PhD

February 7th, 2023

I, Ram Duriseti, MD, PhD, declare as follows:

I am a clinical associate professor at the Stanford Emergency Department. I have been a practicing Board Certified Emergency Physician for over 20 years. My PhD background is in Operations Research with an emphasis computational decision modeling, simulation, and optimization algorithms. I have personal knowledge of the facts set forth below and could testify competently to them if called to do so. A true and correct copy of my *curriculum vitae* is attached to this declaration.

COVID-19 is the disease caused by infection with the SARS-CoV-2 virus. The current generation of COVID-19 vaccines do not significantly limit transmission for any sustained period of time. Transmission of an infectious disease is both a function of behavior and presence of infection. A vaccine mandate with the purpose of limiting transmission must not simply decrease the risk of infection, but must do so by a substantial margin. The primary benefit of COVID-19 vaccination is accrued by the vaccine recipient. The benefit is most positive in those with identifiable risk factors and especially in the absence of a prior infection. Neither infection nor vaccination will definitively prevent future infection. However, both will reduce the severity of a future infection.

1. We must first acknowledge, using the Pfizer COVID-19 mRNA vaccine as a canonical

example, that the vaccine trials were never designed to test for preventing transmission. Pfizer themselves pointed this out to the FDA.[1] The "data gaps" identified by Pfizer were:

- Duration of protection
- Effectiveness in certain populations at high risk of severe COVID-19
- Effectiveness in individuals previously infected with SARS-CoV-2
- Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections
- Vaccine effectiveness against asymptomatic infection
- Vaccine effectiveness against long-term effects of COVID-19 disease
- Vaccine effectiveness against mortality
- Vaccine effectiveness against transmission of SARS-CoV-2

2. It's important to remember that the original Pfizer trial supporting its FDA approval was never structured to test for transmission reduction and this is part of the record in the Emergency Use Authorization (EUA) review. As noted by Dr. Patrick Moore of the University of Pittsburgh Cancer Institute,

"*One question that addresses these two discussion items, I find is really, really central, and important, is that FDA did not ask in its guidance and Pfizer has presented no evidence in its data today that the vaccine has any effect on virus carriage or shedding, which is the fundamental basis for herd immunity (page 342 of transcription).*" [2]

[1] https://www.fda.gov/media/148542/download#page=38
[2] https://www.fda.gov/media/144859/download

3. In the Pfizer trial, 567 patients in placebo and 526 in the treatment arms had evidence of prior COVID-19 infection. In each of these sub-cohorts, there was only 1 reinfection according to the primary endpoint definition (Table 8 page 27).[3] In other words, of 567 patients in the placebo arm who had evidence of prior COVID-19, only 1 developed reinfection. Similarly, out of 526 patients in the vaccine recipient arm with documented prior COVID-19, only 1 patient developed a reinfection. There are several key takeaway points:

    - There was no statistically significant difference in a subsequent COVID-19 infection between placebo and vaccine arms when there was evidence of prior infection.

    - While it is impossible to draw statistical inference from just 1 reinfection out of 567 placebo recipients with prior infection, this compares to 162 infections out of 16,944 placebo recipients with no evidence of prior COVID-19. *In other words, those with prior infection had at least a 100-fold lower rate of infection than those with no prior infection during the trial period*

4. **This led Pfizer to cite the following in its December 2020 FDA filing:** "VE point estimates were uniformly high across the subgroups examined with the exception of … participants with evidence of prior SARS-CoV-2 infection at enrollment, for which too few COVID-19 cases occurred to interpret efficacy data" (page 25).[4]
5. While many COVID-19 immune naïve individuals (no prior infection by SARS-CoV-2 which is the virus that causes COVID-19) likely benefitted from having their immune

[3] https://www.fda.gov/media/144245/download (table 8 page 27)
[4] https://www.fda.gov/media/144245/download (page 25)

systems primed by a vaccine prior to a subsequent infection thereby increasing their protection from more severe disease progression, any imputed impact on disease transmission has been fleeting at best.

6. As early as Summer 2021, emerging data suggested that vaccinated individuals' net reduction in "viral load" during an infection was no more than 30%.[5] Since that time, between waning efficacy and partial "immune escape" from SARS-CoV-2 variants, it's become clear that even that degree of reduction is not sustained. In a more recent study, researchers used longitudinal sampling of nasal swabs for determination of viral load, sequencing, and viral culture in outpatients with newly diagnosed coronavirus disease 2019 (Covid-19). From July 2021 through January 2022 and concluded that, "we did not find large differences in the median duration of viral shedding among participants who were unvaccinated, those who were vaccinated but not boosted, and those who were vaccinated and boosted".[6]
7. When discussing the topic of transmission, it's useful to examine settings where the interactions are high frequency, long duration, and in enclosed spaces that do not have particularly high ceilings, or hospital level ventilation air changes per hour (ACH). We can consider transmission studies in health care settings to be an "extreme case of exposure risk" that would likely far exceed any risk in a Disney setting in almost all cirucmstances.
8. With respect to COVID-19 infections in a health care setting and staff vaccination rates, a July 2021 paper examined infection rates among different vaccinated patient cohorts in a nursing home at different levels of staff vaccination. The most telling table was in the

[5] https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1.full-text
[6] https://www.nejm.org/doi/full/10.1056/NEJMc2202092

supplement. In table S3, there was no association between staff vaccination rates and transmission to residents regardless of the residents' vaccination status.[7]

NURSING HOME VACCINATIONS 8

Table S3. Incident SARS-CoV-2 infections in residents living in nursing homes with low, moderate, and high staff vaccination rates

	Low staff vaccination (Less than 58.7% of staff vaccinated)		Moderate staff vaccination (58.7 - 69.2% of staff vaccinated)		High staff vaccination (69.3 - 95.7% of staff vaccinated)	
	Total	Percent (%) asymptomatic	Total	Percent (%) asymptomatic	Total	Percent (%) asymptomatic
Residents vaccinated with at least dose 1, n	**5691**		**6291**		**6260**	
Tested positive 0-14 days after dose 1, n(%)	266 (4.7%)	71.1%	267 (4.2%)	74.2%	289 (4.6%)	69.2%
Tested positive 15-28 days after dose 1, n(%)	83 (1.5%)	75.9%	50 (0.8%)	62.0%	117 (1.9%)	72.6%
Residents vaccinated with doses 1 & 2, n	**4001**		**4579**		**4468**	
Tested positive 0-14 days after dose 2, n(%)	46 (1.1%)	80.4%	32 (0.7%)	87.5%	52 (1.2%)	86.5%
Tested positive >14 days after dose 2, n(%)	18 (0.4%)	72.2%	8 (0.2%)	75.0%	12 (0.3%)	83.3%
Unvaccinated residents	**1629**		**1296**		**1065**	
Tested positive 0-14 days after clinic 1 held, n(%)	73 (4.5%)	65.8%	65 (5.0%)	66.2%	35 (3.3%)	68.6%
Tested positive 15-28 days after clinic 1 held, n(%)	31 (1.9%)	64.5%	15 (1.2%)	46.7%	23 (2.2%)	65.2%
Tested positive 29-42 days after clinic 1 held, n(%)	6 (0.4%)	83.3%	4 (0.3%)	75.0%	6 (0.6%)	83.3%
Tested positive >42 days after clinic 1 held, n(%)	6 (0.4%)	83.3%	3 (0.2%)	66.7%	3 (0.3%)	100.0%

Notes. Nursing homes stratified by tertiles of staff vaccination rates as of February 17, 2021. Staff vaccinations occurred simultaneously with resident vaccinations and rates were tracked by the organization.

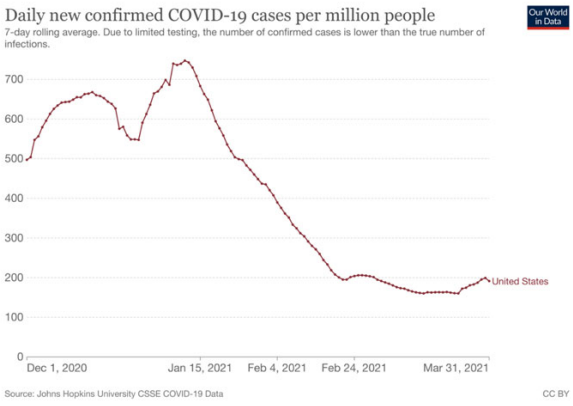
9. The authors could not identify an association with staff vaccination rates because vaccination rates dropped in all individuals. The authors attribute this to vaccination and hereby commit an extremely common error in studies claiming that COVID-19 vaccination has markedly decreased infection rates.

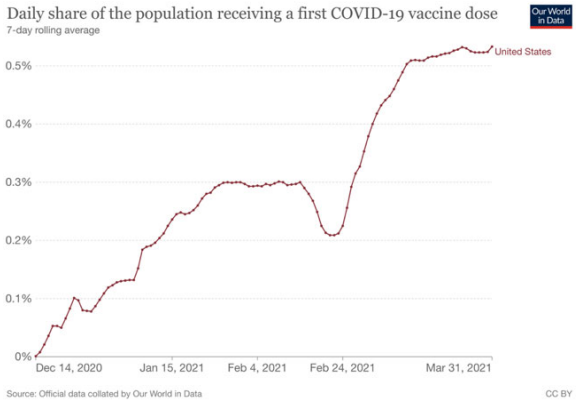
10. <u>The Common Error:</u> Studies of ecological (real world) data that purport to demonstrate a positive effect from COVID-19 mitigation measures, whether we are referring to non-pharmaceutical interventions (NPIs) or vaccines, frequently do not control for background community infection rates. This leads to overly optimistic estimates of infection prevention by the intervention. Without going into further detail, this mistake has been a repeated

[7] https://www.nejm.org/doi/suppl/10.1056/NEJMc2104849/suppl_file/nejmc2104849_appendix.pdf

feature of the COVID-19 literature in both American and European studies.[8,9] With respect to the White et al. nursing home study:

- case rates in the United States during the study period from December 2020 through March 2021, went from 747/million at the peak during vaccine roll out at Nursing Homes in late 2020 through January 2021 to a case rate nadir of 191/million while community vaccination rates remained at only 0.53% by the end of March 2021.
- Therefore, there was a national 3.91-fold reduction in COVID-19 case rates that directly matched the rate decrease in the nursing home (from 4.5% to 1%) which is a roughly comparable 4.5-fold reduction.[10]
- *Therefore the decrease in infection rates in the nursing home directly paralleled the level of decrease in the community at large despite having a a more than 100-fold greater rate of vaccination in the nursing home (58% to 95%) compared to the community vaccination rate by end of March 2021 (0.54%).*

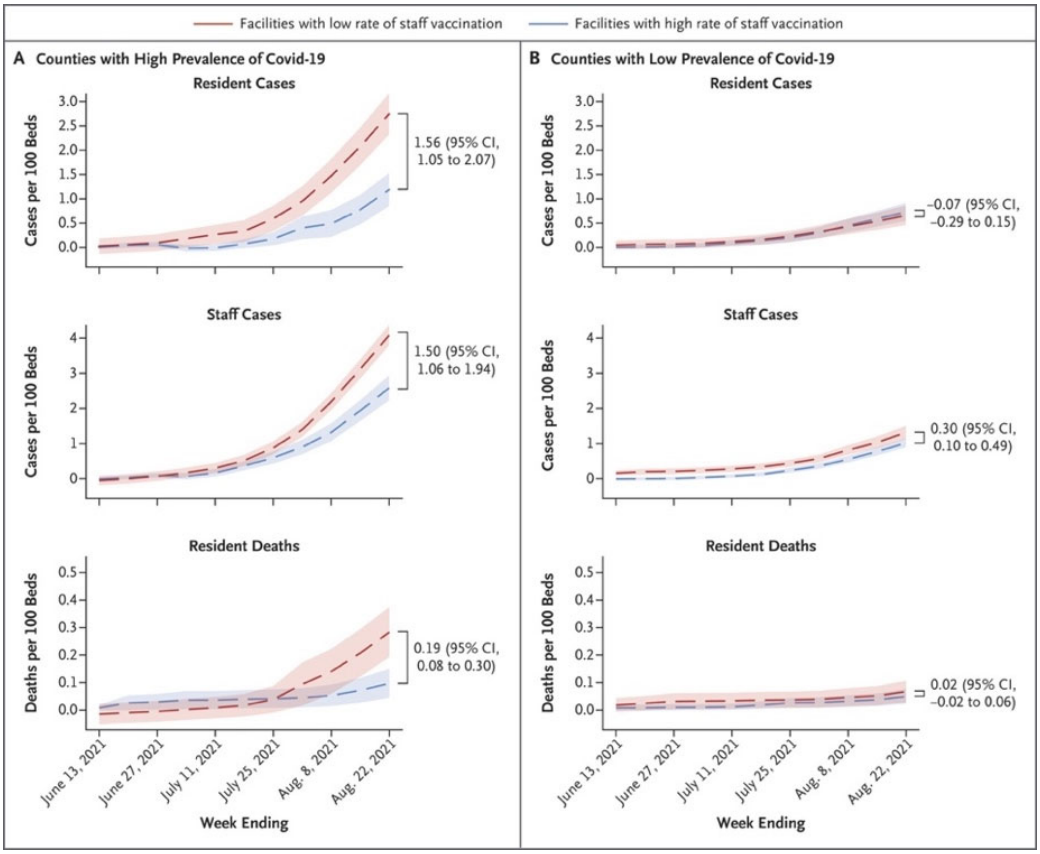




[8] https://jamanetwork.com/journals/jama/fullarticle/2768533
[9] https://ftp.iza.org/dp13319.pdf
[10] https://ourworldindata.org/explorers/coronavirus-data-explorer

11. In conclusion, the White et al. nursing home study in "freshly vaccinated" individuals, even when there was little to no immune escape from the vaccine formulation in use, there was no measurable impact of staff vaccination rates on nursing home resident vaccination rates once one controls for community infection rates.

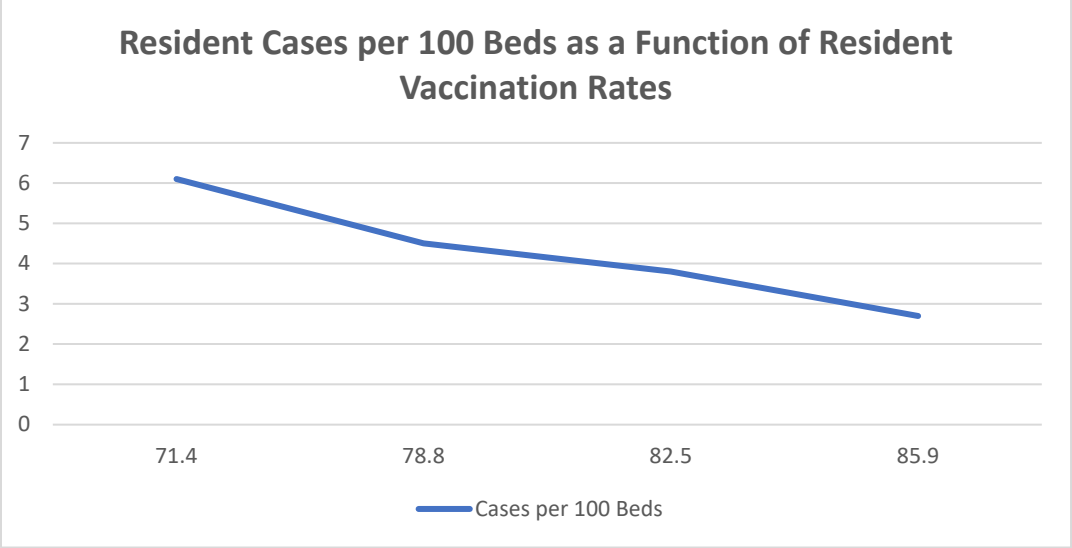
12. Interestingly, there was a follow up study in Nursing Homes examining infection rates and staff vaccination rates from McGarry et al. cites a strong association between staff vaccination rates and nursing COVID-19 case rates.[11] The study period was June 13, 2021 through August 22, 2021. This was a Delta-variant dominant period of infection. At face value, this study seems to support a stronger (albeit no more than 50%) correlation between staff vaccination rates and infection rates.



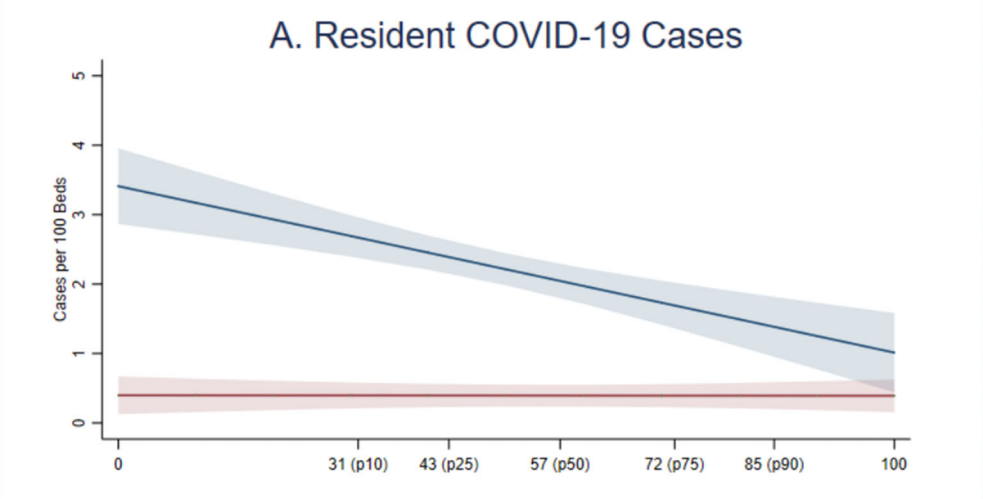
[11] https://www.nejm.org/doi/full/10.1056/NEJMc2115674

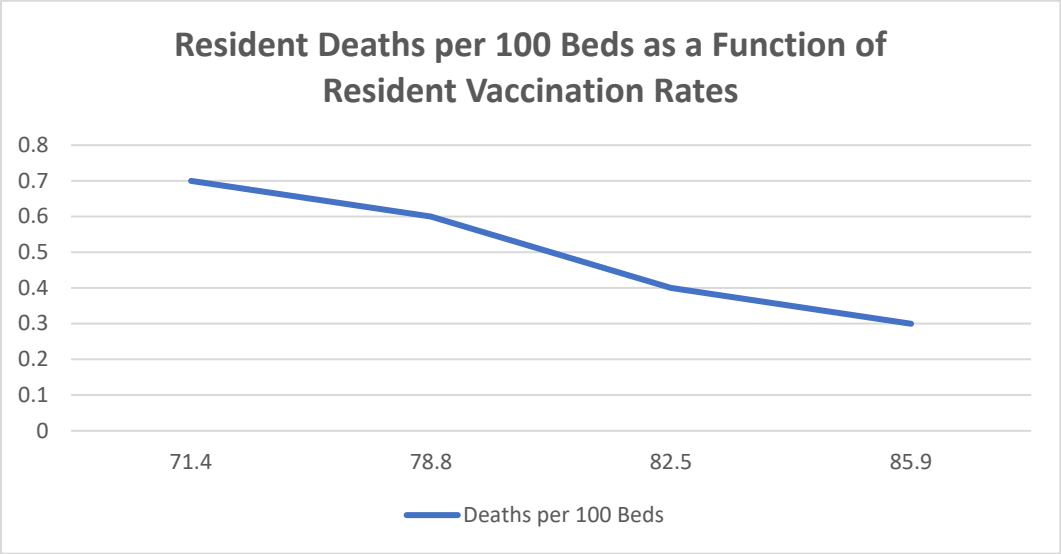
13. However, when examining the study data, it becomes clear that the authors did not pick up on the association between resident symptomatic case rates or death rates per 100 beds plotted against resident vaccination rates.

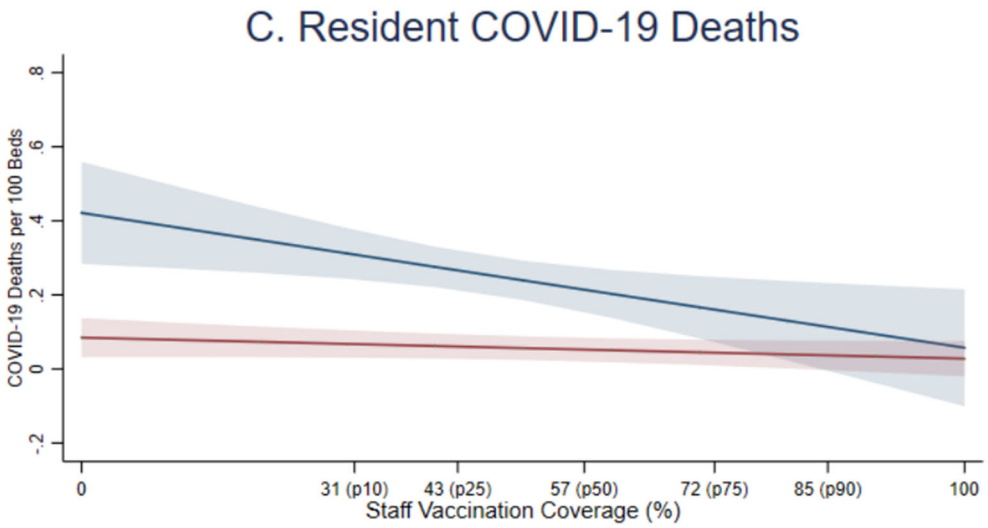
14. While I cannot reproduce the format of the authors' plots without their regression model, drawing from the supplemental appendix Table S1,[12] I can provide a rough trend line for resident case rates and death rates as a function of resident vaccination rates independent of staff vaccination rates. When plotted, we see that the relationship is essentially identical to the slope of the lines for resident case rates and death rates as a function of staff vaccination rates. This is evident by comparing the slope on my plots compared to screen shots of the author's figures in Figure S3. The difference between my plots and the authors' plots is that my x-axis is the resident vaccination rate rather than the staff vaccination rate. The y-axis is the same. ***Comparing the line slopes, almost all (if not all) of the demonstrated variability in resident case and death rates is subsumed by and accounted for by resident vaccination rates.***



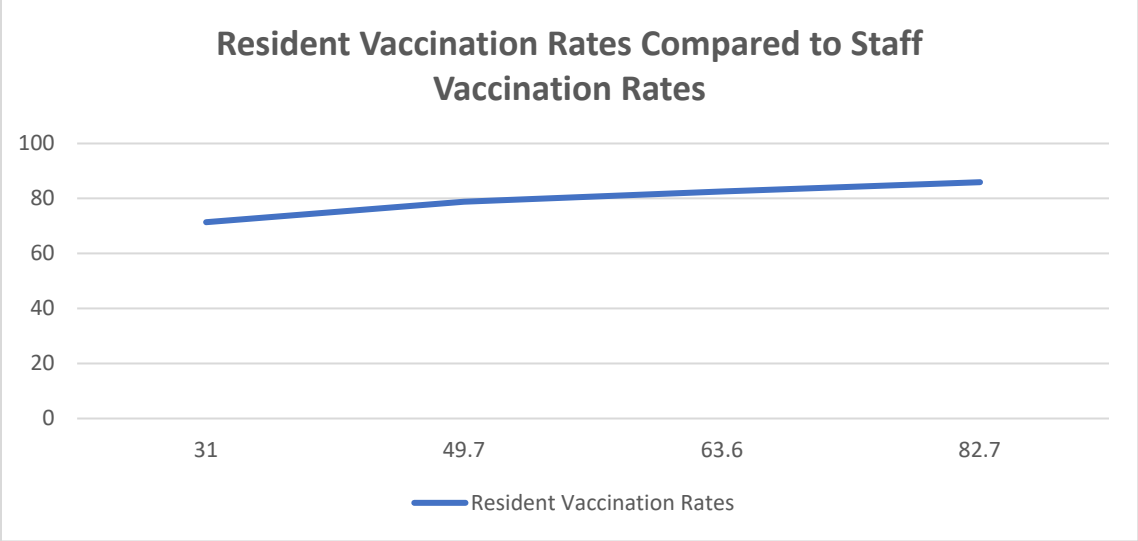
[12] https://www.nejm.org/doi/suppl/10.1056/NEJMc2115674/suppl_file/nejmc2115674_appendix.pdf


A. Resident COVID-19 Cases
Cases per 100 Beds
0
1
2
3
4
5
0
31 (p10)
43 (p25)
57 (p50)
72 (p75)
85 (p90)
100


Resident Deaths per 100 Beds as a Function of Resident Vaccination Rates
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
71.4
78.8
82.5
85.9
Deaths per 100 Beds


C. Resident COVID-19 Deaths
COVID-19 Deaths per 100 Beds
-.2
0
.2
.4
.6
.8
0
31 (p10)
43 (p25)
57 (p50)
72 (p75)
85 (p90)
100
Staff Vaccination Coverage (%)

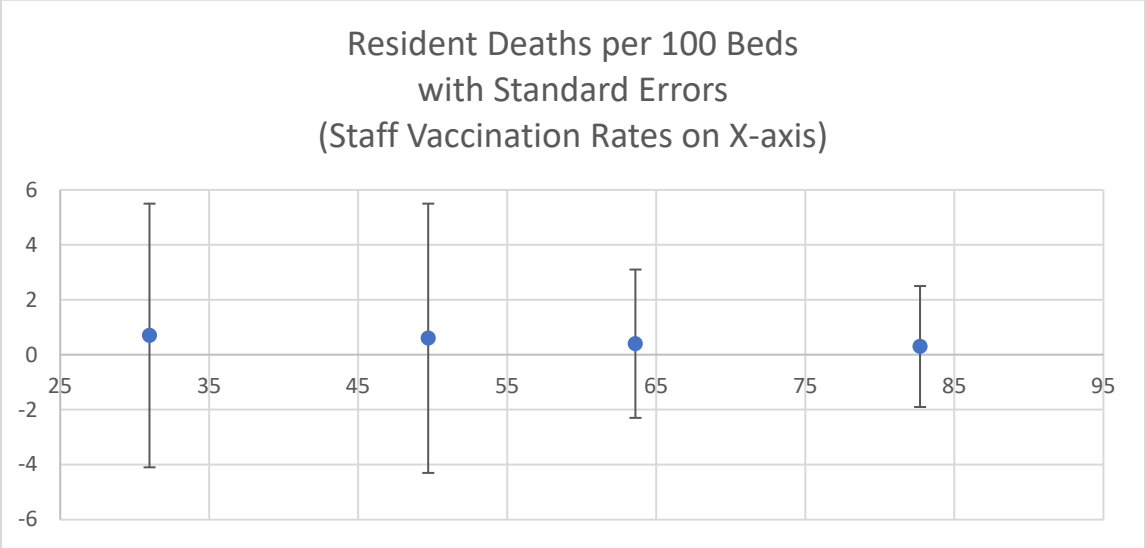
15. We can see why the relationship is the same whether one uses staff or resident vaccination rates by examining the relationship between staff and resident vaccination rates. From the plot below, you can see that it is almost a flat line. ***Mathematically, this means that whether you run the regression analysis against resident vaccination rate or staff vaccination rate, you will get almost no variation in the results and find the same correlation***. It's not surprising to imagine that attitudes towards COVID-19 vaccination in a community will impact both nursing home residents in the community as well as staff living in the same community. It was incorrect for the authors to attribute their findings to staff vaccination rates. As is the case with the vast majority of vaccines, the primary benefit is to the recipient of the vaccine.

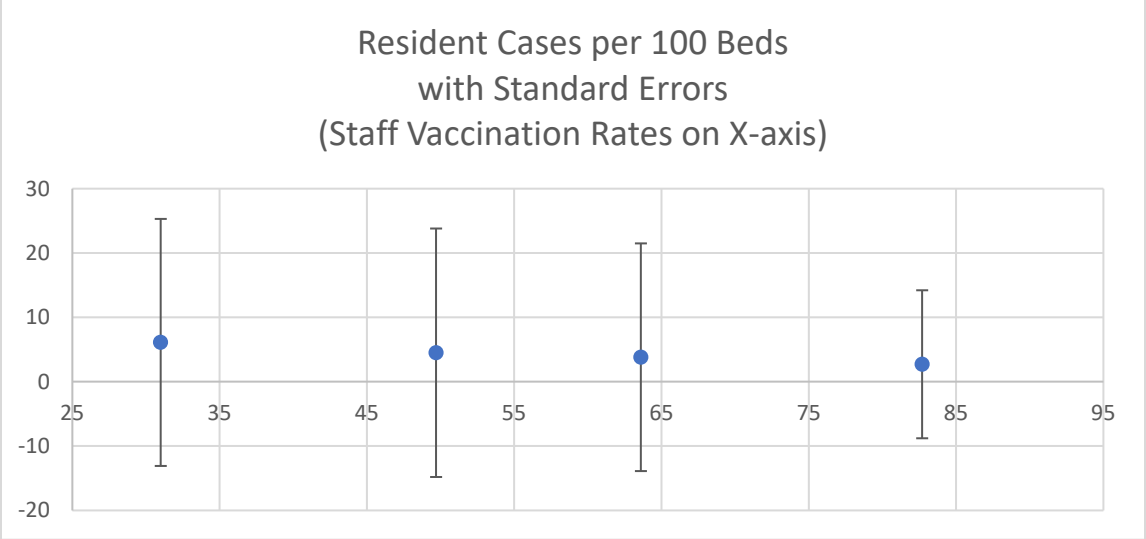


16. The McGarry et al. study also presents a wonderful example of how statistical methods, if not fastidiously applied, can fundamentally obfuscate deeper insights.

17. In particular, I would like to draw the court's attention to the absolute number of resident death rates per 100 beds reported in the study. I've plotted them below with standard deviation error bars taken from Table S1. There is little difference in resident mortality rate in all different categories of resident vaccination with marked overlap of the error bars such

that any differences could be due to chance alone. The plot would look the same if the x-axis were staff vaccination rates (provided upon request). The same is true, it turns out, for resident deaths.

