Government-Mandated Vaccine Requirements: OSHA, Jacobson, and the Legacy of Buck v. Bell

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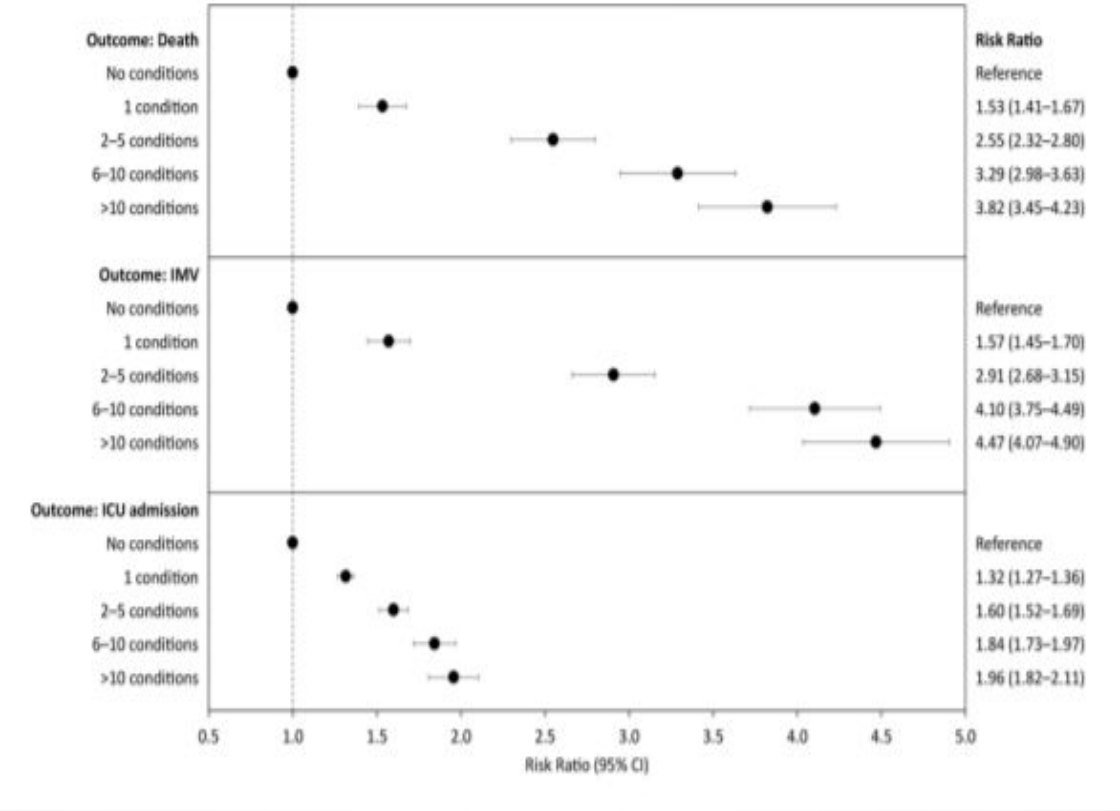
Jacobson v Mass (1905)

- "According to settled principle, the police power of a State must be held to embrace, at least, such **reasonable** regulations established directly by legislative enactment as will protect the public health and the public safety."
- "The mode or manner in which those results are to be accomplished is within the discretion of the State, subject, of course, so far as Federal power is concerned, only to the condition that no rule prescribed by a State, nor any regulation adopted by a **local governmental agency acting under the sanction of state legislation, shall contravene the Constitution of the United States or infringe any right granted or secured by that instrument**. A local enactment or regulation, **even if based on the acknowledged police powers of a State**, must always yield in case of conflict with the exercise by the General Government of any power it possesses under the Constitution, **or with any right which that instrument gives or secures**."
- "The police power of a State, whether exercised by the legislature, or by a local body acting under its authority, may be exerted in such circumstances by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts to prevent wrong and oppression."
- Including "if he is not a fit subject at the time or that vaccination would seriously injure his health or cause his death"
- $5 fine for noncompliance ($155 today)

Risk is Stratified

- Kompaniyets, et al. (July 2021): 95% of hospitalized have comorbidities (March 2020-21)



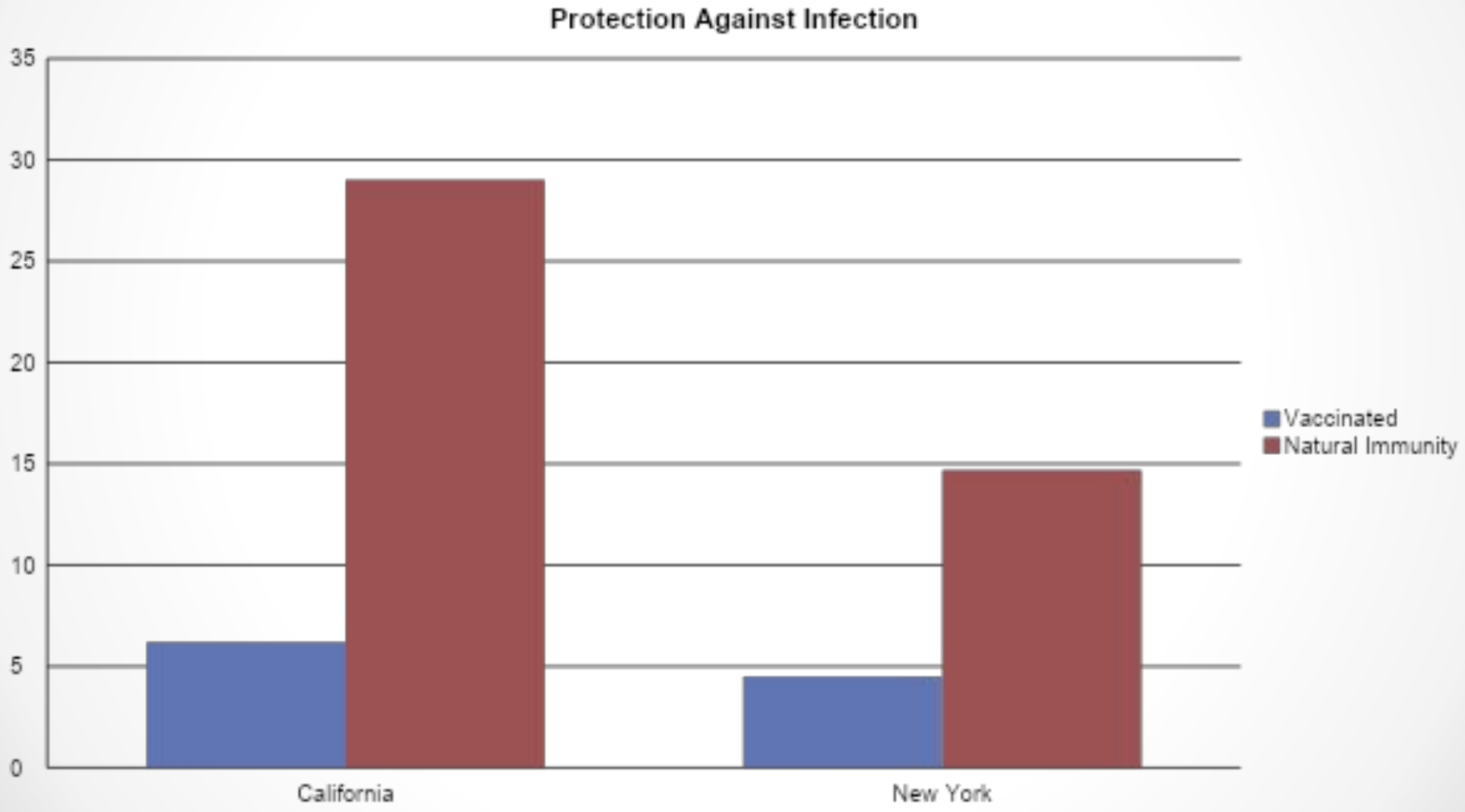
Natural Immunity

- Estimated that 120 million Americans
- 90-95% Efficacy:20 studies
- Israel
- Cleveland Clinic
- England
- Newcastle
- Oxford
- London
- England
- Austria
- Sweden
- Qatar

Efficacy of NI

- 90-95% Efficacy:15+ studies: Israel, Cleveland Clinic, England, Newcastle, Oxford, London, England, Austria, Sweden, Qatar
- Chivese, et al.: 12 million individuals: "Around 90% of people previously infected with SARS-CoV-2 had evidence of immunological memory to SARS-CoV-2, which was sustained for at least 6-8 months after recovery, and had a low risk of reinfection… the pooled prevalence of reinfection was 0.2%"
- Murchu, et al., 615k individuals: "Reinfection was an uncommon event (absolute rate 0%–1.1%), with no study reporting an increase in the risk of reinfection over time. Only one study estimated the population‐level risk of reinfection based on whole genome sequencing in a subset of patients; the estimated risk was low (0.1% [95% CI: 0.08–0.11%]) with no evidence of waning immunity for up to 7 months following primary infection. These data suggest that naturally acquired SARS‐CoV‐2 immunity does not wane for at least 10 months post‐infection."
- Kojima, et al.: 10 million people, 90.4% risk reduction from reinfection (10 months)
- CDC (Oct 29, 2021): "Available evidence shows that fully vaccinated individuals and those previously infected with SARS-CoV-2 each have a low risk of subsequent infection for at least 6 months."
- Much higher than mediocre vaccines (J&J)

Leon (CDC, Jan 2022)



Leon (CDC, Jan 2022)

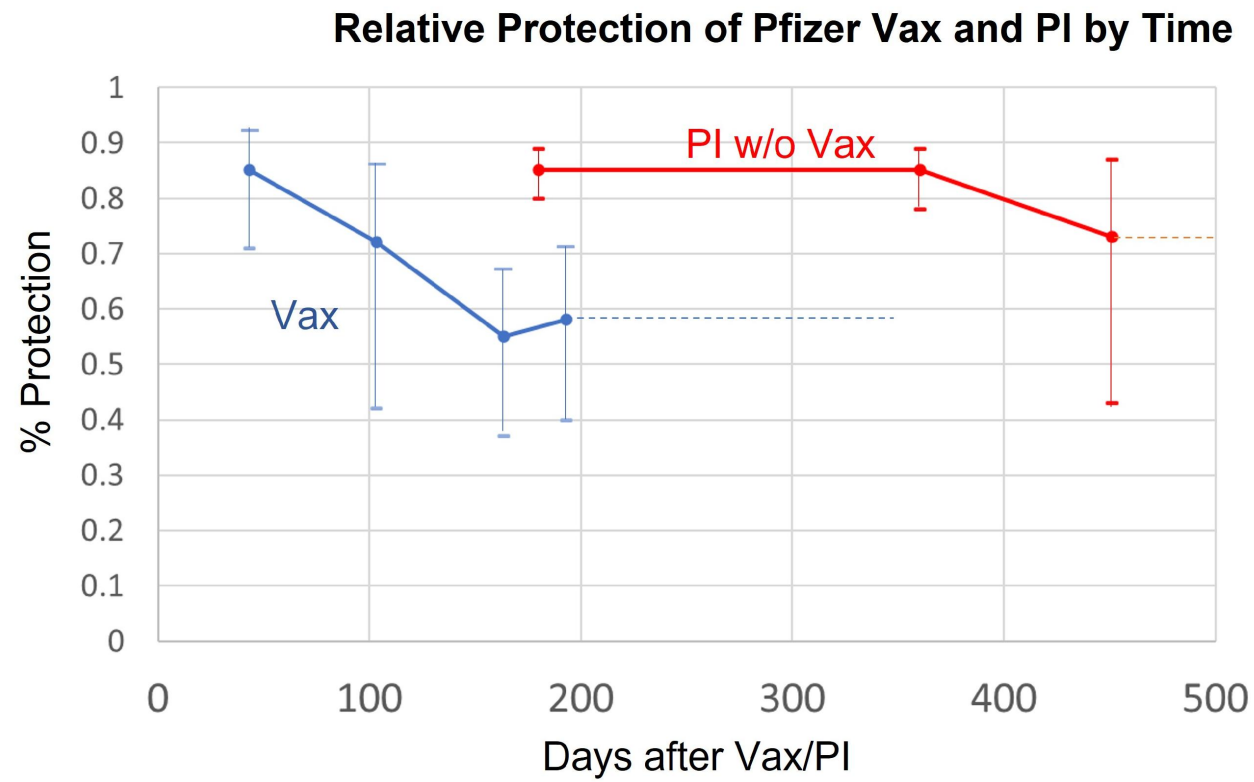
Don’t Just Take it from Me

Fauci said he's 'willing to bet anything' that people who recover from the new coronavirus are 'really protected from reinfection'

Aylin Woodward and Holly Secon Mar 25, 2020, 11:45 AM

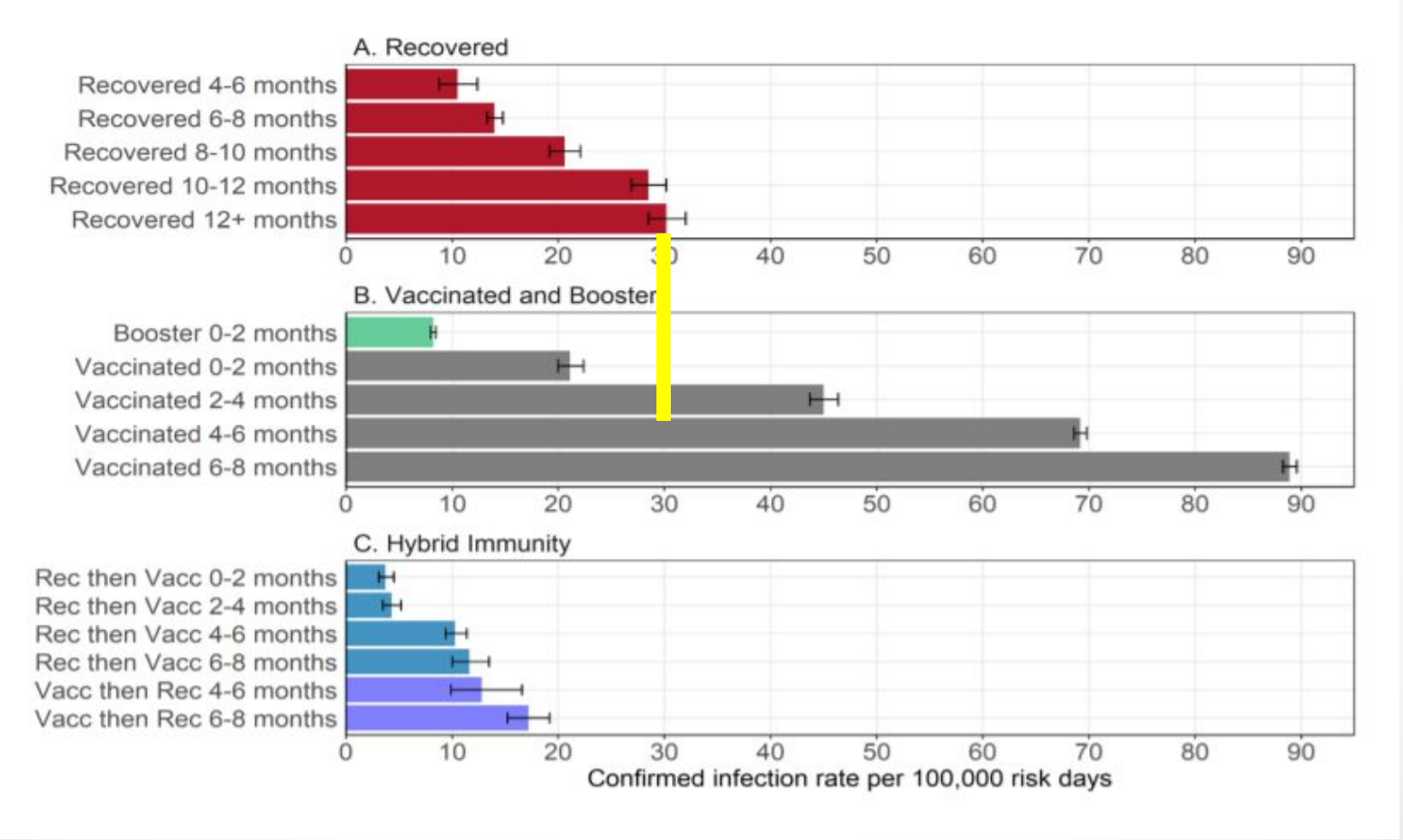
Dr. Anthony Fauci, center, speaks at a White House press conference on the coronavirus outbreak on February 29, 2020, flanked by President Donald Trump, right, and Vice President Mike Pence, left. Andrew Harnik/AP

Comparison (Hall, UK)

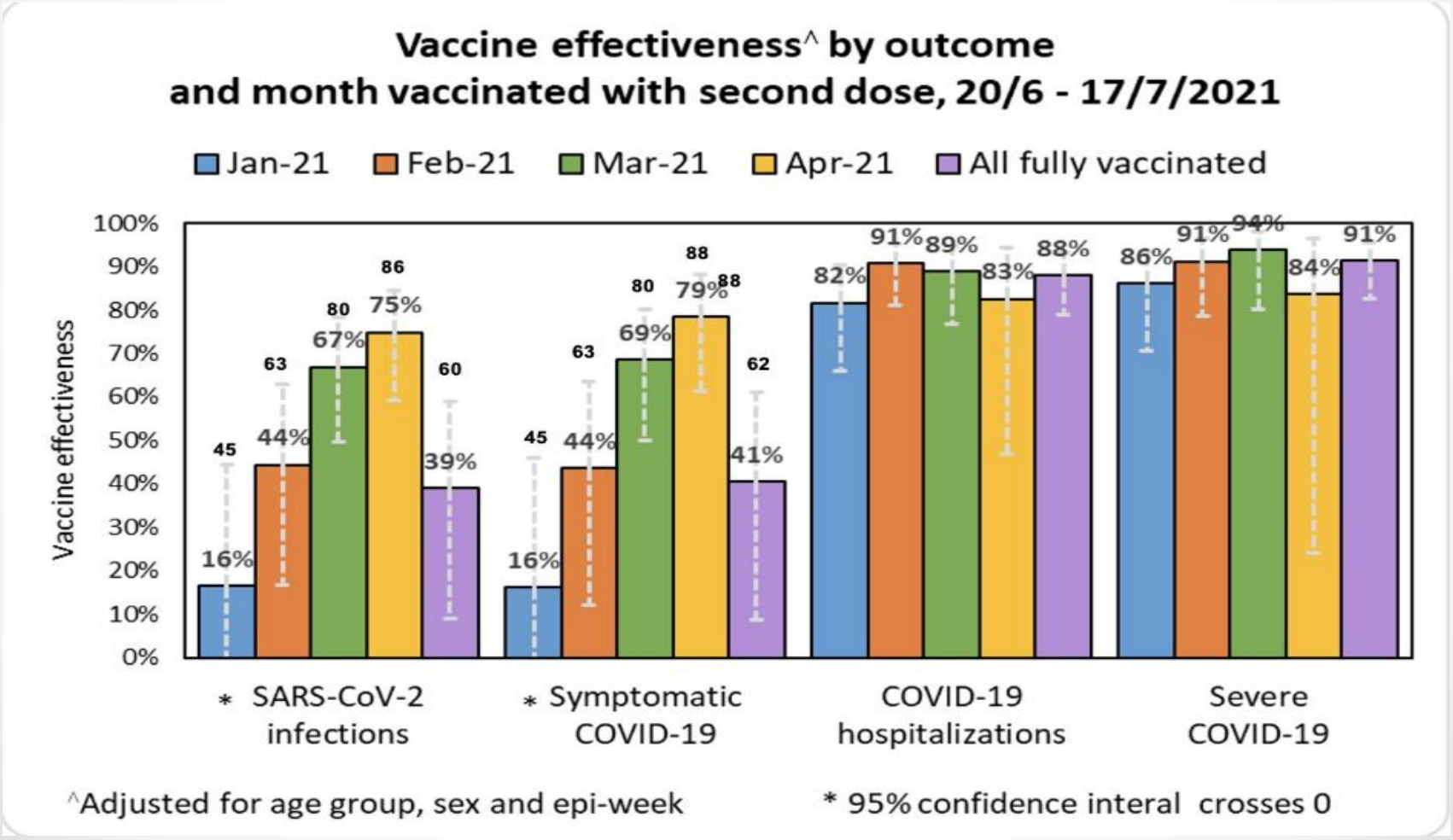


Data taken from Hall et al., (https://www.medrxiv.org/content/10.1101/2021.11.29.21267006v1.full.pdf)
Pfizer VE and %Protection attributed to time midpoint of reported time interval (Table 2 for Vax, Table 3 for PI/Vax), along with reported confidence intervals.
Vax includes naïve and PI persons.