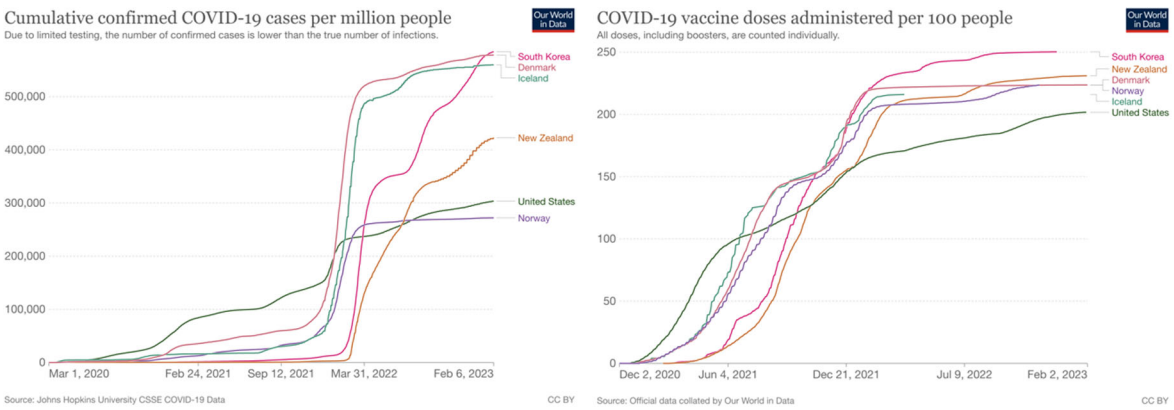




18. *We therefore have 2 nursing home studies (where there is close and sustained contact between patients and care-givers), one pre-Delta and one pre-Omicron during Delta, showing no notable relationship in patient COVID-19 rates and staff vaccinations rates.* Given increased escape from vaccine induced immunity with Omicron variants, there is no reason to believe that this trend, if studied, would not hold and even amplify.

19. What about transmission and vaccination/booster status with Omicron? An early December 2021 paper in Danish Households demonstrated a roughly 40% reduction in household secondary attack rate (SAR) with boosting when compared to the unvaccinated or vaccinated.[13] ***However***, there was no such reduction in susceptibility to infection when comparing vaccinated alone compared to the vaccinated. Focusing on table 2, during the early December 2021 study period, booster vaccination cut the risk of contracting Omicron by roughly 45%+ and passing on Omicron by roughly 40%.[5]

20. While this appeared promising for boosters, the subsequent ecological waves from late December 2022 forward in heavily boosted countries previously lauded for the "stopping COVID-19 infections" demonstrated otherwise. Denmark, Iceland, Norway, New Zealand, Australia, Hong Kong, South Korea all experienced per-capital COVID-19 waves larger than any experienced by the United States.[14] So the advantage of boosting, while demonstrable in an 8-week time frame, appears to rapidly devolve over time.

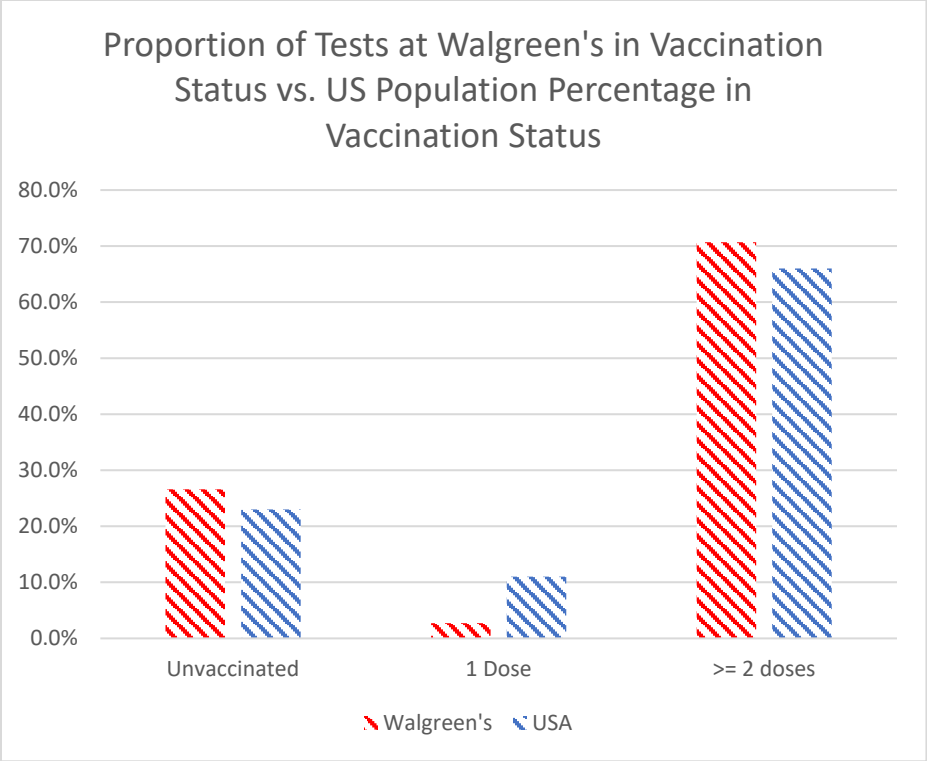


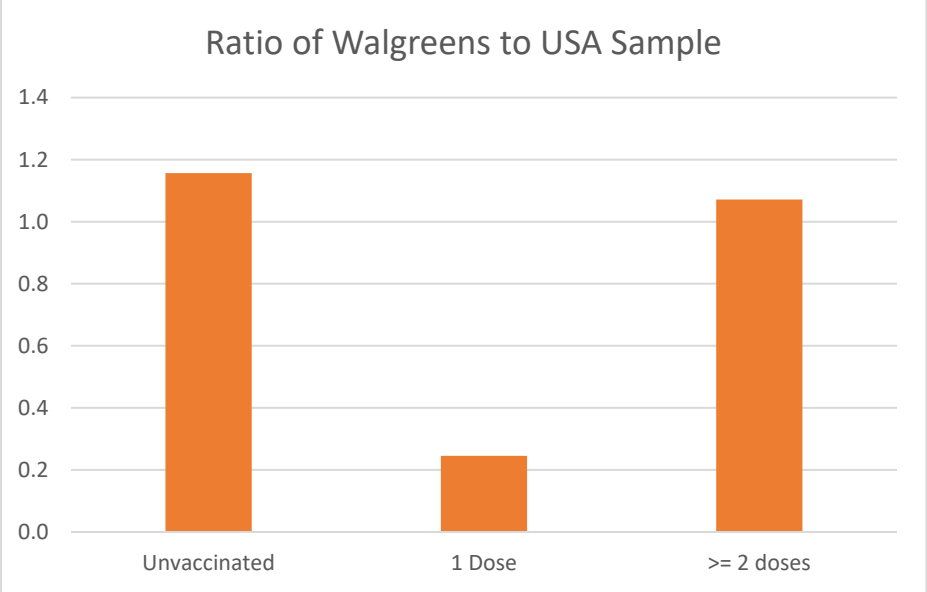
21. Indeed, we are seeing this effect even more so now across multiple data sets: both national and local.

[13] https://www.medrxiv.org/content/10.1101/2021.12.27.21268278v1.full.pdf
[14] https://tinyurl.com/yjr455f4

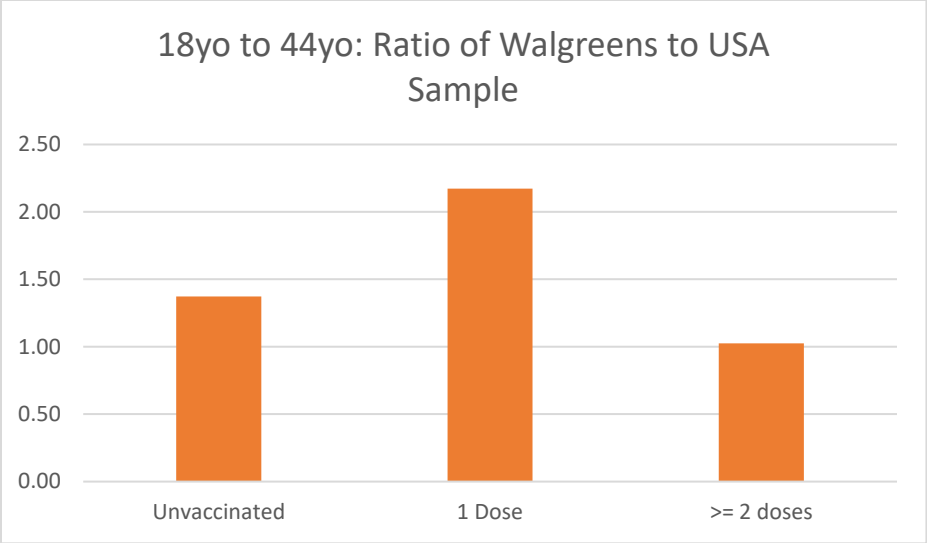
22. Walgreens is a leading nationwide provider of COVID-19 vaccination and testing provider. They maintain a remarkable COVID-19 dashboard that details test positivity by vaccination status broken down by age cohort.[15] Correcting for vaccination rates and population representation. The data appear to show that vaccinated and boosted individuals are testing positive for COVID-19 at a higher rate than unvaccinated individuals. While there likely reflects the fact that unvaccinated individuals are more likely to have had superior protection from a prior infection and more likely required to obtain surveillance testing even when asymptomatic, this does not impact our discussion here as the vast majority of Americans, vaccinated or not, have had a COVID-19 infection (approximately 75% through February 2022 and now at least 95% through August 22nd, 2022).[16]
23. The Walgreen's data is not excessively sampling vaccinated patients thereby biasing the results to suggest vaccinated individuals are testing positive more so than unvaccinated individuals. In fact, the population tested by Walgreens has a small number of single-dose vaccinated than the USA population, with higher proportions of vaccinated and unvaccinated patients – particularly the unvaccinated.

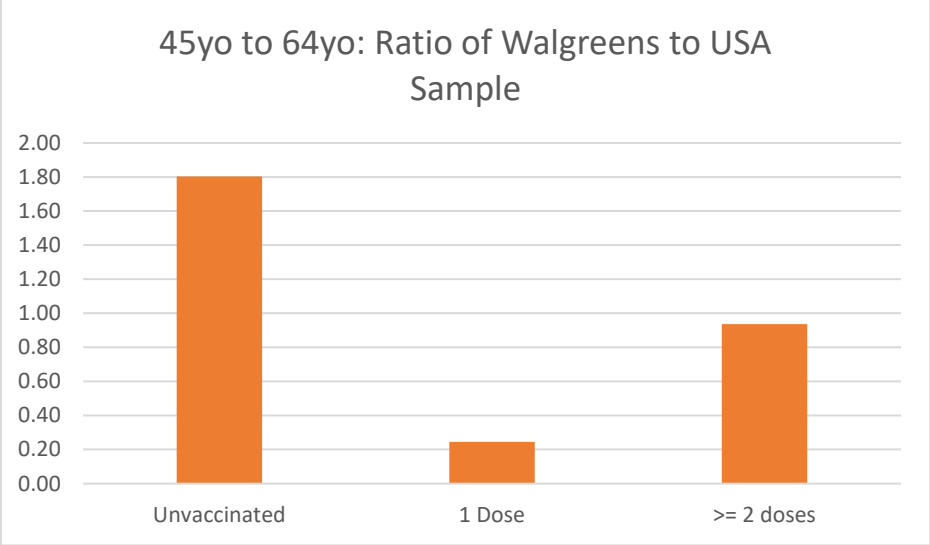
[15] https://www.walgreens.com/businesssolutions/covid-19-index.jsp
[16] https://covid19serohub.nih.gov/

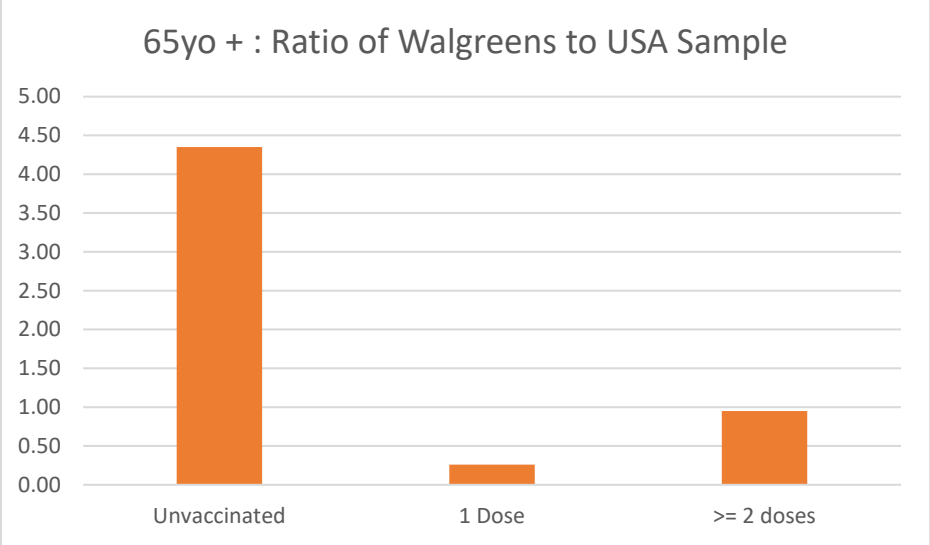




24. In fact, in the over 18-year-old age cohorts, Walgreen's tests unvaccinated patients at significantly higher rate than their representation in the USA population:

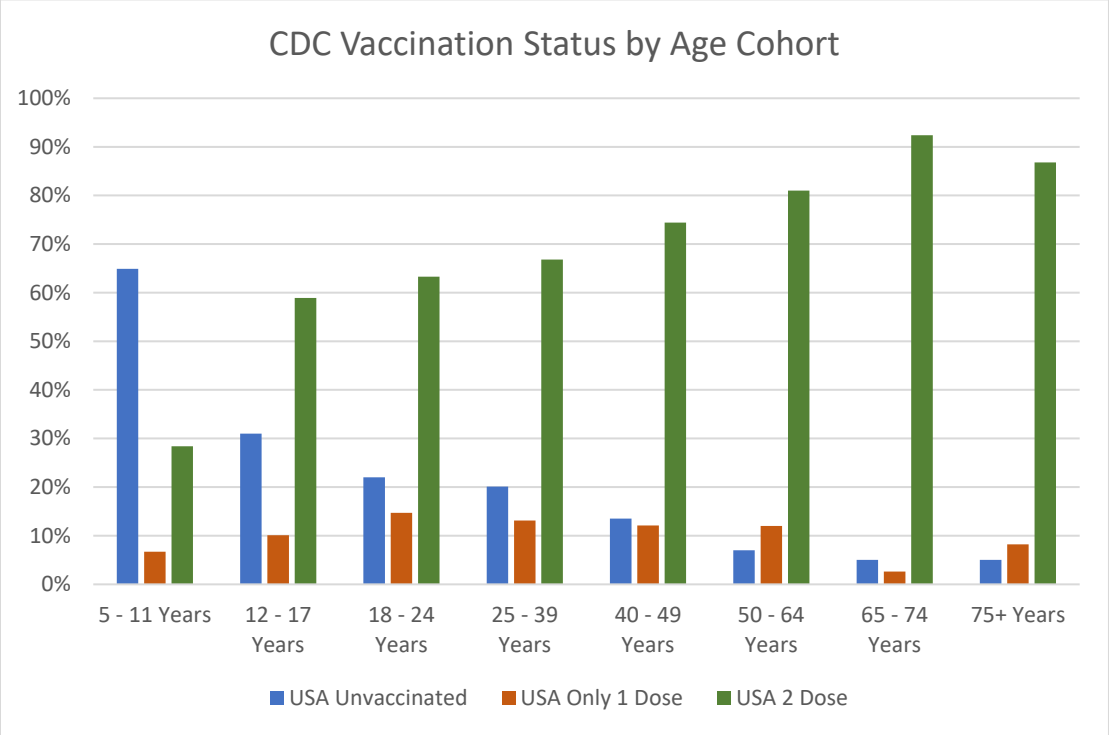

18yo to 44yo: Ratio of Walgreens to USA Sample
2.50
2.00
1.50
1.00
0.50
0.00
Unvaccinated
1 Dose
>= 2 doses


45yo to 64yo: Ratio of Walgreens to USA Sample
2.00
1.80
1.60
1.40
1.20
1.00
0.80
0.60
0.40
0.20
0.00
Unvaccinated
1 Dose
>= 2 doses

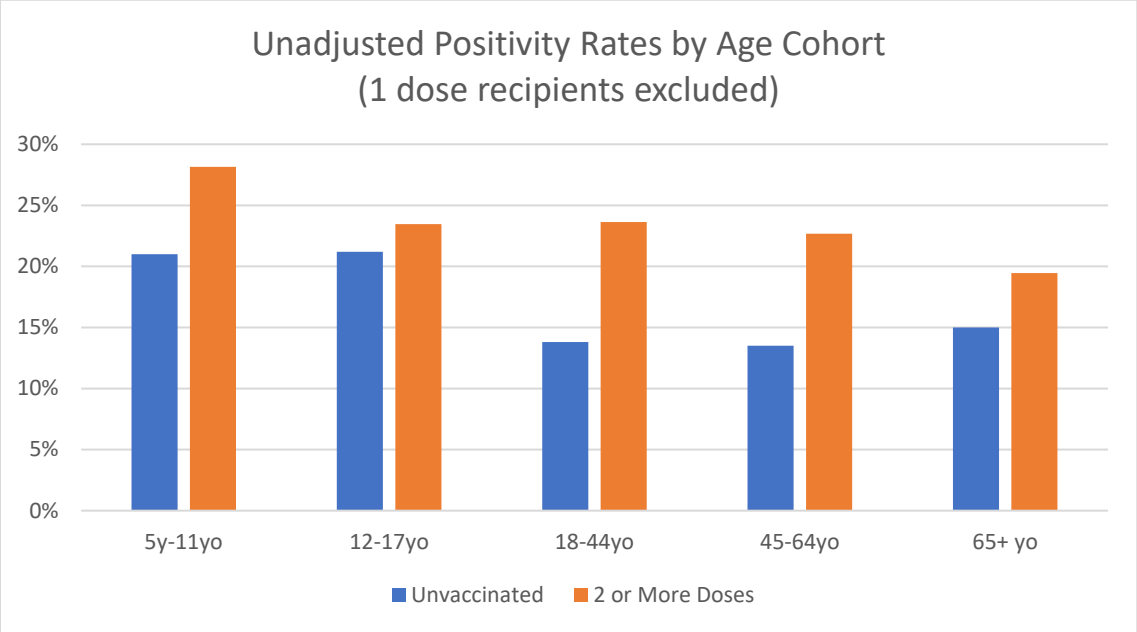

65yo + : Ratio of Walgreens to USA Sample
5.00
4.50
4.00
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
Unvaccinated
1 Dose
>= 2 doses

25. When collecting Walgreens data for a testing week April 28th, 2022, for every age cohort, vaccinated individuals are shown to be testing positive *at a rate that is at least as high*. While there are caveats to this pattern that I will note later, it's important to understand that these are rates so there is no "base rate fallacy". In other words, just because vaccinated individuals are a larger percentage of the population, they will not register a higher rate of positivity.

26. For this analysis, I also obtained CDC data by dose per age cohort through April 2022. This allows us to compare vaccination rates in a particular age cohort to test positivity rates in those cohorts in the Walgreens national testing data:



27. Consolidating fully vaccinated and boosted individuals into a "2 or more doses" category to correspond to the CDC data above, we see the following across all age cohorts from Walgreens:

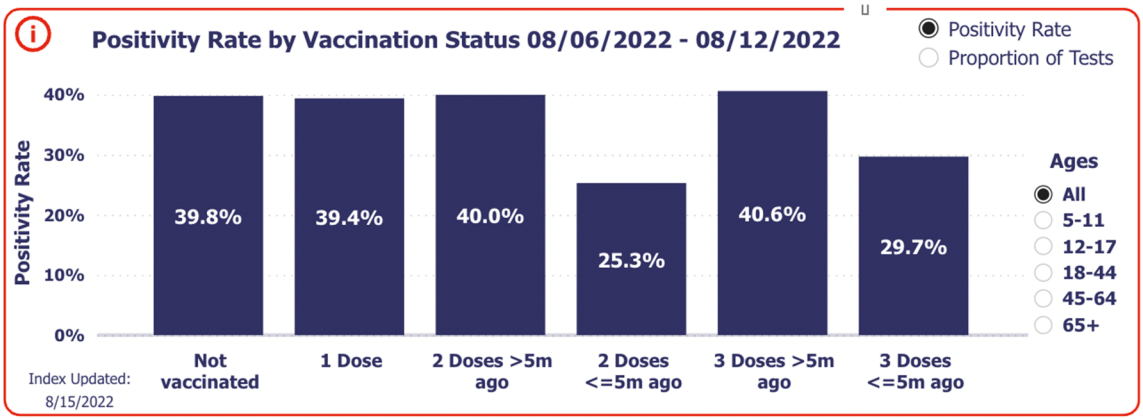


28. To those limitations previously mentioned including high rates of testing among unvaccinated by mandate driving down positivity rates, I will add that, from a conference call I participated in with the Walgreens epidemiologic team on June 16th, 2022, repeat testers are not easily filtered by Walgreen's despite their best attempts. Indeed, my analysis on Walgreen's data from May 2022 is part of what prompted the June 16th, 2022 call. Walgreens provides the following statement:

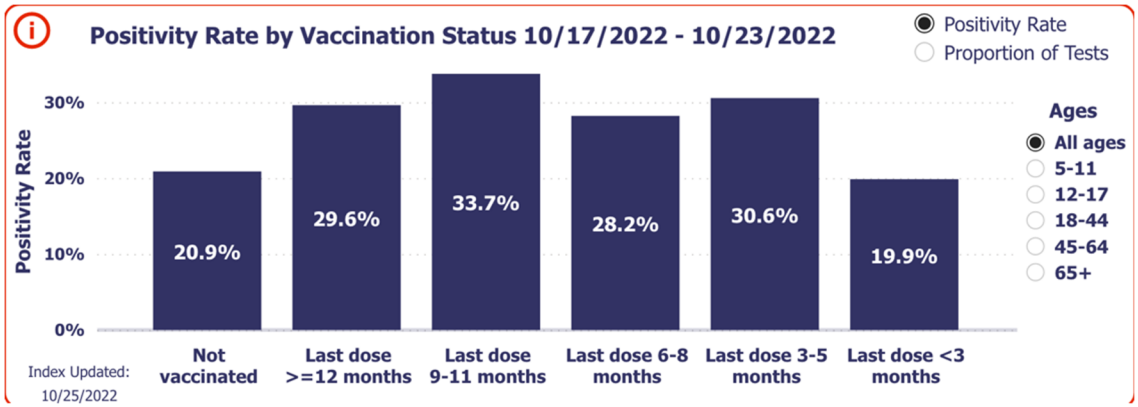
"Controlling for recent COVID-19 cases, results show that the unvaccinated group has a ***17.1% higher positivity rate compared to the 3-dose group*** *(emphasis mine). Controlling for additional factors leads to a larger difference between groups. ... in addition to the changing level of circulating virus in the population, positivity rates are influenced by many factors ... These factors can both increase and decrease the positivity metric."*

29. Notably, my central assertion of transmission reduction on the order of 20-25% for roughly 8 weeks is quite consistent with the imputed value of a 17.1% higher positivity rate among unvaccinated individuals after the post-May 2022 "corrections" were applied by Walgreen's. Furthermore, the evidence for waning efficacy, regardless of testing imbalances, is unmistakable in their data. Indeed, subsequent Walgreen's dashboard demonstrate no evidence to support sustained transmission reduction:

- August 6th, 2022:

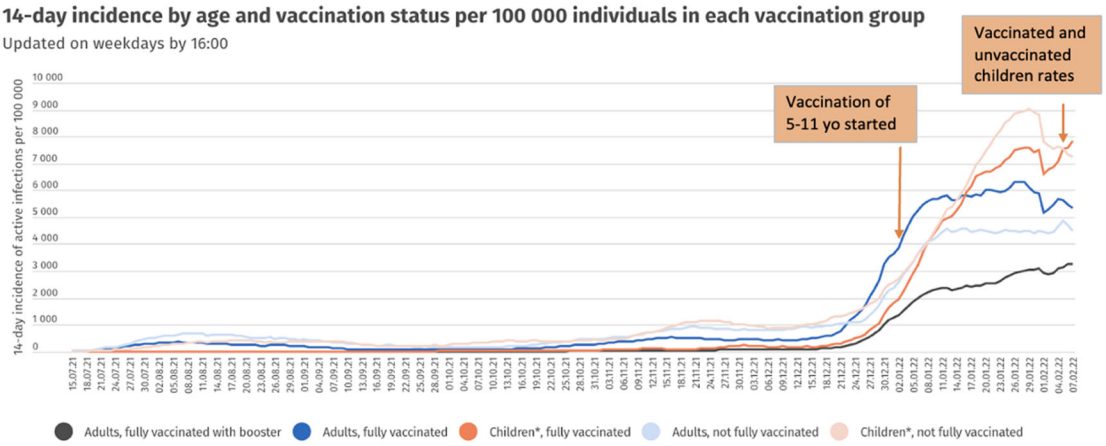


- October 25th, 2022:



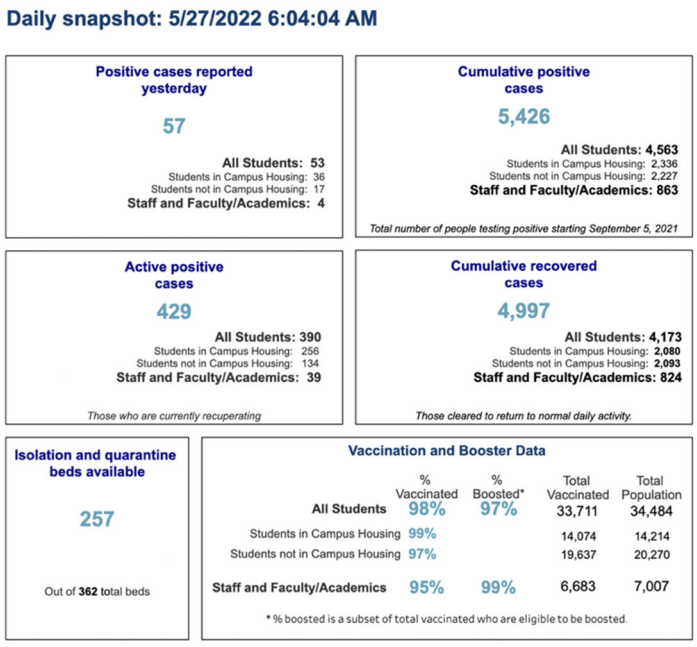
30. High positivity rates in vaccinated individuals, that effectively undermine the argument for COVID-19 vaccine mandates, are duplicated across multiple countries which is why they have been abandoned across most of the Western world. Some of the most

compelling mid-2022 data sets are from the United Kingdom and Iceland.[17,18]

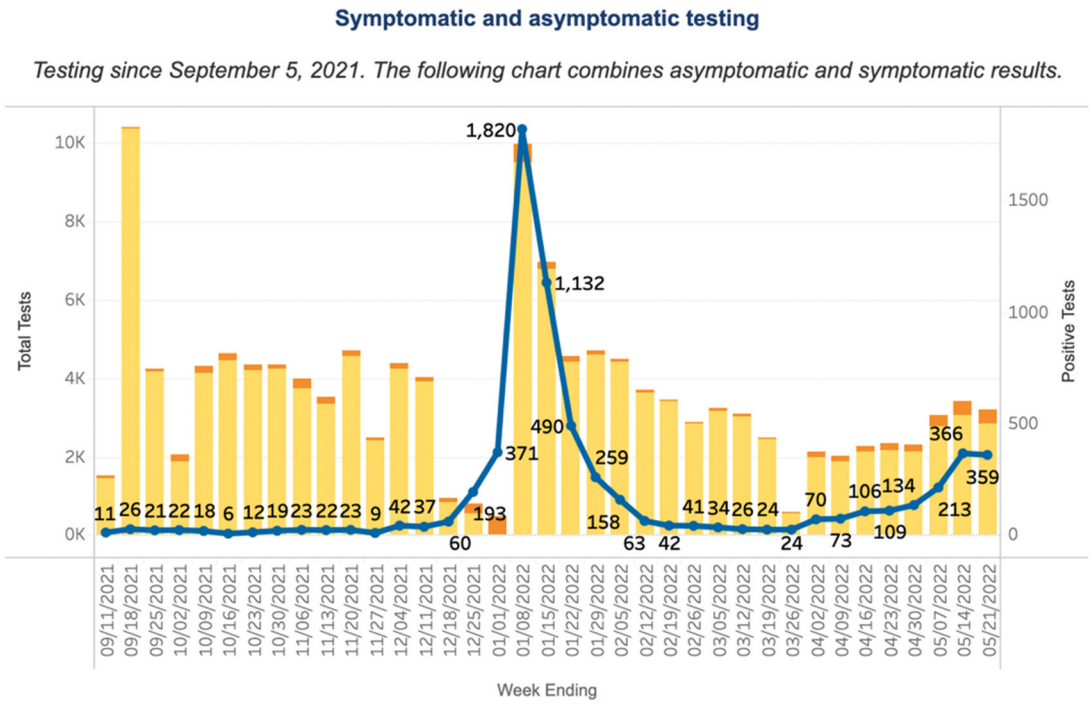


31. And the high infection rates in vaccinated, and even near universally boosted populations is evident in multiple local data sets such as the University of California campuses.