Comparison (Goldberg)



Israel


Vaccine effectiveness^ by outcome
and month vaccinated with second dose, 20/6 - 17/7/2021
Jan-21
Feb-21
Mar-21
Apr-21
All fully vaccinated
Vaccine effectiveness
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
45
16%
63
44%
80
67%
86
75%
60
39%
45
16%
63
44%
80
69%
88
79%
88
62
41%
82%
91%
89%
83%
88%
86%
91%
94%
84%
91%
* SARS-CoV-2 infections
* Symptomatic COVID-19
COVID-19 hospitalizations
Severe COVID-19
^Adjusted for age group, sex and epi-week
* 95% confidence interal crosses 0

NI>Vax

- **Gaziz, et al. (Israel): "Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections"**
- 13x Odds Infection
- 27x Odds Symptomatic Infection
- 8x Odds Hospitalization

Why NI>Vax

- Muscosal Immunity: Respiratory Virus
- Durability
- Resistance to Variants
- Continued Evolution
- Less infectious on breakthrough

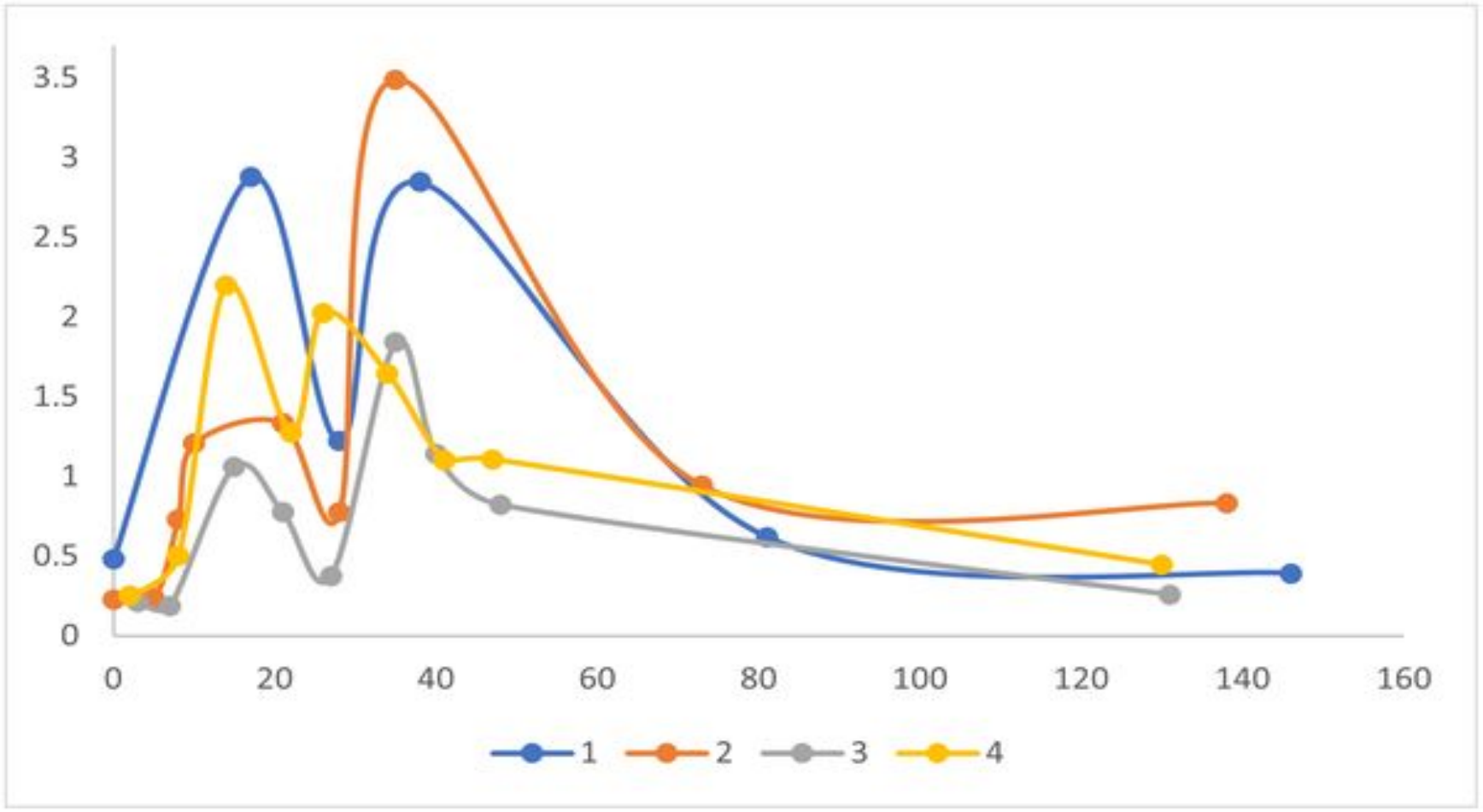
Mucosal Immunity

- Russell, *Frontiers in Immunology* (2020): "Almost all efforts at vaccine development against COVID-19 focus on systemic injection, which predominantly induces circulatory IgG antibodies and, potentially, cytotoxic T cells. ***These routes are poorly effective at generating mucosal immune responses, which can only be induced by mucosal routes of immunization."***
- Sterlin, *Science Translational Medicine* (2021): "We show that SARS-CoV-2 neutralization is more closely correlated with IgA than IgM or IgG in the first weeks after symptom onset."
- Bleier, et al. (Feb. 2021), **"COVID-19 Vaccines May Not Prevent Nasal SARS-CoV-2 Infection and Asymptomatic Transmission"** : "Current COVID-19 vaccine candidates are administered by injection and designed to produce an IgG response, preventing viremia and the COVID-19 syndrome. However, systemic respiratory vaccines generally provide **limited protection** against viral replication and shedding within the airway, as this **requires a local mucosal secretory IgA response.** ***Systemically vaccinated patients, while asymptomatic, may still be become infected and transmit live virus from the upper airway***."

Mucosal Immunity

- Mortari, et al. (2021): “Most importantly, the vaccine triggers a serological IgA response, but does not generate mucosal IgA. The lack of specific IgA strategically located at the virus site of entrance explains why the vaccine does not induce sterilizing immunity.”
- Kumar, et al (2021): “Recent studies have shown that the nasal cavity may become a reservoir for SC2 in the absence of mucosal immunity, placing patients at risk for reinfection or spread of disease to others. IN vaccination can overcome this drawback, as it can serve to stimulate broad immune responses via neutralizing IgG, mucosal IgA, and T cells, which can instigate a local mucosal immunity in the nasal cavity that in turn can block both infection and spread from this reservoir.”

Vax IgA Decay

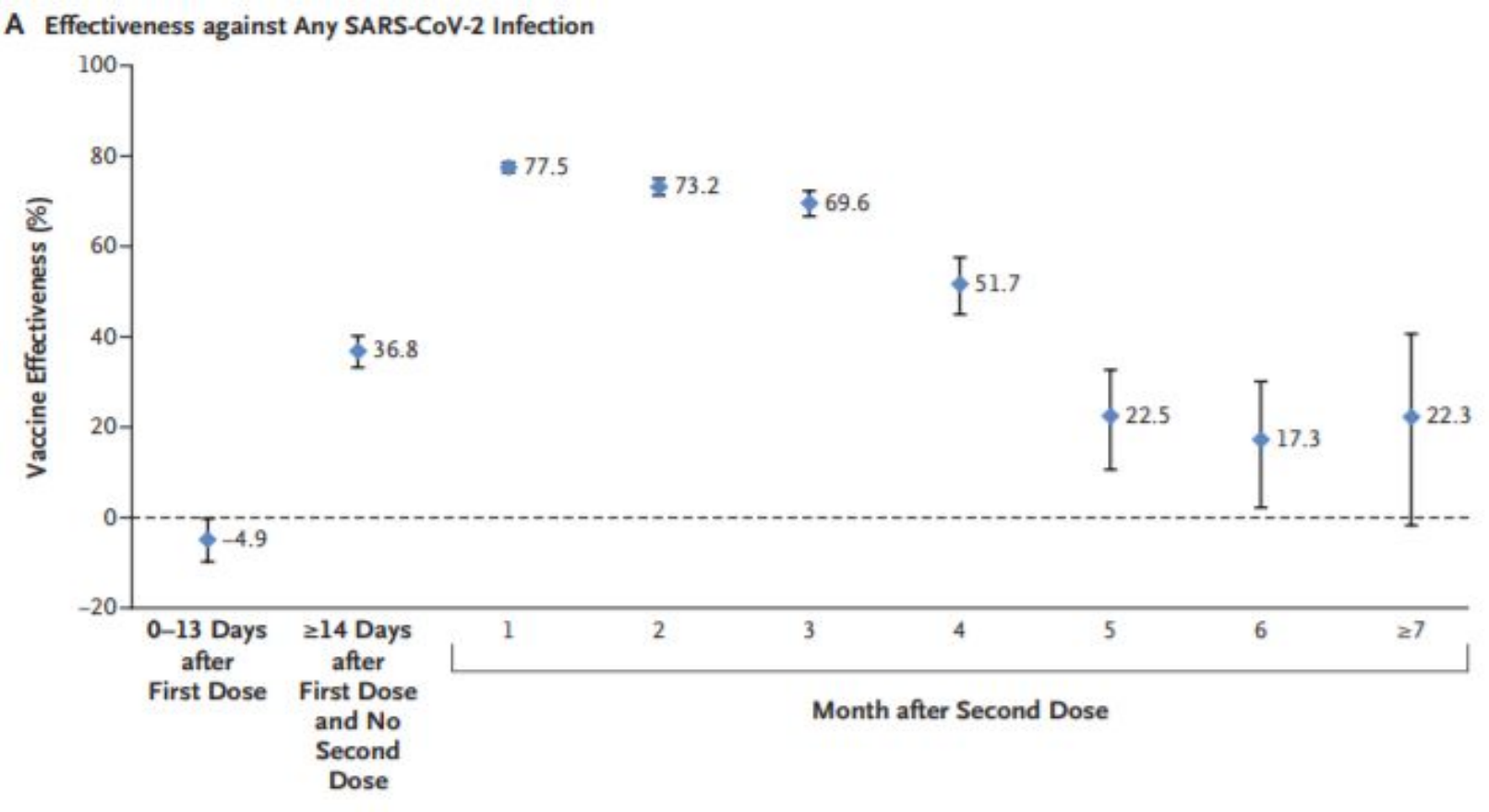


Wisnewski AV, Campillo Luna J, Redlich CA (2021) Human IgG and IgA responses to COVID-19 mRNA vaccines. PLOS ONE 16(6): e0249499. https://doi.org/10.1371/journal.pone.0249499
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0249499

Waning

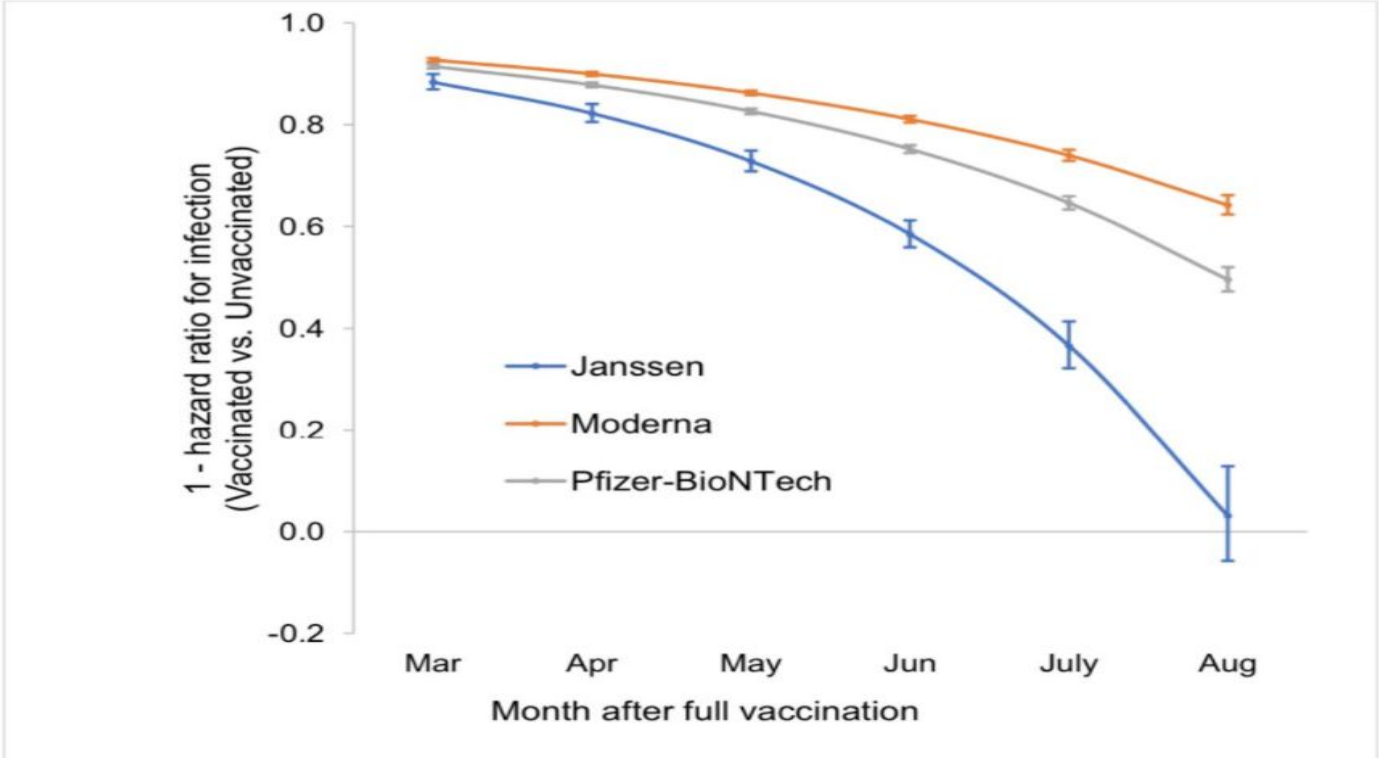
- **Ariel Israel, et al. (2021), "Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection"**
- "In vaccinated subjects, **antibody titers decreased by up to 40% each subsequent month** while in convalescents they decreased by **less than 5% per month**."
- "**Six months** after BNT162b2 vaccination 16.1% subjects had antibody levels below the seropositivity threshold of <50 AU/mL, while only 10.8% of convalescent patients were below <50 AU/mL threshold after **9 months** from SARS-CoV-2 infection."

Qatar (2021, NEJM)

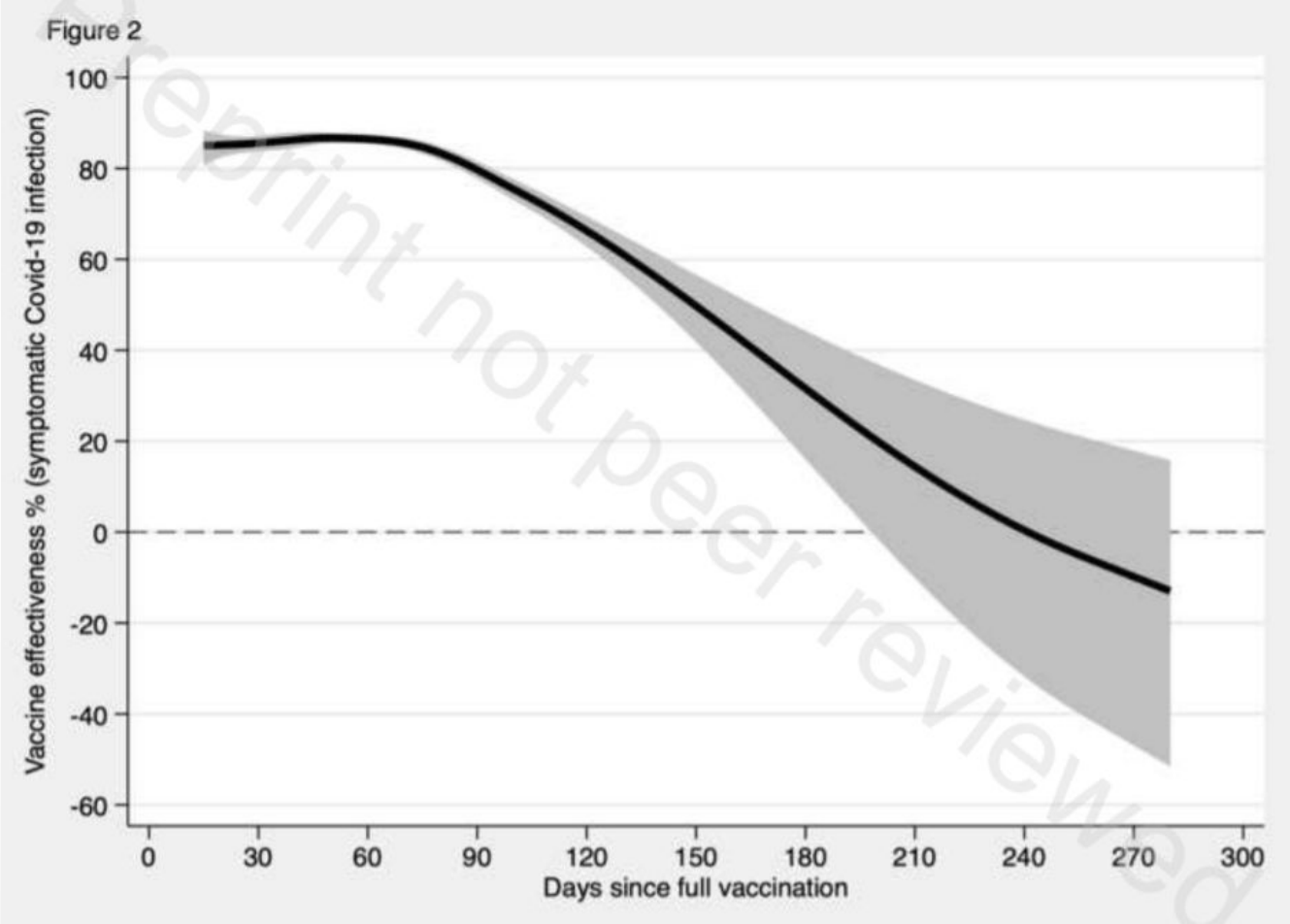


Waning Protection (Cohn, et al. 2021)

Figure 1. Time dependent vaccine protection against SARS-CoV-2 infection as estimated from Cox proportional hazards models, adjusted for age, race, ethnicity, sex and comorbidity Associations are presented as 1 – hazard ratios and 95% confidence intervals. Associations for each month were estimated from contrasts using product terms for vaccination status by time to most recent RT-PCR.