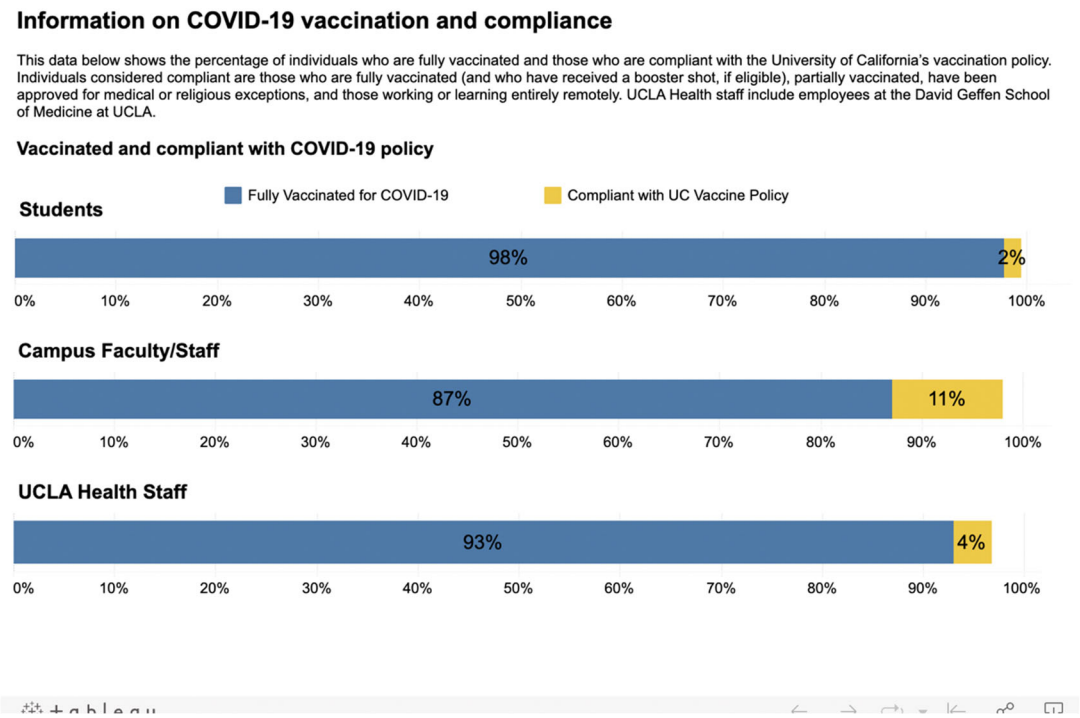
32. The University of California at Irvine:[19]



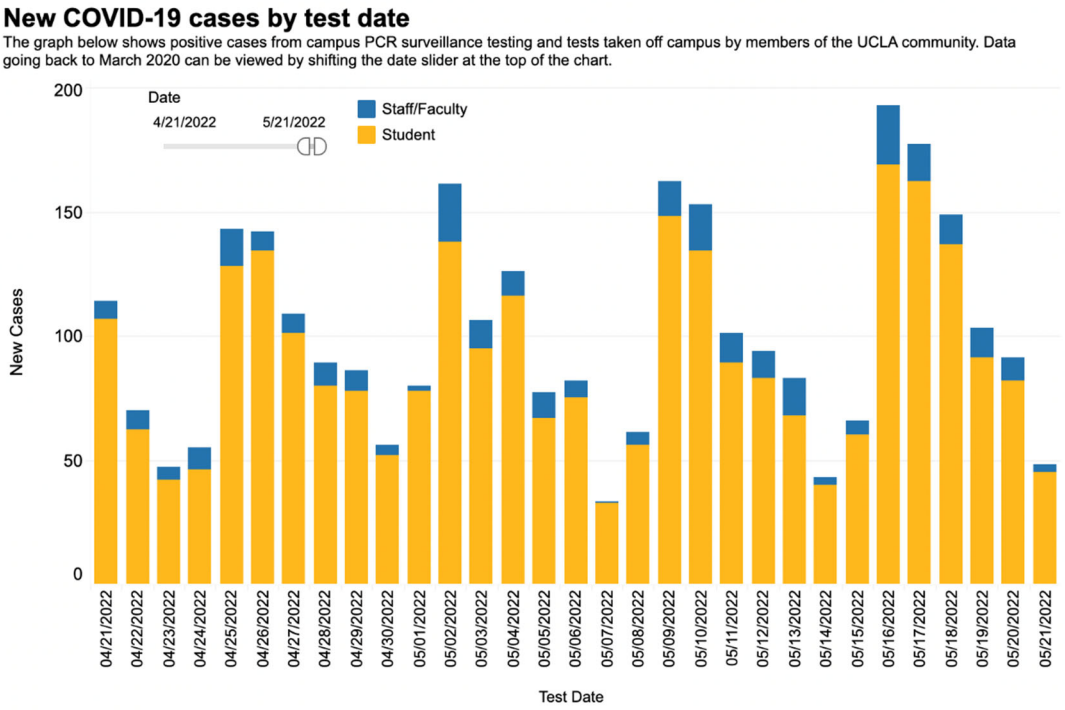
[17] https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports
[18] https://www.covid.is/data
[19] https://uci.edu/coronavirus/dashboard/index.php



33. University of California at Los Angeles:[20]



[20] https://covid-19.ucla.edu/confirmed-cases-of-covid-19-among-the-ucla-campus-community/



34. Fast forward to Omicron and related variants, we can revisit Danish research on transmission with the BA.2 Omicron variant (dominant now) versus the BA.1 Omicron variant (dominant through the winter of 2021-22), they noted:[21]

> Both unvaccinated, fully vaccinated and booster-vaccinated individuals had a higher susceptibility for BA.2 compared to BA.1, indicating an inherent increased transmissibility of BA.2 (Table 3). However, the relative increase in susceptibility was significantly greater in vaccinated individuals compared to unvaccinated individuals (appendix Figure 6, which points towards immune evasive properties of the BA.2 conferring an even greater advantage for BA.2 in a highly vaccinated population such as Denmark. Because previous studies of the Omicron VOC has focused on the BA.1 (Pearson et al., 2021; Planas et al., 2021), new studies are needed to further investigate these properties for BA.2.

35. None of this observation data is particularly surprising. Indeed, much of this could have been inferred from our prior experience with Influenza. Both SARS-CoV-2 and Influenza

[21] https://www.medrxiv.org/content/10.1101/2022.01.28.22270044v1

are enveloped RNA respiratory viruses of roughly 100 nanometers per virion in size. Both SARS-CoV-2 and Influenza are transmitted by droplets and aerosols, and the impacts of vaccination are quite similar. COVID-19 has followed the path of Influenza: now, as with influenza, cases of COVID-19 will continue to appear, but the number and severity of those infections will be significantly reduced even while neither vaccination or prior infection represents an impenetrable shield to subsequent infection.[22,23] In fact, a 2018 study positively correlated amount of virus in exhaled breath with vaccination status thereby suggesting that in the study population, those vaccinated with the Influenza vaccine were spreading more viral particles.[24] It is well established that the benefits of Influenza vaccination extend to the individual receiving the vaccination which is traditionally why Influenza vaccination in health care settings has been recommended and not mandated (until recently at some institutions). Coming back to studies performed hin health care settings, a 2017 study established that patient benefit from healthcare worker was not established:

> *"The impression that unvaccinated HCWs place their patients at great influenza peril is exaggerated. Instead, the HCW-attributable risk and vaccine-preventable fraction both remain unknown and the NNV to achieve patient benefit still requires better understanding. Although current scientific data are inadequate to support the ethical implementation of enforced HCW influenza vaccination, they do not refute approaches to support voluntary vaccination or other more broadly protective practices, such as staying home or masking when acutely ill."* [25]

[22] https://www.eurekalert.org/news-releases/694958
[23] https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00180-4/fulltext
[24] https://www.pnas.org/doi/10.1073/pnas.1716561115
[25] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0163586

36. This has led Dr. Michael Osterholm, formerly a member of the Biden Administration's COVID-19 Task Force to state:

"We have to make public health recommendations based on good science," Osterholm added, "but we do not have the justification to take punitive action against healthcare workers if they don't get vaccinated [for Influenza]." [26]

37. Now in 2023, Dr. Anthony Fauci, who needs no introduction, has finally weighed in on the matter:[27]

> *"However, as variant SARS-CoV-2 strains have emerged, deficiencies in these vaccines reminiscent of influenza vaccines have become apparent. The vaccines for these two very different [mucosal respiratory] viruses have common characteristics: they elicit incomplete and short-lived protection against evolving virus variants that escape population immunity … Taking all of these factors into account, it is not surprising that none of the predominantly mucosal respiratory viruses have ever been effectively controlled by vaccines. This observation raises a question of fundamental importance: if natural mucosal respiratory virus infections do not elicit complete and long-term protective immunity against reinfection, how can we expect vaccines, especially systemically administered non-replicating vaccines, to do so?"*

Once again, the primary benefit of a COVID-19 vaccination is to the recipient and it is for decreasing the risk of severe disease.

[26] https://www.cidrap.umn.edu/news-perspective/2017/01/health-worker-flu-vaccine-data-insufficient-show-protection-patients

[27] https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(22)00572-8

38. Inevitably, the topic of COVID-19 in children arises in any discussion around COVID-19 vaccination especially as it might pertain to Disney's clientele. To that end, it's appropriate to discuss COVID-19 in children specifically.

39. The most recent CDC update to Pediatric infection through August 22nd, 2022 estimated infection induced seroprevalence in the under-18yo group to be at least 95%.[28] It's no doubt higher than that now.

40. **Durability Over Time of Immune Memory to SARS-CoV-2 Infection:** A healthy immune system mounts an effective response to SARS-CoV-2 infection and this response persists over time. A recent July 2022 publication where 96.7% of study participants had mild or asymptomatic infection shows that children mount a robust antibody response that will fade with time, but remains measurably present.[29]

Table 1. Serologic Data of 769 Serum Samples Obtained From 659 Individuals With Confirmed COVID-19 Among Different Age Classes, Overall and Stratified by Time From Baseline[a]

	Anti-RBD, median (IQR), kBAU/L			
Variable	All data	1-4 mo from onset	5-9 mo from onset	>10 mo from onset
Age class, y				
<3	304.83 (139.0-519.6)	342.8 (179.5-519.6)	284.3 (162.5-519.6)	146.2 (62.8-231.2)
≤3	169.3 (103.1-277.1)	234.6 (113.5-347.9)	118.2 (70.6-192.5)	115.6 (45.9-160.6)
≤6	126.2 (74.0-207.8)	164.1 (79.1-236)	119.7 (77.4-165.2)	90.6 (62.4-111.8)
≤12-18	98.2 (44.7-169.0)	103.1 (46.3-170.2)	89.6 (45.9-170.2)	48.6 (18.1-95.7)
≥18	55.6 (24.2-136.0)	64.5 (26.2-140.9)	49.8 (22.5-114.7)	36.7 (13.5-108.5)
P value[b]	<.001	<.001	<.001	.02

Abbreviations: kBAU/L, kilo-binding antibody units per liter; RBD, receptor-binding domain.

[a] Serum samples at the last time point for 17 people whose last S-RBD IgG titer was higher than the previous one were excluded from the analysis.

[b] Kruskal-Wallis test.

41. Once again this speaks to an expected pattern of less severe disease with any subsequent infection. This study reinforced prior research that measured these responses up to 12 months. This latter point is extremely important to fully understand as more than 95% of American children have had a COVID-19 infection:[30]

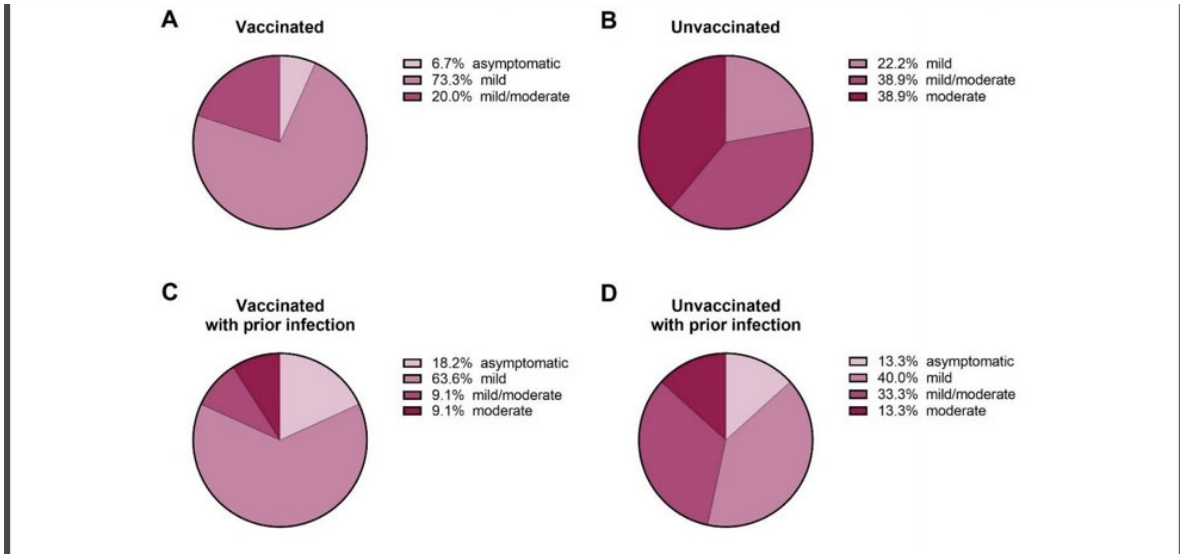
> *"Importantly, children retained antibody and cellular responses 6 months after infection, whereas relative waning occurred in adults. Spike-specific responses were*

[28] https://covid19serohub.nih.gov/
[29] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794167
[30] https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence

also broadly stable beyond 12 months. Therefore, children generate robust, cross-reactive and sustained immune responses to SARS-CoV-2 with focused specificity for the spike protein."[31]

42. More recent data in a post-Omicron infection sample, shows that those with prior infection, with or without associated vaccination, have a robust rise in neutralizing antibodies after an Omicron infection. Indeed, those who were vaccinated alone with no prior infection had modal titers similar to those who were unvaccinated.[32]

43. And, as repeatedly asserted throughout my declaration and in this response to the Defendant's expert declarations, neither prior infection nor vaccination will prevent a subsequent SARS-CoV-2 infection, but they both reduce the severity of outcomes. In this study, the differences were minor if there was a prior infection:



Once again, the primary benefit of a COVID-19 vaccination is to the recipient.

[31] https://www.nature.com/articles/s41590-021-01089-8
[32] https://www.nejm.org/doi/full/10.1056/NEJMc2201607

44. It's worth noting that in this same study, *47% of the vaccinees had an mRNA vaccination within the preceding 3 months and 40% had been boosted*.[31]

Table S2. Patient characteristics of vaccinated individuals without prior history of pre-Omicron infection

AGE (YEARS)	SEX#	DAYS SINCE BA.1 INFECTION*	VACCINATION	WEEKS SINCE LAST VACCINATION$	SEVERITY OF COVID-19
<20	f	10	BNT162b/BNT162b	16.3	mild
50-59	m	18	BNT162b/BNT162b	unknown	mild
50-59	f	18	BNT162b/BNT162b	unknown	mild
30-39	m	20	BNT162b/BNT162b	unknown	mild
30-39	m	8	BNT162b/BNT162b/BNT162b	3.1	mild/moderate
20-29	m	14	BNT162b/BNT162b/BNT162b%	1.6	mild/moderate
20-29	m	33	ChAdOx1	22.1	mild
20-29	f	35	BNT162b	6.0	mild
30-39	m	23	mRNA-1273/mRNA-1273/mRNA-1273%	0.6	mild
20-29	f	10	BNT162b/BNT162b	23.3	mild
30-39	f	6	mRNA-1273/mRNA-1273/BNT162b%	0.1	mild
20-29	f	10	BNT162b/BNT162b	23.0	mild/moderate
20-29	f	5	Ad26.COV2.S/BNT162b	7.6	asymptomatic
80-89	m	9	BNT162b/BNT162b/BNT162b	12.0	mild
40-49	f	12	ChAdOx1/ChAdOx1	29.3	mild

f = female; m = male; * Days since first positive PCR for omicron BA.1 infection; %Interval between last dose of vaccination and first positive PCR for omicron BA.1 infection less than 14 days; $Interval between last dose of vaccination and first positive PCR for omicron BA.1 infection

But chasing and citing "infections" as the reason for any policy intervention is doomed to fail. Even as it pertains to measuring antibody levels attained with vaccine dosing, disease severity does not determine the potency or longevity of response with commercially available assay levels correlating with separate neutralizing-antibody titers.[33]

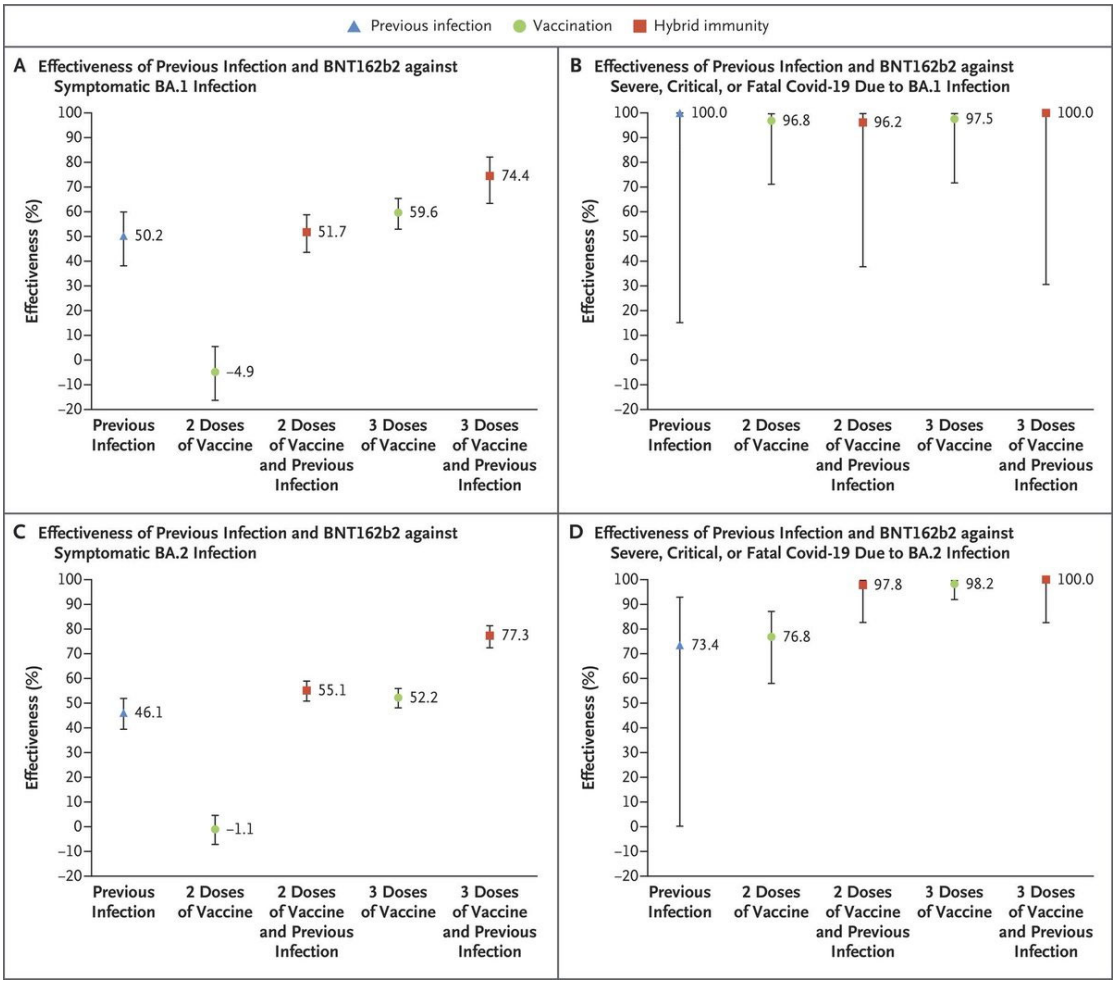
45. A recent publication from Iceland has offered unique insights into what we can expect with post-Omicron reinfections in different vaccination categories.[34] While I felt there were significant problems with possible ascertainment bias and grouping of unvaccinated with 1 dose recipients, the authors found:

> *"Surprisingly, 2 or more doses of vaccine were associated with a slightly higher probability of reinfection compared with 1 dose or less. This finding should be interpreted with caution because of limitations of our study, which include the inability to adjust for the complex relationships among prior infection, vaccine eligibility, and underlying conditions."*

[33] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794167
[34] https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2794886

46. A more robust nationwide study from Qatar, once again, provides corroborating evidence for the potency of prior infection.[35] Per the authors:

> *"No discernable differences in protection against symptomatic BA.1 and BA.2 infection were seen with previous infection, vaccination, and hybrid immunity. Vaccination enhanced protection among persons who had had a previous infection. Hybrid immunity resulting from previous infection and recent booster vaccination conferred the strongest protection. [All provided excellent protection against severe outcomes]"*



[35] https://www.nejm.org/doi/full/10.1056/NEJMoa2203965

47. But as pertaining to the absolute risk reduction of a recent booster or vaccination on top of a prior infection, a detailed examination of the data tables reveals a striking pattern. In addition to robust protection from severe disease afforded by prior infection in patients with little difference after subsequent vaccination, symptomatic infection rate differences after a prior infection with various doses of vaccine corroborate the authors' conclusion:

Table 2. Effectiveness of Previous Infection, Vaccination with BNT162b2, and Hybrid Immunity against Symptomatic Omicron Infections and against Severe, Critical, or Fatal Covid-19.*

Infection and Immune Status	Case Participants with Symptomatic Infection (PCR-Positive)†		Controls (PCR-Negative)†		Effectiveness against Symptomatic Infection (95% CI)	Case Participants with Severe, Critical, or Fatal Covid-19‡		Control
	Exposed	Unexposed§	Exposed	Unexposed§		Exposed	Unexposed§	Expos
	number				*percent*			*number*
infection					55.9)			
Three doses and previous infection	153	6051	489	5372	77.3 (72.4 to 81.4)	0	43	23
Any omicron infection								
Previous infection and no vaccination	637	7837	1,113	6904	50.8 (45.4 to 55.7)	4	100	24
Two doses and no previous infection	13,033	7837	10,600	6904	−0.2 (−5.5 to 4.9)	63	100	320
Two doses and previous infection	1,360	7837	2,501	6904	55.5 (51.8 to 59.0)	3	100	79
Three doses and no previous infection	2,234	7837	3,586	6904	54.0 (50.4 to 57.3)	12	100	164
Three doses and previous infection	187	7837	584	6904	76.3 (71.7 to 80.1)	0	100	47

48. More recent literature has examined local tissue and mucosal immunity generated by an infection compared to vaccination alone.[36,37] As confirmed by the 2023 publication from Dr. Fauci and co-authors alluded to above, vaccination for common mucosal respiratory viruses like SARS-CoV-2 does not generate an effective mucosal immune response. Infection, however, as noted above, does. Furthermore, disease severity does not determine the potency or longevity of response with commercially available assay levels correlating with separate

[36] https://www.science.org/doi/10.1126/sciimmunol.add4853
[37] https://www.science.org/doi/10.1126/sciimmunol.abl9105

neutralizing-antibody titers.[38] A COVID-19 infection, at least once, is an inevitability and may be an immunologic requirement.

49. The stimulation of an immune response after a mild infection can even be demonstrated in the absence of actual antibody seroconversion (detectable prior infection by antibodies) at the level of T-cells.[39] The presence of effective immune memory, both humoral (antibody) and cellular components, after even a mild SARS-CoV-2 infection is no longer a matter of debate.

50. **Comparison to other Respiratory Viruses (RVs):** This brings us full circle to considering COVID-19 and its severity in children as compared to other respiratory viruses. Prior to COVID-19, we have **never** tested every single admission to the hospital or possible death for a highly contagious respiratory virus. We haven't even done this for Influenza during prior Influenza seasons. Had we done so, there is a good chance that we would have had many minimally symptomatic or asymptomatic admissions testing positive for Influenza even while it was not the primary reason for admission. With respect to COVID-19, this has been an undeniable phenomenon that took more than 1.5 years for the CDC to acknowledge.

51. This is particularly true in Pediatric COVID-19 admissions given the overwhelming trend for mild disease. It has been globally demonstrated and has accelerated with even milder disease from Omicron. Pre-Omicron, in children and young people, the rate of incidental COVID-19 positive admissions where COVID-19 was not deemed to be central to the reason for admission was 59% in the United Kingdom, 38% in Canada, in the United States

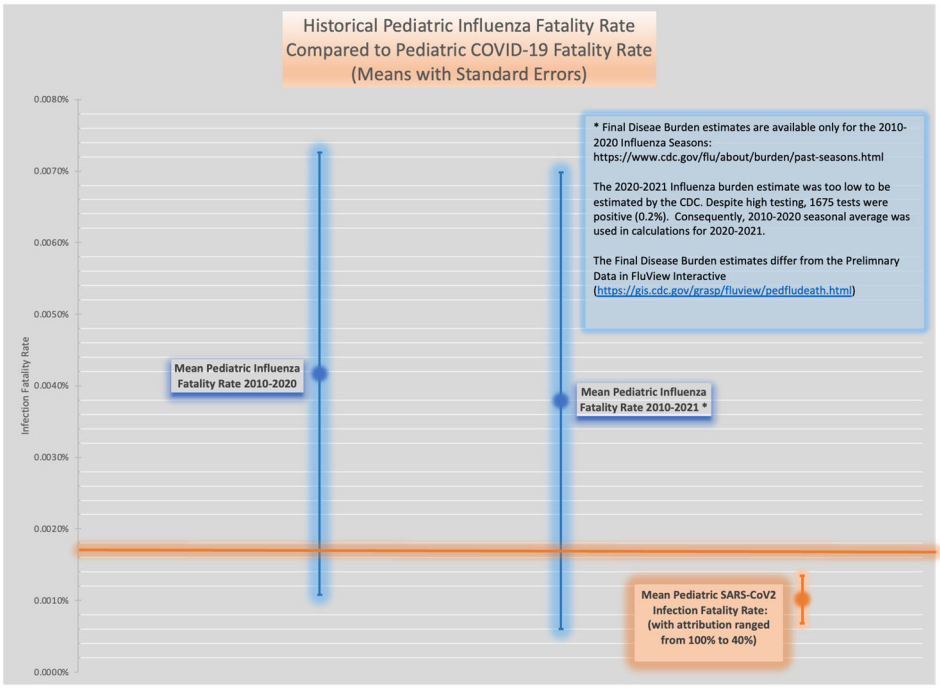
[38] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794167
[39] https://www.sciencedirect.com/science/article/pii/S0092867420310084

39% asymptomatic and an additional 28% with mild or moderate disease, in France 45% were asymptomatic.[40,41,42,43] Consequently, when we assess hospitalizations and deaths from COVID-19 in Pediatric patients, reported numbers, on average, are not representative of attribution to severe COVID-19 itself in at least 40% of cases.

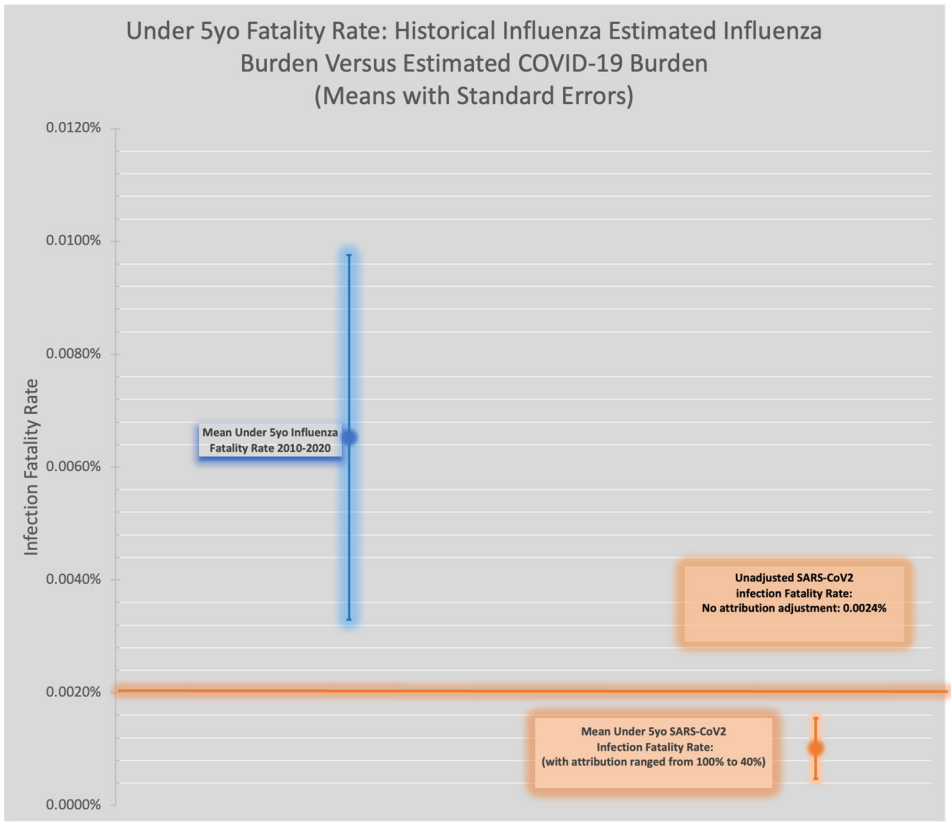
52. Having said the above, we can still perform a bounding analysis with data obtained from the CDC for US children. The following analysis represents data obtained from the CDC through February 22nd, 2022 representing the conclusion of the first Omicron (BA.1) wave through most of the US.

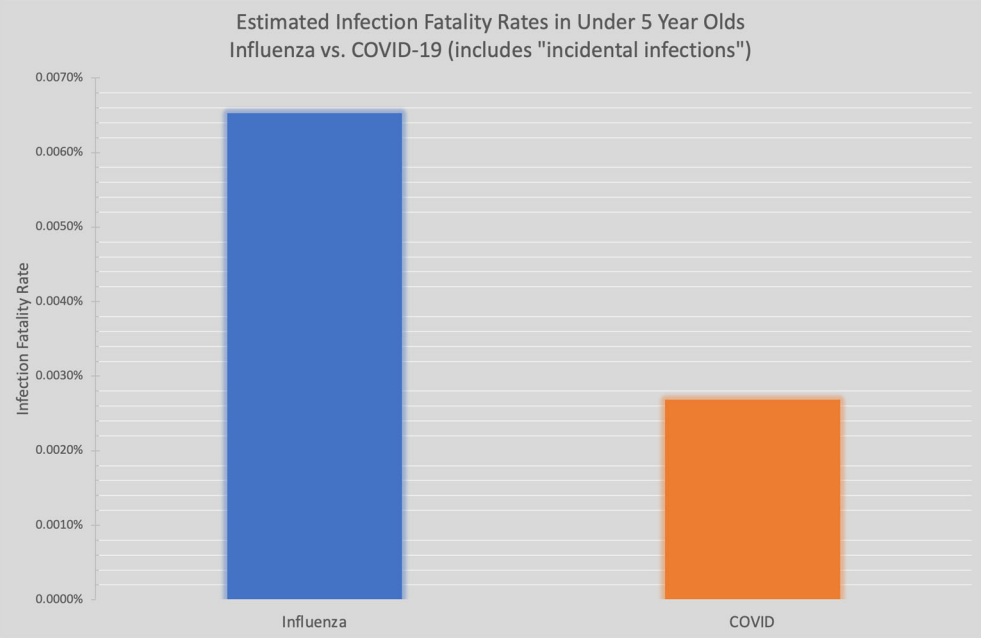
53. Utilizing data from the CDC on past Influenza disease burden as well as COVID-19 cases and deaths reported to the CDC, when looking at all children, we can see that in the worst-case scenario, COVID-19 is at worse a severe Influenza risk.[44,45,46,47] In a more realistic scenario, it is less than a standard Influenza risk and slightly more than that for obese teenagers. 95% confidence intervals are displayed:

[40] https://www.researchsquare.com/article/rs-689684/v1
[41] https://pubmed.ncbi.nlm.nih.gov/34580141/
[42] https://publications.aap.org/hospitalpediatrics/article/11/8/e151/179740/For-COVID-or-With-COVID-Classification-of-SARS-CoV
[43] https://academic.oup.com/cid/article/72/12/2215/5876373
[44] https://www.cdc.gov/flu/about/burden/past-seasons.html
[45] https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3
[46] https://covid.cdc.gov/covid-data-tracker/#cases
[47] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

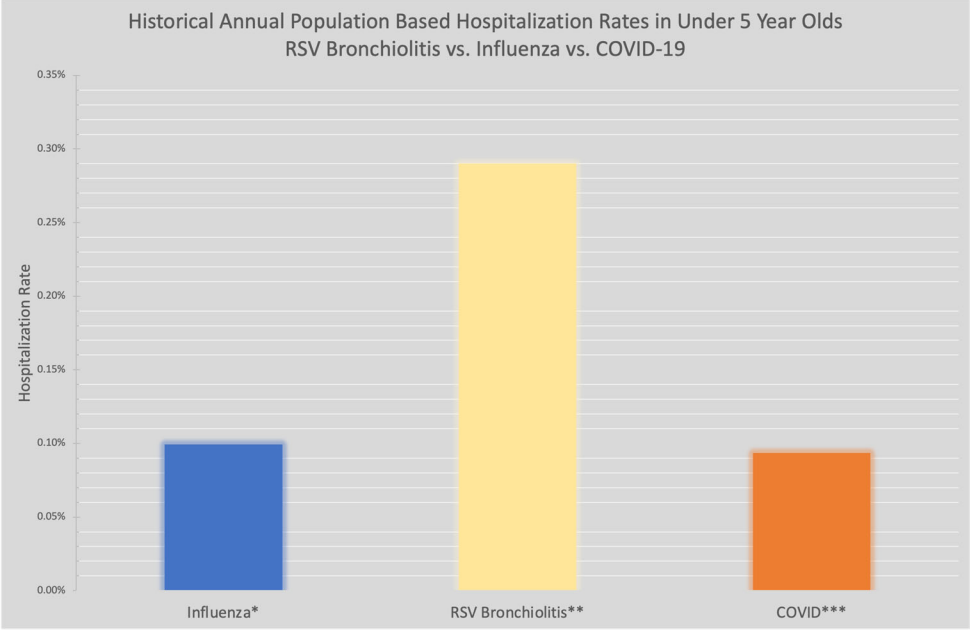


54. When isolating our view to the under 5yo population, we see a similar phenomenon:





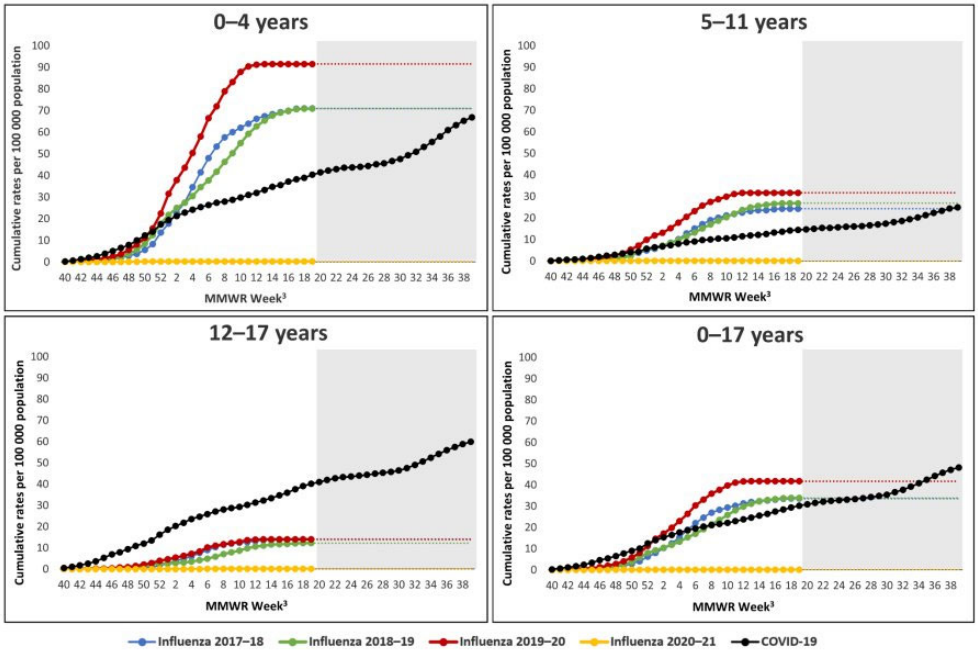
55. Hospitalization rates are similar when compared to other common under 5yo respiratory viruses:[48,49]



[48] https://www.cdc.gov/rsv/research/us-surveillance.html
[49] https://www.cdc.gov/rsv/research/us-surveillance.html

56. A pre-Omicron CDC analysis through September 2021 is concordant with my conclusions and numbers above demonstrating that the main elevated risk from COVID-19 when compared to Influenza in Children was a subset of high body-mass-index adolescents. This analysis was before mass infection and would likely be far different:[50]

Figure 2. Cumulative influenza- and COVID-19-associated hospitalization rates per 100,000 children <18 years old, by age group – FluSurv-NET[1] and COVID-NET[2], 2017–2021



57. **Pediatric Populations at Risk of Severe COVID-19 and MIS-C:** Since the beginnings of the COVID-19 pandemic, clear risk factors for severe Pediatric disease emerged. Outside of obesity and major neurodevelopmental issues that might also be associated with abnormalities of immune response, no clear risk factors have been identified.[51,52,53,54] While asthma itself has not been associated with an increased risk of severe COVID-19 in

[50] https://www.medrxiv.org/content/10.1101/2022.03.09.22271788v1
[51] https://www.jpeds.com/article/S0022-3476(20)31393-7/fulltext
[52] https://www.researchsquare.com/article/rs-689684/v1
[53] https://publications.aap.org/pediatrics/article/149/1/e2021053418/183463/Risk-Factors-for-Severe-COVID-19-in-Children?autologincheck=redirected
[54] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2788844

children or adults, children with a prior history of severe asthma requiring hospitalization are at increased risk of hospitalization with a COVID-19 infection as would hold for any respiratory virus.[55,56] Somewhat surprisingly, and divergent from results with adults, immunocompromised children have not been consistently found to be at increased risk of severe COVID.[57,58,59] That said, immunocompromised children are at an increased risk of hospitalization, even if only out of an abundance of caution, for any febrile illness and this, at times, would apply to COVID-19 as well.

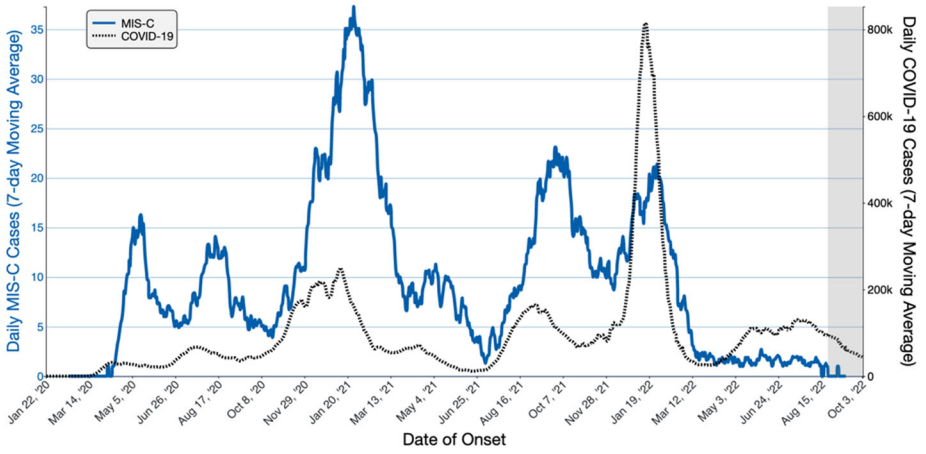
58. **Long COVID:** The topic of "Long COVID" comes up frequently as a concern with otherwise non-critical COVID-19 infections. However, high quality studies show that post-infection symptoms after COVID-19 infection in children are similar to those after other common childhood infections. This includes a large UK database analysis, which found no difference in prevalence of Long COVID-like symptoms among children who had COVID-19 and control children who had not been infected.[60] A recent large Danish study confirmed these findings.[61]

59. MIS-C (Multisystem Inflammatory Syndrome): MIS-C is a rare non-specific inflammatory condition that has been identified as a late sequelae of COVID-19 infection. Out of the more than 24 million Pediatric COVID-19 infections in the United States, there have been only ~8600 cases of MIS-C identified and tied to 70 COVID-19 deaths.[62] Without

[55] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00491-4/fulltext
[56] https://jkms.org/DOIx.php?id=10.3346/jkms.2022.37.e35
[57] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8590622/
[58] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8149202/
[59] https://www.sciencedirect.com/science/article/pii/S016344532100548X
[60] https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/articles/technicalarticleupdatedestimatesoftheprevalenceofpostacutesymptomsamongpeoplewithcoronaviruscovid19intheuk/26april2020to1august2021
[61] https://link.springer.com/article/10.1007/s00431-021-04345-z
[62] https://covid.cdc.gov/covid-data-tracker/#mis-national-surveillance

belaboring this point further, the association between COVID-19 infection and the development of MIS-C has almost completed faded in the Omicron era.

Daily MIS-C Cases and COVID-19 Cases Reported to CDC (7-Day Moving Average)



60. This "decoupling" of COVID-19 cases and MIS-C has been confirmed in the United Kingdom as well.[63]

61. **Long COVID:** The topic of "Long COVID" comes up frequently as a concern with otherwise non-critical COVID-19 infections. We can put aside, for the moment, that neither vaccination or infection are going to definitively prevent reinfection in perpetuity such that any risk from "Long COVID" is faced by all regardless of their vaccination status. That said, high quality studies show that post-infection symptoms after COVID-19 infection are similar to those after other common respiratory infections.[64,65,66,67,68,69] This includes children as evidenced in a large UK database analysis, which found no difference in prevalence of Long COVID-like symptoms among children who had COVID-19 and

[63] https://www.journalofinfection.com/article/S0163-4453(22)00617-X/fulltext#relatedArticles
[64] https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003773
[65] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2785832
[66] https://www.acpjournals.org/doi/10.7326/M21-4905
[67] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2796097
[68] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2799116

control children who had not been infected.[69] A recent large Danish study and a metanalysis in children confirmed these findings.[70,71]

62. Risks of COVID-19 mRNA Vaccinations: **While we are all accustomed to, and largely comfortable with, local injection site irritation post-vaccination or even post-vaccination fever with many standard scheduled childhood vaccines, *it does appear that the mRNA vaccinations have a more unique set of features that require careful consideration***. Whether it's the increased rate of "other infections", the notable white blood cell count reductions (leukopenia),[72] drops in the platelet count,[73] a possible trend towards increased reinfection rates, a trend towards increased cases of appendicitis, abnormal menses (however transient),[74,75] or the more acknowledged myopericarditis (myocarditis/myopericarditis is inflammation of the heart tissue and/or the pericardial lining of the heart), we do not know the underlying process causing these adverse events.
63. Myocarditis/Myopericarditis with mRNA Vaccination: mRNA vaccine associated myocarditis/myopericarditis is an uncommon, but well-documented issue with COVID vaccines, particularly after 2nd or 3rd doses, and particularly in otherwise healthy individuals. While rare, the insistence, that it is "always mild" is patently false with autopsy confirmed deaths and documented admissions for cardiogenic shock.[76,77,78,79]

[69] https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/articles/technicalarticleupdatedestimatesoftheprevalenceofpostacutesymptomsamongpeoplewithcoronaviruscovid19intheuk/26april2020to1august2021
[70] https://link.springer.com/article/10.1007/s00431-021-04345-z
[71] https://www.medrxiv.org/content/10.1101/2022.03.18.22272582v1.full
[72] https://www.nejm.org/doi/suppl/10.1056/NEJMoa2027906/suppl_file/nejmoa2027906_appendix.pdf
[73] https://www.sciencedirect.com/science/article/pii/S0264410X22014931
[74] https://www.science.org/doi/10.1126/sciadv.abm7201
[75] https://www.cureus.com/articles/125060-the-effect-of-the-covid-19-vaccine-on-the-menstrual-cycle-among-reproductive-aged-females-in-saudi-arabia
[76] https://www.nejm.org/doi/full/10.1056/NEJMoa2110737
[77] https://pubmed.ncbi.nlm.nih.gov/35812802/
[78] https://pubmed.ncbi.nlm.nih.gov/35157759/
[79] https://pubmed.ncbi.nlm.nih.gov/34664804/

64. The oft cited counterpoint that COVID-19 associated myocarditis is more frequent than myocarditis/pericarditis (myopericarditis) from mRNA vaccination carries its own exaggerations and inaccuracies. To date, there is no histopathological evidence of SARS-CoV-2 induced myocarditis.[80,81] When true myocarditis in COVID-19 occurs as compared to vaccine-induced myocarditis, they are distinct entities occurring in different populations and different clinical circumstances. For the large part, "COVID myocarditis" is a "critical care cardiomyopathy" seen in those who are very ill with COVID-19. "Critical Care Cardiomyopathy" is seen in a wide variety of illnesses and is not just limited to COVID-19. SARS-CoV-2 does not have notable cardiac tropism. Cardiac enzymes measured in the blood, which serve as a proxy for amount cardiac damage, are uniformly lower with critical care cardiomyopathy of COVID-19 compared to mRNA induced myopericarditis.[82] It is why June 2020-May 2021 myocarditis/pericarditis population wide case levels in Italy were comparable to a pre-pandemic period of June 2018-May 2019.[83] This is consistent with the fact that autopsy-based studies do not show histopathologic evidence of virus mediated inflammation outside of lung tissue.[81,84,85]

65. In a population wide study of of 23 million residents in Scandinavia, vaccine-induced myocarditis outstripped COVID myocarditis at a rate of 4-to-28-fold depending on dose and the vaccine received (Moderna rates higher).[86]

[80] https://pubmed.ncbi.nlm.nih.gov/34506211/
[81] https://pubmed.ncbi.nlm.nih.gov/34440669/
[82] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8426796/
[83] https://pubmed.ncbi.nlm.nih.gov/35763765/
[84] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30243-5/fulltext
[85] https://www.annualreviews.org/doi/10.1146/annurev-med-042220-023859?
[86] https://jamanetwork.com/journals/jamacardiology/fullarticle/2791253

66. Vaccine-induced myocarditis has been shown to occur at a rate of between 1/10,000 and 1/3300 with the highest rates in adolescent boys and young adult males.[87,88] A Kaiser chart review demonstrated that official reporting undercounted cases.[89] **Risking vaccine-induced myocarditis in otherwise healthy young adults, most of which could be avoided given the majority have resistance to severe COVID-19 from prior infection, is imprudent regardless of the presumed clinical course of such a complication**.[90,91] These cases would constitute clear avoidable life-altering harm.

67. It's both dangerous and incorrect to assume that the elevated risk of vaccine-induced myopericarditis is isolated to young adults. In an underappreciated study of vaccinated HCWs in the 40 hospital Providence Health system, they detected increased rates of myopericarditis associated with vaccine roll out to their employees.[92] In this study, the median age for vaccine-induced myocarditis was 36 years old and the median age for vaccine-induced pericarditis was 59 years old.

68. There has always been a standing concern about asymptomatic post-vaccine myocarditis: this is not unique to the COVID vaccines. In May 2003, there was some evidence that Smallpox vaccination could be associated with myocarditis, but CDC, at that time, still noted that "signal" was not clearly abnormal.[93] 12 years later, a subsequent study

[87] https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab989/6445179?login=true
[88] https://www.epi-phare.fr/rapports-detudes-et-publications/myocardite-pericardite-vaccination-covid19/
[89] https://www.medrxiv.org/content/10.1101/2021.12.21.21268209v1
[90] https://onlinelibrary.wiley.com/doi/10.1111/eci.13759
[91] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6713107/
[92] https://jamanetwork.com/journals/jama/fullarticle/2782900
[93] https://www.cidrap.umn.edu/news-perspective/2003/03/link-between-smallpox-vaccine-and-myocarditis-looks-more-likely

published a 60-fold increased rate of myocarditis when active screening of asymptomatic cases was added to normal passive surveillance.[94]

69. After initial CDC denial of any evidence of post-vaccine myocarditis with the COVID-19 vaccines, they had to backtrack on this premature proclamation. In fact, the FDA tasked Pfizer with studying the rate of asymptomatic myocarditis with study completion November 30, 2023 and final report submission May 31st, 2024.[95]

70. A recent Thai pre-print that performed active surveillance for asymptomatic myopericarditis is the first of its kind. Out of 301 13-year-old to 18-year-old enrollees, 3 had symptomatic myocarditis/myopericarditis and 7 of the 301 enrollees had asymptomatic troponin elevations such that the additional 4 were classified as having myocarditis/pericarditis. Important caveats:

- all patients had resolution of symptoms and, for the one patient who had a cardiac MRI, resolution of imaging abnormalities at 5 months.
- Additionally, we don't know the long-term clinical significance, if any, of subclinical myocarditis/myopericarditis.

71. That said, it would be reckless to completely dismiss any concerns about myopericarditis and potential long-term consequences. In the near term, it is a known cause of Sudden Cardiac Death in those under 50-years-old even while it is chronically under-investigated and incompletely reported.[96]

72. In a recent study from the United Kingdom, while all 519 eligible patients followed for more than 90 days returned to pre-pandemic functioning, of 151 patients who had a

[94] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4368609/
[95] https://www.fda.gov/media/151710/download (page 8)
[96] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6713107/

cardiac MRI (cMRI), 13% had evidence of swelling and 54% had abnormalities.[97] This is concordant with other studies showing up to 2/3 having late follow cMRI abnormalities. That said, in all such studies, overall numbers are small and all patients recover.

73. The has FDA tasked Pfizer with studying the rate of asymptomatic myocarditis from booster vaccination with study completion September 2023.[98,99]

74. "Sterilizing Vaccines" and Mandates: When we refer to "sterilizing vaccines", we are referring to vaccines that confer both protection from infection thereby effectively eliminating infection risk as well as providing protection from severe illness. Traditionally, as canonical examples of "sterilizing vaccines", we consider the Measles/Mumps/Rubella (MMR) vaccine as it pertains to Measles and the Hepatitis B vaccine. Measles, like Influenza and SARS-CoV-2 (the virus that causes COVID-19) are respiratory viruses. Measles transmission while through droplets and aerosols, is more droplet mediated than with COVID-19 or Influenza, and yet remains highly contagious. In the case of Measles and Hepatitis B, there is a major component of the infection that is bloodborne (unlike SARS-CoV-2 or Influenza) such that blood-borne vaccine or infection induced antibodies can perform a pivotal role in preventing subsequent infection. But even in the context of Measles and Hepatitis B vaccines, "sterilizing" is a relative term.

75. Numerous studies have shown that those vaccinated against Measles can develop infections, even as the primary value remains protection from severe illness. In a recent 2018 study of an outbreak in a French Psychiatric ward, 14% of fully vaccinated index

[97] https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(22)00244-9/fulltext
[98] https://www.fda.gov/media/151710/download (page 8)
[99] https://clinicaltrials.gov/ct2/show/NCT04955626?term=C4591031&draw=2&rank=1

cases from a primary unvaccinated case developed Measles. 2 of the cases had 2 Measles vaccinations and one even had vaccination with a prior infection in the preceding 6 years.[100] A less contained outbreak in New York was traced to a vaccinated index case.[101]

76. All of this said, an outbreak of Measles in the Marshall Islands demonstrated that non-vaccine eligible infants were more likely to be infected as secondary contacts than adults (46% versus 13%).[102] In this outbreak, the largest in the United States or associated area in more than a decade, 41% of cases were reported to have been previously vaccinated. Given that Measles vaccine is not recommended under 12 months of age, the biggest lesson of the Marshall Islands outbreak was the susceptibility of vulnerable non-vaccine eligible populations. It is thought that 90% vaccine coverage is required for the prevention of such outbreaks.

77. In the case of Hepatitis B, transmission is through body fluid contact. Vaccination, or infection, followed by documented threshold antibody levels is highly effective in preventing infection and transmission. Once again, "sterilizing immunity" in this context remains "relative" with documented Hepatitis B cases in previously vaccinated individuals. In one study, roughly 10% of previously vaccinated individuals with no evidence of prior infection had detectable Hepatitis B virus through DNA-testing suggesting evidence of an undetected "breakthrough" infection.[103] Once again, as with protection from a Measles vaccination, the benefit accrued to the vaccinated individual is substantial. In East Asian countries, Hepatitis B is endemic (spreads at baseline through

[100] https://journals.lww.com/pidj/FullText/2019/09000/Measles_Transmission_in_a_Fully_Vaccinated_Closed.27.aspx
[101] https://academic.oup.com/cid/article/58/9/1205/2895266
[102] https://pubmed.ncbi.nlm.nih.gov/16392073/
[103] https://journals.lww.com/md-journal/fulltext/2016/12060/hepatitis_b_viremia_in_completely_immunized.92.aspx

the population). With the advent of universal Hepatitis B vaccination of newborns in Taiwan, the infant mortality rate from hepatitis B dropped by 3-fold and severe hepatitis almost disappeared in older children.[104,105,106]

78. Summary: While we can establish significant distinctions between "sterilizing vaccines" and vaccines such as the ones for COVID-19 and Influenza, it remains the case that the main benefit of vaccination is accrued to the individual receiving the vaccination. For vaccines such as the COVID-19 and Influenza vaccines where there is minimal prevention of subsequent infection and transmission, it's extremely difficult to supplant individual bodily autonomy particularly at threat of unemployment or violation of one's religious beliefs.

79. Even adopting a policy of perpetual boosting for COVID-19 is not biologically sound. Per an NIH study, Omicron specific boosters did not elicit increases in Omicron specific neutralizing antibodies which is a concerning finding for a process called "imprinting".[107] This is not a fringe opinion as it was even cited by Dr. Paul Offit in a New England Journal of Medicine editorial.[108] NIH re-analysis of the Moderna trial data indicated that 93% of subsequently infected placebo participants formed anti-N (anti-nucleocapsid) antibodies while only 40% of vaccine recipients formed these same antibodies.[109] We don't know the long-term significance of this finding, but we have known since mid-2021 that the presence of anti-N antibodies correlates with a reduced risk of reinfection.[110]

[104] https://pubmed.ncbi.nlm.nih.gov/11562612/
[105] https://pubmed.ncbi.nlm.nih.gov/14752823/
[106] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3630933/

[107] https://www.biorxiv.org/content/10.1101/2022.02.03.479037v1.full.pdf
[108] https://www.nejm.org/doi/full/10.1056/NEJMe2203329
[109] https://www.medrxiv.org/content/10.1101/2022.04.18.22271936v1.full.pdf
[110] https://www.thelancet.com/journals/lanhl/article/PIIS2666-7568(21)00093-3/fulltext

80. Based upon the evidence presented above, including findings from the initial Pfizer COVID-19 trials, vaccine mandates for COVID-19 vaccines were an ill-conceived policy dating back to at least mid-2021. Every piece of data since that time, both from formal studies and ecological data, has reinforced that reality.

81. Consequently, it is well past time to reconsider our approach to COVID-19 especially as it pertains to COVID-19 vaccine mandates even if one truly believes that *any* reduction in transmission is demonstrable. *"Natural infection will not stop this outbreak"* is a common refrain from some official sources. This statement is both materially true and irrelevant. If it hasn't been made clear yet, neither will vaccination for a mutating respiratory virus which, unlike Measles, does not have a notable viremic (hematogenous/blood-borne) phase. When considering the susceptibility of the general population to COVID-19 in October of 2022, at least 95% of Americans are no longer immune-naïve to SARS-CoV-2 through infection alone, and even more when considering either vaccination, infection, or a combination (also known as hybrid immunity).[111]

82. On May 15th Denmark phased out the COVID vaccination program with possible, but no guaranteed, resumption in the fall:[112]

> *"The current wave of covid-19 has flattened. One of the main reasons for this is a high expected immunity in the Danish population due to a high vaccine coverage against covid-19 in Denmark* ***and the fact that many Danes have been infected with covid-19 within the last months following the onset of the omicron variant.****" (emphasis mine)*

83. As noted by FDA voting member Dr. Paul Offitt, it is clear that neither vaccination or mass testing will stop COVID-19, but both vaccination and prior infection will confer

[111] https://covid19serohub.nih.gov/
[112] https://www.sst.dk/en/english/corona-eng/vaccination-against-covid-19

resistance to severe disease.[113] This "herd resistance to severe disease " will not confer iron-clad protection from an "infection" moving forward, but it's main value will be protection from severe disease and there is historical precedent for this belief.[114] With at least 95% of Americans (through November 22nd, 2022)[115] falling into a category of prior infection with or without an associated vaccination, we have achieved as much meaningful population level protection from severe disease as is possible. Moving forward, every individual, based upon their individual age, metabolic risks, immune status, and personal preferences, will have to decide how best to proceed with future vaccine doses or therapeutics.[116] ***Nothing will be gained by coercing or depleting a workforce with COVID-19 vaccine mandates as our nation recovers in the post-pandemic era and it was unjustifiable based upon the vaccine trial data, rapidly emerging data post vaccine release, and every piece of ecological data since that time.***

I declare under penalty of perjury, under the laws of the State of California, that the foregoing is true and correct.

Ram Duriseti MD, PhD

February 7th, 2023

[113] https://www.inquirer.com/health/expert-opinions/covid-19-pandemic-immunity-boosters-normal-20220304.html?
[114] https://www.eurekalert.org/news-releases/694958
[115] https://covid19serohub.nih.gov/
[116] https://www.nature.com/articles/s41574-021-00608-9

EXHIBIT "A"

Ram Duriseti, M.D., Ph.D.
ramduriseti@gmail.com

Educational Background:

Engineering:

•9/01-5/07: Doctoral degree from the Stanford University School of Engineering with a concentration in Decision/Risk Analysis, Machine Learning, and Clinical Decision Support. Coursework included Decision and Risk Analysis, Probability and Statistical Inference, Bayesian Networks, Machine Learning, Computer Science, and Clinical Informatics. Funded through a VA Medical Informatics Fellowship.

- Computing Background: C++, Java, Matlab, C, Ruby On Rails, Javascript and HTML with Ajax, Drools (JBoss Rules Engine), controlled medical terminology deployment (IMO services, SNOMED-CT, RxNorm, and other UMLS resources), Apelon server deployment, LISP, PostGreSQL, MySQL, JBoss application server, UNIX environment, Visual Basic (Excel Modules), Git, Subversion and Mercurial version control

Medical and Undergraduate:

•11/97-11/2001: Residency training in Emergency Medicine at Stanford Medical Center.
•5/96: M.D. with highest honors, University of Michigan Medical School
•6/92: B.S. in Biololgy, and B.A in Political Economy, with distinction Stanford University.

Select Relevant Employment Experience:

11/00 – Present: Clinical Associate Professor, Stanford Emergency Department. Contacts: Dr. Bernard Dannenberg and Dr. Matthew Strehlow. Numbers available upon request.

3/01- Present: Mills Peninsula Emergency Medical Associates shareholder. President and CEO until 6/2017

6/08 – Present: Founder, CEO, and Product Engineer (principle algorithm and product design architect) for ShiftRx, L.L.C. ShiftRx provides the ShiftGen service that provides a cloud based enterprise workforce management tool. Key elements: machine learning algorithms, schedule optimization, workforce management, revenue cycle management with payroll integration, Java, Ruby on Rails, MySQL, SaaS on ec2.

10/08 – Present: Special consultant and subject matter expert to Sutter Health for Epic EHR implementation. Provided technical design for the billing extracts to migrate clinical information into a file sharing framework for billing companies supporting Sutter Emergency Medicine groups. Contacts: Multiple. Numbers available upon request.

4/15 – 3/2017: CEO and subsequently CTO and CMO of LifeQode Inc. which provides the Lifesquare product. Helped craft and secure 4 different patents, with continuations, around the central business processes for the product. Contacts: Larry Leisure and Steve Shulman. Numbers available upon request.

7/09 – 10/09: Technical consultant to Rise Health, Inc.. Contacts: Eric Langshur, Forrest Claypool, and Inder-Jeet Gujral. Numbers available upon request.

1/07 – 9/08: Chief Medical Officer and Director of Medical Informatics for Enfold, Inc. Responsibilities include design and implementation of intelligent medical functionality and a taxonomy engine as well as oversight of medical content driving the system. Implementation

details: Java, Ruby on Rails, Drools, Apelon Server, Oracle 10g Database, MySQL. Contacts: Inder-jeet Gujral, Kimberly Higgins-Mays. Numbers are available upon request.
10/06 – 3/08: Medical Informatics Director Working Group Stanford University Hospitals and Clinics CIS Initiative. Particular emphasis on hand held technology integration into the Epic Initiative and organizing patient encounter level reportable data on clinical documentation events. Contacts: Kevin Tabb, President and CEO Beth Israel Deaconess Medical Center. Contact information is available upon request.
6/05 –12/06: Design and implementation of an attribute matching expert system in Java as a consultant to Wellnet Inc. Implemented in a Java environment with Hibernate DBMS and MySQL. Contacts: Kimberly Higgins-Mays. Number available upon request.

Select Research Experience:
7/11-Present: Design and implementation of a computational model for stochastic stimulation of the cost-effectiveness of various strategies to diagnose pediatric appendicitis (manuscript in progress).
10/05-Present: Design and implementation of an asymmetric cost Support Vector Machine to evaluate a large clinical database on chest pain patients presenting to the University of Pennsylvania Hospital Emergency Department (manuscript in progress).
09/02-9/04: Medical Informatics Fellow, Palo Alto Veteran's Administration Hospital.
04/03-Present: Development of Bayesian decision network for evaluation of the clinical utility of the quantitative Vidas ELISA Ddimer Assay. Published work listed.
02/04-Present: Bayesian decision network implementation modeling reasoning in the clinical domain of chest pain and associated pathology in the Emergency Department.
6/05-3/06: Using portable digital devices to generate a standard electronic medical record that can be downloaded directly to a relational database to facilitate data mining for prospective clinical research.
11/99 – 4/00: Retrospective chart review to examine the incidence of electrolyte and cardiac enzyme abnormalities in patients presenting to the Stanford Emergency Department with Supraventricular Tachycardia.