Negative VE (Nordstrom)



Durability

- At least 15 months (UK Study above)
- CDC/IDSA Clinician Call (July 17, 2021) summary

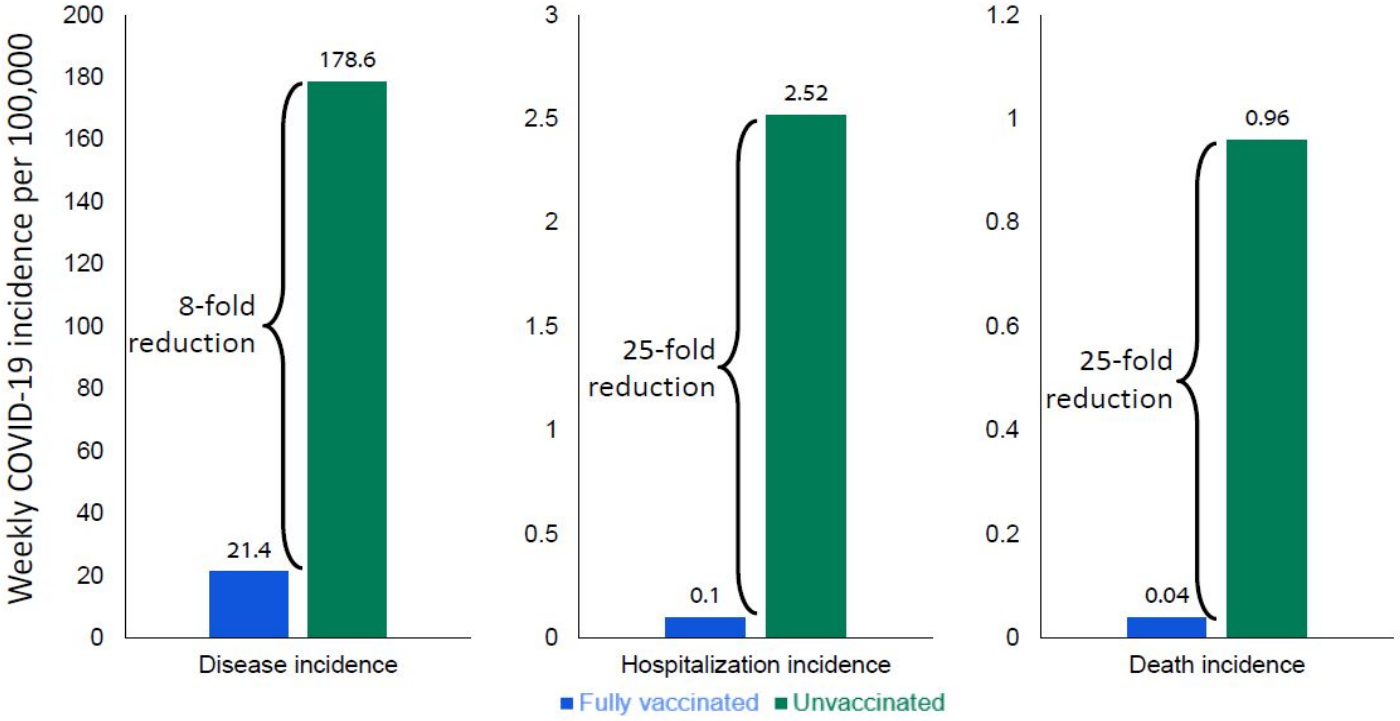
Natural Immunity to SARS-CoV-2

Immune Responses

- Immune responses to SARS-CoV-2 following natural infection can persist for months (maximum follow-up time is ~11 months)[1-3]

Breakthrough Cases

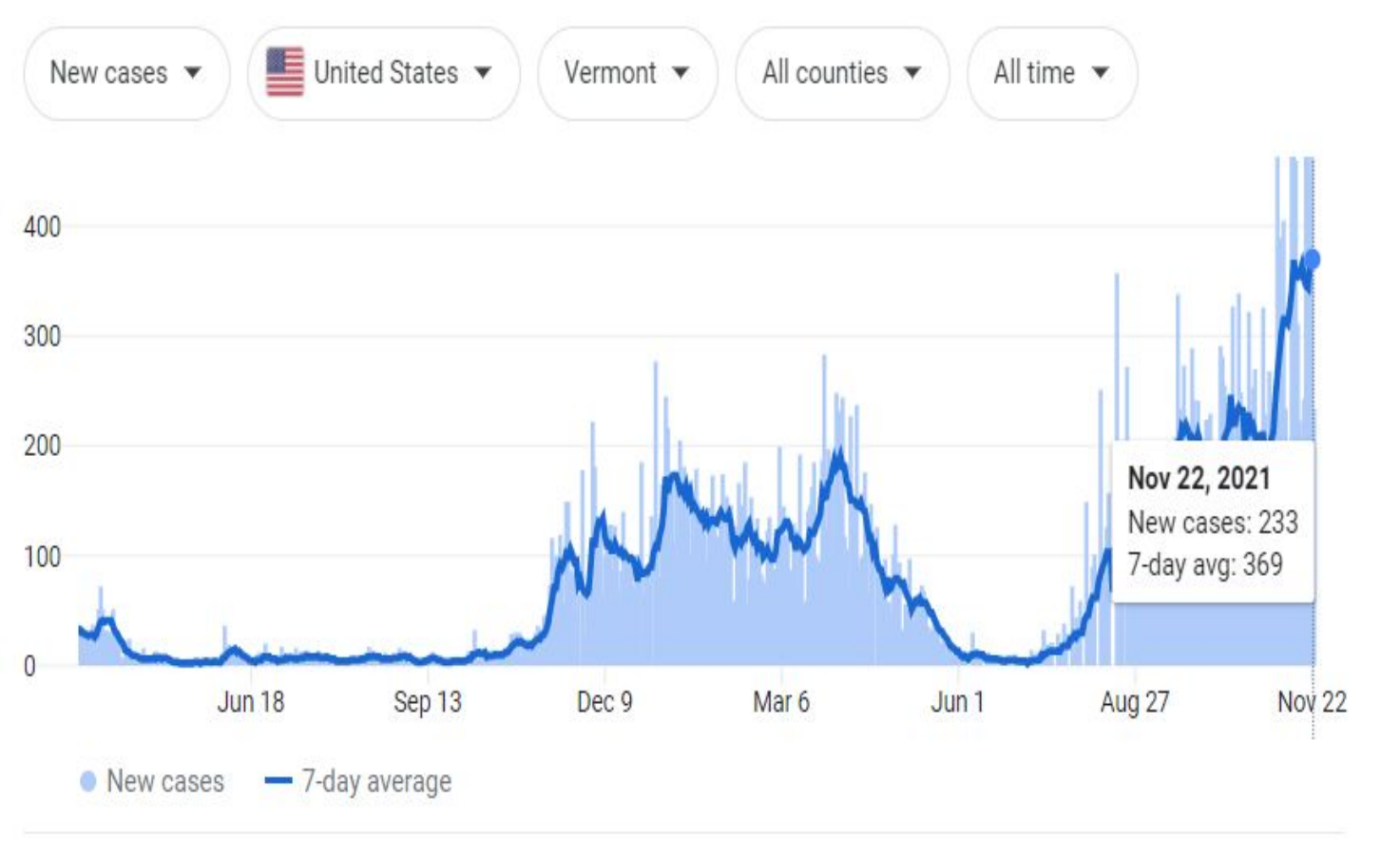
Greater risk of disease, hospitalization and death among unvaccinated vs. vaccinated people: National estimates



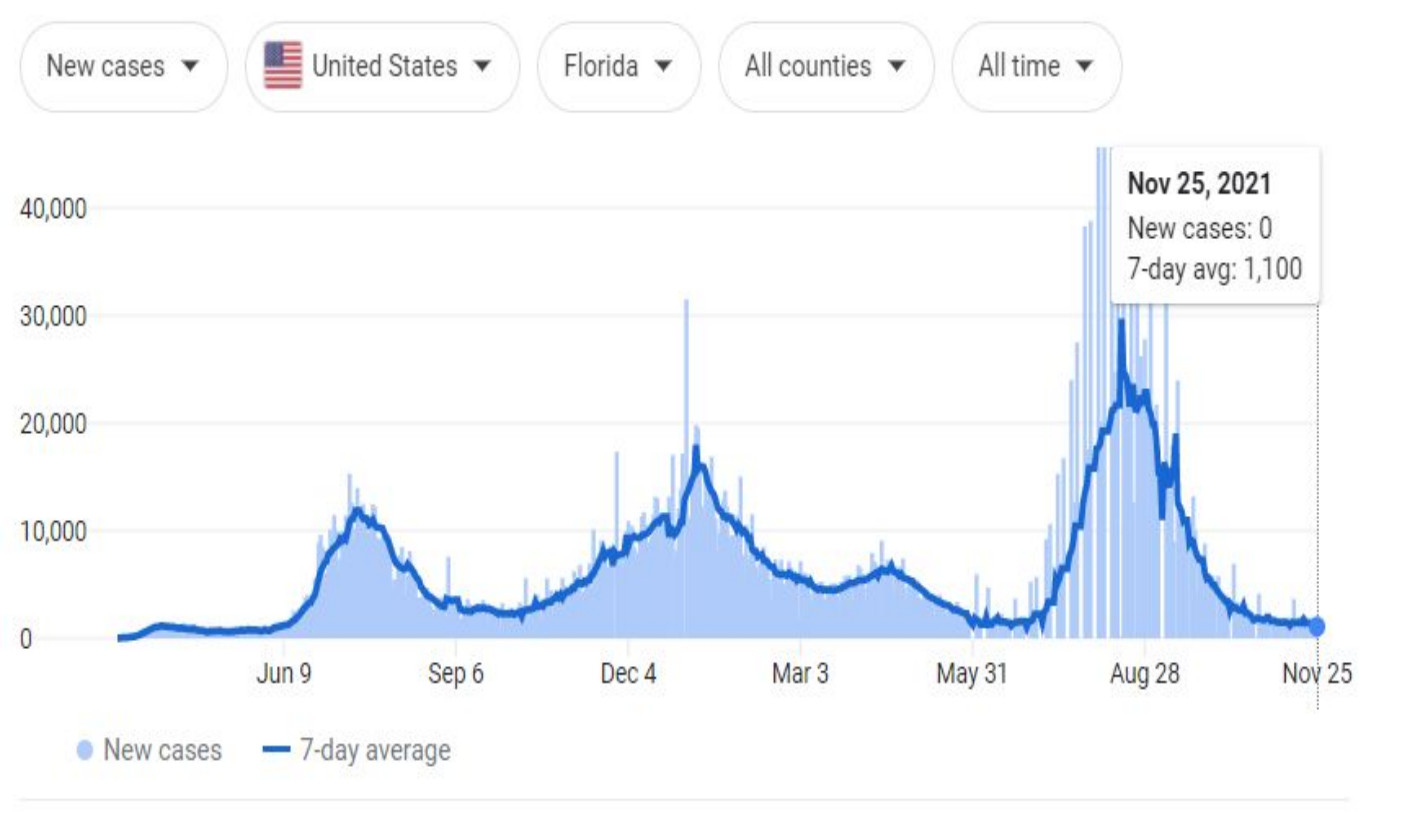
At current incidence, 35,000 symptomatic infections per week among 162 million vaccinated Americans

Data from COVID Tracker as of July 24, 2021. Average incidence 100 cases per 100,000 persons per week. Vaccine effectiveness against symptomatic illness = 88% (Lopez Bernal et al. NEJM 2021), where risk is [1 – VE] or 12%. Vaccine effectiveness hospitalization (or death) = 96% (Stowe et al. PHE preprint), where risk is [1 – VE] or 4%. Rate in unvaccinated = Community rate/((1-fully vaccinated coverage) + (1-VE)*fully vaccinated

Vermont


New cases
United States
Vermont
All counties
All time
400
300
200
100
0
Jun 18
Sep 13
Dec 9
Mar 6
Jun 1
Aug 27
Nov 22
Nov 22, 2021
New cases: 233
7-day avg: 369
New cases
7-day average

Florida


New cases
United States
Florida
All counties
All time
Nov 25, 2021
New cases: 0
7-day avg: 1,100
40,000
30,000
20,000
10,000
0
Jun 9
Sep 6
Dec 4
Mar 3
May 31
Aug 28
Nov 25
New cases
7-day average

Breakthrough Infections

Pfizer Performance July 2021 ; Israeli Gov. Data

Israel Confirmed Cases, July 4th - July 10th				
Age Group	Cases Fully Vaccinated	Cases Unvaccinated	Percent of Cases Fully Vaccinated	Percentage of Population Fully Vaccinated
20-29	215	61	77.9%	71.8%
30-39	248	84	74.7%	77.3%
40-49	356	54	86.8%	80.8%
50-59	237	26	90.1%	84.3%
60-69	227	14	94.2%	86.8%
70-79	143	12	92.3%	92.7%
80-89	42	6	87.5%	91.1%
90+	9	2	81.8%	89.6%
Total	**Total**	**Total**	**Average**	**Average**
20-90+	**1477**	**259**	**85.7%**	**84.3%**

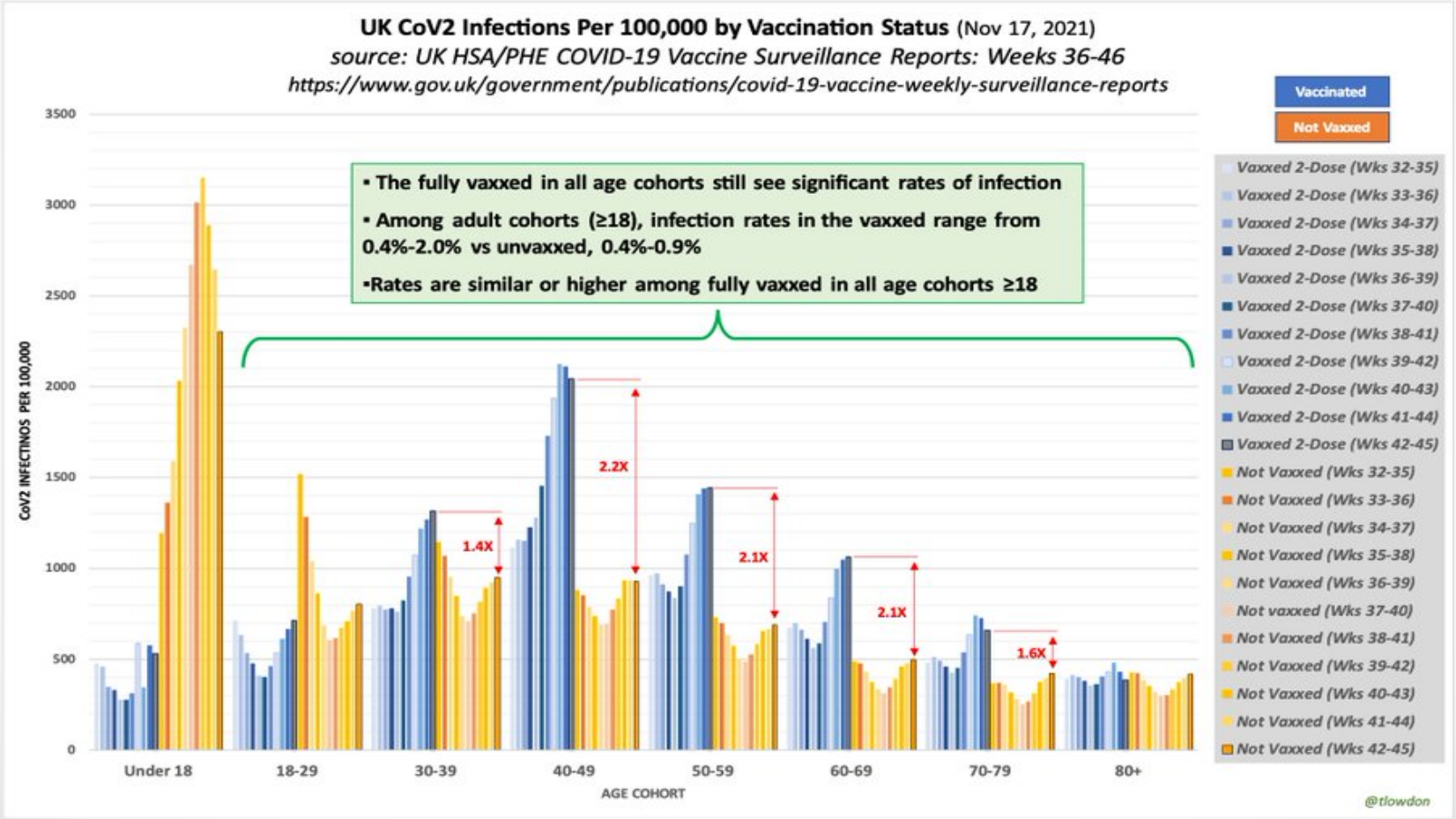
Israel Confirmed Cases, July 11th - July 17th				
Age Group	Cases Fully Vaccinated	Cases Unvaccinated	Percent of Cases Fully Vaccinated	Percentage of Population Fully Vaccinated
20-29	441	124	78.1%	71.8%
30-39	481	127	79.1%	77.3%
40-49	554	113	83.1%	80.8%
50-59	366	53	87.4%	84.3%
60-69	363	33	91.7%	86.8%
70-79	236	13	94.8%	92.7%
80-89	68	8	89.5%	91.1%
90+	14	2	87.5%	89.6%
Total	**Total**	**Total**	**Average**	**Average**
20-90+	**2523**	**473**	**86.4%**	**84.3%**

Israel Confirmed Cases, July 18th - July 24th				
Age Group	Cases Fully Vaccinated	Cases Unvaccinated	Percent of Cases Fully Vaccinated	Percentage of Population Fully Vaccinated
20-29	761	192	79.9%	71.8%
30-39	898	245	78.6%	77.3%
40-49	917	171	84.3%	80.8%
50-59	576	105	84.6%	84.3%
60-69	584	48	92.4%	86.8%
70-79	349	20	94.6%	92.7%
80-89	146	14	91.3%	91.1%
90+	33	9	78.6%	89.6%
Total	**Total**	**Total**	**Average**	**Average**
20-90+	**4264**	**804**	**85.5%**	**84.3%**

Israel Confirmed Cases, July 25th - July 31st				
Age Group	Cases Fully Vaccinated	Cases Unvaccinated	Percent of Cases Fully Vaccinated	Percentage of Population Fully Vaccinated
20-29	1272	418	75.3%	72.2%
30-39	1549	425	78.5%	77.7%
40-49	1476	297	83.2%	81.1%
50-59	1021	175	85.4%	84.6%
60-69	1026	92	91.8%	87.1%
70-79	656	55	92.3%	93.0%
80-89	284	33	89.6%	91.4%
90+	86	7	92.5%	90.1%
Total	**Total**	**Total**	**Average**	**Average**
20-90+	**7370**	**1502**	**86.1%**	**84.7%**

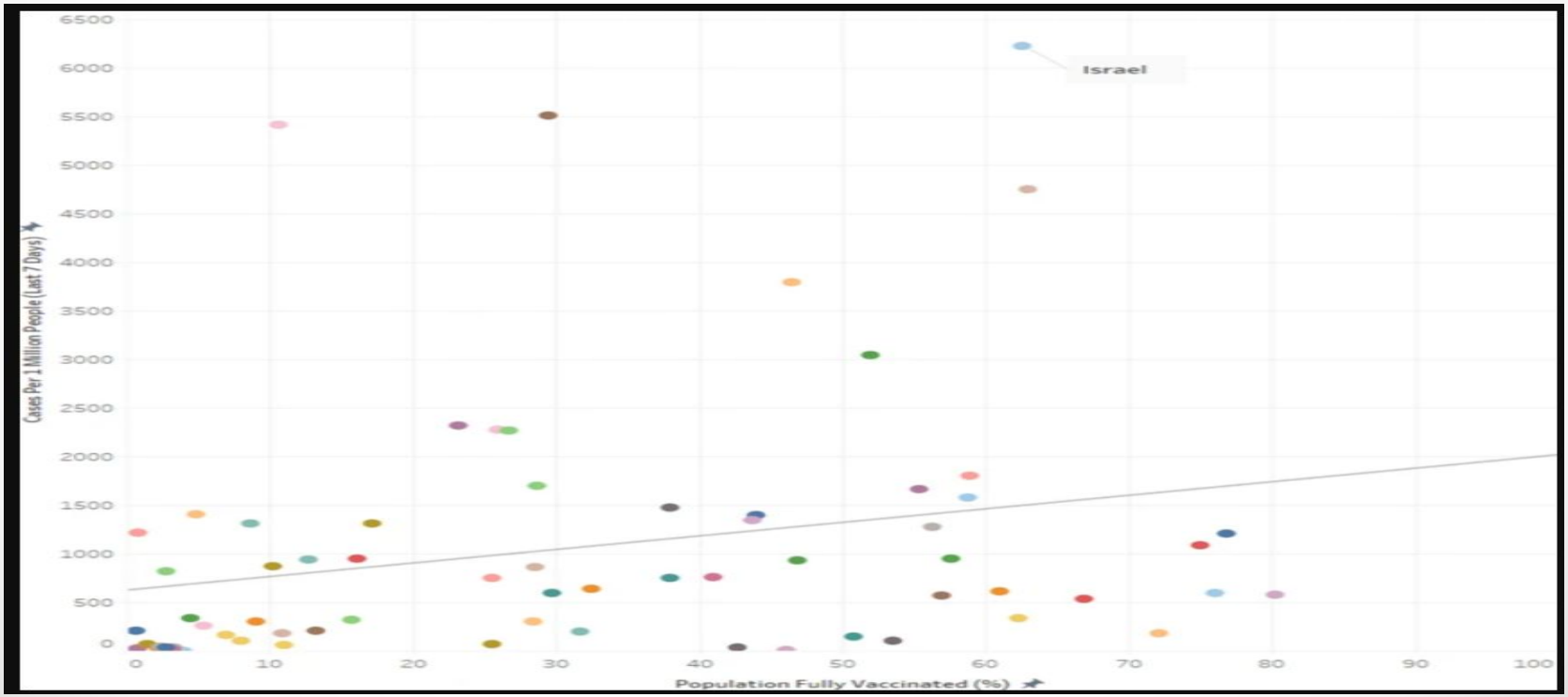
Israel Confirmed Cases, July 4th - July 31st				
Age Group	Cases Fully Vaccinated	Cases Unvaccinated	Percent of Cases Fully Vaccinated	Percentage of Population Fully Vaccinated
Total	**Total**	**Total**	**Average**	**Average**
20-90+	**15634**	**3038**	**85.9%**	**84.4%**
Source 01 :https://data.gov.il/dataset/covid-19/resource/9b623a64-f7df-4d0c-9f57-09bd99a88880				
Source 02 :https://datadashboard.health.gov.il/COVID-19/general				