Select Administrative Experience:
6/09 – Present: CEO and Founder of ShiftRx, LLC
6/09 – Present: Regional Information Services Steering Committee for Sutter Health
6/08 – 6/18: President of CEO of Mills Peninsula Emergency Medical Associates
9/12 – 3/17: Acting CMO and CEO of Lifesquare, Inc.
6/07 – 9/08: Chief Medical Officer and Director of Medical Informatics at Enfold, Inc.
5/05-9/08: Member of Medical Informatics Director Working Group and RFP phase of evaluation for the Epic initiative at Stanford University Hospitals and Clinics
4/05-6/06: Served on the Mills-Peninsula Health Information Management and Medical Records Committee.

Select Honors and Distinctions:
- Guest Lecturer at the Wharton School of Business (University of Pennsylvania) 2007/2008/2009 for health economics and information technology course
- VA Medical Informatics Fellowship
- Alpha Omega Alpha Medical Honor Society

- Graduation with Distinction from the University of Michigan Medical School (top 5%)
- Recommended for Graduation with Distinction from Stanford University
- National Merit Scholarship Recipient
- Telluride Foundation Fellow

Select Papers and Publications:

- Lowe, T., Brown, I., Duriseti, R. "Emergency Department Access During COVID-19: Dis parities in Utilization by Race/Ethnicity, Insurance, and Income", Western Journal of Emergency Medicine; April, 2021

- Duriseti, R., Brandeau M. "Cost-Effectiveness of Strategies for Diagnosing Pulmonary Embolism Among Emergency Department Patients Presenting with Undifferentiated Symptoms", Annals of Emergency Medicine; October, 2010

- Duriseti, R., Wu, T. "Gastrointestinal introduction and abdominal pain – Pediatric Abdominal Pain in the Emergency Department", A Practical Guide to Pediatric Emergency Medicine, Cambridge University Press, Cambridge, 2010

- Duriseti, R. "Musculoskeletal Trauma: fractures", A Practical Guide to Pediatric Emergency Medicine, Cambridge University Press, Cambridge, 2010

- Duriseti, R. "Using Influence Diagrams in Cost Effectiveness Analysis for Medical Decisions", Optimization in Biology and Medicine, Auerbach Press, New York, 2008

- Duriseti, R. "Non-Bayesian Classification to Obtain High Quality Clinical Decisions", Optimization in Biology and Medicine, Auerbach Press, New York, 2008

- Duriseti, R., Shachter R., Brandeau M. "Implications of a Sequential Decision Model on the Use of Quantitative D-Dimer Assays in the Diagnosis of Pulmonary Embolism", Academic Emergency Medicine; July, 2006

- Duriseti R, VanderVlugt T. Paroxysmal supraventricular tachycardia is not associated with clinically significant coronary ischemia. ACEP Abstracts. ACEP Scientific Assembly 10/2001

- VanderVlugt T., Duriseti R. Electrolyte findings in patients with paroxysmal supraventricular tachycardia. ACEP Abstracts. ACEP Scientific Assembly 10/2001

- Contributing Editor for Trauma Reports for the topic, "Trauma in Pregnancy"; published 2/2001

- Duriseti R. Cost Effective Management of Common Infections in the Emergency Department. Resident Reporter. Wyeth Ayerst Resident Scholars Program. March, 2000

Select Professional Lectures:

- Commonly Encountered Statistical Concepts in the Emergency Medicine Literature
- Medical Decision Making, Clinical Information Systems, and Cost Control: Complexity Collides with Uncertainty

EXHIBIT C

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Plaintiffs' Class Counsel

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNIFYSCC, an unincorporated California association on behalf of employees in Santa Clara County; **TOM DAVIS**, individually, and on behalf of all others similarly situated; **MARIA RAMIREZ**, individually, and on behalf of all others similarly situated; **ELIZABETH BALUYUT**, individually, and on behalf of all others similarly situated;

Plaintiffs,

vs.

SARA H. CODY, in her official capacity as the Santa Clara County Public Health Officer; **JAMES WILLIAMS**, in his official capacity as the County Counsel of Santa Clara County; **JEFFREY SMITH**, in his official capacity as the County Executive of Santa Clara County; and **SANTA CLARA COUNTY**;

Defendants.

Case No. 22-cv-01019 BLF

EXPERT REPORT OF RAM DURISETI, M.D., PH.D.

I, Ram Duriseti, MD, PhD, declare as follows:

1. I am a clinical associate professor at the Stanford Emergency Department. I have been a practicing Board Certified Emergency Physician for over 20 years. My PhD background is in Operations Research with an emphasis in computational decision modeling, simulation, statistical computing, and optimization algorithms. I have personal knowledge of the facts set forth below and could testify competently to them if called to do so. A true and correct copy of my *curriculum vitae* is attached to this declaration.

I. SUMMARY OF OPINIONS

2. There have been numerous declarations filed on behalf of both the defendants and the plaintiffs in this action. The Defendants' general claims are that their 1) policies followed the data, 2) were not applied in an arbitrary or discriminatory fashion, and 3) recommendations and decision makers' beliefs evolved with the data and science. In the interests of brevity and time, I will not be addressing points from declarations in any itemized fashion. The claims and content from both sides are extensive, substantiated with competing facts, and stand on their own.

3. In the roughly 4.5 years since the start of the COVID-19 pandemic, there has been such an avalanche of publications on the topic, that even by the end of 2022, roughly 17% of all of the medical literature that had ever been indexed related to COVID-19. There is no person who can legitimately claim to have reviewed it all.

4. That said, there is nothing in the literature from the randomized controlled trials regarding the COVID vaccines in 2020 or any observational or randomized controlled trial since 2020 in the last 4 years that definitively establishes that the COVID-19 vaccines attenuate infection, and therefore transmission, by any more than 30% or for any longer than 5 months.

5. Having: i) reviewed and analyzed the evolving data, from the outset of the pandemic, ii) published on all matters related to COVID-19 from Non-Pharmaceutical Interventions, to vaccine efficacy, to policy matters such as school closures, and iii) having treated thousands of COVID-19 patients, it is my conclusion that the defendants at best provide selective favorable interpretations of incomplete and confounded data that supports their positions while rejecting similar data widely available that undermine their claims. While both sides are subject to

this criticism, only one side has used that information to curtail any party's free exercise of their rights and bodily autonomy.

6. It is my opinion that the defendants failed to perform systematic careful analysis of internal data or adapt to react to rapidly changing epidemiologic positions to guide the policies instituted. Furthermore, it is my opinion that high-quality data in 2020 from the vaccine trials themselves should have, at the very least, given them pause before instituting policies that denied any employee's free exercise of their beliefs and bodily autonomy as a condition to maintaining employment and support their household.

7. COVID-19 is the disease caused by infection with the SARS-CoV-2 virus. The current generation of COVID-19 vaccines do not significantly limit transmission for any sustained period of time. **Transmission of an infectious disease is both a function of behavior and presence of infection.** A vaccine mandate with the purpose of limiting transmission must not simply decrease the risk of infection but must do so by a substantial margin.

8. The primary benefit of COVID-19 vaccination is accrued by the vaccine recipient. The benefit is largest in those with identifiable risk factors and is further amplified in the absence of a prior infection. Neither infection nor vaccination will definitively prevent future infection. However, both will reduce the severity of a future infection.

9. We must first acknowledge, using the Pfizer COVID-19 mRNA vaccine as a canonical example, that the vaccine trials were never designed to test for preventing transmission. Pfizer themselves pointed this out to the FDA.[1] The "data gaps" identified by Pfizer were:

- Duration of protection
- Effectiveness in certain populations at high risk of severe COVID-19
- Effectiveness in individuals previously infected with SARS-CoV-2
- Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections
- Vaccine effectiveness against asymptomatic infection
- Vaccine effectiveness against long-term effects of COVID-19 disease
- Vaccine effectiveness against mortality

[1] https://www.fda.gov/media/148542/download#page=38.

- Vaccine effectiveness against transmission of SARS-CoV-2.[2]

10. It's important to remember that the original Pfizer trial supporting its FDA approval was never structured to test for transmission reduction and this is part of the record in the Emergency Use Authorization (EUA) review. As noted by Dr. Patrick Moore of the University of Pittsburgh Cancer Institute,

> "*One question that addresses these two discussion items, I find is really, really central, and important, is that FDA did not ask in its guidance and Pfizer has presented no evidence in its data today that the vaccine has any effect on virus carriage or shedding, which is the fundamental basis for herd immunity.*" [3]

11. At the most basic level of immunology, and even first-order logic, denying the immunologic impact of a COVID-19 infection is tantamount to denying the efficacy of a vaccination. **There is no "alternative immune system" through which vaccination works that is separate from the immune system through which an infection primes the same immune system.**

12. In the *original Pfizer trial*, 567 patients in placebo and 526 in the treatment arms had evidence of prior COVID-19 infection. In each of these sub-cohorts, there was only 1 reinfection according to the primary endpoint definition (Table 8 page 27).[4] In other words, of 567 patients in the placebo arm who had evidence of prior COVID-19, only 1 developed reinfection. Similarly, out of 526 patients in the vaccine recipient arm with documented prior COVID-19 infection, only 1 patient developed a reinfection. There are several key takeaway points:

a. There was no statistically significant difference in a subsequent COVID-19 infection between placebo and vaccine arms when there was evidence of prior infection.

b. While it is impossible to draw statistical inference from just 1 reinfection out of 567 placebo recipients with prior infection, this compares to 162 infections out of 16,944 placebo recipients with no evidence of prior COVID-19. *In other words, those with*

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[2] *Id.*

[3] https://www.fda.gov/media/144859/download at 342:1-7.

[4] https://www.fda.gov/media/144245/download (Table 8, pp. 26-27).

prior infection had at least a 100-fold lower rate of infection than those with no prior infection during the trial period.

13. **This led Pfizer to cite the following in its December 2020 FDA filing:** "VE [vaccine efficacy] point estimates were uniformly high across the subgroups examined with the exception of … participants with evidence of prior SARS-CoV-2 infection at enrollment, for which too few COVID-19 cases occurred to interpret efficacy data."[5]

14. While many COVID-19 immune naïve individuals (no prior infection by SARS-CoV-2 which is the virus that causes COVID-19) likely benefitted from having their immune systems primed by a vaccine prior to a subsequent infection thereby increasing their protection from more severe disease progression, any imputed impact on disease transmission has been fleeting at best.

15. As early as Summer 2021, emerging data suggested that vaccinated individuals' net reduction in "viral load" during an infection was no more than 30%.[6] Since that time, between waning efficacy and partial "immune escape" from SARS-CoV-2 variants, it's become clear that even that degree of reduction is not sustained. In a more recent study, researchers used longitudinal sampling of nasal swabs for determination of viral load, sequencing, and viral culture in outpatients with newly diagnosed coronavirus disease 2019 (Covid-19) from July 2021 through January 2022 and concluded that, "we did not find large differences in the median duration of viral shedding among participants who were unvaccinated, those who were vaccinated but not boosted, and those who were vaccinated and boosted."[7]

16. When discussing the topic of transmission, it's useful to examine settings where the interactions are high frequency, long duration, and in enclosed spaces that do not have particularly high ceilings, or hospital level ventilation air changes per hour (ACH).

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[5] https://www.fda.gov/media/144245/download, p. 25.

[6] https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1.full-text.

[7] https://www.nejm.org/doi/full/10.1056/NEJMc2202092.

17. Borrowing terminology from Santa Clara County's definition of a "high-risk work setting", we can consider transmission studies in health care settings to be an "extreme case of exposure risk" that would likely exceed transmission risk in any other county work setting.

18. With respect to COVID-19 infections in a health care setting and staff vaccination rates, **a July 2021 paper by White et al. examined infection rates among different vaccinated patient cohorts in a nursing home at different levels of staff vaccination**. The most telling table was in the supplement. In table S3, there was no association between staff vaccination rates and transmission to residents regardless of the residents' vaccination status.[8]

NURSING HOME VACCINATIONS 8

Table S3. Incident SARS-CoV-2 infections in residents living in nursing homes with low, moderate, and high staff vaccination rates

	Low staff vaccination (Less than 58.7% of staff vaccinated)		Moderate staff vaccination (58.7 - 69.2% of staff vaccinated)		High staff vaccination (69.3 - 95.7% of staff vaccinated)	
	Total	Percent (%) asymptomatic	Total	Percent (%) asymptomatic	Total	Percent (%) asymptomatic
Residents vaccinated with at least dose 1, n	**5691**		**6291**		**6260**	
Tested positive 0-14 days after dose 1, n(%)	266 (4.7%)	71.1%	267 (4.2%)	74.2%	289 (4.6%)	69.2%
Tested positive 15-28 days after dose 1, n(%)	83 (1.5%)	75.9%	50 (0.8%)	62.0%	117 (1.9%)	72.6%
Residents vaccinated with doses 1 & 2, n	**4001**		**4579**		**4468**	
Tested positive 0-14 days after dose 2, n(%)	46 (1.1%)	80.4%	32 (0.7%)	87.5%	52 (1.2%)	86.5%
Tested positive >14 days after dose 2, n(%)	18 (0.4%)	72.2%	8 (0.2%)	75.0%	12 (0.3%)	83.3%
Unvaccinated residents	**1629**		**1296**		**1065**	
Tested positive 0-14 days after clinic 1 held, n(%)	73 (4.5%)	65.8%	65 (5.0%)	66.2%	35 (3.3%)	68.6%
Tested positive 15-28 days after clinic 1 held, n(%)	31 (1.9%)	64.5%	15 (1.2%)	46.7%	23 (2.2%)	65.2%
Tested positive 29-42 days after clinic 1 held, n(%)	6 (0.4%)	83.3%	4 (0.3%)	75.0%	6 (0.6%)	83.3%
Tested positive >42 days after clinic 1 held, n(%)	6 (0.4%)	83.3%	3 (0.2%)	66.7%	3 (0.3%)	100.0%

Notes. Nursing homes stratified by tertiles of staff vaccination rates as of February 17, 2021. Staff vaccinations occurred simultaneously with resident vaccinations and rates were tracked by the organization.

19. The authors could not identify an association with staff vaccination rates because vaccination rates dropped in all individuals. The authors attribute this impact to vaccination and thereby commit an extremely common error in studies and analyses of observational data which is also evident in Santa Clara County's analysis.

20. **The Common Error of Excluding "Falsification Endpoints":** This is a technical topic, but in order to critique Santa Clara County's repeated invocation of their data and the positive

[8] https://www.nejm.org/doi/suppl/10.1056/NEJMc2104849/suppl_file/nejmc2104849_appendix.pdf.

impact of their chosen interventions, we cannot avoid discussing this topic.

21. Studies of ecological (real world) data, including data collected by Santa Clara County, that purport to demonstrate a positive effect from COVID-19 mitigation measures, whether we are referring to non-pharmaceutical interventions (NPIs) or vaccines, frequently do not control for background community infection rates. This leads to overly optimistic estimates of infection prevention by the intervention. This mistake of not critically examining what we call a "Falsification Endpoint" has been a repeated feature of the COVID-19 literature in both American and European studies.[9,10] Formally speaking, a Falsification Endpoint (also known as a "negative control"), is an outcome that is not causally affected by the primary exposure that is being studied (in this case a measure to mitigate a COVID-19 infection).

22. With respect to the White et al. nursing home study cited above:

a. Case rates in the United States during the study period from December 2020 through March 2021 went from 747/million at the peak during vaccine roll out at Nursing Homes in late 2020 through January 2021 to a case rate nadir of 191/million **while community vaccination rates remained at only 0.53% by the end of March 2021**.

b. Therefore, there was a national 3.91-fold reduction in COVID-19 case rates that directly matched the rate decrease in the nursing homes (from 4.5% to 1%) which is a roughly comparable 4.5-fold reduction.[11] In other words, the magnitude of COVID-19 reduction attributed to vaccination in the nursing home was almost identical to the decrease in COVID-19 rates nationwide during the study period when community vaccination rates were extremely low (0.54% by the end of March 2021).

c. *Therefore, the decrease in infection rates in the nursing home is directly proportional to the level of decrease in the community at large despite having a more than 100-*

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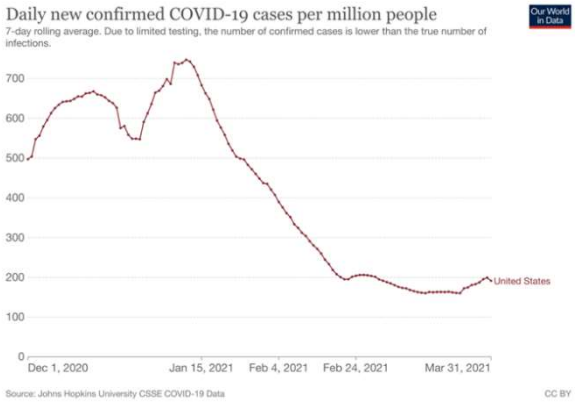
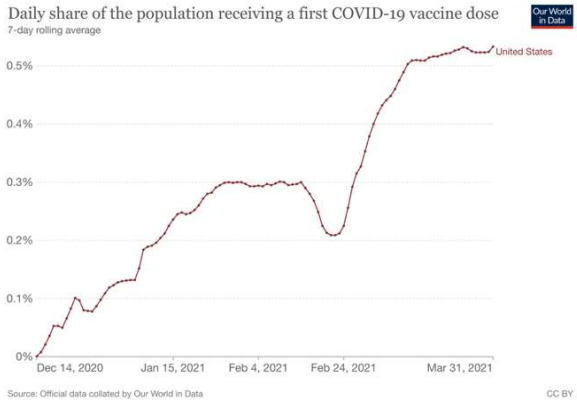
[9] https://jamanetwork.com/journals/jama/fullarticle/2768533.

[10] https://ftp.iza.org/dp13319.pdf.

[11] https://ourworldindata.org/explorers/coronavirus-data-explorer.

fold greater rate of vaccination in the nursing home (58% to 95%) compared to the community vaccination rate by end of March 2021 (0.54%).

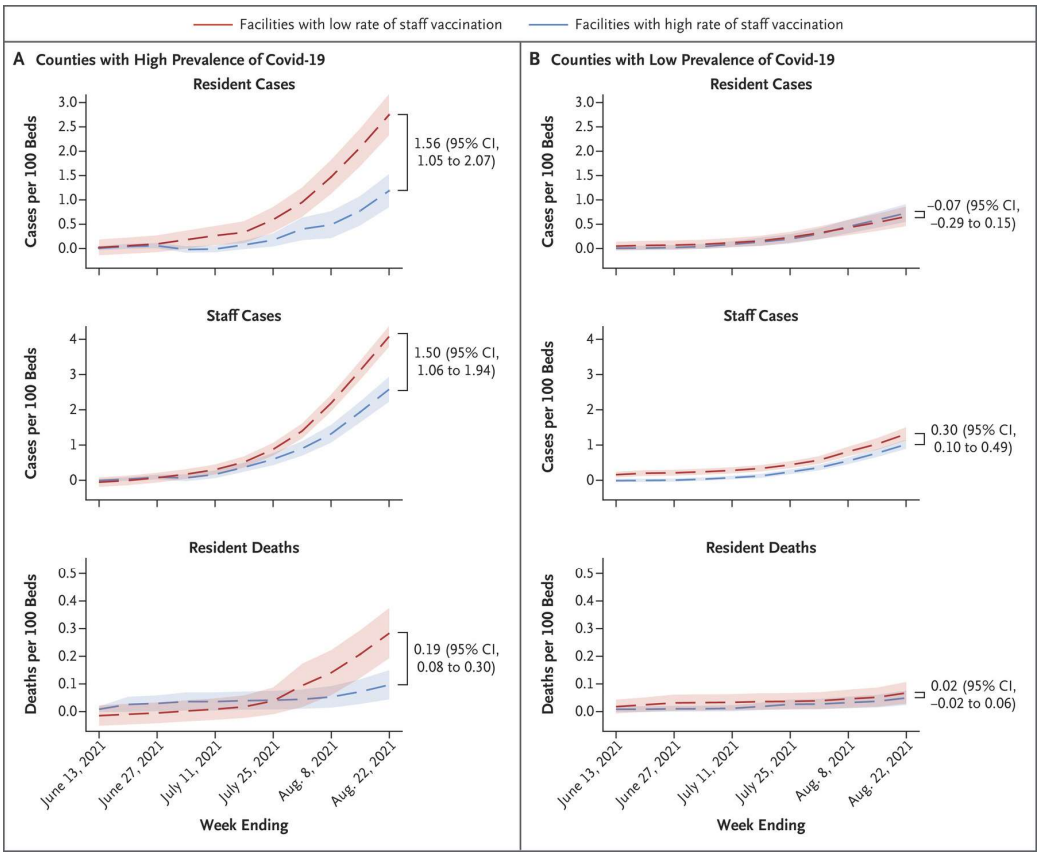




23. In conclusion, in the White et al. nursing home study in "freshly vaccinated" individuals, even when there was little to no immune escape from the vaccine formulation in use, there was no measurable impact of staff vaccination rates on nursing home resident infection rates once one controls for community infection rates.

24. To this point, a follow up study in Nursing Homes (again, paralleling the "high-risk" designation of Santa Clara County) examining infection rates and staff vaccination rates from McGarry et al. cites a strong association between staff vaccination rates and nursing home COVID-19 case rates.[12] The study period was June 13, 2021 through August 22, 2021. This was a Delta-variant dominant period of infection. At face value, this study seems to support a stronger (albeit no more than 50%) correlation between staff vaccination rates and infection rates.

[12] https://www.nejm.org/doi/full/10.1056/NEJMc2115674.

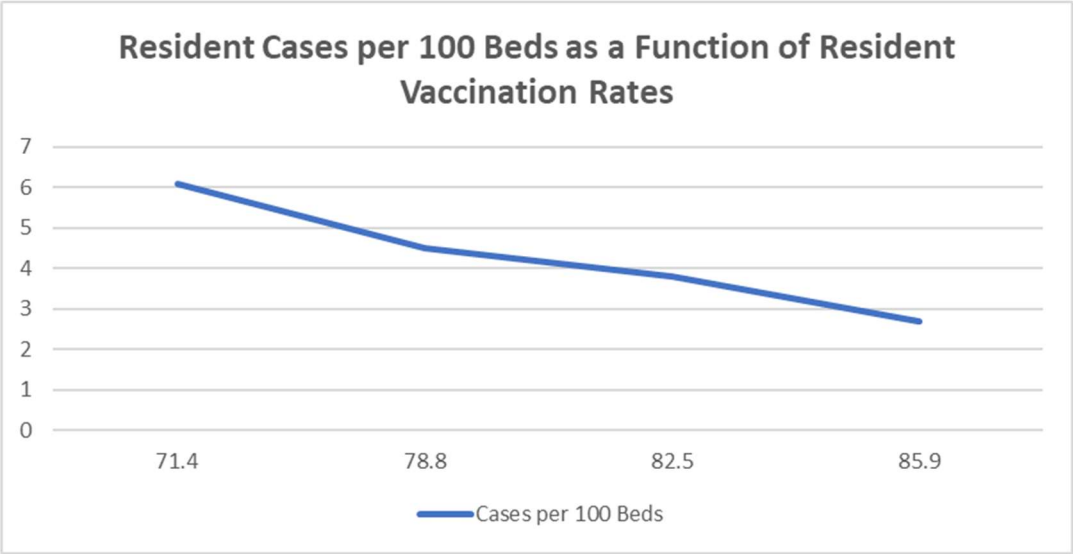


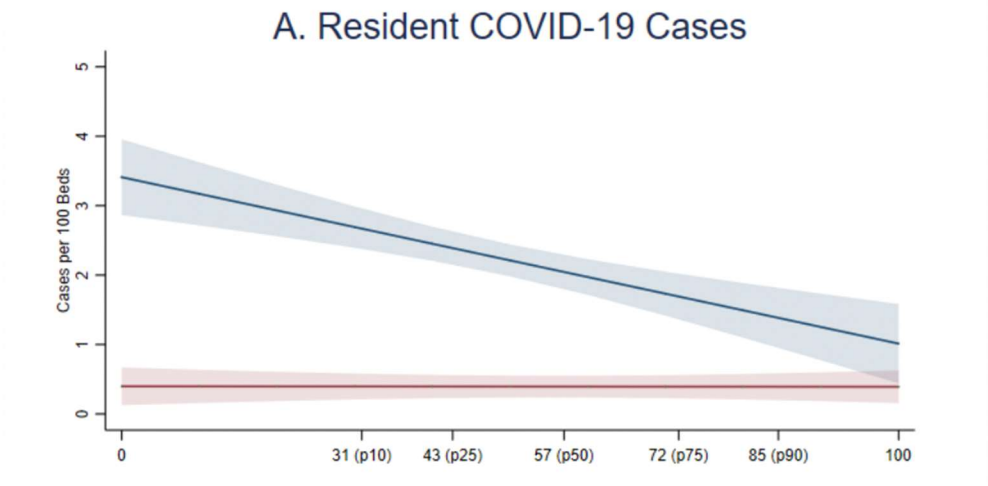
25. However, when examining the study data, it becomes clear that the authors did not pick up on the association between resident symptomatic case rates or death rates per 100 beds plotted against resident vaccination rates. A careful evaluation that I walk through below would have shown that almost all of the benefit accrued to residents from vaccination was a direct result of resident vaccination rates and largely independent of staff vaccination rates.

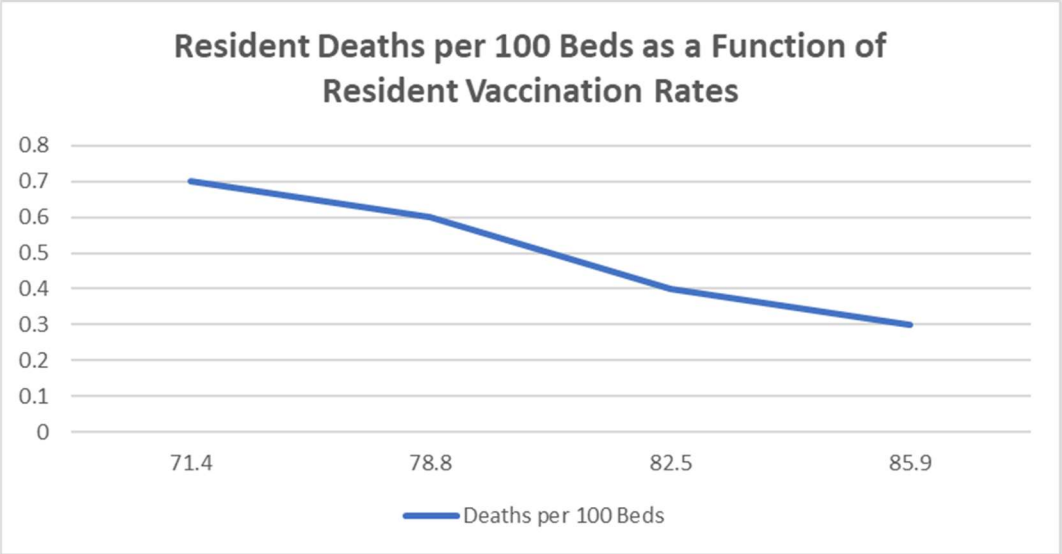
26. While I cannot reproduce the format of the authors' plots without their regression model, drawing from the supplemental appendix Table S1,[13] I can provide a rough trend line for resident case rates and death rates as a function of resident vaccination rates independent of staff vaccination rates. When plotted, we see that the relationship is essentially identical to the slope of the lines for resident case rates and death rates as a function of staff vaccination rates. This is

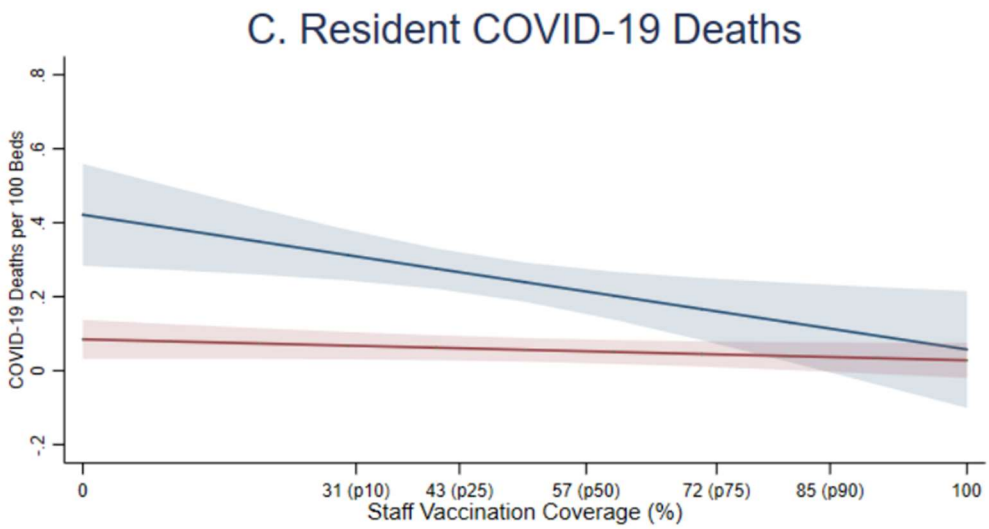
[13] https://www.nejm.org/doi/suppl/10.1056/NEJMc2115674/suppl_file/nejmc2115674_appendix.pdf.

evident by comparing the slope on my plots compared to screen shots of the author's figures in Figure S3. The difference between my plots and the authors' plots is that my x-axis is the resident vaccination rate rather than the staff vaccination rate. The y-axis is the same. ***Comparing the line slopes, almost all (if not all) of the demonstrated variability in resident case and death rates is subsumed by and accounted for by resident vaccination rates.***





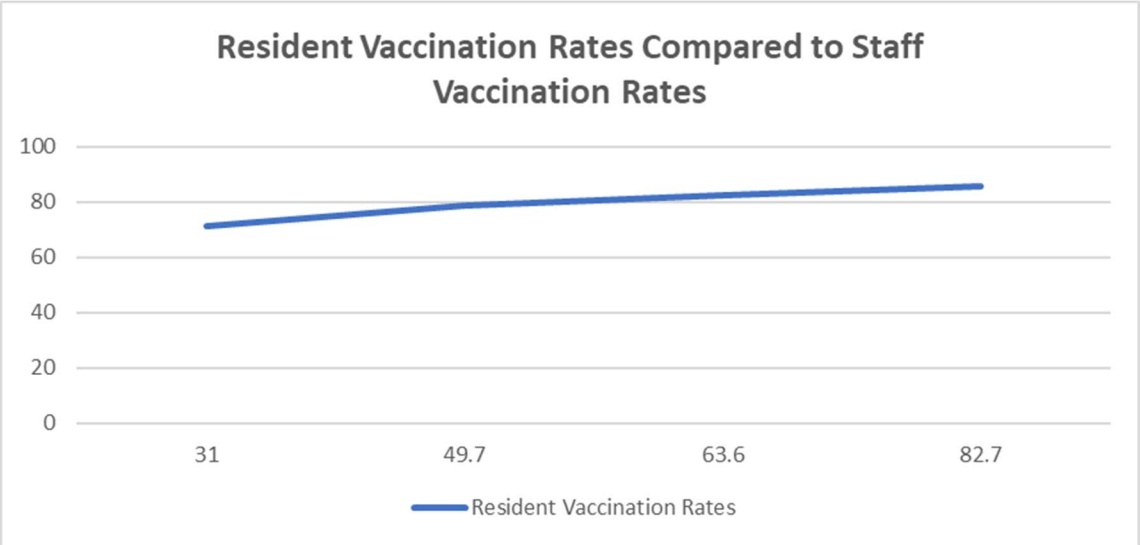




27. We can see why the relationship is the same whether one uses staff or resident vaccination rates by examining the relationship between staff and resident vaccination rates. From the plot below, you can see that it is almost a flat line. ***Mathematically, this means that whether you run the regression analysis against resident vaccination rate or staff vaccination rate, you will get almost no variation in the results and find the same correlation***.