UK


UK CoV2 Infections Per 100,000 by Vaccination Status (Nov 17, 2021)
source: UK HSA/PHE COVID-19 Vaccine Surveillance Reports: Weeks 36-46
https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports
▪ The fully vaxxed in all age cohorts still see significant rates of infection
▪ Among adult cohorts (≥18), infection rates in the vaxxed range from 0.4%-2.0% vs unvaxxed, 0.4%-0.9%
▪Rates are similar or higher among fully vaxxed in all age cohorts ≥18
CoV2 INFECTINOS PER 100,000
3500
3000
2500
2000
1500
1000
500
0
1.4X
2.2X
2.1X
2.1X
1.6X
Under 18
18-29
30-39
40-49
50-59
60-69
70-79
80+
AGE COHORT
Vaccinated
Not Vaxxed
Vaxxed 2-Dose (Wks 32-35)
Vaxxed 2-Dose (Wks 33-36)
Vaxxed 2-Dose (Wks 34-37)
Vaxxed 2-Dose (Wks 35-38)
Vaxxed 2-Dose (Wks 36-39)
Vaxxed 2-Dose (Wks 37-40)
Vaxxed 2-Dose (Wks 38-41)
Vaxxed 2-Dose (Wks 39-42)
Vaxxed 2-Dose (Wks 40-43)
Vaxxed 2-Dose (Wks 41-44)
Vaxxed 2-Dose (Wks 42-45)
Not Vaxxed (Wks 32-35)
Not Vaxxed (Wks 33-36)
Not Vaxxed (Wks 34-37)
Not Vaxxed (Wks 35-38)
Not Vaxxed (Wks 36-39)
Not vaxxed (Wks 37-40)
Not Vaxxed (Wks 38-41)
Not Vaxxed (Wks 39-42)
Not Vaxxed (Wks 40-43)
Not Vaxxed (Wks 41-44)
Not Vaxxed (Wks 42-45)
@tlowdon

Overall Efficacy

- "At the country-level, there appears to be no discernable relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days. In fact, the trend line suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people." (Subramanian & Kumar 2021)



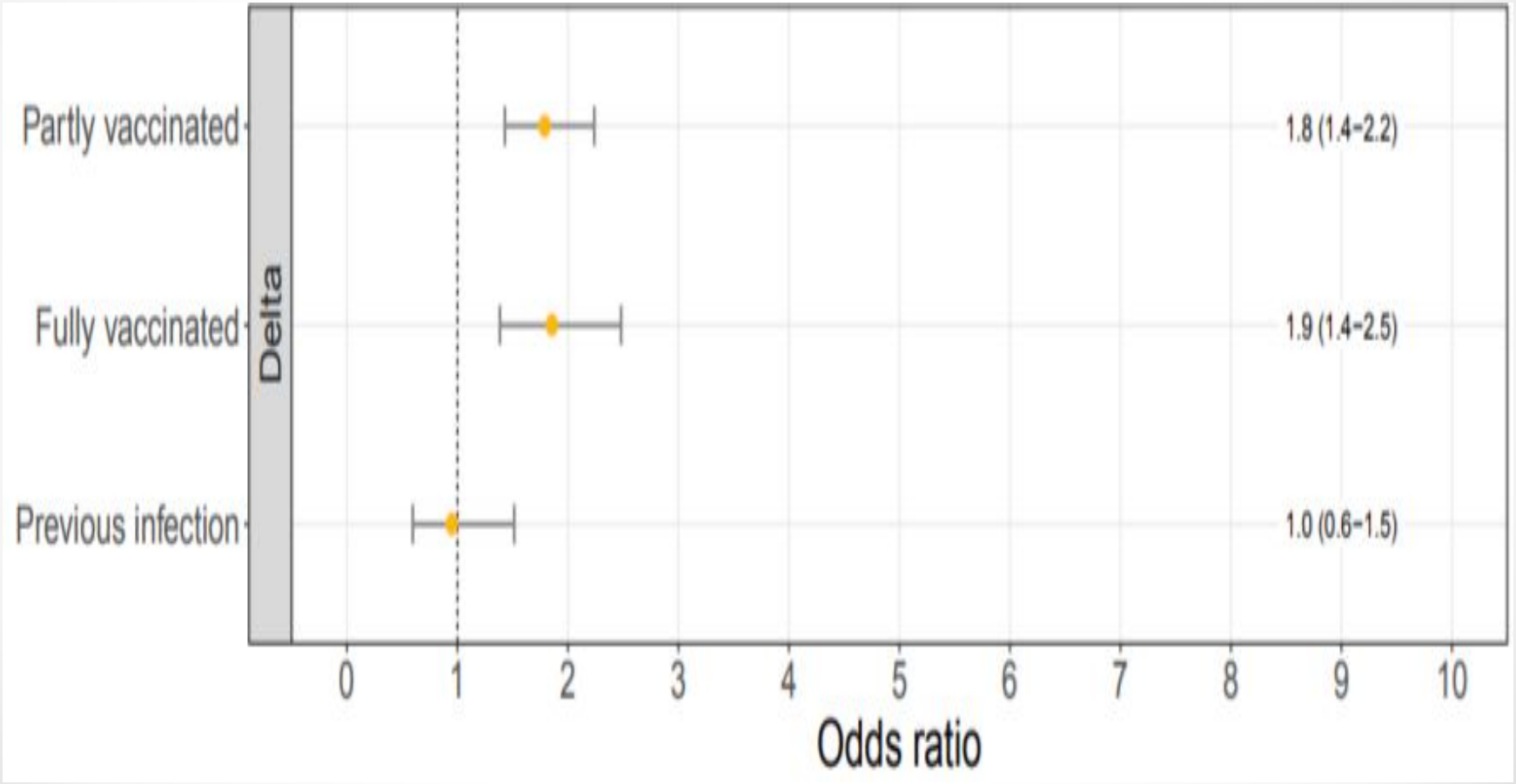
Variants

- **Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021 (MMWR)**
- "Adjusted VE during this Delta predominant period was 66% (95% CI = 26%–84%) compared with 91% (95% CI = 81%–96%) during the months preceding Delta predominance."

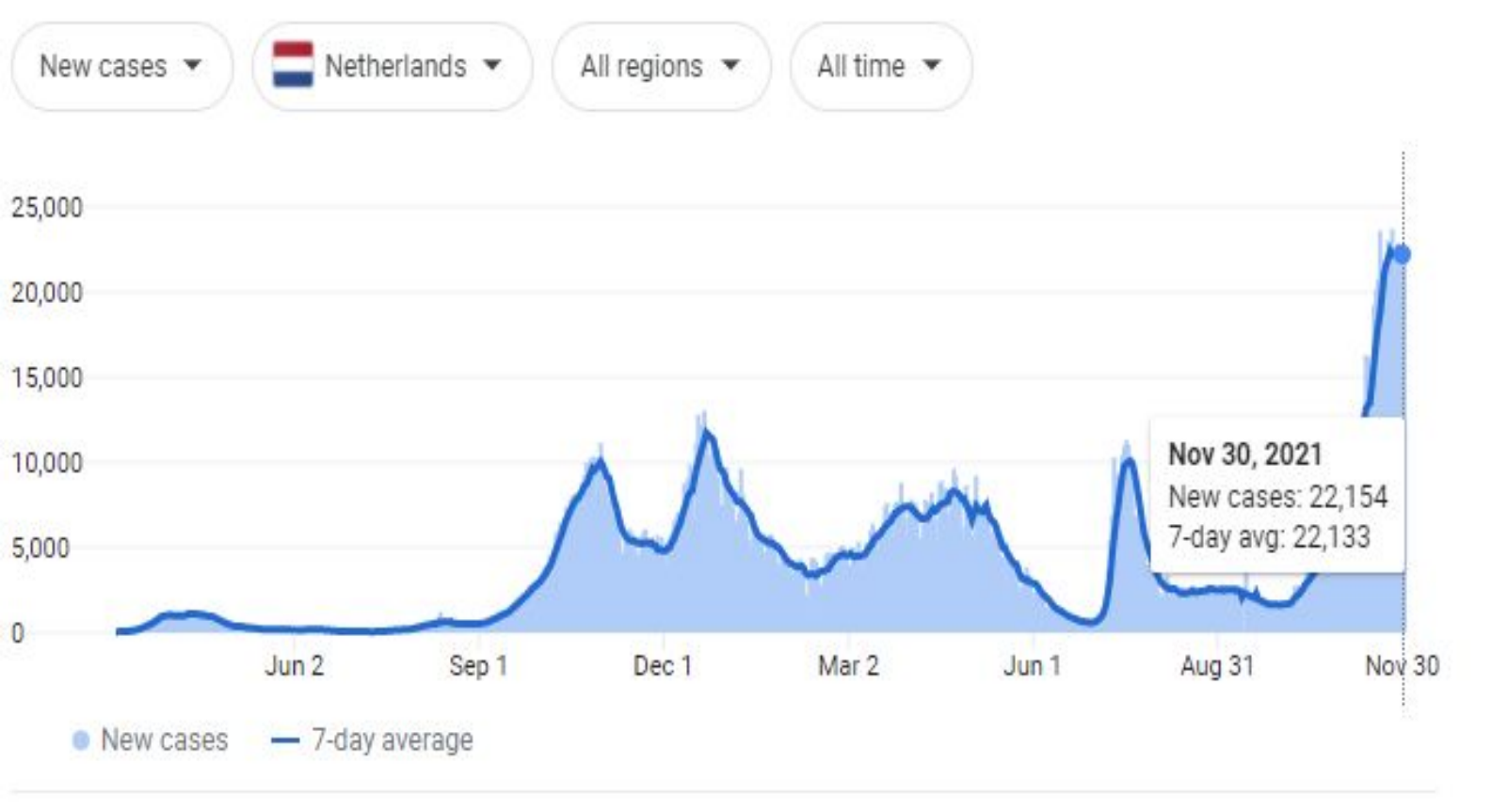
Variants

- **Andeweg, et al. (Netherlands): Increased risk of infection with SARS-CoV-2 Beta, Gamma, and Delta variant compared to Alpha variant in vaccinated individuals**
- "We find evidence for an increased risk of infection by the Beta (B.1.351), Gamma (P.1), or Delta 45 (B.1.617.2) variants compared to the Alpha (B.1.1.7) variant after vaccination. In contrast to vaccine-induced immunity, no increased risk for reinfection with Beta, Gamma or Delta variants relative to Alpha variant was found in 49 individuals with infection-induced immunity."

Delta


Partly vaccinated
Fully vaccinated
Previous infection
Delta
1.8 (1.4–2.2)
1.9 (1.4–2.5)
1.0 (0.6–1.5)
0
1
2
3
4
5
6
7
8
9
10
Odds ratio

Netherlands (85% vax)



Natural Immunity and Variants

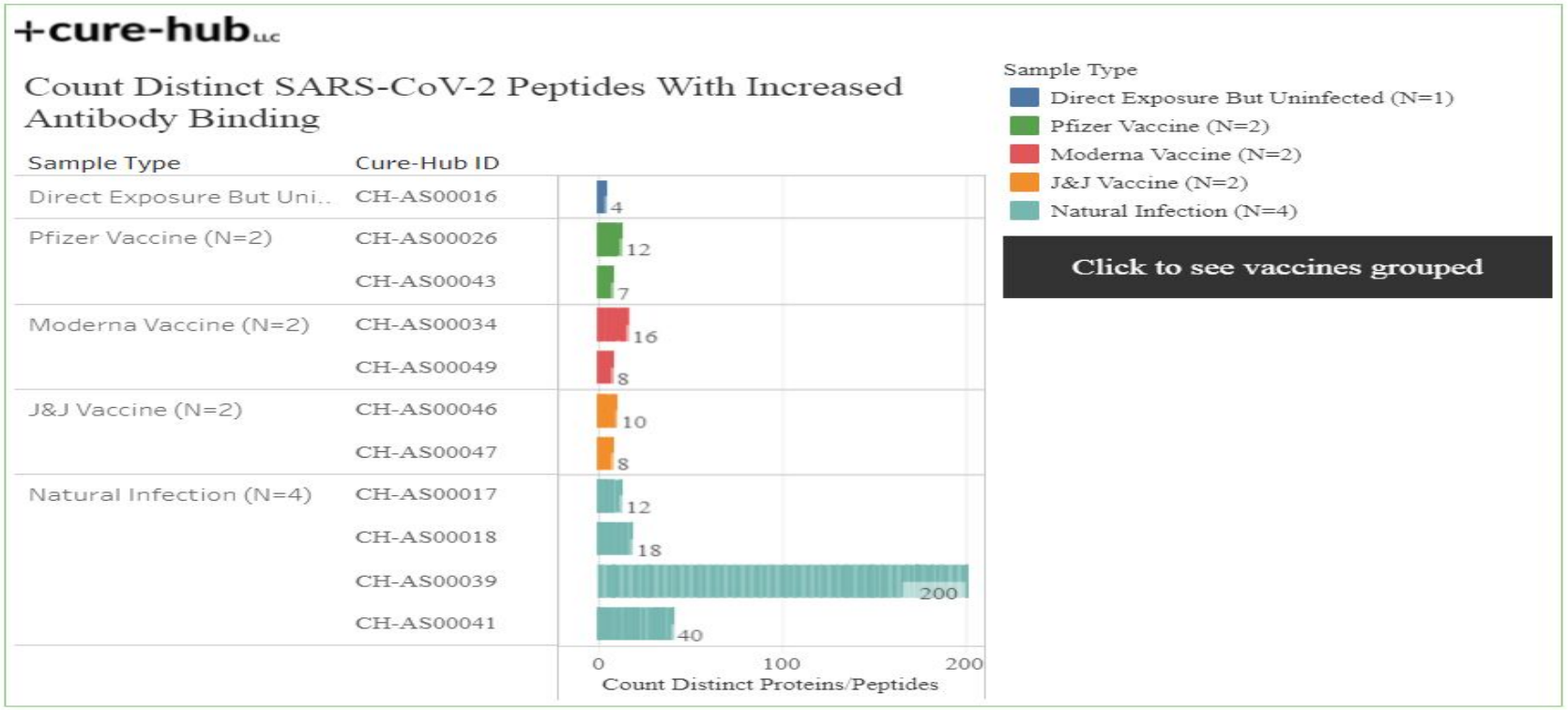


Figure 1. Count of unique full length SARS-CoV-2 proteins and peptide sequences that show increased antibody binding after COVID-19 vaccination or natural infection. Chart is interactive, hover or click the button to see the vaccines grouped.

Spike Protein

Two natural infection super responders have antibodies against peptides across the spike protein. The other 2 natural infections have around the same spike protein antibody diversity as those who received the vaccine (Figure 2).

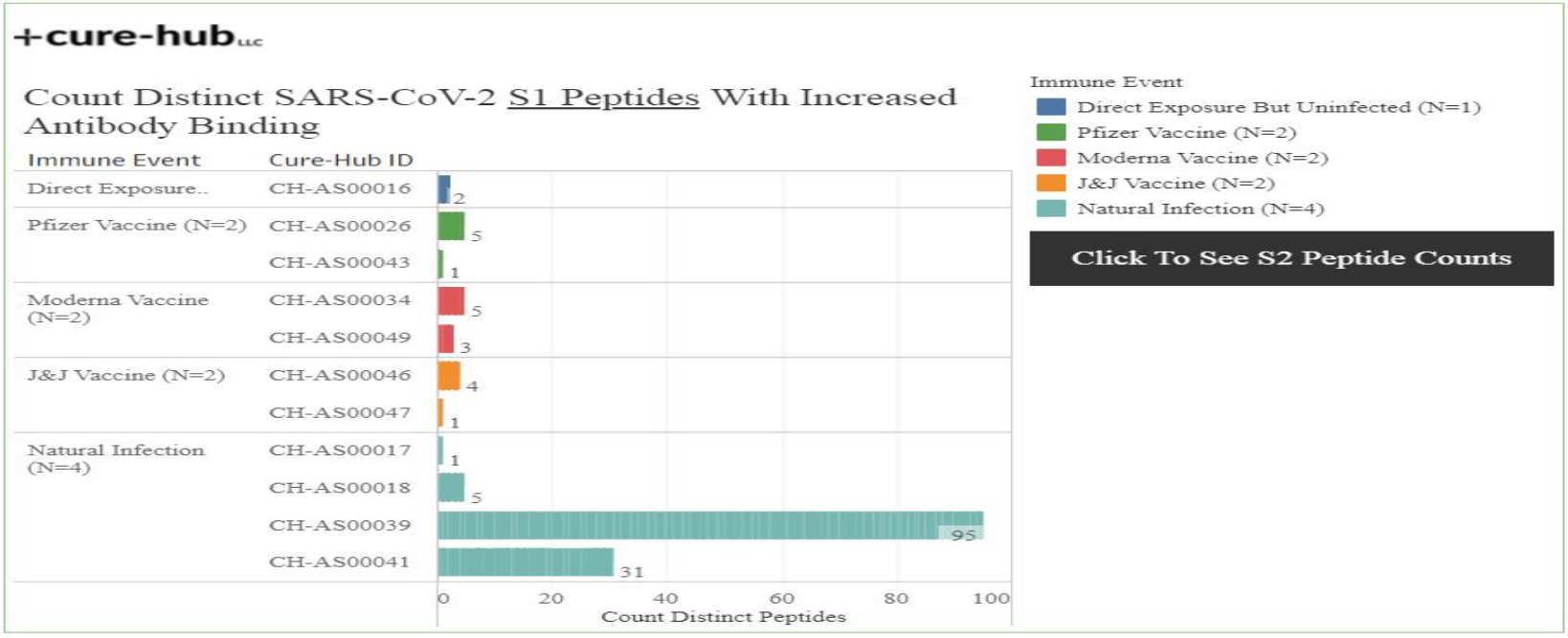
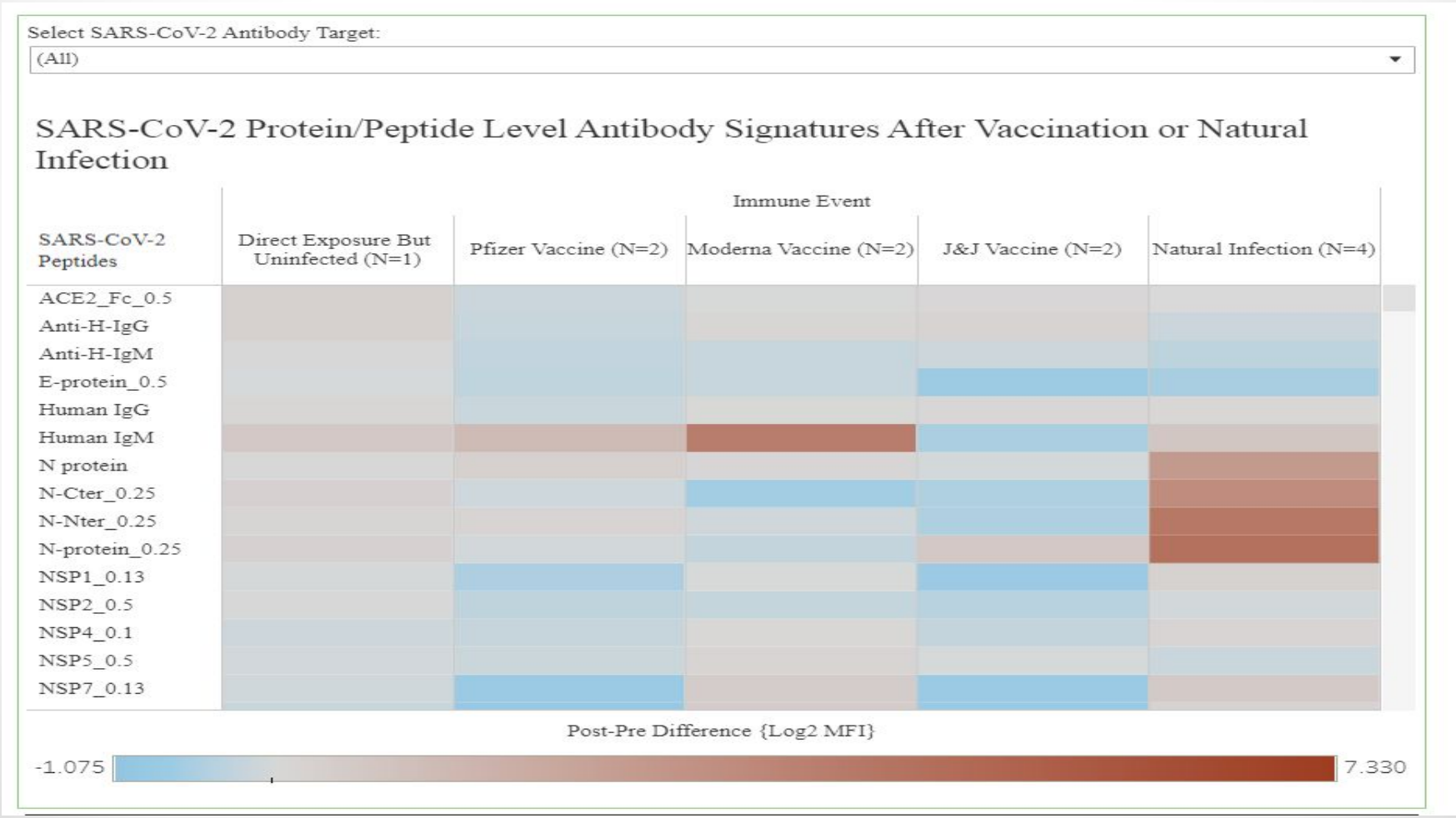


Figure 2. Count of unique SARS-CoV-2 peptide sequences from Spike protein subunits, S1 and S2 that show increased antibody binding after COVID-19 vaccination or natural infection. Chart is interactive, hover or click the button to swap between S1 and S2 peptide counts.

Nucleocapsid Antibodies



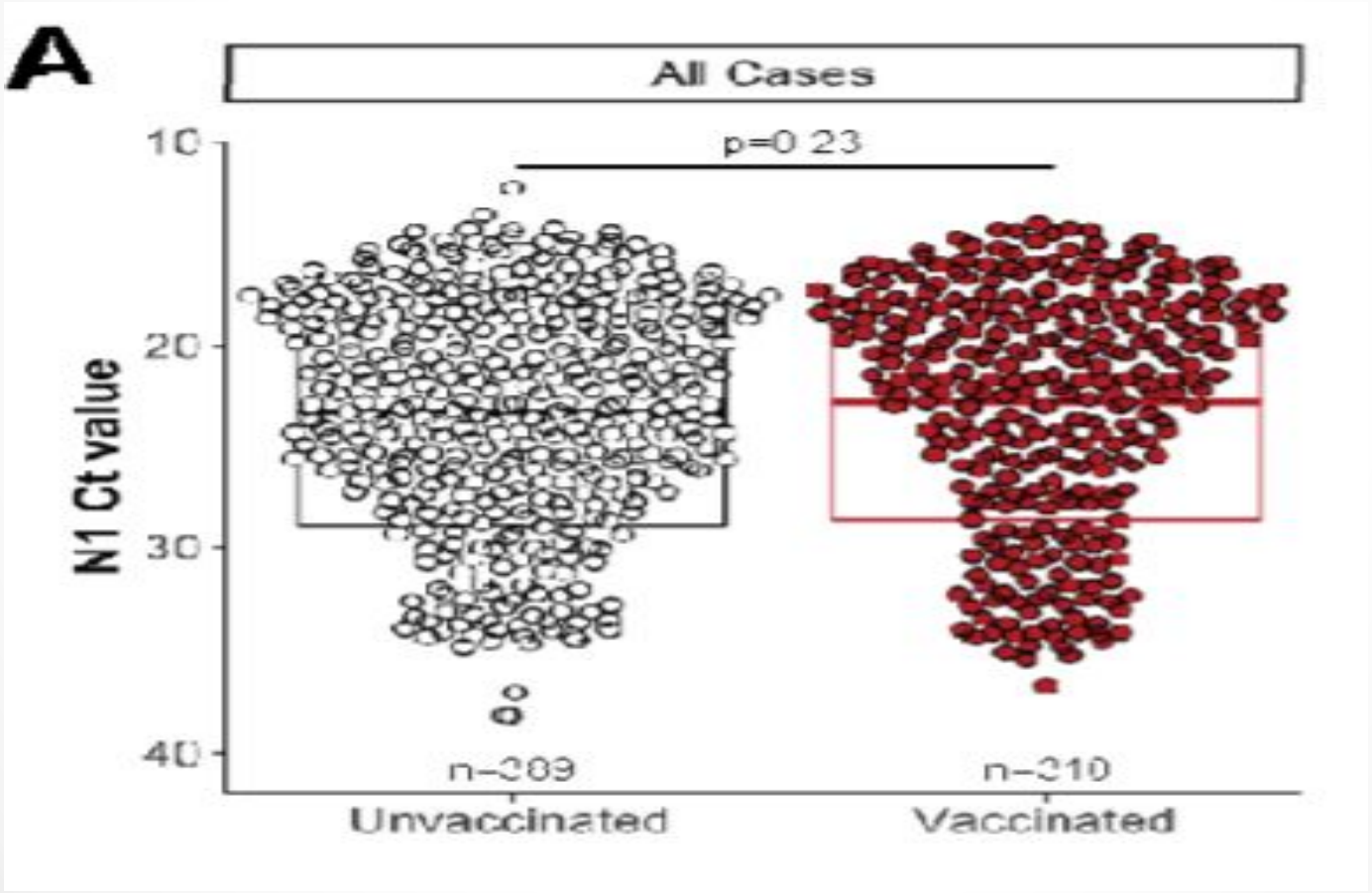
Antibody Evolution

- **Antibody Evolution after SARS-CoV-2 mRNA Vaccination**
- "We examine memory B cell evolution 5 months after vaccination with either Moderna or Pfizer-BioNTech mRNA vaccines. Between prime and boost, memory B cells produce antibodies that evolve increased neutralizing activity, but there is no further increase in potency or breadth thereafter. **Instead, memory B cells that emerge 5 months after vaccination of naïve individuals express antibodies that are equivalent to those that dominate the initial response. We conclude that memory antibodies selected over time by natural infection have greater potency and breadth than antibodies elicited by vaccination.**"

Infectiousness of Breakthrough Infections

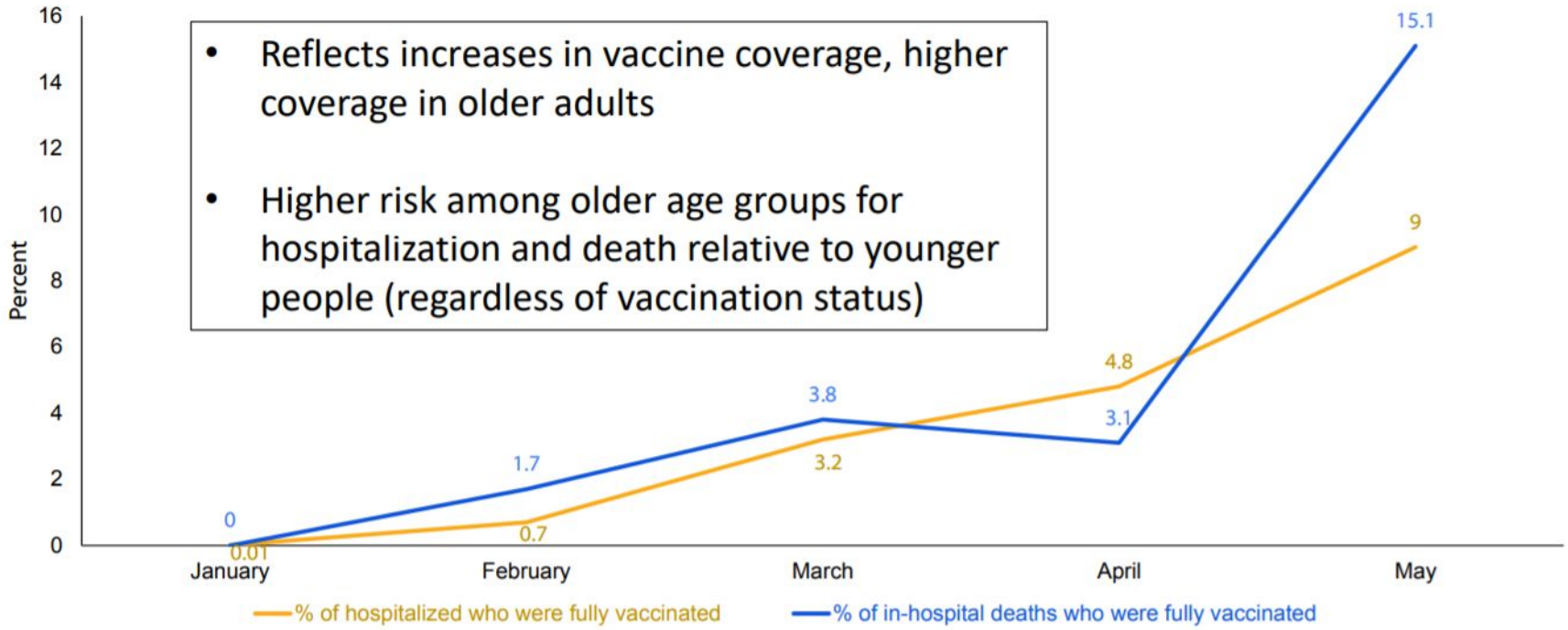
- **Riemersma (Provincetown)**, "Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta Variant"
- **Reimersma, "Shedding of Infection SARS-CoV-2 Virus Despite Vaccination":** "We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people."
- **Abu-Raddad, "Effect of vaccination and of prior infection on infectiousness of vaccine breakthrough infections and reinfections":** "The mean Ct value was higher in all cohorts of breakthrough infections compared to the cohort of primary infections in unvaccinated individuals. The Ct value was 1.3 (95% CI: 0.9-1.8) cycles higher for BNT162b2 breakthrough infections, 3.2 (95% CI: 1.8-4.5) cycles higher for mRNA-1273 breakthrough infections, **and 4.0 (95% CI: 3.4-4.6) cycles higher for reinfections in unvaccinated individuals**."
- **Acharya, et al. (2021):** "No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant"

Ct counts/shedding (Riemersma)



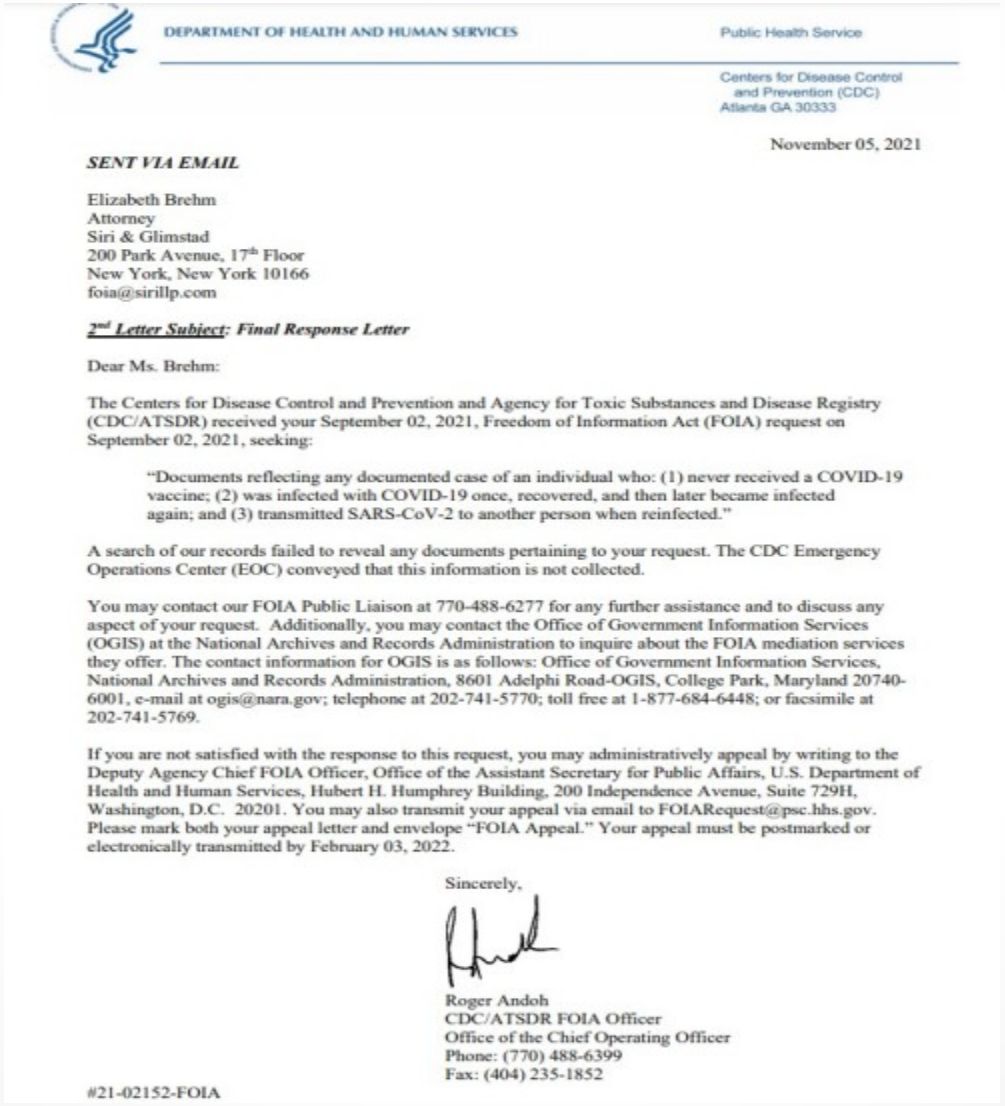
CDC (Leaked May)

Increasing percentage of vaccinated persons among those hospitalized in COVID-NET



(CONFIDENTIAL – preliminary data, subject to change)

NI Transmission



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

November 05, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

2nd Letter Subject: Final Response Letter

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your September 02, 2021, Freedom of Information Act (FOIA) request on September 02, 2021, seeking:

> "Documents reflecting any documented case of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected."

A search of our records failed to reveal any documents pertaining to your request. The CDC Emergency Operations Center (EOC) conveyed that this information is not collected.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by February 03, 2022.

Sincerely,

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#21-02152-FOIA

Lancet Summary

- Kampf, “The epidemiological relevance of the COVID-19-vaccinated population is increasing” (Dec 1, 2021)
- “Many decisionmakers assume that the vaccinated can be excluded as a source of transmission. It appears to be grossly negligent to ignore the vaccinated population as a possible and relevant source of transmission when deciding about public health control measures.”

Vax post-NI

- Efrati, *Nature Scientific Reports* (Aug 21): "Short-term severe symptoms that required medical attention were found in **6.8% among the post-infected individuals**, while none were found in the infection naïve population."
- Life (Mathioudakis): "A prior COVID-19 infection was associated with an 8% increase in the risk of having any side effects after the first vaccine dose (RR 1.08, 95% CI (1.05–1.11), Table 1, Figure 1)….**More importantly, a prior COVID-19 infection was associated with the risk of experiencing a severe side effect requiring hospital care (1.56 (1.14–2.12)).**"
- Shenai, et al. (2021): Pooled NNT 218 (NI) v 6.5 (Naïve)=33.5x to prevent one *infection*=15 hospitalization/ER visits

JAMA (Aug 16, 2021)

Table. Significant Symptoms and Antibody Measurement Following SARS-CoV-2 mRNA Vaccines

Characteristic	Significant symptoms		
	Following dose 1	Following dose 2	Following dose 1 or 2
Adjusted odds ratio (95% CI) of symptoms following dose 1, dose 2, either dose			
Significant symptoms following dose 1	NA	1.21 (0.67-2.17)	NA
Age >60 y	1.42 (0.64-3.14)	0.46 (0.29-0.72)	0.47 (0.31-0.73)
Male sex[a]	0.82 (0.37-1.79)	0.88 (0.63-1.25)	0.88 (0.63-1.24)
Vaccine type[b]: Moderna	1.65 (0.87-3.11)	2.44 (1.75-3.42)	2.33 (1.67-3.26)
Prior SARS-CoV-2 infection	4.59 (2.36-8.92)	0.60 (0.36-0.99)	0.83 (0.51-1.33)
Median antibody measurement (IQR) and adjusted relative median antibody measurement (95% CI) >14 d following second dose vaccine			

Studies that show post-PI vax is safer than Naïve vax

Omicron

- **Harvey, et al., *Nature Review Microbiology* (July 2021): "SARS-CoV-2 variants, spike mutations and immune escape"**
- "The emergence of SARS-CoV-2 in late 2019 was followed by a period of relative evolutionary stasis lasting about 11 months. Since late 2020, however, SARS-CoV-2 has been characterized by the emergence of sets of mutations, in the context of 'variants of concern', that impact virus characteristics, including transmissibility and antigenicity, ***probably in response to the changing immune profile of the human population***."

Evolutionary Pressure

- Van Egeren (2021), "**Risk of rapid evolutionary escape from biomedical interventions targeting SARS-CoV-2 spike protein**": "Our modeling suggests that SARS-CoV-2 mutants with one or two mildly deleterious mutations are expected to exist in high numbers due to neutral genetic variation, and consequently resistance to vaccines or other prophylactics that rely on one or two antibodies for protection can develop quickly -and repeatedly- under positive selection."
- "This has implications for SARS-CoV-2 disease control strategies, as one possible solution to the problem of immune evasion by SARS-CoV-2 that has been proposed is to develop a new vaccine update every year, similar to influenza. In practice, such a solution will only work in the face of a moderate pace of evolution of SARS-CoV-2 and a low degree of clonal diversity among various clades of SARS-CoV-2 as they evolve to evade the current crop of vaccines. **Further, if within-host evolution of SARS-CoV-2 contributes to population-level immune evasion, the valley-crossing mechanism described in this paper could accelerate the emergence of vaccine-resistant strains in the months following vaccine deployment.** To the extent that new strains of SARS-CoV-2 are antigenically distinct, this may also lead to increased risk of antibody-dependent enhancement (ADE), as one mechanism for ADE involves antibodies that bind to the pathogen but fail to neutralize it."

Evolutionary Pressure

- Wang (2021), “Mechanisms of SARS-CoV-2 Evolution Revealing Vaccine-Resistant Mutations in Europe and America”
- “By tracking the evolutionary trajectories of vax-resistant mutations in more than 2.2 million SARS-CoV-2 genomes, we reveal that the occurrence and frequency of vaccine-resistant mutations correlate strongly with the vax rates in Europe and America.”