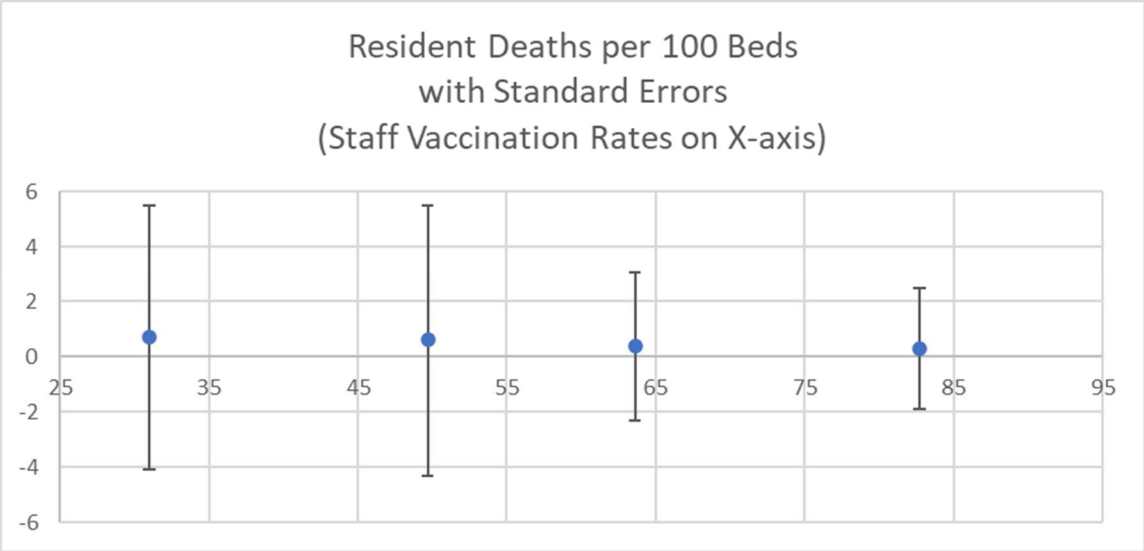
28. It's not surprising to imagine that attitudes towards COVID-19 vaccination in a community will impact both nursing home residents in the community as well as staff living in the same community. It was an error, albeit understandable, for the authors to attribute their findings

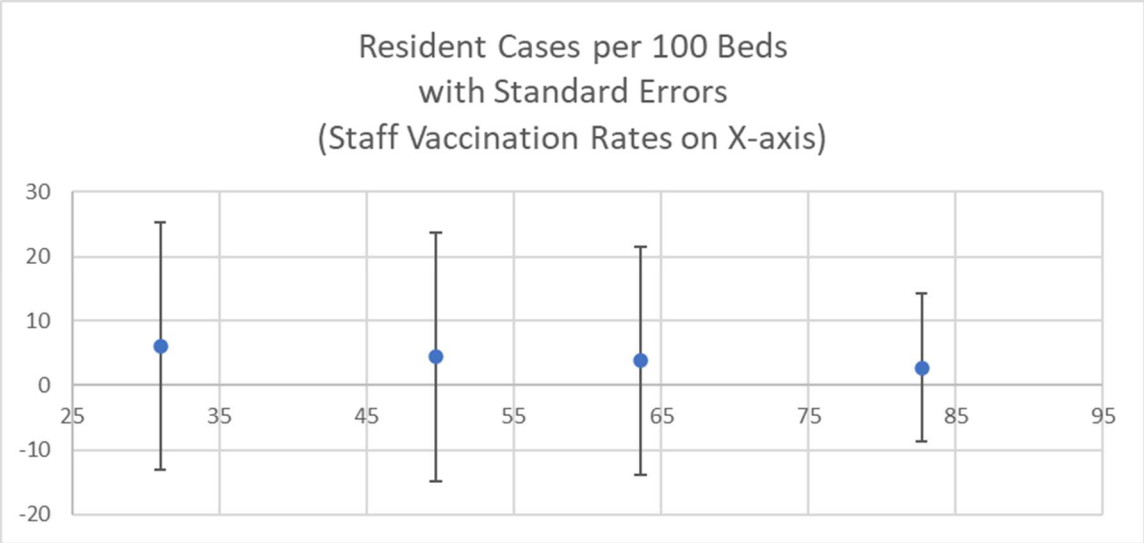
to staff vaccination rates. As stated before, the primary benefit to a COVID-19 vaccination is to the recipient of the vaccine.



29. The McGarry et al. study also presents a wonderful example of how statistical methods, if not fastidiously applied with an open mind to all possibilities, can fundamentally obfuscate deeper insights.

30. In particular, I would like to draw the court's attention to the absolute number of resident death rates per 100 beds reported in the study. I've plotted them below with standard deviation error bars taken from Table S1. There is little difference in resident mortality rate in all different categories of resident vaccination with marked overlap of the error bars such that any differences could be due to chance alone. The plot would look the same if the x-axis were staff vaccination rates (provided upon request). The same is true, it turns out, for resident deaths.



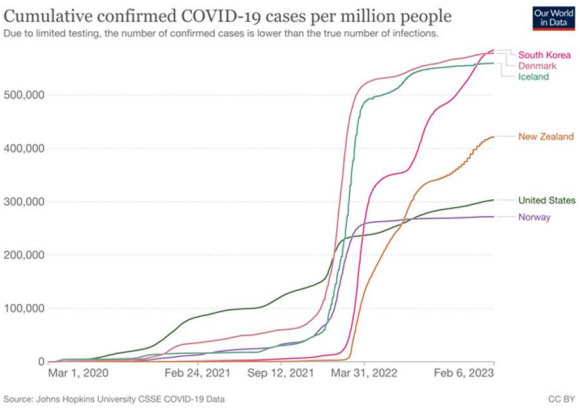


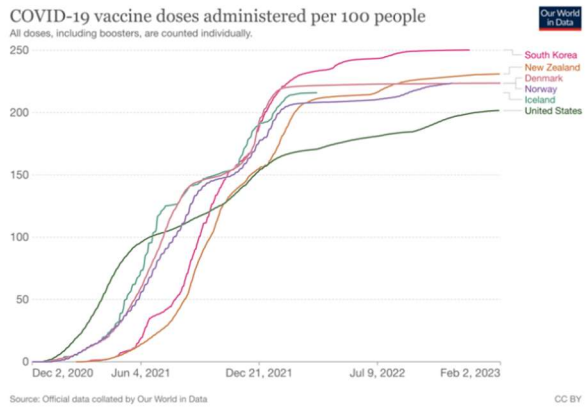
31. We therefore have 2 nursing home studies (correlating to Santa Clara County's designation of a "high-risk" work setting), one pre-Delta and one pre-Omicron during Delta, showing no notable relationship in patient COVID-19 rates and staff vaccinations rates. Given increased escape from vaccine induced immunity with Omicron variants, there is no reason to believe that this trend, if studied, would not just hold, but get amplified.

32. What about transmission and vaccination/booster status with Omicron? An early December 2021 paper in Danish Households demonstrated a roughly 40% reduction in household

secondary attack rate (SAR) with boosting when compared to the unvaccinated or vaccinated.[14] ***However***, there was no such reduction in susceptibility to infection when comparing vaccinated alone to the unvaccinated. Focusing on table 2, during the early December 2021 study period, booster vaccination cut the risk of contracting Omicron by roughly 45%+ and passing on Omicron by roughly 40%.[5]

33. While this appeared promising for boosters, the subsequent ecological waves from late December 2022 forward in heavily boosted countries previously lauded for the "stopping COVID-19 infections" demonstrated otherwise. Denmark, Iceland, Norway, New Zealand, Australia, Hong Kong, South Korea all experienced per-capita COVID-19 waves larger than any experienced by the United States.[15] So the advantage of boosting, while demonstrable in an 8-week time frame, appears to rapidly devolve over time. In effect, Santa Clara County observational data as reported by the County in its declarations is not supported by data sets from entire nations with far more robust centralized systems for vaccination status and testing and higher COVID-19 vaccination rates.





34. As a "front-line health care provider", I can attest to the fact that vaccination status data is incomplete and imperfect. I have admitted numerous patients with COVID-19, with admittable sequelae due directly to the infection or simply testing positive with admission for an

[14] https://www.medrxiv.org/content/10.1101/2021.12.27.21268278v1.full.pdf.

[15] https://tinyurl.com/yjr455f4.

unrelated issue, where the vaccination status in the Electronic Medical Record remains discordant with the patient's reported vaccination status through their entire admission and even after their discharge and, at times, subsequent return to the hospital for the same or another illness. Self-reporting has been found to be highly correlated with an accurate representation of vaccination status (93.9% to 95.9% correlation).[16]

35. Because the quality of the data is critical to a reasonable evaluation of epidemiologic trends, I spent some time in 2022 analyzing Walgreens' COVID "dashboard." I am going to walk the Court through how looking at a different observational data set can lead to very different conclusions. I am not maintaining that the Walgreens data set is "better" than Santa Clara County's data set or that of any other organization. However, the Walgreen's data set is more likely to have complete vaccination data given that it was a leading nationwide provider of COVID-19 vaccination and a testing provider.

36. Walgreens maintained a remarkable COVID-19 dashboard that details test positivity by vaccination status broken down by age cohort.[17] Correcting for vaccination rates and population representation, the data appeared to show that vaccinated and boosted individuals were testing positive for COVID-19 at a rate at least as high as unvaccinated individuals. While there is an impact from the fact that unvaccinated individuals are more likely to have superior protection due to a prior infection and more likely required to obtain surveillance testing even when asymptomatic, this does not impact our discussion here as the vast majority of Americans, vaccinated or not, have had a COVID-19 infection (approximately 75% through February 2022 and now at least 95% through August 22, 2022).[18]

37. Walgreens was not excessively sampling vaccinated patients in a way that might bias the results against vaccination. In fact, the population tested by Walgreens had a smaller number of single-dose vaccinated than the USA population, with higher proportions of vaccinated

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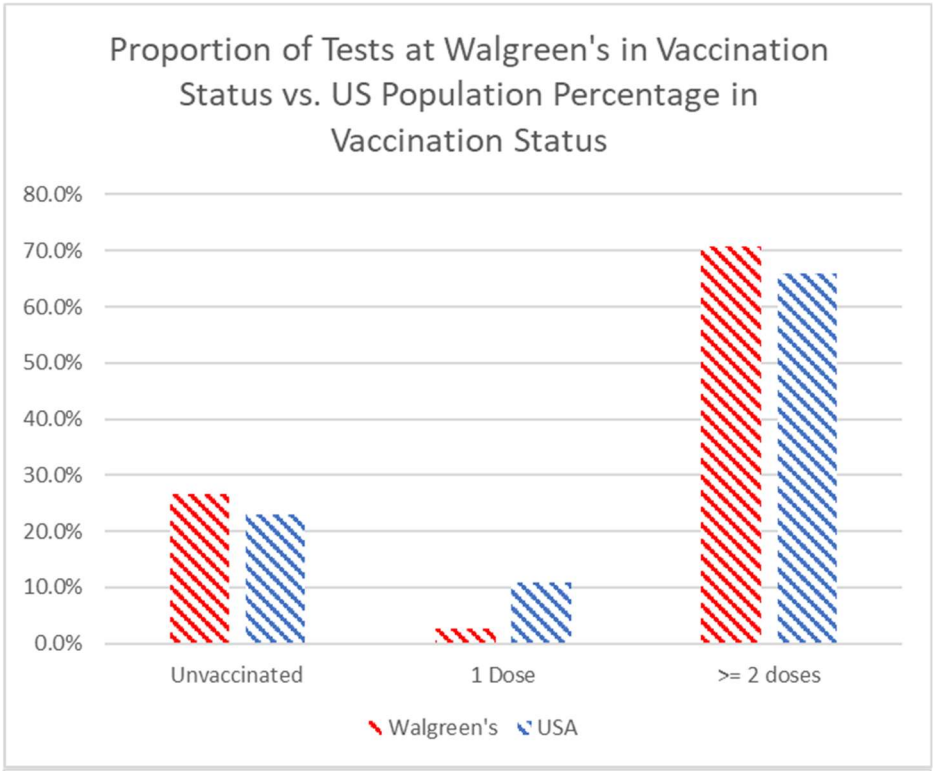
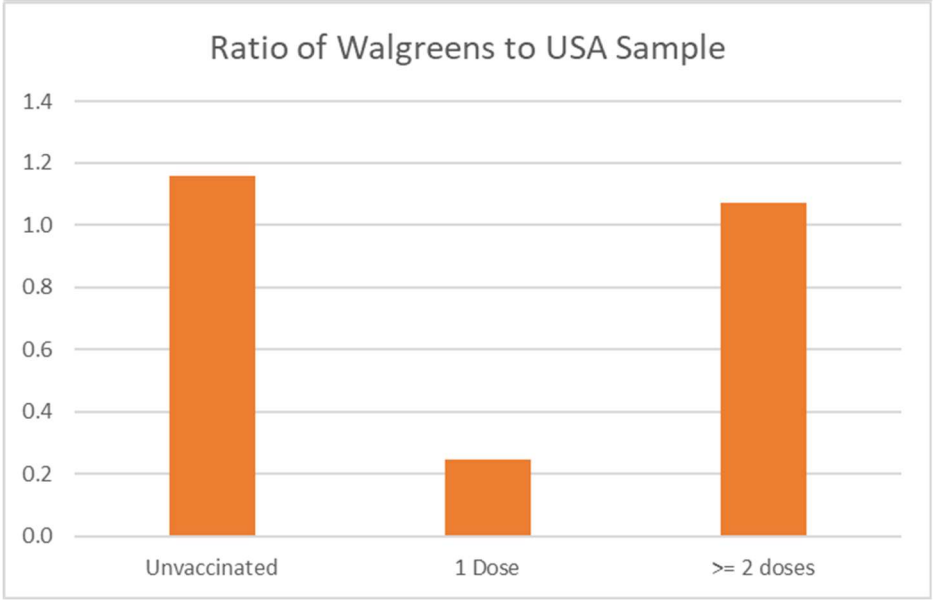
[16] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9350035/.

[17] https://www.walgreens.com/businesssolutions/covid-19-index.jsp.

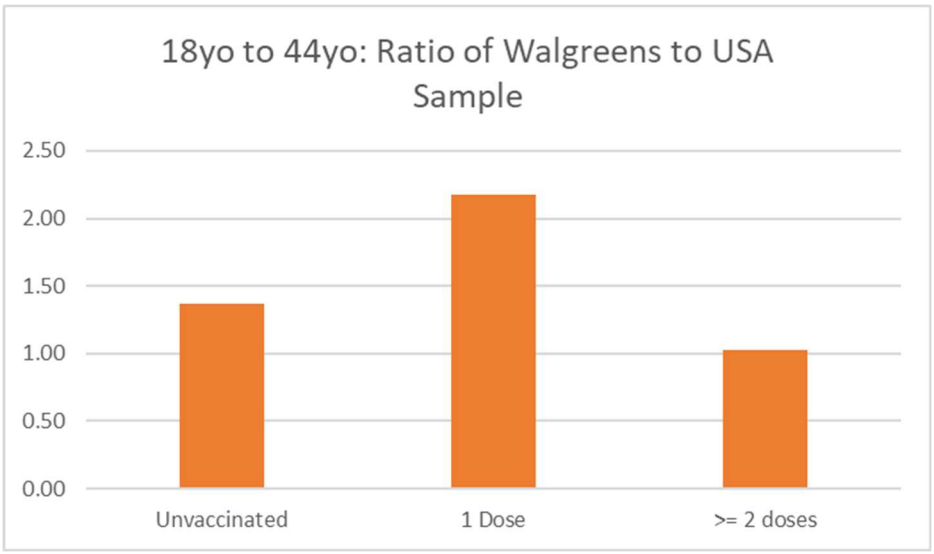
[18] https://covid19serohub.nih.gov/.

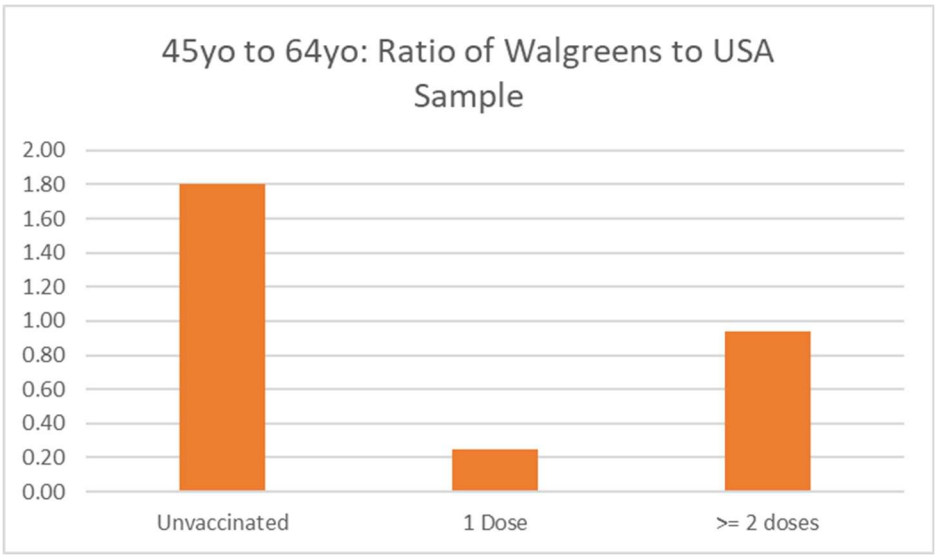
and unvaccinated patients – particularly the unvaccinated.

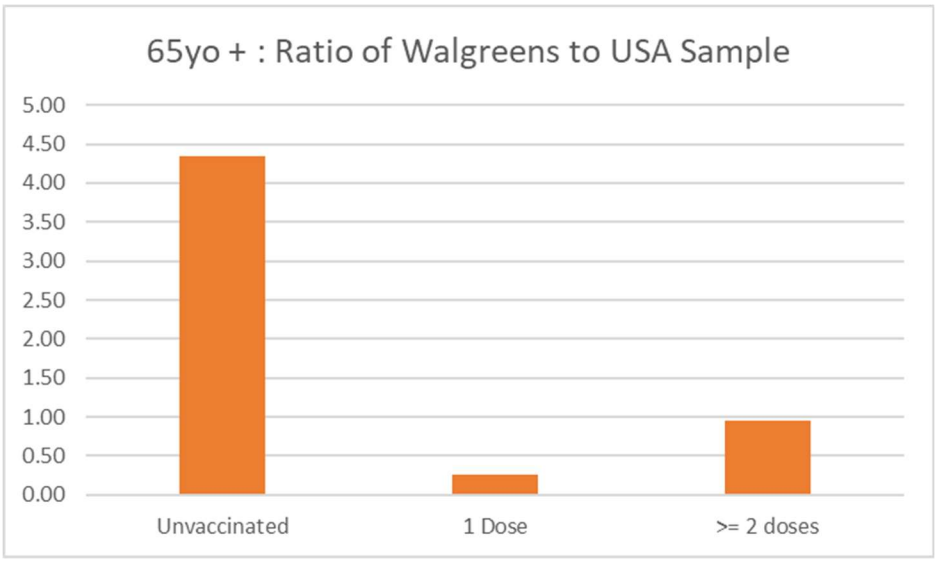




38. In fact, in the over 18-year-old age cohorts, Walgreen's was testing unvaccinated patients at significantly higher rate than their representation in the USA population:

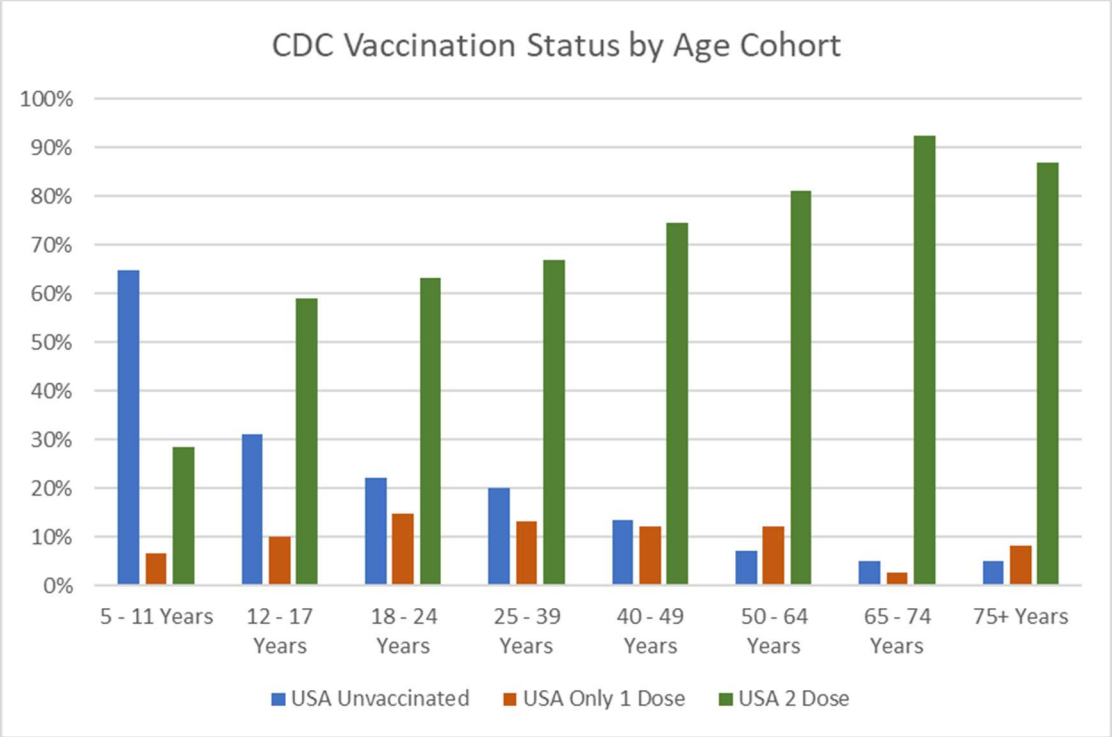

18yo to 44yo: Ratio of Walgreens to USA Sample
2.50
2.00
1.50
1.00
0.50
0.00
Unvaccinated
1 Dose
>= 2 doses


45yo to 64yo: Ratio of Walgreens to USA Sample
2.00
1.80
1.60
1.40
1.20
1.00
0.80
0.60
0.40
0.20
0.00
Unvaccinated
1 Dose
>= 2 doses

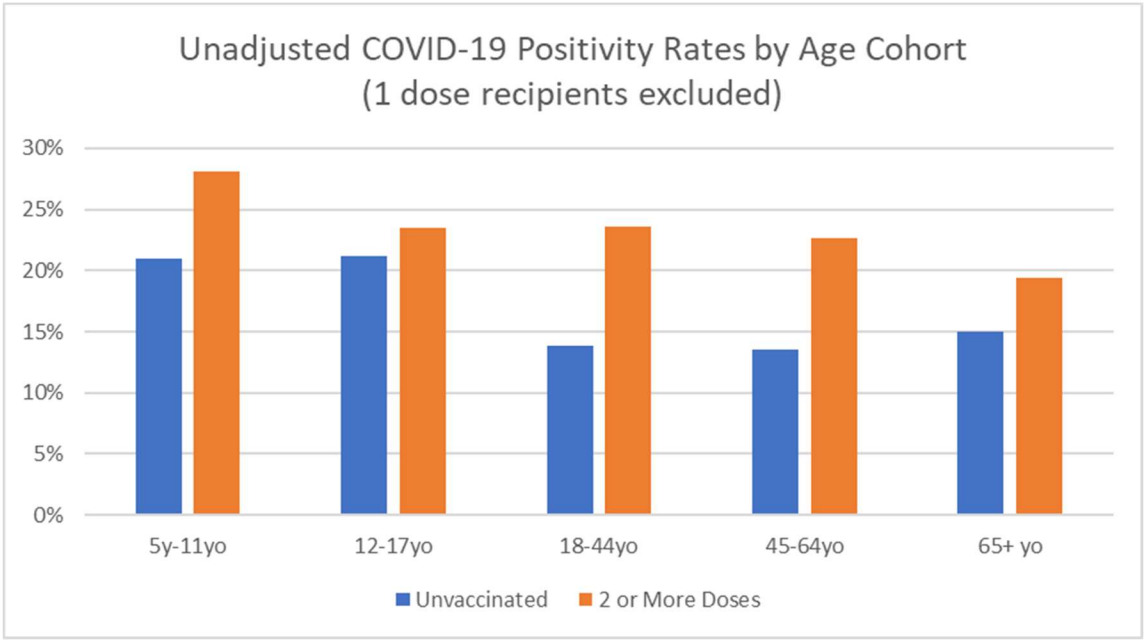


39. Walgreens data for a testing week April 28, 2022, showed that for every age cohort, vaccinated individuals are shown to be testing positive *at a rate that is at least as high as unvaccinated individuals*. While there are caveats to this pattern that I will note later, it's important to understand that these are rates and not cases so there is no "base rate fallacy". In other words, just because vaccinated individuals are a larger percentage of the population, they will not register a higher rate of positivity on the Walgreen's dashboard.