Wang: Spread of Vaccine-Resistant Mutation

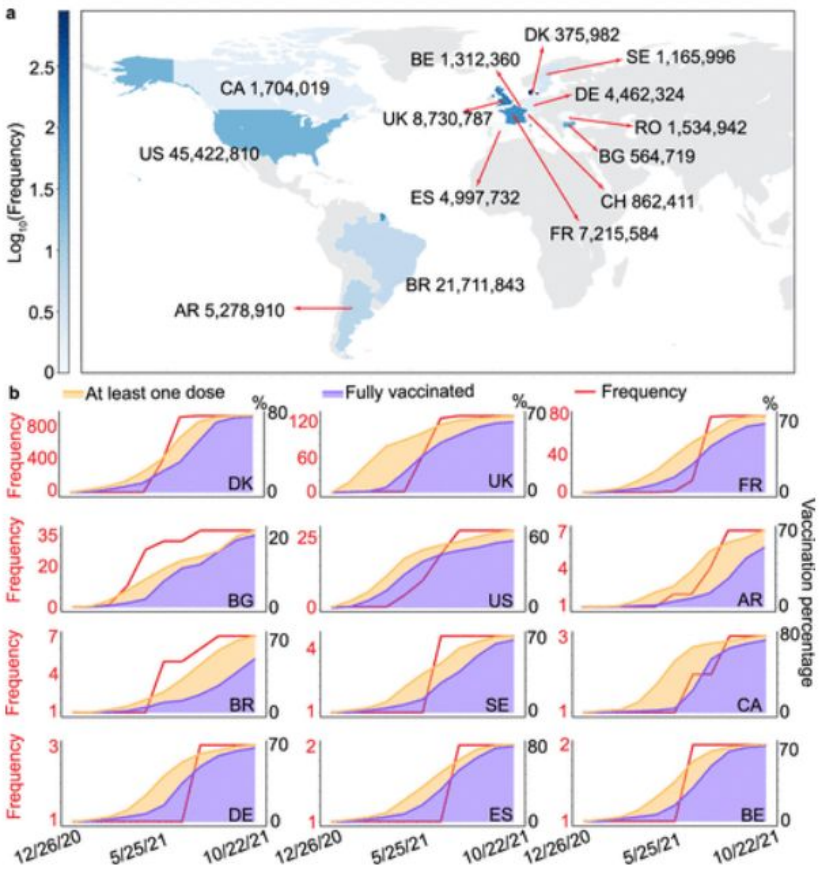
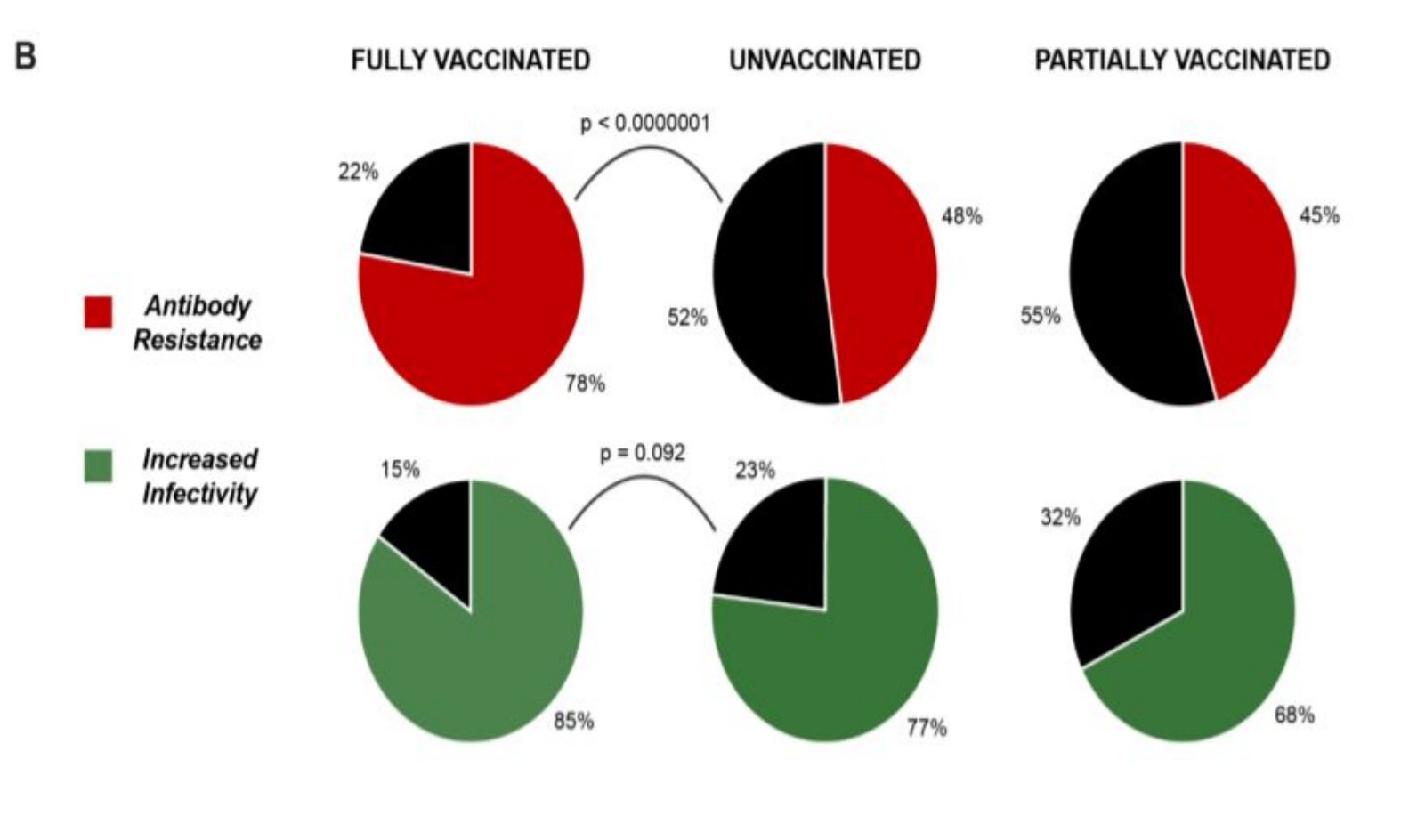


Figure 4. (a) Distribution of vaccine-resistant mutation Y449S. The

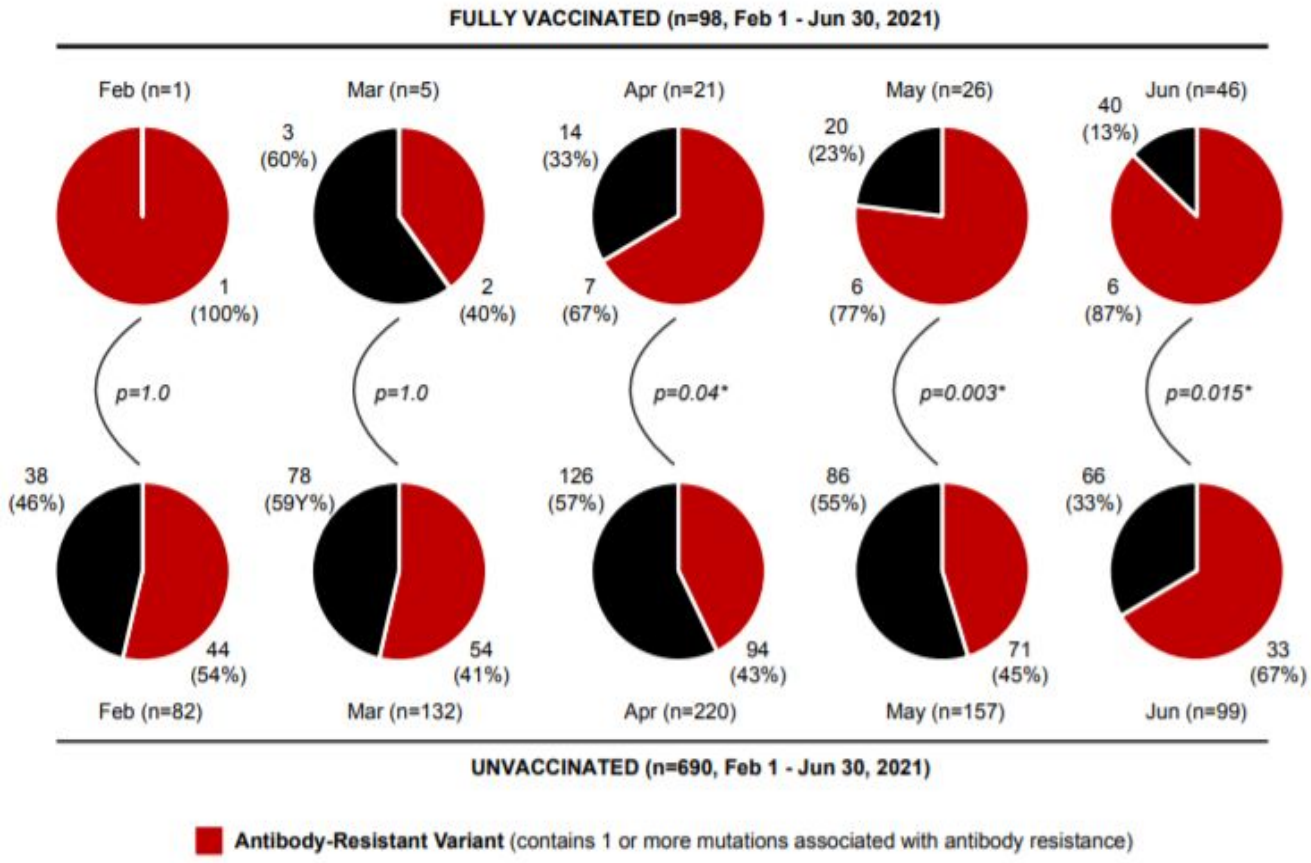
Evolutionary Pressure

- **Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California**
- **"Fully vaccinated were more likely than unvaccinated persons to be infected by variants carrying mutations associated with decreased antibody neutralization** (78% versus 48%, p = 1.96e-08), but not by those associated with increased infectivity (85% versus 77%, p = 0.092)."
- "Differences in viral loads were non-significant between unvaccinated and fully vaccinated persons overall and according to lineage."
- "Symptomatic vaccine breakthrough infections had similar viral loads to unvaccinated infections."
- "findings suggest that vaccine breakthrough cases are preferentially caused by circulating antibody-resistant SARS-CoV-2 variants, and that symptomatic breakthrough infections may potentially transmit COVID-19 as efficiently as unvaccinated infections, regardless of the infecting lineage."
- **Egeren, et al, (April 2021), "Risk of rapid evolutionary escape from biomedical interventions targeting SARS-CoV2 spike protein"**: "SARS-CoV-2 mutants with one or two mildly deleterious mutations are expected to exist in high numbers due to neutral genetic variation, and consequently resistance to vaccines or other prophylactics that rely on one or two antibodies for protection can develop quickly -and repeatedly- under positive selection"

San Francisco



San Francisco



Vaccine Escape

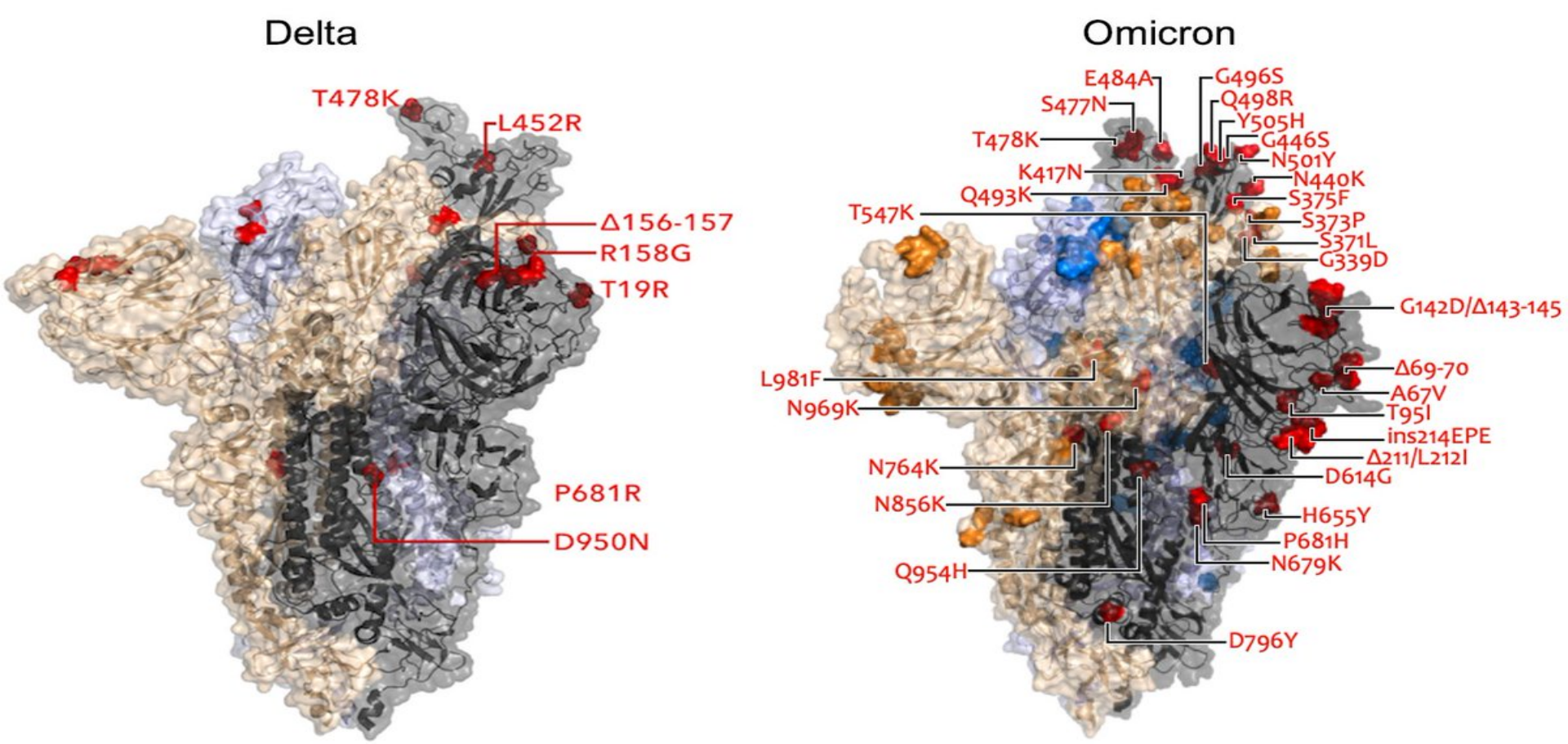
The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines

Authors:
Yafei Liu[1,2], Noriko Arase[3], Jun-ichi Kishikawa[4], Mika Hirose[4], Songling Li[5], Asa Tada[2], Sumiko Matsuoka[1], Akemi Arakawa[2], Kanako Akamatsu[6], Chikako Ono[7,8], Hui Jin[1], Kazuki Kishida[2], Wataru Nakai[1,2], Masako Kohyama[1,2], Atsushi Nakagawa[9], Yoshiaki Yamagishi[10], Hironori Nakagami[11], Atsushi Kumanogoh[12,13], Yoshiharu Matsuura[6,14], Daron M. Standley[5,15], Takayuki Kato[4], Masato Okada[6,15], Manabu Fujimoto[3], Hisashi Arase[1,2,15]*

Omicron

- **32 of 50 mutations are on the spike protein**
- One Israeli carrier recently triple-vaxxed
- Two fully-vaxxed Israeli Doctors transmitted between
- Seems to be more transmissible but unclear whether more virulent
- **Moderna chief predicts 'material drop' in effectiveness of vaccines against omicron:**"There is no world, I think, where [the effectiveness] is the same level...we had with [the] delta [variant]"

Omicron


Delta
T478K
L452R
Δ156-157
R158G
T19R
P681R
D950N
Omicron
E484A
G496S
S477N
Q498R
Y505H
T478K
G446S
N501Y
K417N
N440K
Q493K
S375F
T547K
S373P
S371L
G339D
G142D/Δ143-145
L981F
Δ69-70
N969K
A67V
T95I
ins214EPE
N764K
Δ211/L212I
D614G
N856K
H655Y
P681H
Q954H
N679K
D796Y

Mderna v Omicron

- Reuters (Nov 3):“The head of drugmaker Moderna (MRNA.O) said COVID-19 vaccines are unlikely to be as effective against the Omicron variant of the coronavirus as they have been previously, sparking fresh worry in financial markets about the trajectory of the pandemic.
- "There is no world, I think, where (the effectiveness) is the same level . . . we had with Delta," Moderna Chief Executive Stéphane Bancel told the Financial Times in an interview.
- "I think it's going to be a material drop. I just don't know how much because we need to wait for the data. But all the scientists I've talked to . . . are like 'this is not going to be good.'"

Pfizer Omicron

- “The two doses, they’re not enough for omicron,” Pfizer CEO Albert Bourla said.
- Bourla said the two-dose vaccine does not provide robust protection against infection and its ability to prevent hospitalization has also declined.
- He said third shots are providing good protection against death, and “decent” protection against hospitalization.

Bancel and Bourla what they are talking about

- Garcia-Beltran (Cell 2021): “Omicron neutralization was dramatically decreased among all subgroups, including recently vaccinated mRNA-1273 and BNT162b recipients, *which demonstrated a complete loss of neutralization* in >50% of individuals and [geometic mean neutralization titers] decrease of 43-fold for mRNA-1273 and 122-fold for BNT162b.”
- “Taken together, we demonstrate that Omicron drastically escapes vaccine-induced immunity after primary vaccination series with mRNA-1273 (Moderna), BNT162b2 (Pfizer-BioNTech), or Ad26.COV2.S (Johnson & Johnson/Janssen) and exhibits increased pseudovirus infection rates *in vitro*, raising the potential for increased transmissibility.”

(Hansen, Denmark)

Table Estimated vaccine effectiveness for BNT162b2 and mRNA-1273 against infection with the SARS-CoV-2 Omicron and Delta variants during November 20 – December 12, 2021, Denmark.

	Pfizer – BNT162b2				Moderna - mRNA-1273			
Time since vaccine protection	Omicron		Delta		Omicron		Delta	
	Cases	VE, % (95% CI)	Cases	VE, % (95% CI)	Cases	VE, % (95% CI)	Cases	VE, % (95% CI)
1-30 days	14	55.2 (23.5; 73.7)	171	86.7 (84.6; 88.6)	4	36.7 (-69.9; 76.4)	29	88.2 (83.1; 91.8)
31-60 days	32	16.1 (-20.8; 41.7)	454	80.9 (79.0; 82.6)	8	30.0 (-41.3; 65.4)	116	81.5 (77.7; 84.6)
61-90 days	145	9.8 (-10.0; 26.1)	3,177	72.8 (71.7; 73.8)	48	4.2 (-30.8; 29.8)	1,037	72.2 (70.4; 74.0)
91-150 days	2,851	-76.5 (-95.3;-59.5)	34,947	53.8 (52.9; 54.6)	393	-39.3 (-61.6;-20.0)	3,459	65.0 (63.6; 66.3)
1-30 days after booster vaccination protection	29	54.6 (30.4; 70.4)	453	81.2 (79.2; 82.9)	-	-	5	82.8 (58.8; 92.9)

CI = confidence intervals; VE = vaccine effectiveness. VE estimates adjusted for 10-year age groups, sex and region (five geographical regions). Vaccine protection was assumed 14 days post 2nd dose. Insufficient data to estimate mRNA-1273 booster VE against Omicron.

(Hansen, Denmark)

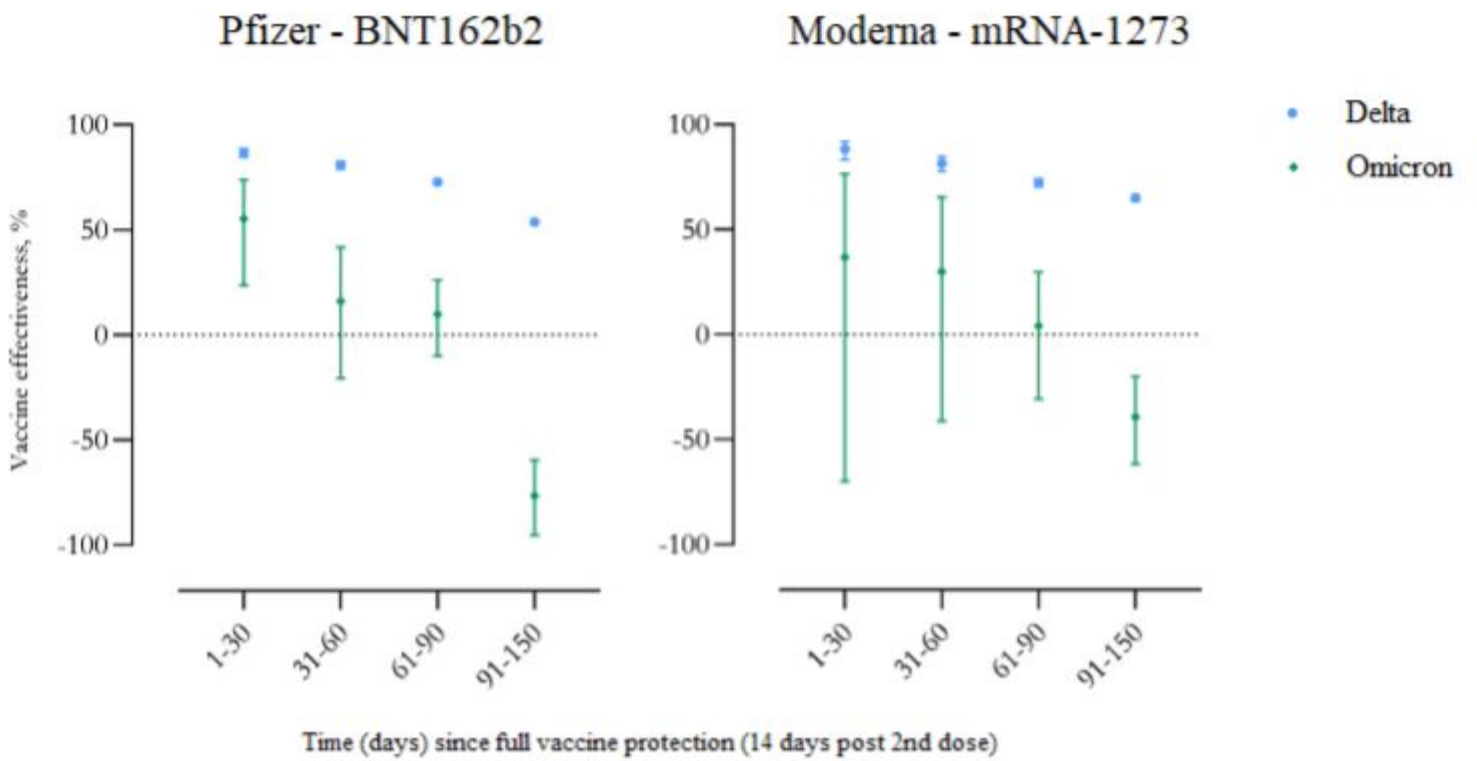


Figure Vaccine effectiveness against SARS-CoV-2 infection with the Delta and Omicron variants, shown separately for the BNT162b2 and mRNA-1273 vaccines. Vertical bars indicate 95% confidence intervals.

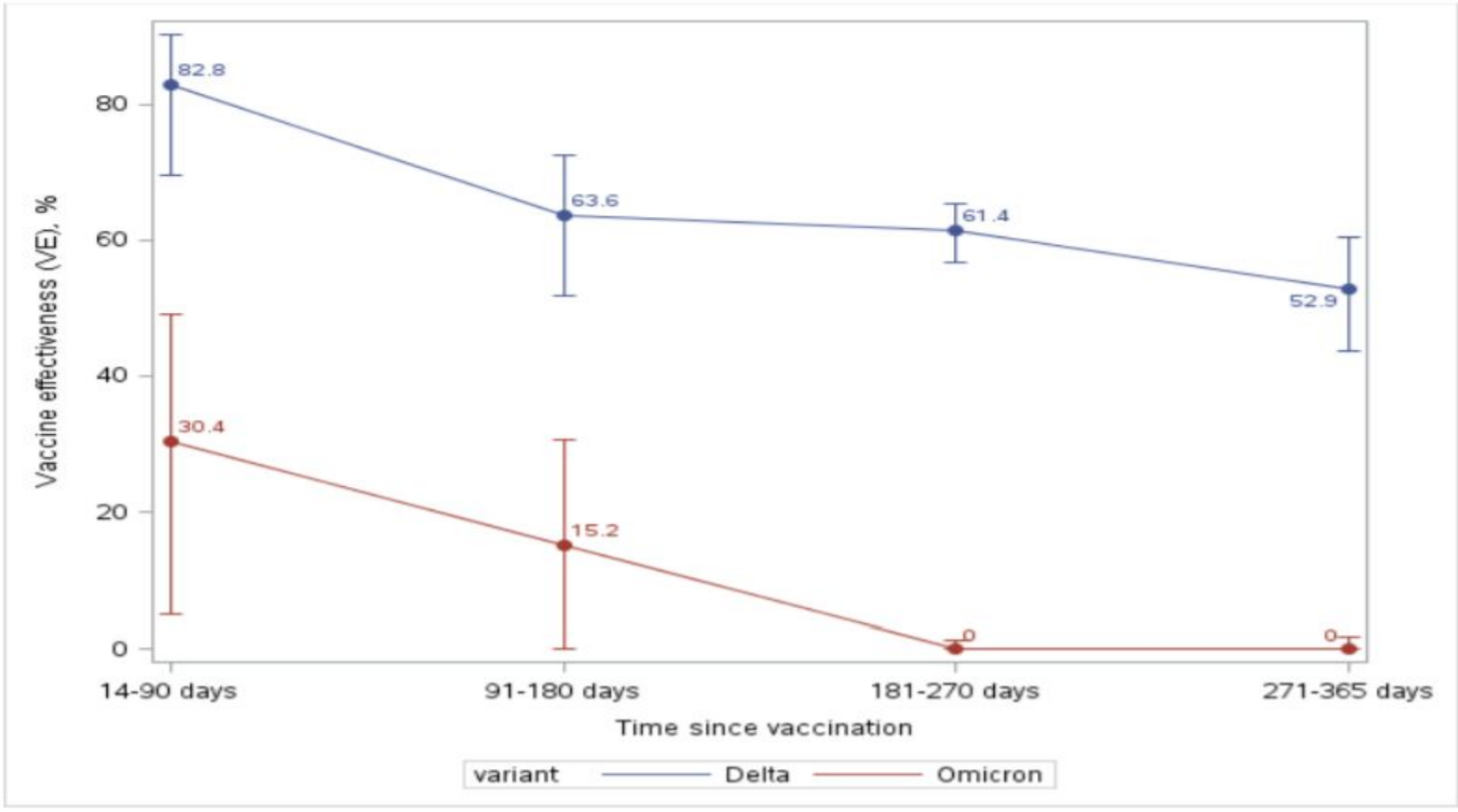
Tseng (Kaiser)

- Moderna (2 doses)

Omicron	1855 (55.7%)	1473 (44.3%)	8326 (50.0%)	8314 (50.0%)	1.268 (1.175, 1.368)	1.051 (0.969, 1.141)	0.0% (0.0%, 0.0%)	0.0% (0.0%, 3.1%)
14-90 days	48 (3.2%)	1473 (96.8%)	370 (4.3%)	8314 (95.7%)	0.733 (0.540, 0.995)	0.696 (0.510, 0.950)	26.7% (0.5%, 46.0%)	30.4% (5.0%, 49.0%)
91-180 days	126 (7.9%)	1473 (92.1%)	732 (8.1%)	8314 (91.9%)	0.972 (0.798, 1.183)	0.848 (0.693, 1.037)	2.8% (0.0%, 20.2%)	15.2% (0.0%, 30.7%)
181-270 days	1265 (46.2%)	1473 (53.8%)	5489 (39.8%)	8314 (60.2%)	1.301 (1.198, 1.413)	1.080 (0.988, 1.181)	0.0% (0.0%, 0.0%)	0.0% (0.0%, 1.2%)
>270 days	416 (22.0%)	1473 (78.0%)	1735 (17.3%)	8314 (82.7%)	1.353 (1.200, 1.527)	1.116 (0.983, 1.267)	0.0% (0.0%, 0.0%)	0.0% (0.0%, 1.7%)

Tseng (Kaiser)

Figure 1. Vaccine effectiveness of 2-dose mRNA-1273 against omicron and delta variants by time since vaccination



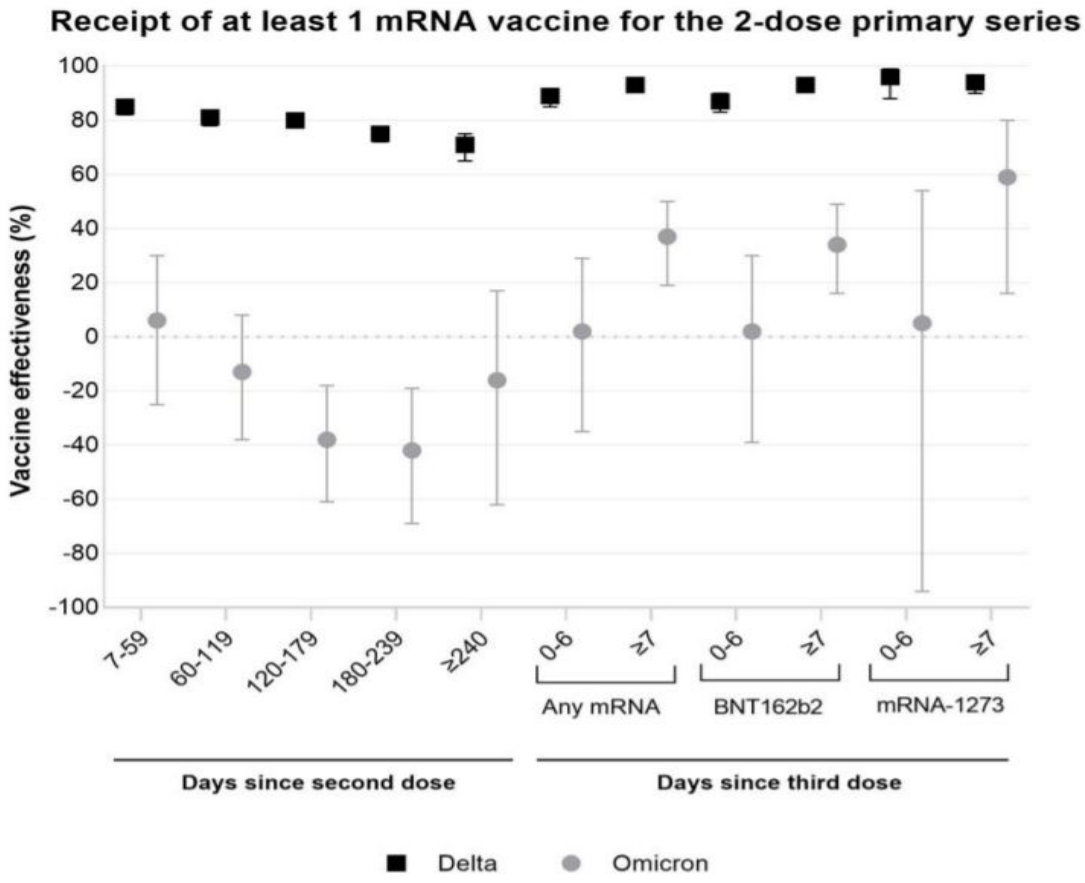
Buchan (Toronto)

Table 2. Vaccine effectiveness against infection by Omicron or Delta among adults aged ≥18 years by time since latest dose

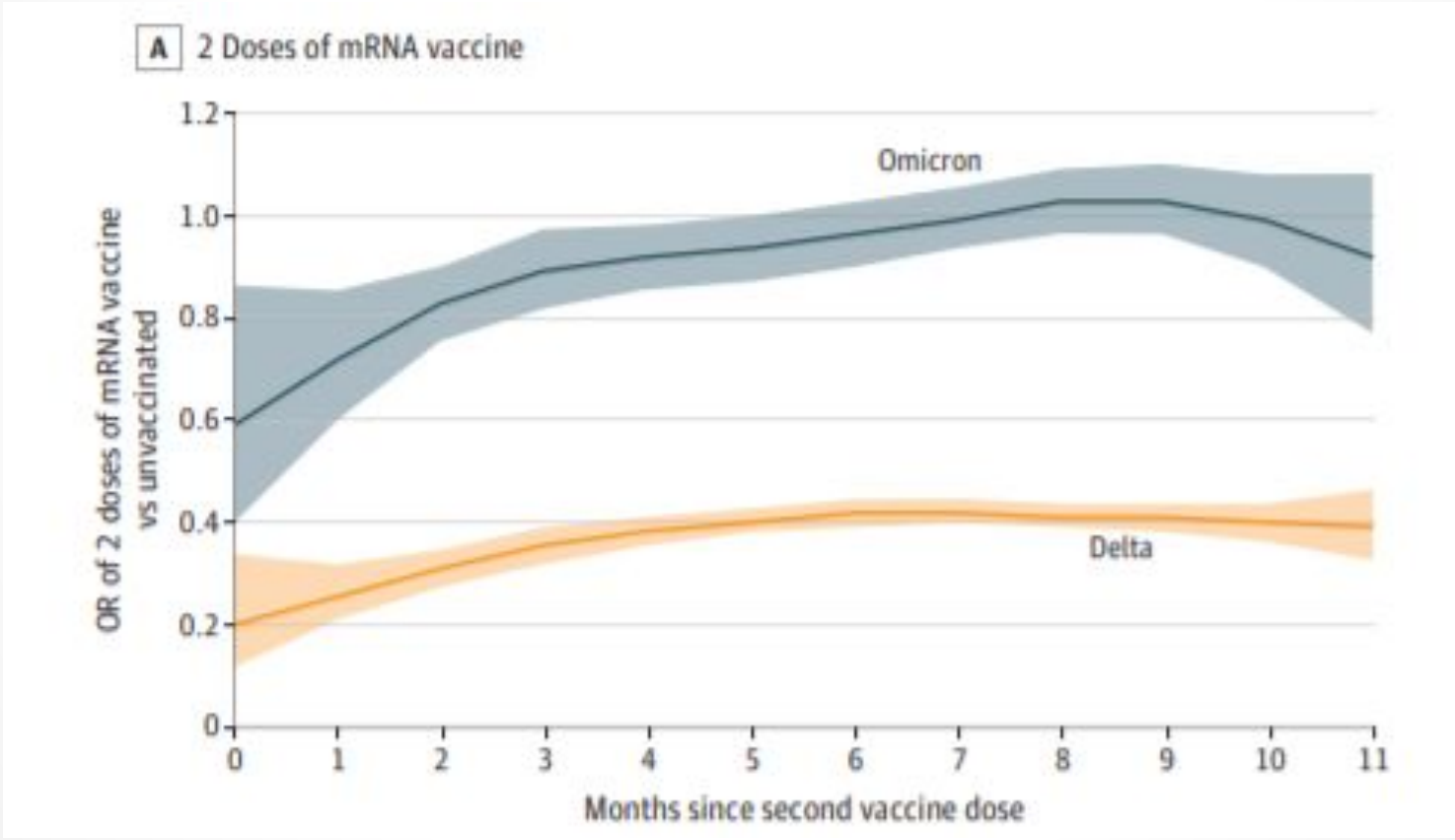
Doses	Vaccine products	Days since latest dose	SARS-CoV-2 negative controls, n	Omicron-positive cases, n	Vaccine effectiveness against Omicron (95% CI)	Delta-positive cases, n	Vaccine effectiveness against Delta (95% CI)
First 2 doses	≥1 mRNA vaccine	7-59	14,288	63	6 (-25, 30)	204	84 (81, 86)
		60-119	34,741	214	-13 (-38, 8)	562	81 (79, 82)
		120-179	282,977	2,257	-38 (-61, -18)	4,342	80 (79, 81)
		180-239	47,282	522	-42 (-69, -19)	635	74 (72, 76)
		≥240	10,285	46	-16 (-62, 17)	203	71 (66, 75)

Buchan

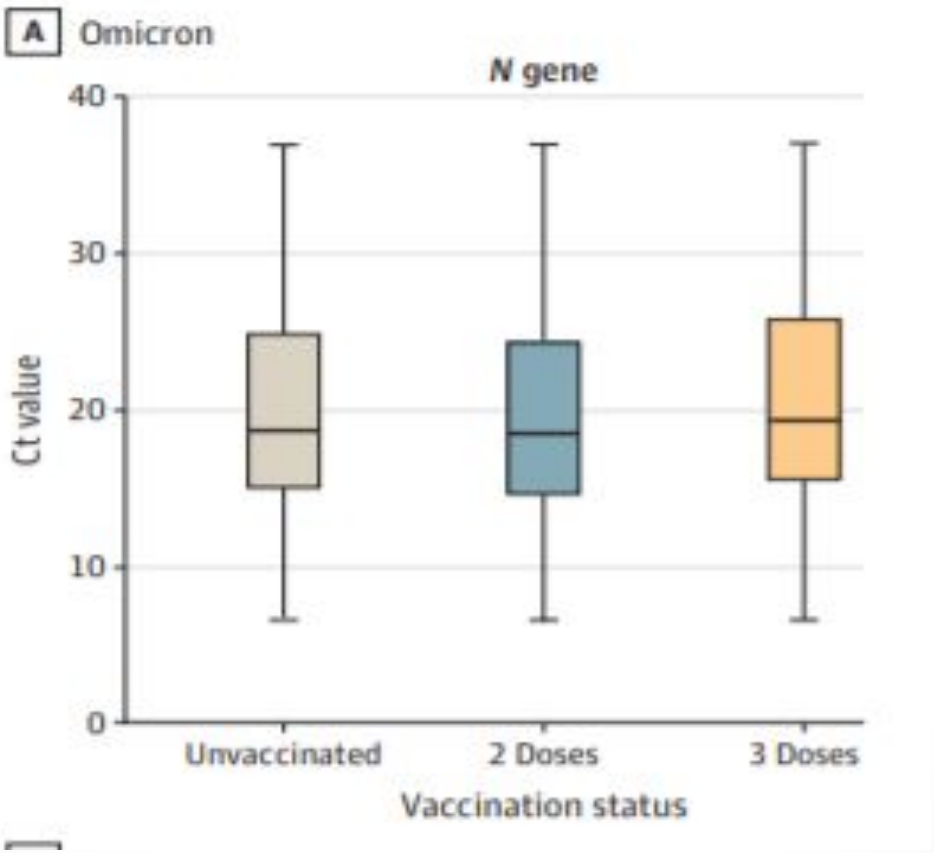
Figure 1. Vaccine effectiveness against infection by Omicron or Delta among adults aged ≥18 years by time since latest dose



JAMA Accorsi (2022)



Accorsi (Ct value)



Altarawneh (Qatar)

Table 3. Effectiveness of SARS-CoV-2 prior infection against reinfection with Alpha, Beta, Delta, or Omicron variant.