40. For this analysis, I also obtained CDC data by dose per age cohort through April 2022. This allows us to compare vaccination rates in a particular age cohort to test positivity rates in those cohorts in the Walgreens national testing data at that point in time:



41. Consolidating fully vaccinated and boosted individuals into a "2 or more doses" category to correspond to the CDC vaccination data above, we see that all age cohorts from Walgreens had a higher test-positivity rate than unvaccinated patients:

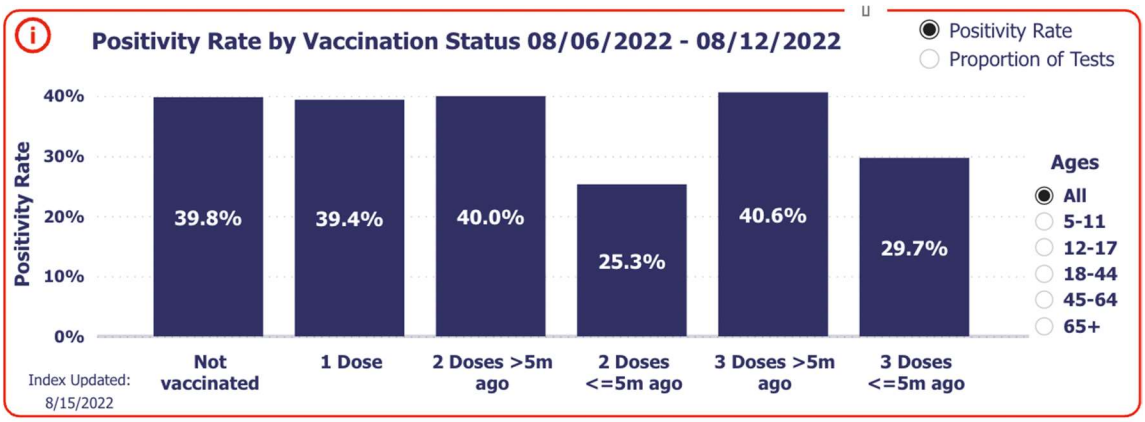


42. To those limitations previously mentioned including high rates of testing among unvaccinated by mandate driving down positivity rates, I will add that, from a conference call I participated in with the Walgreen's epidemiologic team on June 16, 2022, repeat testers are not easily filtered by Walgreen's despite their best attempts. Indeed, my analysis on Walgreen's data from May 2022 is part of what prompted the June 16, 2022 call. Walgreen's subsequently provided the following statement:

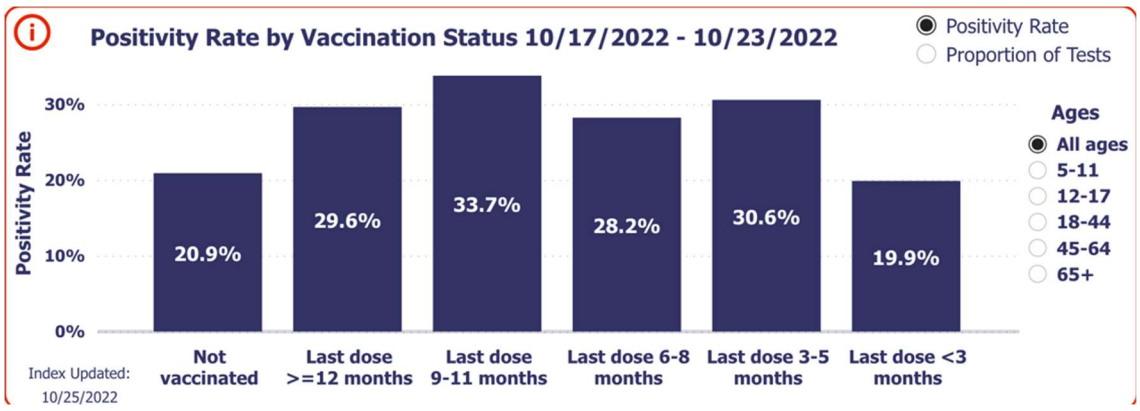
> *"Controlling for recent COVID-19 cases, results show that the unvaccinated group has a **17.1% higher positivity rate compared to the 3-dose group** (emphasis mine). Controlling for additional factors leads to a larger difference between groups. … in addition to the changing level of circulating virus in the population, positivity rates are influenced by many factors … These factors can both increase and decrease the positivity metric."*

43. Notably, my central assertion of transmission reduction on the order of 20-25% for roughly 8 weeks is highly consistent with the imputed value of a 17.1% higher positivity rate among unvaccinated individuals after the post-May 2022 "corrections" were applied by Walgreen's. Furthermore, the evidence for waning efficacy, regardless of testing imbalances, is unmistakable in their data. Indeed, subsequent Walgreen's dashboard snapshots demonstrate no evidence to support sustained transmission reduction:

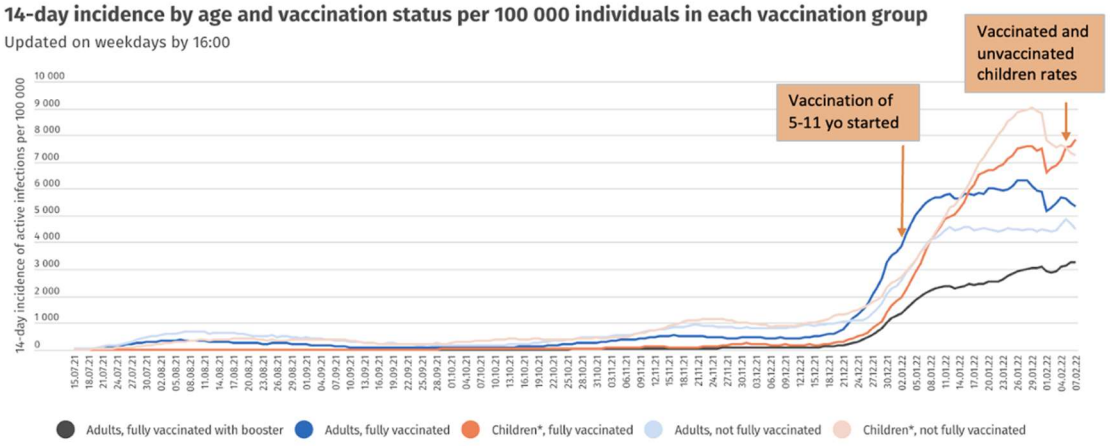
- August 6th, 2022:



- October 17th, 2022:



44. High positivity rates in vaccinated individuals, that effectively undermine the argument for COVID-19 vaccine mandates, are duplicated across multiple countries which is why they were abandoned across most of the Western world by the end of 2022. Some of the most compelling mid-2022 data sets are from the United Kingdom and Iceland.[19,20]

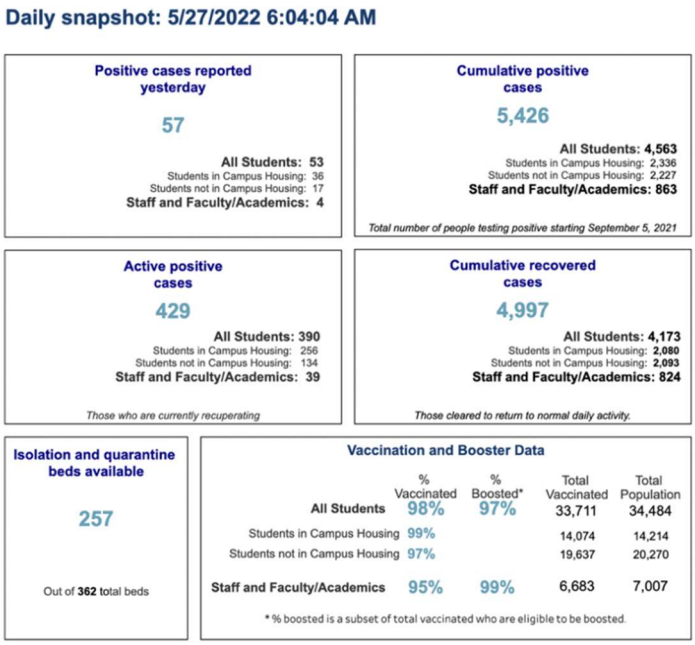


45. And the high infection rates in vaccinated, and even near universally boosted, populations is evident in multiple local data sets such as the University of California campuses.

[19] https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports.

[20] https://web.archive.org/web/20220218014505/https://www.covid.is/data -- site retired

The University of California at Irvine:[21]



Daily snapshot: 5/27/2022 6:04:04 AM

Positive cases reported yesterday
57
All Students: 53
Students in Campus Housing: 36
Students not in Campus Housing: 17
Staff and Faculty/Academics: 4

Cumulative positive cases
5,426
All Students: 4,563
Students in Campus Housing: 2,336
Students not in Campus Housing: 2,227
Staff and Faculty/Academics: 863
Total number of people testing positive starting September 5, 2021

Active positive cases
429
All Students: 390
Students in Campus Housing: 256
Students not in Campus Housing: 134
Staff and Faculty/Academics: 39
Those who are currently recuperating

Cumulative recovered cases
4,997
All Students: 4,173
Students in Campus Housing: 2,080
Students not in Campus Housing: 2,093
Staff and Faculty/Academics: 824
Those cleared to return to normal daily activity.

Isolation and quarantine beds available
257
Out of 362 total beds

Vaccination and Booster Data

	% Vaccinated	% Boosted*	Total Vaccinated	Total Population
All Students	98%	97%	33,711	34,484
Students in Campus Housing	99%		14,074	14,214
Students not in Campus Housing	97%		19,637	20,270
Staff and Faculty/Academics	95%	99%	6,683	7,007

* % boosted is a subset of total vaccinated who are eligible to be boosted.

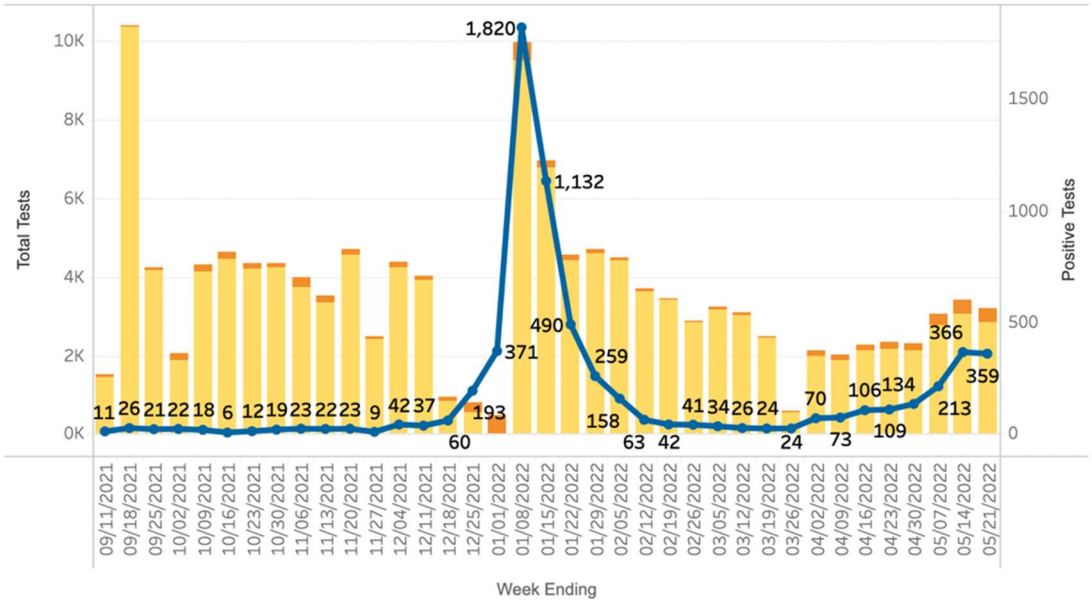
University of California at Los Angeles:[22]

[21] https://web.archive.org/web/20220527060317/https://uci.edu/coronavirus/dashboard/index.php

[22] https://covid-19.ucla.edu/confirmed-cases-of-covid-19-among-the-ucla-campus-community/.

Symptomatic and asymptomatic testing

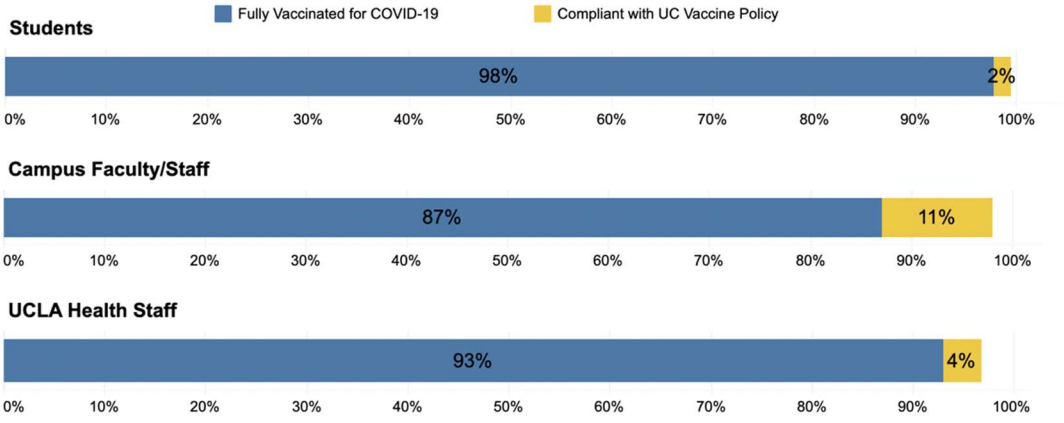
Testing since September 5, 2021. The following chart combines asymptomatic and symptomatic results.

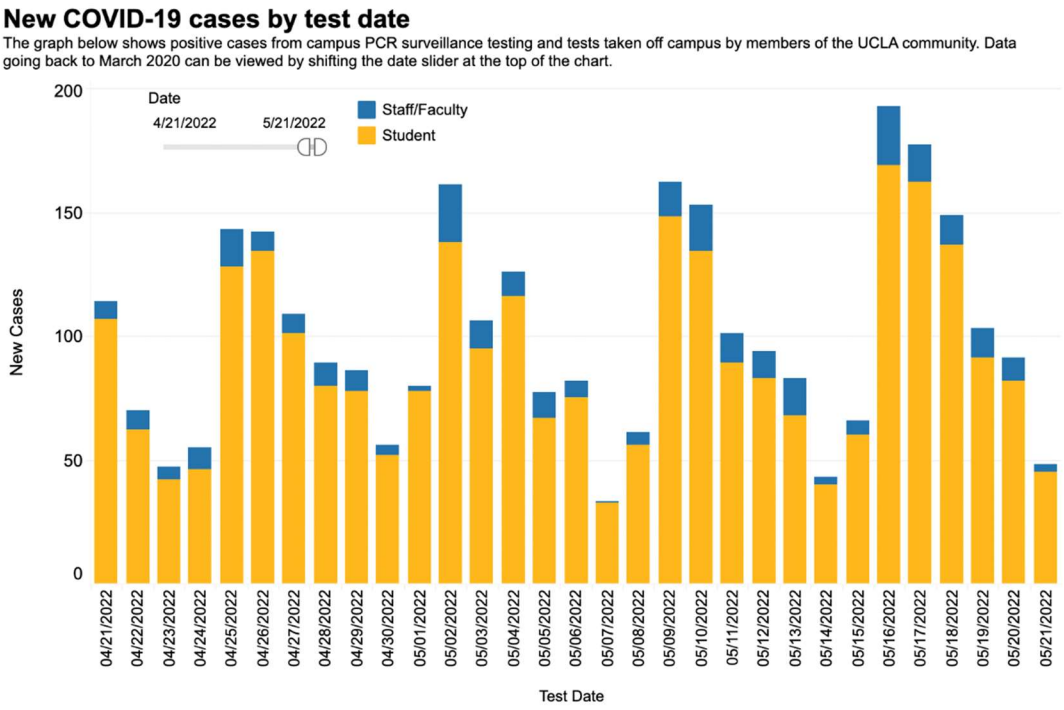


Information on COVID-19 vaccination and compliance

This data below shows the percentage of individuals who are fully vaccinated and those who are compliant with the University of California's vaccination policy. Individuals considered compliant are those who are fully vaccinated (and who have received a booster shot, if eligible), partially vaccinated, have been approved for medical or religious exceptions, and those working or learning entirely remotely. UCLA Health staff include employees at the David Geffen School of Medicine at UCLA.

Vaccinated and compliant with COVID-19 policy





46. Fast forward to Omicron and related variants, we can revisit Danish research on transmission with the BA.2 Omicron variant (dominant now) versus the BA.1 Omicron variant (dominant through the winter of 2021-22), they noted:[23]

> Both unvaccinated, fully vaccinated and booster-vaccinated individuals had a higher susceptibility for BA.2 compared to BA.1, indicating an inherent increased transmissibility of BA.2 (Table 3). However, the relative increase in susceptibility was significantly greater in vaccinated individuals compared to unvaccinated individuals (appendix Figure 6, which points towards immune evasive properties of the BA.2 conferring an even greater advantage for BA.2 in a highly vaccinated population such as Denmark. Because previous studies of the Omicron VOC has focused on the BA.1 (Pearson et al., 2021; Planas et al., 2021), new studies are needed to further investigate these properties for BA.2.

47. None of this observational data is particularly surprising. Indeed, much of this could have been inferred from our prior experience with Influenza. Both SARS-CoV-2 and Influenza are

[23] https://www.medrxiv.org/content/10.1101/2022.01.28.22270044v1.

enveloped RNA respiratory viruses of roughly 80-120 nanometers per virion in size. Both SARS-CoV-2 and Influenza are transmitted by droplets and aerosols, and the impacts of vaccination are quite similar.

48. COVID-19 has followed the path of Influenza: now, as with influenza, cases of COVID-19 will continue to appear, but the number and severity of those infections will be significantly reduced even while neither vaccination or prior infection represents an impenetrable shield to subsequent infection.[24,25] In fact, a 2018 study positively correlated amount of Influenza virus in exhaled breath with vaccination status thereby suggesting that in the study population, those vaccinated with the Influenza vaccine were spreading more viral particles.[26] It is well established that the benefits of Influenza vaccination extend to the individual receiving the vaccination which is traditionally why Influenza vaccination in health care settings has been recommended and not mandated (until recently at some institutions).

49. Extending the parallels to Influenza and coming back to studies performed in health care settings, a 2017 study established that patient benefit from healthcare worker Influenza vaccination was not established:

> *"The impression that unvaccinated HCWs place their patients at great influenza peril is exaggerated. Instead, the HCW-attributable risk and vaccine-preventable fraction both remain unknown and the NNV to achieve patient benefit still requires better understanding. Although current scientific data are inadequate to support the ethical implementation of enforced HCW influenza vaccination, they do not refute approaches to support voluntary vaccination or other more broadly protective practices, such as staying home or masking when acutely ill."* [27]

50. This has led Dr. Michael Osterholm, formerly a member of the Biden Administration's COVID-19 Task Force, to state:

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[24] https://www.eurekalert.org/news-releases/694958.

[25] https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00180-4/fulltext.

[26] https://www.pnas.org/doi/10.1073/pnas.1716561115.

[27] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0163586.

> *"We have to make public health recommendations based on good science," Osterholm added, "but we do not have the justification to take punitive action against healthcare workers if they don't get vaccinated [for Influenza]."* [28]

51. In 2023, Dr. Anthony Fauci, who needs no introduction, finally formally weighed in on the matter:[29]

> *"However, as variant SARS-CoV-2 strains have emerged, deficiencies in these vaccines reminiscent of influenza vaccines have become apparent. The vaccines for these two very different [mucosal respiratory] viruses have common characteristics: they elicit incomplete and short-lived protection against evolving virus variants that escape population immunity … Taking all of these factors into account, it is not surprising that none of the predominantly mucosal respiratory viruses have ever been effectively controlled by vaccines. This observation raises a question of fundamental importance: if natural mucosal respiratory virus infections do not elicit complete and long-term protective immunity against reinfection, how can we expect vaccines, especially systemically administered non-replicating vaccines, to do so?"*

52. Once again, the primary benefit of a COVID-19 vaccination is to the recipient and it is for decreasing the risk of severe disease. There is no strong evidence for its impact on substantial or any sustained transmission reduction.

53. **Durability Over Time of Immune Memory to SARS-CoV-2 Infection:** A healthy immune system mounts an effective response to SARS-CoV-2 infection and this response persists over time. A recent July 2022 publication where 96.7% of study participants had mild or asymptomatic infection shows that children mount a robust antibody response that will fade with time but remains measurably present.[30]

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[28] https://www.cidrap.umn.edu/news-perspective/2017/01/health-worker-flu-vaccine-data-insufficient-show-protection-patients.

[29] https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(22)00572-8.

[30] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794167.

Table 1. Serologic Data of 769 Serum Samples Obtained From 659 Individuals With Confirmed COVID-19 Among Different Age Classes, Overall and Stratified by Time From Baseline[a]

Variable	Anti-RBD, median (IQR), kBAU/L			
	All data	1-4 mo from onset	5-9 mo from onset	>10 mo from onset
Age class, y				
<3	304.83 (139.0-519.6)	342.8 (179.5-519.6)	284.3 (162.5-519.6)	146.2 (62.8-231.2)
≤3	169.3 (103.1-277.1)	234.6 (113.5-347.9)	118.2 (70.6-192.5)	115.6 (45.9-160.6)
≤6	126.2 (74.0-207.8)	164.1 (79.1-236)	119.7 (77.4-165.2)	90.6 (62.4-111.8)
≤12-18	98.2 (44.7-169.0)	103.1 (46.3-170.2)	89.6 (45.9-170.2)	48.6 (18.1-95.7)
≥18	55.6 (24.2-136.0)	64.5 (26.2-140.9)	49.8 (22.5-114.7)	36.7 (13.5-108.5)
P value[b]	<.001	<.001	<.001	.02

Abbreviations: kBAU/L, kilo-binding antibody units per liter; RBD, receptor-binding domain.

[a] Serum samples at the last time point for 17 people whose last S-RBD IgG titer was higher than the previous one were excluded from the analysis.

[b] Kruskal-Wallis test.

54. Once again, this speaks to an expected pattern of less severe disease with any subsequent infection. This study reinforced prior research that measured these responses up to 12 months. This latter point is extremely important to fully understand as more than 95% of American children have had a COVID-19 infection:[31]

> *"Importantly, children retained antibody and cellular responses 6 months after infection, whereas relative waning occurred in adults. Spike-specific responses were also broadly stable beyond 12 months. Therefore, children generate robust, cross-reactive and sustained immune responses to SARS-CoV-2 with focused specificity for the spike protein*."[32]

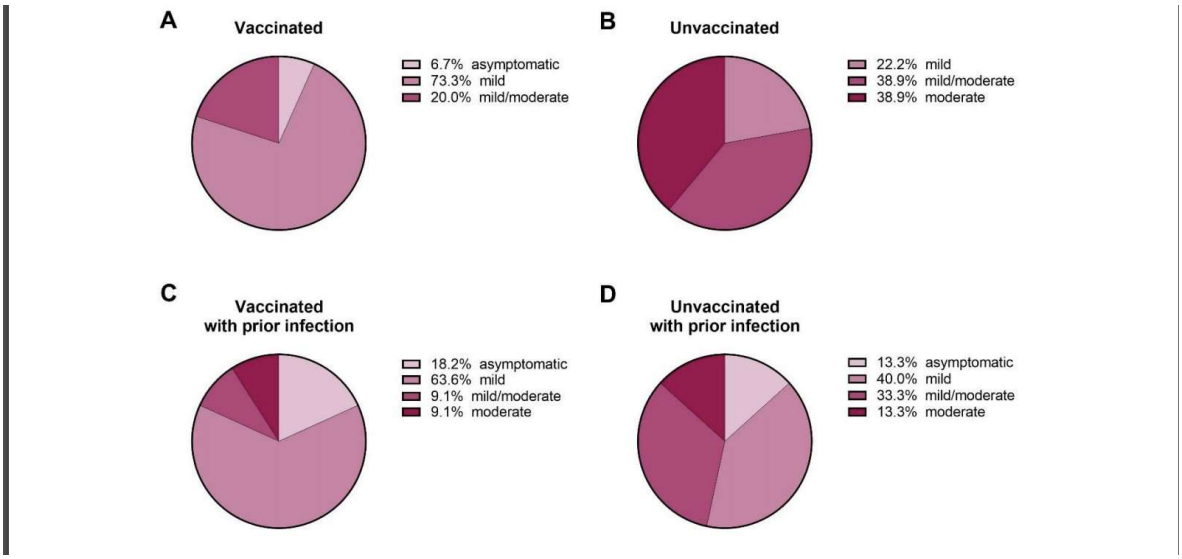
55. More recent data in a post-Omicron infection sample, shows that those with prior infection, with or without associated vaccination, have a robust rise in neutralizing antibodies after an Omicron infection. Indeed, those who were vaccinated alone with no prior infection had modal titers similar to those who were unvaccinated.[33]

56. And, as repeatedly asserted throughout my declaration, neither prior infection nor vaccination will prevent a subsequent SARS-CoV-2 infection, but they both reduce the severity of outcomes. In this March 2022 study, the differences were minor if there was a prior infection:

[31] https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence.

[32] https://www.nature.com/articles/s41590-021-01089-8.

[33] https://www.nejm.org/doi/full/10.1056/NEJMc2201607.



Once again, the primary benefit of a COVID-19 vaccination is to the recipient.

57. As it pertains to Santa Clara County's COVID-19 early 2022 booster requirement, it's worth noting that in this same March 2022 study, *47% of the vaccinees had an mRNA vaccination within the preceding 3 months and 40% had been boosted*.[34]

Table S2. Patient characteristics of vaccinated individuals without prior history of pre-Omicron infection

AGE (YEARS)	SEX#	DAYS SINCE BA.1 INFECTION*	VACCINATION	WEEKS SINCE LAST VACCINATION$	SEVERITY OF COVID-19
<20	f	10	BNT162b/BNT162b	16.3	mild
50-59	m	18	BNT162b/BNT162b	unknown	mild
50-59	f	18	BNT162b/BNT162b	unknown	mild
30-39	m	20	BNT162b/BNT162b	unknown	mild
30-39	m	8	BNT162b/BNT162b/BNT162b	3.1	mild/moderate
20-29	m	14	BNT162b/BNT162b/BNT162b%	1.6	mild/moderate
20-29	m	33	ChAdOx1	22.1	mild
20-29	f	35	BNT162b	6.0	mild
30-39	m	23	mRNA-1273/mRNA-1273/mRNA-1273%	0.6	mild
20-29	f	10	BNT162b/BNT162b	23.3	mild
30-39	f	6	mRNA-1273/mRNA-1273/BNT162b%	0.1	mild
20-29	f	10	BNT162b/BNT162b	23.0	mild/moderate
20-29	f	5	Ad26.COV2.S/BNT162b	7.6	asymptomatic
80-89	m	9	BNT162b/BNT162b/BNT162b	12.0	mild
40-49	f	12	ChAdOx1/ChAdOx1	29.3	mild

f = female; m = male; * Days since first positive PCR for omicron BA.1 infection; %Interval between last dose of vaccination and first positive PCR for omicron BA.1 infection less than 14 days; $Interval between last dose of vaccination and first positive PCR for omicron BA.1 infection

[34] https://www.nejm.org/doi/suppl/10.1056/NEJMc2201607/suppl_file/nejmc2201607_appendix.pdf

But chasing and citing "infections" as the reason for any policy intervention is doomed to fail. Even as it pertains to measuring antibody levels attained with vaccine dosing, disease severity does not determine the potency or longevity of response with commercially available assay levels correlating with separate neutralizing-antibody titers.[35]

58. An early publication from Iceland offered unique insights into what we could expect with post-Omicron reinfections in different vaccination categories.[36] While I felt there were significant problems with possible ascertainment bias and grouping of unvaccinated with 1 dose recipients, the authors found:

> *"Surprisingly, 2 or more doses of vaccine were associated with a slightly higher probability of reinfection compared with 1 dose or less. This finding should be interpreted with caution because of limitations of our study, which include the inability to adjust for the complex relationships among prior infection, vaccine eligibility, and underlying conditions."*

59. Additional studies since that early Icelandic paper that are far higher quality, including those of health care workers at the Cleveland Clinic, have demonstrated similar patterns.[37]

60. **The main takeaway from the above discussion is NOT that the COVID vaccines "do not work."**

a. The main takeaway is that observational data can be fraught with confounding variables and completely different conclusions can be reached from similar data sets even if the same analytic methods are used.

b. Utilizing observational data sets to curtail the freedoms of individuals must be done with extreme caution and circumspection as there is a high probability of being mostly wrong.

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[35] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794167.

[36] https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2794886.

[37] https://academic.oup.com/ofid/article/10/6/ofad209/7131292?login=false.

c. In the case of Santa Clara County, and really much of the United States, their data is confounded by the same limitations faced by the CDC whose policies the Defendants frequently cite in defense of Santa Clara County guidelines and policies:

i. Hospitalizations and cases are not associated with accurate vaccination data.

ii. County policies, simply by virtue of testing mandates, tested unvaccinated populations with a higher frequency than unvaccinated individuals. County declarations indicate that in low and moderate risk categories, Santa Clara County mandated up to twice a week testing for unvaccinated employees.

iii. There are other confounders that are active in many different types of clinical intervention studies. For example, with my co-authors, we demonstrated that post-release Pfizer sponsored vaccine (booster and 2-dose regimen) studies performed with Clalit Health were deeply confounded by "Healthy User Bias." Healthy User Bias is a process whereby individuals who follow a particular recommendation under study are also far more likely to engage in other healthy habits that contribute to improved outcomes along aspects that are unrelated to the intervention in particular. For example, people who follow vaccination recommendations are more likely to exercise, eat well, not smoke and therefore have a lower rate of death or disability that has nothing to do with the efficacy of the medical intervention itself. This phenomenon has been well demonstrated with a wide array of medical interventions including Influenza vaccination.[38] In our New England Journal of Medicine correspondence, my coauthors and I found that size of the Healthy User Bias was essentially equal to the reported benefit attributed from additional doses of the COVID-19 vaccine.[39] These studies from Clalit Health were extensively cited in FDA and CDC hearings and guidance as well as meetings of the Advisory Committee on Immunization Practices (ACIP).

[38] https://academic.oup.com/ije/article/35/2/337/694702?login=false.

[39] https://www.nejm.org/doi/full/10.1056/NEJMc2306683.

iv. Santa Clara County has not cited the use of any Falsification Endpoints (or negative controls) in its declarations as part of any attempts to draw more robust conclusions from their observational data.

61. **Vaccination Versus Infection Immune Response for COVID-19:** More recent literature has examined local tissue and mucosal immunity generated by an infection compared to vaccination alone.[40,41] As confirmed by the 2023 publication from Dr. Fauci and co-authors alluded to above, vaccination for common mucosal respiratory viruses like SARS-CoV-2 does not generate an effective mucosal immune response. Infection, however, as noted above, does. Furthermore, disease severity does not determine the potency or longevity of response with commercially available assay levels correlating with separate neutralizing-antibody titers.[42] In effect, a prior infection provides defenses against reinfection and transmission that a COVID-19 vaccination only generally does not.

62. The stimulation of an immune response after a mild infection can even be demonstrated in the absence of actual antibody seroconversion (detectable prior infection by antibodies) at the level of T-cells.[43] The presence of effective immune memory, both humoral (antibody) and cellular components, after even a mild SARS-CoV-2, infection is no longer a matter of debate.

63. Inevitably, the topic of COVID-19 in children arises in any discussion around COVID-19 vaccination especially as it might pertain to Santa Clara County residents. To that end, it's appropriate to discuss COVID-19 in children specifically.

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[40] https://www.science.org/doi/10.1126/sciimmunol.add4853.

[41] https://www.science.org/doi/10.1126/sciimmunol.abl9105.

[42] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794167.

[43] https://www.sciencedirect.com/science/article/pii/S0092867420310084.

64. The last notable CDC update to Pediatric infection was through August 22, 2022, and it estimated infection induced seroprevalence in the under-18yo group to be at least 95%.[44] It is no doubt significantly higher than that now.

65. **Comparison to other Respiratory Viruses (RVs):** It is helpful and epidemiologically literate, not "minimizing" or "careless", to consider COVID-19 and its severity in children as compared to other respiratory viruses. Prior to COVID-19, we have **never** tested every single admission to the hospital or possible death for a highly contagious respiratory virus. We haven't even done this for Influenza during prior Influenza seasons. Had we done so, there is a good chance that we would have had many minimally symptomatic or asymptomatic admissions testing positive for Influenza even while it was not the primary reason for admission. With respect to COVID-19, this has been an undeniable phenomenon that took more than 1.5 years for the CDC to acknowledge.

66. This is particularly true in Pediatric COVID-19 admissions given the overwhelming trend for mild disease. It has been globally demonstrated and has accelerated with even milder disease from Omicron. Pre-Omicron, in children and young people, the rate of incidental COVID-19 positive admissions where COVID-19 was not deemed to be central to the reason for admission was 59% in the United Kingdom, 38% in Canada, in the United States 39% asymptomatic and an additional 28% with mild or moderate disease, in France 45% were asymptomatic.[45,46,47,48] Consequently, when we assess hospitalizations and deaths from COVID-19, especially in Pediatric patients, reported numbers, on average, are not representative of attribution to severe COVID-19 itself in at least 40% of cases.

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[44] https://covid19serohub.nih.gov/.

[45] https://www.researchsquare.com/article/rs-689684/v1.

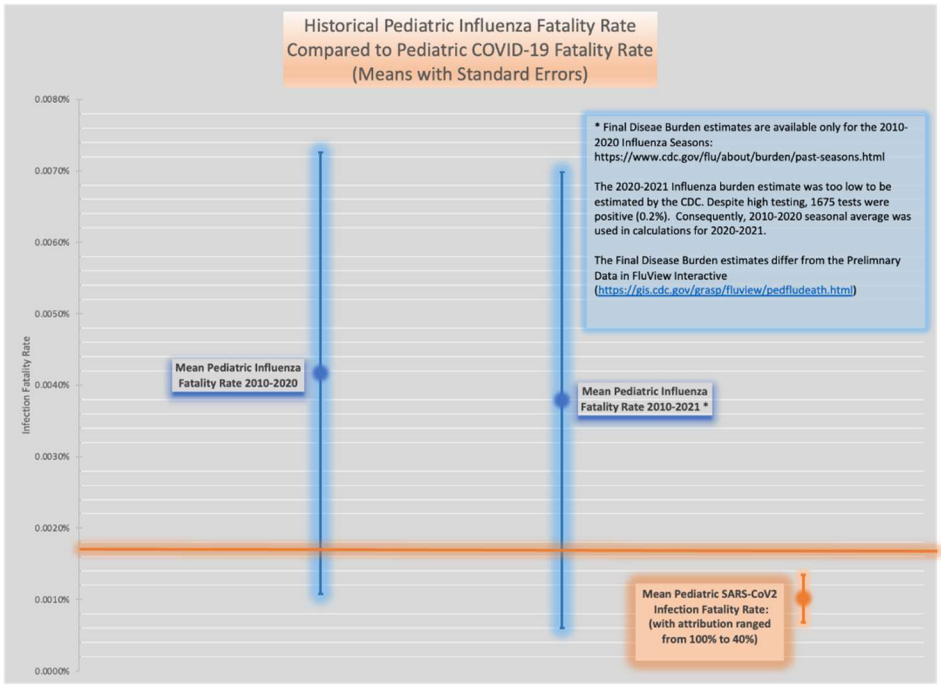
[46] https://pubmed.ncbi.nlm.nih.gov/34580141/.

[47] https://publications.aap.org/hospitalpediatrics/article/11/8/e151/179740/For-COVID-or-With-COVID-Classification-of-SARS-CoV.

[48] https://academic.oup.com/cid/article/72/12/2215/5876373.

67. Having said the above, we can still perform a bounding analysis with data obtained from the CDC for US children. The following analysis represents data obtained from the CDC through February 22, 2022, representing the conclusion of the first Omicron (BA.1) wave through most of the US.

68. Utilizing data from the CDC on past Influenza disease burden as well as COVID-19 cases and deaths reported to the CDC, when looking at all children, we can see that in the worst-case scenario, COVID-19 is at worst a severe Influenza risk.[49,50,51,52] In a more realistic scenario, it is less than a standard Influenza risk and slightly more than that for obese teenagers. 95% confidence intervals are displayed:



69. When isolating our view to the under 5yo population, we see a similar phenomenon:

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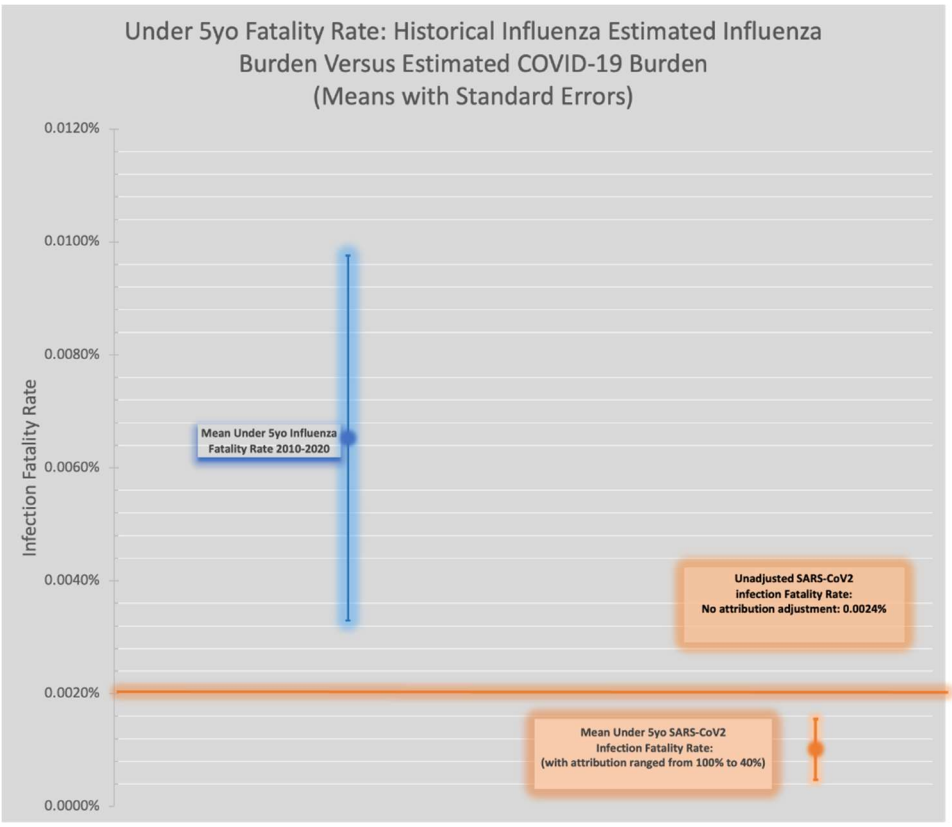
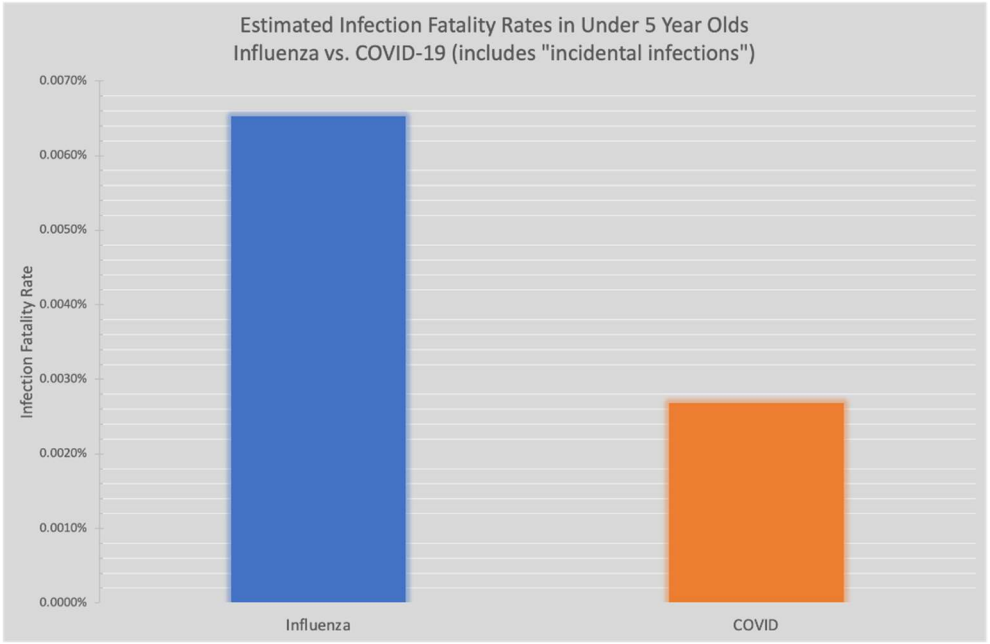
[49] https://www.cdc.gov/flu/about/burden/past-seasons.html.

[50] https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3.

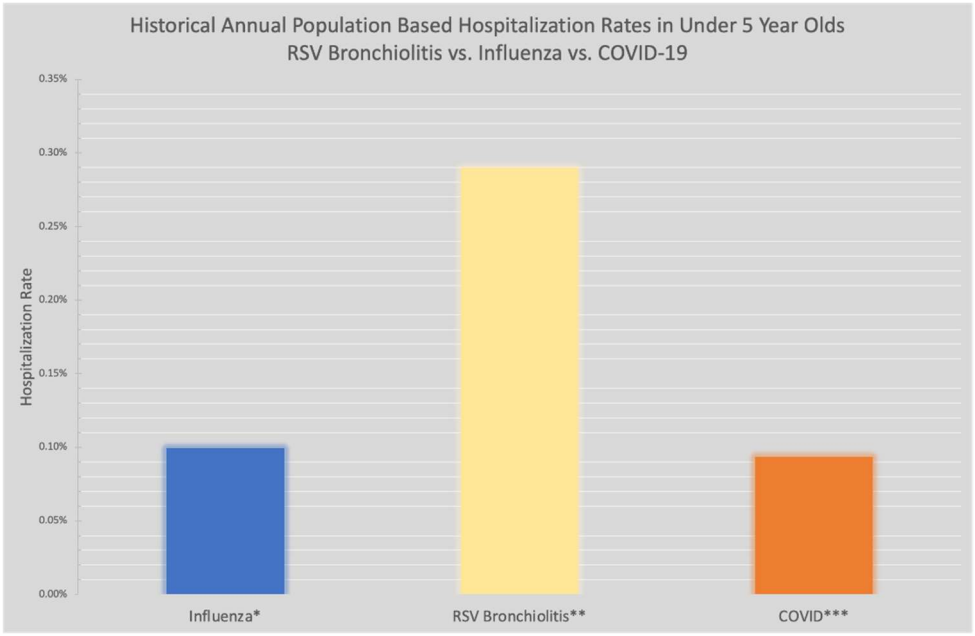
[51] https://covid.cdc.gov/covid-data-tracker/#cases.

[52] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html.

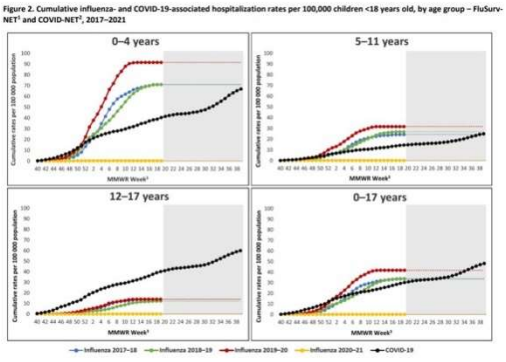

Under 5yo Fatality Rate: Historical Influenza Estimated Influenza Burden Versus Estimated COVID-19 Burden
(Means with Standard Errors)
Infection Fatality Rate
0.0120%
0.0100%
0.0080%
0.0060%
0.0040%
0.0020%
0.0000%
Mean Under 5yo Influenza Fatality Rate 2010-2020
Unadjusted SARS-CoV2 infection Fatality Rate: No attribution adjustment: 0.0024%
Mean Under 5yo SARS-CoV2 Infection Fatality Rate: (with attribution ranged from 100% to 40%)


Estimated Infection Fatality Rates in Under 5 Year Olds
Influenza vs. COVID-19 (includes "incidental infections")
Infection Fatality Rate
0.0070%
0.0060%
0.0050%
0.0040%
0.0030%
0.0020%
0.0010%
0.0000%
Influenza
COVID

70. Hospitalization rates are similar when compared to other common under 5yo respiratory viruses:[53,54]



71. A pre-Omicron CDC analysis through September 2021 is concordant with my conclusions and numbers above demonstrating that the main elevated risk from COVID-19 when compared to Influenza in Children was a subset of high body-mass-index adolescents. This analysis was before mass infection and would likely be even more reassuring even for those high risk cohorts within Pediatric populations:[55]



[53] https://www.cdc.gov/rsv/research/rsv-net/index.html.

[54] https://www.cdc.gov/rsv/research/rsv-net/overview-methods.html.

[55] https://www.medrxiv.org/content/10.1101/2022.03.09.22271788v1.

72. **Pediatric Populations at Risk of Severe COVID-19 and MIS-C:** Since the beginnings of the COVID-19 pandemic, clear risk factors for severe Pediatric disease emerged. Outside of obesity and major neurodevelopmental issues that might also be associated with abnormalities of immune response, no clear risk factors have been identified.[56,57,58,59] While asthma itself has not been associated with an increased risk of severe COVID-19 in children or adults, children with a prior history of severe asthma requiring hospitalization are at increased risk of hospitalization with a COVID-19 infection as would hold for any respiratory virus.[60,61] Somewhat surprisingly, and divergent from results with adults, immunocompromised children have not been consistently found to be at increased risk of severe COVID.[62,63,64] That said, immunocompromised children are at an increased risk of hospitalization, even if only out of an abundance of caution, for any febrile illness and this, at times, would apply to COVID-19 as well.

73. **Long COVID:** The topic of "Long COVID" comes up frequently as a concern with otherwise non-critical COVID-19 infections. We can put aside, for the moment, that neither vaccination or infection are going to definitively prevent reinfection in perpetuity such that any risk from "Long COVID" is faced by all regardless of their vaccination status. That said, high quality studies show that post-infection symptoms after COVID-19 infection are similar to those

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[56] https://www.jpeds.com/article/S0022-3476(20)31393-7/fulltext.

[57] https://www.researchsquare.com/article/rs-689684/v1.

[58] https://publications.aap.org/pediatrics/article/149/1/e2021053418/183463/Risk-Factors-for-Severe-COVID-19-in-Children?autologincheck=redirected.

[59] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2788844.

[60] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00491-4/fulltext.

[61] https://jkms.org/DOIx.php?id=10.3346/jkms.2022.37.e35.

[62] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8590622/.

[63] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8149202/.

[64] https://www.sciencedirect.com/science/article/pii/S016344532100548X.

after other common respiratory infections.[65,66,67,68,69,69] This includes children as evidenced in a large UK database analysis, which found no difference in prevalence of Long COVID-like symptoms among children who had COVID-19 and control children who had not been infected.[70] A large Danish study and a metanalysis in children confirmed these findings.[71,72]

74. **Risks of COVID-19 mRNA Vaccinations**: **While we are all accustomed to, and largely comfortable with, local injection site irritation post-vaccination or even post-vaccination fever with many standard scheduled childhood vaccines, *it does appear that the mRNA vaccinations have a more unique set of features that require careful consideration***. Whether it's the increased rate of "other infections", the notable white blood cell count reductions (leukopenia),[73] drops in the platelet count,[74] a possible trend towards increased reinfection rates, a

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[65] https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003773.

[66] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2785832.

[67] https://www.acpjournals.org/doi/10.7326/M21-4905.

[68] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2796097.

[69] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2799116.

[70] https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/articles/technicalarticleupdatedestimatesoftheprevalenceofpostacutesymptomsamongpeoplewithcoronaviruscovid19intheuk/26april2020to1august2021.

[71] https://link.springer.com/article/10.1007/s00431-021-04345-z.

[72] https://www.medrxiv.org/content/10.1101/2022.03.18.22272582v1.full.

[73] https://www.nejm.org/doi/suppl/10.1056/NEJMoa2027906/suppl_file/nejmoa2027906_appendix.pdf.

[74] https://www.sciencedirect.com/science/article/pii/S0264410X22014931.

trend towards increased cases of appendicitis, abnormal menses (however transient),[75,76] or the more acknowledged myopericarditis (myocarditis/myopericarditis is inflammation of the heart tissue and/or the pericardial lining of the heart), we do not know the underlying process causing these adverse events.

75. **Myocarditis/Myopericarditis with mRNA Vaccination**: mRNA vaccine associated myocarditis/myopericarditis is an uncommon, but well-documented issue with COVID vaccines, particularly after 2nd or 3rd doses, and particularly in otherwise healthy individuals. While rare, the insistence, that it is "always mild" is patently false with autopsy confirmed deaths and documented admissions for cardiogenic shock.[77,78,79,80]

76. The oft cited counterpoint that COVID-19 associated myocarditis is more frequent than myocarditis/pericarditis (myopericarditis) from mRNA vaccination carries its own exaggerations and inaccuracies. To date, there is no histopathological evidence of SARS-CoV-2 induced myocarditis.[81,82] When true myocarditis in COVID-19 occurs as compared to vaccine-induced myocarditis, they are distinct entities occurring in different populations and different clinical circumstances. For the large part, "COVID myocarditis" is a "critical care cardiomyopathy" seen in those who are very ill with COVID-19. "Critical Care Cardiomyopathy" is seen in a wide variety of illnesses and is not just limited to COVID-19. SARS-CoV-2 does not have notable cardiac tropism. Cardiac enzymes measured in the blood, which serve as a proxy for

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[75] https://www.science.org/doi/10.1126/sciadv.abm7201.

[76] https://www.cureus.com/articles/125060-the-effect-of-the-covid-19-vaccine-on-the-menstrual-cycle-among-reproductive-aged-females-in-saudi-arabia.

[77] https://www.nejm.org/doi/full/10.1056/NEJMoa2110737.

[78] https://pubmed.ncbi.nlm.nih.gov/35812802/.

[79] https://pubmed.ncbi.nlm.nih.gov/35157759/.

[80] https://pubmed.ncbi.nlm.nih.gov/34664804/.

[81] https://pubmed.ncbi.nlm.nih.gov/34506211/.

[82] https://pubmed.ncbi.nlm.nih.gov/34440669/.

the amount of cardiac damage, are uniformly lower with critical care cardiomyopathy of COVID-19 compared to mRNA induced myopericarditis.[83] It is why June 2020-May 2021 myocarditis/pericarditis population wide case levels in Italy were comparable to a pre-pandemic period of June 2018-May 2019.[84] This is consistent with the fact that autopsy-based studies do not show histopathologic evidence of virus mediated inflammation outside of lung tissue.[81,85,86]

77. In a population wide study of 23 million residents in Scandinavia, vaccine-induced myocarditis outstripped COVID myocarditis at a rate of 4-to-28-fold depending on dose and the vaccine received (Moderna rates higher).[87]

78. Vaccine-induced myopericarditis has been shown to occur at a rate of between 1/10,000 and 1/3300 with the highest rates in adolescent boys and young adult males.[88,89] A Kaiser study demonstrated official reporting undercounts cases.[90] **Issuing vaccine mandates that risk vaccine-induced myocarditis in otherwise healthy young adults, most of which could be avoided given the majority have resistance to severe COVID-19 from prior infection, is imprudent regardless of the presumed clinical course of such a complication**.[91,92] These cases would constitute clear avoidable life-altering harm.

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[83] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8426796/.

[84] https://pubmed.ncbi.nlm.nih.gov/35763765/.

[85] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30243-5/fulltext.

[86] https://www.annualreviews.org/doi/10.1146/annurev-med-042220-023859.

[87] https://jamanetwork.com/journals/jamacardiology/fullarticle/2791253.

[88] https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab989/6445179?login=true.

[89] https://www.epi-phare.fr/rapports-detudes-et-publications/myocardite-pericardite-vaccination-covid19/.

[90] https://www.medrxiv.org/content/10.1101/2021.12.21.21268209v1.

[91] https://onlinelibrary.wiley.com/doi/10.1111/eci.13759.

[92] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6713107/.

79. **It's both dangerous and incorrect to assume that the elevated risk of vaccine-induced myopericarditis is isolated to young adults.** In an underappreciated study of vaccinated HCWs in the 40 hospital Providence Health system, they detected increased rates of myopericarditis associated with vaccine roll out to their employees.[93] In this study, the median age for vaccine-induced myocarditis was 36 years old and the median age for vaccine-induced pericarditis was 59 years old.

80. There has always been a standing concern about asymptomatic post-vaccine myocarditis: this is not unique to the COVID vaccines. In May 2003, there was some evidence that Smallpox vaccination could be associated with myocarditis, but CDC, at that time, still noted that "signal" was not clearly abnormal.[94] 12 years later, a subsequent study published a 60-fold increased rate of myocarditis when active screening of asymptomatic cases was added to normal passive surveillance.[95]

81. After initial CDC denial of any evidence of post-vaccine myocarditis with the COVID-19 vaccines, they had to backtrack on this premature proclamation. In fact, the FDA tasked Pfizer with studying the rate of asymptomatic myocarditis with study completion slated for November 30, 2023, and final report submission expected May 31, 2024.[96]

82. A recent Thai pre-print that performed active surveillance for asymptomatic myopericarditis is the first of its kind. Out of 301 13-year-old to 18-year-old enrollees, 3 had symptomatic myocarditis/myopericarditis and 7 of the 301 enrollees had asymptomatic troponin elevations such that the additional 4 were classified as having myocarditis/pericarditis. Important caveats:

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[93] https://jamanetwork.com/journals/jama/fullarticle/2782900.

[94] https://www.cidrap.umn.edu/news-perspective/2003/03/link-between-smallpox-vaccine-and-myocarditis-looks-more-likely.

[95] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4368609/.

[96] https://www.fda.gov/media/151710/download (page 8).

- all patients had resolution of symptoms and, for the one patient who had a cardiac MRI, resolution of imaging abnormalities at 5 months.
- Additionally, we don't know the long-term clinical significance, if any, of subclinical myocarditis/myopericarditis.

83. That said, it would be reckless to completely dismiss any concerns about myopericarditis and potential long-term consequences. In the near term, it is a known cause of Sudden Cardiac Death in those under 50-years-old even while it is chronically under-investigated and incompletely reported.[97]

84. In a recent study of vaccine myopericarditis from the United Kingdom, while all 519 eligible patients followed for more than 90 days returned to pre-pandemic functioning, of 151 patients who had a cardiac MRI (cMRI), 13% had evidence of swelling and 54% had abnormalities.[98] This is concordant with other studies showing up to 2/3 having late follow up cMRI abnormalities. That said, in all such studies, overall numbers are small and all patients recovered with time.

85. **"Sterilizing Vaccines" and Mandates:** When we refer to "sterilizing vaccines", we are referring to vaccines that confer both protection from infection thereby effectively eliminating infection risk as well as providing protection from severe illness. Traditionally, as canonical examples of "sterilizing vaccines", we consider the Measles/Mumps/Rubella (MMR) vaccine as it pertains to Measles and the Hepatitis B vaccine. Measles, like Influenza and SARS-CoV-2 (the virus that causes COVID-19) are respiratory viruses. Measles transmission, while through droplets and aerosols, is more droplet mediated than with COVID-19 or Influenza, and yet remains highly contagious. In the case of Measles and Hepatitis B, there is a major component of the infection that is bloodborne (unlike SARS-CoV-2 or Influenza) such that blood-borne vaccine or infection induced antibodies can perform a pivotal role in preventing subsequent

[97] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6713107/.

[98] https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(22)00244-9/fulltext.

infection. But even in the context of Measles and Hepatitis B vaccines, "sterilizing" is a relative term.

86. Numerous studies have shown that those vaccinated against Measles can develop infections, even as the primary value remains protection from severe illness. In a recent 2018 study of an outbreak in a French psychiatric ward, 14% of fully vaccinated index cases from a primary unvaccinated case developed Measles. Two of the cases had two Measles vaccinations and one even had vaccination with a prior infection in the preceding six years.[99] A less contained outbreak in New York was traced to a vaccinated index case.[100]

87. All of this said, an outbreak of Measles in the Marshall Islands demonstrated that non-vaccine eligible infants were more likely to be infected as secondary contacts than adults (46% versus 13%).[101] In this outbreak, the largest in the United States or associated area in more than a decade, 41% of cases were reported to have been previously vaccinated. Given that Measles vaccine is not recommended under 12 months of age, the biggest lesson of the Marshall Islands outbreak was the susceptibility of vulnerable non-vaccine eligible populations. It is thought that 90% vaccine coverage is required for the prevention of such outbreaks.

88. In the case of Hepatitis B, transmission is through body fluid contact. Vaccination, or infection, followed by documented threshold antibody levels is highly effective in preventing infection and transmission. Once again, "sterilizing immunity" in this context remains "relative" with documented Hepatitis B cases in previously vaccinated individuals. In one study, roughly 10% of previously vaccinated individuals with no evidence of prior infection had detectable Hepatitis B virus through DNA-testing suggesting evidence of an undetected "breakthrough"

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[99] https://journals.lww.com/pidj/FullText/2019/09000/Measles_Transmission_in_a_Fully_Vaccinated_Closed.27.aspx.

[100] https://academic.oup.com/cid/article/58/9/1205/2895266.

[101] https://pubmed.ncbi.nlm.nih.gov/16392073/.

infection.[102] Once again, as with protection from a Measles vaccination, the benefit accrued to the vaccinated individual is substantial. In East Asian countries, Hepatitis B is endemic (spreads at baseline through the population). With the advent of universal Hepatitis B vaccination of newborns in Taiwan, the infant mortality rate from hepatitis B dropped by 3-fold and severe hepatitis almost disappeared in older children.[103,104,105]

89. **Summary:** While we can establish significant distinctions between "sterilizing vaccines" and vaccines such as the ones for COVID-19 and Influenza, it remains the case that the main benefit of vaccination is accrued to the individual receiving the vaccination. For vaccines such as the COVID-19 and Influenza vaccines where there is minimal prevention of subsequent infection and transmission, it's extremely difficult to supplant individual bodily autonomy, particularly at threat of unemployment or violation of one's religious beliefs.

90. Even adopting a policy of perpetual boosting for COVID-19 is not biologically sound. Per an NIH study, Omicron specific boosters did not elicit increases in Omicron specific neutralizing antibodies, which is a concerning finding for a process called "imprinting".[106] This is not a fringe opinion as it was even cited by Dr. Paul Offit, an FDA voting member and a national vaccine advocate, in a New England Journal of Medicine editorial in early 2022.[107] NIH re-analysis of the Moderna trial data indicated that 93% of subsequently infected placebo participants formed anti-N (anti-nucleocapsid) antibodies while only 40% of vaccine recipients formed these same

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[102] https://journals.lww.com/md-journal/fulltext/2016/12060/hepatitis_b_viremia_in_completely_immunized.92.aspx.

[103] https://pubmed.ncbi.nlm.nih.gov/11562612/.

[104] https://pubmed.ncbi.nlm.nih.gov/14752823/.

[105] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3630933/.

[106] https://www.biorxiv.org/content/10.1101/2022.02.03.479037v1.full.pdf.

[107] https://www.nejm.org/doi/full/10.1056/NEJMe2203329.

antibodies.[108] We don't know the long-term significance of this finding, but we have known since mid-2021 that the presence of anti-N antibodies correlates with a reduced risk of reinfection.[109]

91. Based upon the evidence presented above, including findings from the initial Pfizer COVID-19 trials, vaccine mandates for COVID-19 vaccines were an ill-conceived policy dating back to at least mid-2021. Every piece of data since that time, both from formal studies and ecological data, has reinforced that reality.

92. The primary beneficiary of a COVID-19 vaccination is the individual recipient of the vaccine. As presented in this declaration, even studies in high-risk settings that purported to show a benefit to non-vaccine recipients did not actually show this benefit when subject to careful analysis and scrutiny, even as presented in the limited confines of this declaration.

93. Every individual, based upon their individual age, metabolic risks, immune status, and personal preferences, had to decide how best to proceed with a COVID-19 vaccination.[110] This was the case in 2021 and remains the case today.

94. *Nothing* was gained by coercing, harassing, and, in some cases, depleting a critical and willing workforce with COVID-19 vaccine mandates. It was unjustifiable based upon the vaccine trial data, rapidly emerging data post vaccine release, observational studies in high-risk settings, and all ecological data since that time. At the very least, those data points, which include the original FDA trial documents in late 2020, should have given scientifically literate, apolitical, and inquisitive health professionals pause in any enthusiasm they may have held for COVID-19 vaccine mandates in any risk tier.

II. TESTIMONIAL HISTORY

- *Brown v. Mills-Peninsula,* No. CIV536321 (San Mateo Cnty. Super. Ct. 2015);
- *Sullivan v. The Super. Ct. of Santa Clara,* No. 18FL001837 (Santa Clara Cty. Super. Ct. 2018);

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[108] https://www.medrxiv.org/content/10.1101/2022.04.18.22271936v1.full.pdf.

[109] https://www.thelancet.com/journals/lanhl/article/PIIS2666-7568(21)00093-3/fulltext.

[110] https://www.nature.com/articles/s41574-021-00608-9.

- *YouTsai v. County of Los Angeles,* No. 21STCV36298 (Los Angeles Cnty. Super. Ct. 2021);
- *Guilfoyle v. Beutner,* No. 2:2021-cv-05009-VAP (C.D. Cal. 2021);
- *State of Missouri and Eric Schmitt v. Columbia Public Schools*, No.: 21BA-CV02754 (Boone Cnty. Circ. Ct. 2021);
- *Montana Medical Association v. Knudsen*, No. 9:21-CV-00108 (D. Mont. Sept. 16, 2022);
- *Calvary Chapel San Jose v. Cody*, No. 5:20-cv-03794-BLF (N.D. Cal. Dec. 16, 2022, Jan. 5, 2023).

III. STATEMENT OF COMPENSATION

I have been retained for $200 per hour for my research, study, and testimony in this case. I charge $400 an hour for depositions, including reasonable travel expenses.

IV. DATA AND OTHER INFORMATION CONSIDERED

In addition to the materials cited in this declaration, I considered the following materials from this case in forming my opinions:

- Order Granting in Part and Denying in Part Class Certification, Jan. 29, 2024;
- Verified First Amended Class Action Complaint for Declaratory and Injunctive Relief and Damages (with Exhibits), Aug. 23, 2022;
- County-UnifySCC_009098-99;
- Declaration of Lindolfo Ortega in Support of Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, ECF No. 31-2, Apr. 29, 2022;
- Declaration of County of Santa Clara's Chief Operating Officer Miguel Marquez in Support of Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, ECF No. 31-3, Apr. 29, 2022;
- Declaration of Dr. Sarah Rudman in support of Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, ECF No. 31-4, Apr. 29, 2022;
- Declaration of Sonia Menzies in Support of Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, ECF No. 31-5, Apr. 29, 2022;

- Declaration of Matthew Fisk in Support of Defendants' Opposition to Plaintiff's Motion for Class Certification, ECF No. 100, Oct. 18, 2023;
- Declaration of Megan Doyle in Support of Defendants' Opposition to Plaintiffs' Motin for Class Certification, ECF No. 101, Oct. 18, 2023;
- Declaration of Sonia Menzies in Support of Defendants' Opposition to Plaintiff's Motion for Class Certification, ECF No. 102, Oct. 18, 2023;
- Declaration of Dr. Sarah Rudman in Support of Defendants' Opposition to Plaintiffs' Motion for Class Certification, ECF No. 95, Oct. 18, 2023;
- Declaration of Christopher Grumbos in Support of Defendants' Opposition to Plaintiff's Motion for Class Certification, ECF No. 97, Oct. 18, 2023;
- Declaration of Jeff Draper in Support of Defendants' Opposition to Plaintiff's Motion for Class Certification, ECF No. 98, Oct. 18, 2023;
- Deposition Testimony of Sarah Rudman, M.D., March 12, 2024;
- County of Santa Clara Public Health Department, "Health Order Requiring Use of Face Coverings in Higher-Risk Settings; and Rescission of Prior Health Orders," dated September 12, 2022, ECF No. 95, Oct. 18, 2023 at p. 117.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 26th day of April 2024 at Menlo Park, California.

Ram Duriseti MD, PhD