	Cases (PCR-positive)		Controls (PCR-negative)		Effectiveness in % (95% CI)‡
	Prior infection	No prior infection	Prior infection	No prior infection	
Effectiveness against symptomatic infection					
A) Main analysis*					
Alpha	2	334	94	1,548	90.2 (60.2 to 97.6)
Beta	15	1,321	450	6,084	84.8 (74.5 to 91.0)
Delta	23	2,153	1,154	8,782	92.0 (87.9 to 94.7)
Omicron	412	5,284	1,620	9,053	56.0 (50.6 to 60.9)
B) Adjusting for vaccination status in conditional logistic regression*					
Alpha	2	334	94	1,548	90.3 (60.4 to 97.6)
Beta	15	1,321	450	6,084	84.0 (73.1 to 90.5)
Delta	23	2,153	1,154	8,782	91.9 (87.8 to 94.7)
Omicron	412	5,284	1,620	9,053	55.9 (50.5 to 60.8)
C) Excluding vaccinated individuals†					
Alpha	1	285	94	1,294	95.3 (66.0 to 99.3)
Beta	11	1,084	312	4,976	83.9 (70.4 to 91.2)
Delta	11	1,026	400	3,966	90.5 (81.9 to 94.6)
Omicron	60	1,031	258	1,738	61.9 (48.2 to 72.0)

Boosters

- **Koren, et al., "Green Pass and COVID-19 Booster Shots in Israel"**: Lower initial response and faster waning than initial vaccination:
  - 1.54-fold protection over first 3 months (35% relative protection)
  - *Negative* 2.44 VE/August, 3.45 VE/Sept, 2.75 VE/October
  - "The analysis suggests that the relative protection of the booster shot against infection is likely to be around 60% at best. This also implies that the absolute number of infected individuals in the Vaccinated group is likely to be at least as high as in the Unvaccinated, raising serious concerns that the new Green Pass is inefficient in preventing infection spread, and could expose high risk individuals to risk."
- Why? Theories:
  - **Immune Exhaustion**: Mazzoni, et al., (J. Clinical Investigation, 2021), "We cannot exclude that the second injection might even be detrimental in this context, possibly leading to a functional exhaustion of Spike-specific lymphocytes . Indeed, we observed a decrease in the frequency of both B and T cells at day 28 (1 week after second dose), but also a decline in the titer of neutralizing Ab at day 50."
  - **Original Antigenic Sin/Antigenic Seniority**: Horndier, "DECREASED BREADTH OF THE ANTIBODY RESPONSE TO THE SPIKE PROTEIN OF SARS-CoV-2 AFTER REPEATED VACCINATION"
  - **High-Zone/Immunological Tolerance:** Medawar, Medicine Nobel (1960): "Immunological tolerance" may be described as a state of indifference or non-reactivity towards a substance that would normally be expected to excite an immunological response."

Boosters

Table 5. Immunogenicity Populations – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (30 µg)

	Vaccine Group (as Randomized)
	BNT162b2 (30 µg) n[a] (%)
Rerandomized[b]	312 (100.0)
Dose 3 booster all-available immunogenicity population	306 (98.1)
Subjects excluded from Dose 3 booster all-available immunogenicity population	6 (1.9)
Reason for exclusion	
Did not have at least 1 valid and determinate immunogenicity result after booster vaccination	6 (1.9)
Dose 3 booster evaluable immunogenicity population	268 (85.9)
Without evidence of infection up to 1 month after booster dose[c]	234 (75.0)
Subjects excluded from Dose 3 booster evaluable immunogenicity population	44 (14.1)
Reason for exclusion[d]	
Did not receive Dose 2 within 19-42 days after Dose 1	1 (0.3)
Did not receive a booster vaccination of BNT162b2 or BNT162b2$_{5A}$ as rerandomized	6 (1.9)

4th Shot?

- Regev-Yochay (2021), "4th Dose COVID mRNA Vaccines' Immunogenicty and Efficacy Aginst Omicron VOC": "Breakthrough infections were common, mostly very mild, yet, with high viral loads. Vaccine efficacy against infection was 30% (95%CI:-9% to 55%) and 11% (95%CI:-43% to +43%) for BNT162b2 and mRNA1273, respectively. Local and systemic adverse reactions were reported in 80% and 40%, respectively."
- VE=11-30%
- AE=40-80%

4th Shot

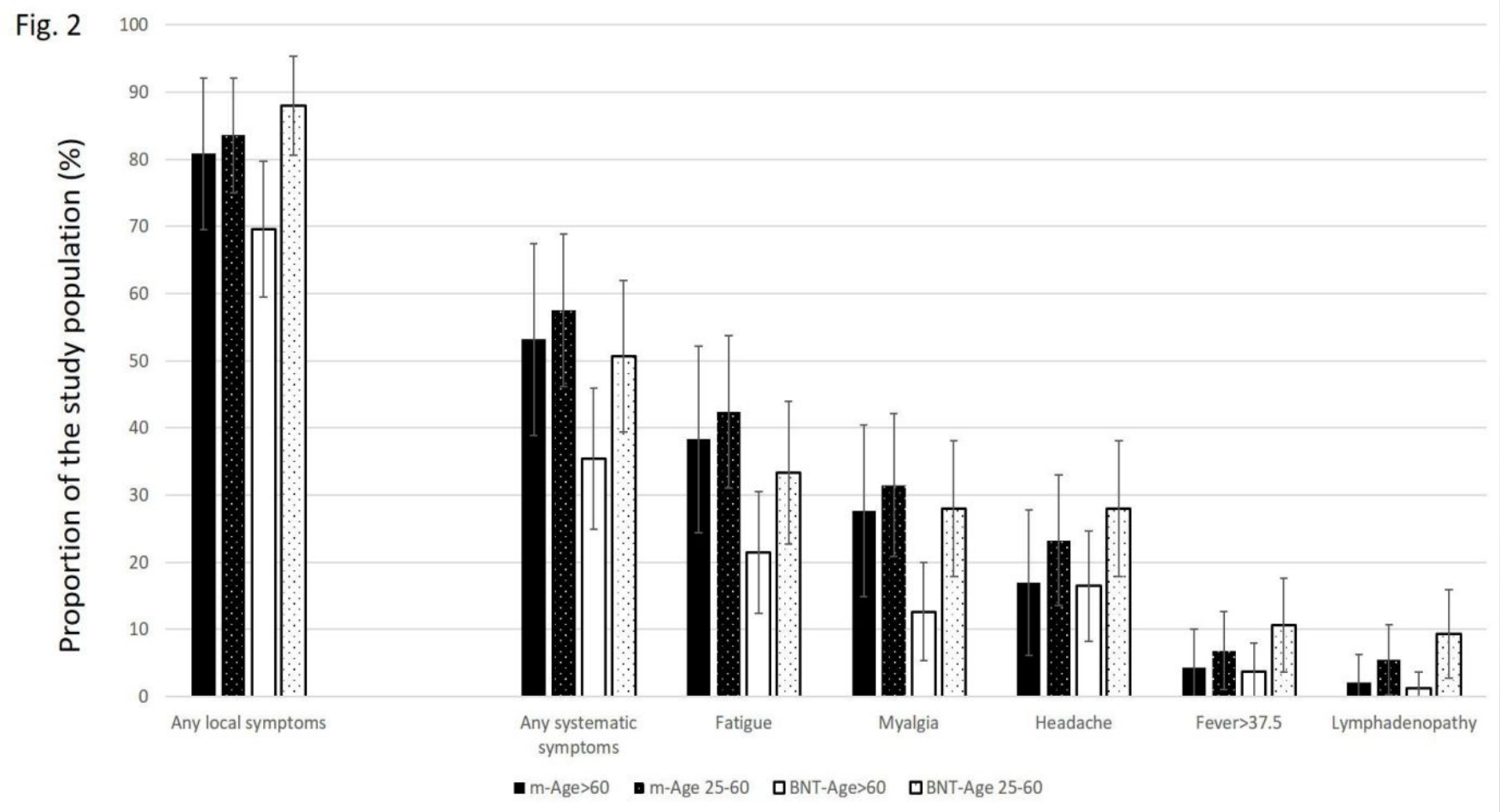


Fig. 2
Proportion of the study population (%)
100
90
80
70
60
50
40
30
20
10
0
Any local symptoms
Any systematic symptoms
Fatigue
Myalgia
Headache
Fever>37.5
Lymphadenopathy
m-Age>60
m-Age 25-60
BNT-Age>60
BNT-Age 25-60

4th Shot

- VE for Pfizer and Moderna

Vaccine efficacy against infection	30.0% (-8.8%-55%)	Ref	10.8% (-43%-44%)	Ref
Vaccine efficacy against symptomatic disease	43.1% (6.6%-65.4%)	Ref	31.4% (-18.4-60.2%)	Ref

OAS

- **Whitaker, et al., (2021), "Nucleocapsid antibody positivity as a marker of past SARS-CoV-2 infection in population serosurveillance studies: impact of variant, vaccination, and choice of assay cut-off**": "We find lower seroconversion rates particularly following Alpha-variant vaccine breakthrough infections."
- **Allen, et al. (2021),** "Only 6/23 (26% [of vaccine breakthrough infections] had detectable anti-N antibodies in response to their infection, compared to 663/812 (82%) of all participants in the study with previous PCR-confirmed infection having detectable anti-N antibodies"
- **NEJM Moderna Trial (2021):**
  - 50-66% of naturally infected generate Nucleocapsid abs
  - 23% of infections post-vax generate Nucleocapisid abs

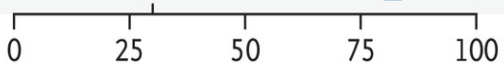
Booster Concerns

- Long-term health effect of repeat boosters unclear
- OAS/Antigenic Sin would reduce efficacy of boosters with new variants
- **Gagne et al. (2021),** "The observation that boosting with either mRNA-1273 or mRNA-Omicron resulted in the expansion of a similarly high frequency of cross-reactive B cells likely stems from the principle of original antigenic sin, otherwise termed antigenic imprinting, whereby prior immune memory is recalled by a related antigenic encounter (Davenport and Hennessy, 1957; Davenport et al., 344 1953)."
- **Patterson, et al. (2021), Persistence of SARS CoV-2 S1 Protein in CD16+ Monocytes in Post-Acute Sequelae of COVID-19 (PASC) Up to 15 Months Post-Infection**

Moderna Trial (Sahli NEJM Sept. 2021)

- 61% of naturally infected seroconverted Nucleocapsid and only 22% post-vax https://www.nejm.org/doi/full/10.1056/NEJMoa2113017

Subgroup	Placebo (N=14,164)	mRNA-1273 (N=14,287)	Vaccine Efficacy (95% CI)
	number of events		*percent*
Covid-19	744	55	93.2 (91.0–94.8)
Severe Covid-19	106	2	98.2 (92.8–99.6)
Covid-19 (secondary definition)	807	58	93.4 (91.4–94.9)
Death from Covid-19	3	0	100.0 (NE–100.0)
Covid-19 ≥14 days after first injection	769	56	93.3 (91.1–94.9)
Covid-19 regardless of previous SARS-CoV-2 status	754	58	92.8 (90.6–94.5)
Asymptomatic	498	214	63.0 (56.6–68.5)
Asymptomatic seroconversion	306	48	—
SARS-CoV-2 infection	1339	280	82.0 (79.5–84.2)



Whitaker (J., Infec., 2021)

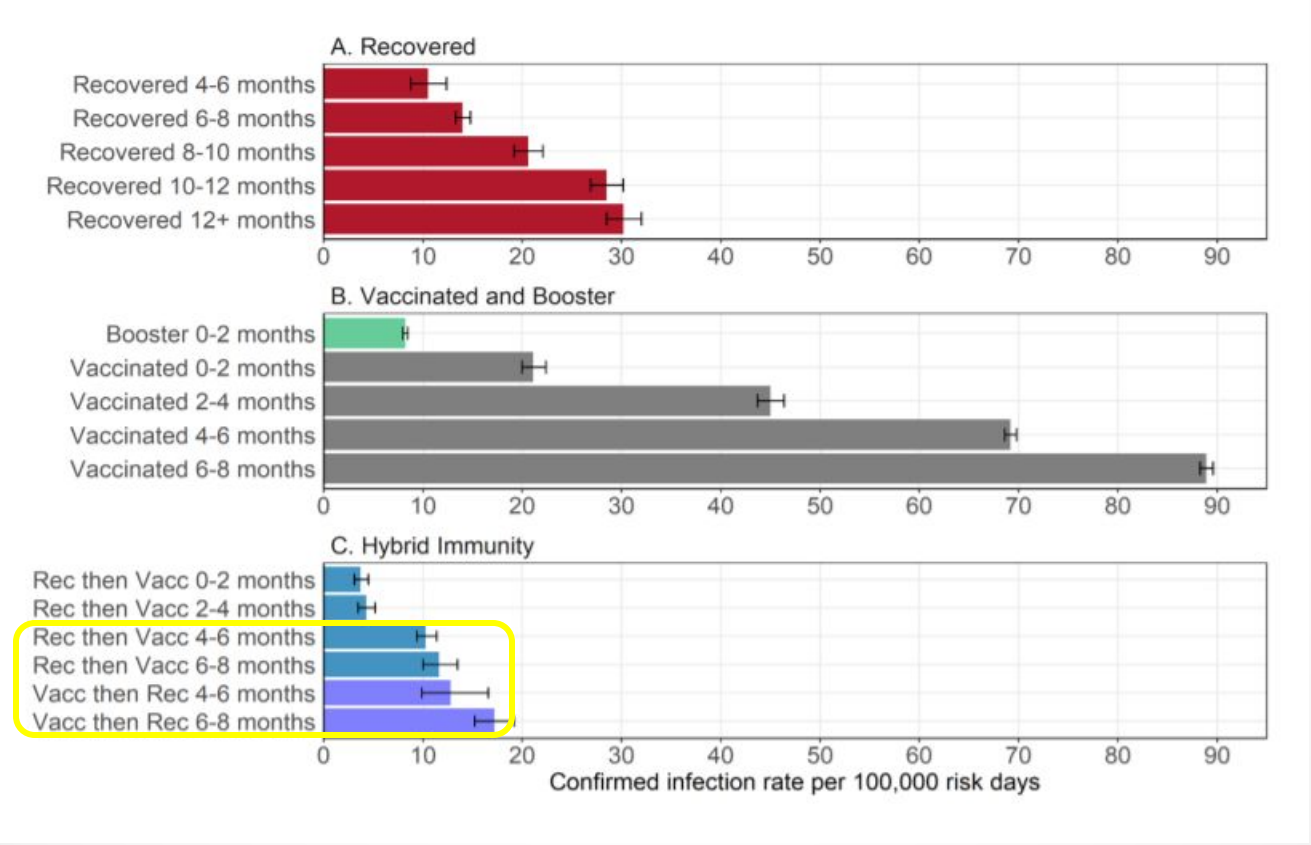
- https://www.medrxiv.org/content/10.1101/2021.10.25.21264964v1.full.pdf

Table 1

	N seropositivity		N antibody levels (AU/ml)	
	n pos / N (%pos)	prevalence ratio (95% CI)*	median (IQR)	geometric mean ratio (95% CI)*
Alpha				
unvaccinated	103 / 110 (94%)	1 (ref)	46.1 (13.2 - 104)	1 (ref)
single dose	125 / 142 (88%)	0.93 (0.86 - 1.01)	9.2 (3.1 - 31.6)	0.24 (0.15 - 0.38)
fully vaccinated	21 / 27 (78%)	0.84 (0.68 - 1.03)	6.3 (1.1 - 19)	0.19 (0.09 - 0.39)
Delta				
unvaccinated	23 / 24 (96%)	1 (ref)	39 (14.3 - 94.6)	1 (ref)
single dose	20 / 20 (100%)	1.02 (0.93 - 1.11)	29.9 (5.5 - 42.8)	0.52 (0.18 - 1.52)
fully vaccinated	42 / 44 (95%)	0.98 (0.88 - 1.09)	12.7 (5 - 34.6)	0.36 (0.15 - 0.86)

Israel (Goldberg)

- NI+vax>vax+infection (consistent with OAS)
- What about vax+boost+infection?



Jacobson and Lochner

- Jacobson decided Feb. 20, 1905 and Lochner argued Feb. 23, 1905 (same term)
- Lochner, "That case [Jacobson] is also far from covering the one now before the court."
- "It must, of course, be conceded that there is a limit to the valid exercise of the police power by the State. There is no dispute concerning this general proposition. Otherwise the Fourteenth Amendment would have no efficacy, and the legislatures of the States would have unbounded power, and it would be enough to say that any piece of legislation was enacted to conserve the morals, the health or the safety of the people; such legislation would be valid no matter how absolutely without foundation the claim might be. The claim of the police power would be a mere pretext -- become another and delusive name for the supreme sovereignty of the State to be exercised free from constitutional restraint."
- "It is a question of which of two powers or rights shall prevail -- the power of the State to legislate or the right of the individual to liberty of person and freedom of contract. The mere assertion that the subject relates though but in a remote degree to the public health does not necessarily render the enactment valid. The act must have a more direct relation, as a means to an end, and the end itself must be appropriate and legitimate, before an act can be held to be valid which interferes with the general right of an individual to be free in his person and in his power to contract in relation to his own labor."

Lochner (Holmes, Dissenting)

- "It is settled by various decisions of this court that state constitutions and state laws may regulate life in many ways which we, as legislators, might think as injudicious, or, if you like, as tyrannical, as this, and which, equally with this, interfere with the liberty to contract. Sunday laws and usury laws are ancient examples. A more modern one is the prohibition of lotteries. The liberty of the citizen to do as he likes so long as he does not interfere with the liberty of others to do the same, which has been a shibboleth for some well known writers, is interfered with by school laws, by the Post Office, by every state or municipal institution which takes his money for purposes thought desirable, whether he likes it or not. The Fourteenth Amendment does not enact Mr. Herbert Spencer's Social Statics. ***The other day, we sustained the Massachusetts vaccination law. Jacobson v. Massachusetts, 197 U. S. 11.***"
- "***I think that the word liberty in the Fourteenth Amendment is perverted when it is held to prevent the natural outcome of a dominant opinion***, unless it can be said that a rational and fair man necessarily would admit that the statute proposed would infringe fundamental principles as they have been understood by the traditions of our people and our law. It does not need research to show that no such sweeping condemnation can be passed upon the statute before us. A reasonable man might think it a proper measure on the score of health."

Buck v Bell (1927)

- Holmes's Revenge
- "Carrie Buck is a feeble minded white woman who was committed to the State Colony above mentioned in due form. She is the daughter of a feeble minded mother in the same institution, and the mother of an illegitimate feeble minded child."
- "An Act of Virginia, approved March 20, 1924, recites that the health of the patient and the welfare of society may be promoted in certain cases by the sterilization of mental defectives"
- "the sterilization may be effected …without serious pain or substantial danger to life; that the Commonwealth is supporting in various institutions many defective persons who, if now discharged, would become a menace, but, if incapable of procreating, might be discharged with safety and become self-supporting with benefit to themselves and to society"
- "**experience has shown that heredity plays an important part in the transmission of insanity, imbecility**, &c. The statute then enacts that, whenever the superintendent of certain institutions, including the above-named State Colony, shall be of opinion that it is for the best interests of the patients and of society that an inmate under his care should be sexually sterilized, he may have the operation performed upon any patient afflicted with hereditary forms of insanity, imbecility, &c., on complying with the very careful provisions by which the act protects the patients from possible abuse."

Scientific Consensus: Eugenics

- "It is better for all the world if, instead of waiting to execute degenerate offspring for crime or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. **The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. *Jacobson v. Massachusetts*, 197 U. S. 11. Three generations of imbeciles are enough.**"
- 32 US states passed sterilization laws between 1907-37 based on eugenic laws
- More than 60,000 people were sterilized
- Stern (2020): "The United States was an international leader in eugenics. Its sterilization laws actually informed Nazi Germany. The Third Reich's 1933 'Law for the Prevention of Offspring with Hereditary Diseases' was modeled on laws in Indiana and California."

Who was sterilized

- Stern (2020): "It is no coincidence that sterilization rates for Black women rose as desegregation got underway."
- Stern, "That Time the United States Sterilized 60,000 Of Its Citizens," Huffington Post (Jan 7, 2016)
- "those sterilized in state institutions often were young women pronounced promiscuous; the sons and daughters of Mexican, Italian, and Japanese immigrants, frequently with parents too destitute to care for them; and men and women who transgressed sexual norms. Preliminary statistical analysis demonstrates that during the peak decade of operations from 1935 to 1944 Spanish-surnamed patients were 3.5 times more likely to be sterilized than patients in the general institutional population"
- "Between 2006 and 2010, 146 female inmates in two of California's women's prisons received tubal ligations... The majority of these female inmates were first-time offenders, African-American or Latina. Echoing the rationale of the eugenicists who championed sterilization in the 1930s, the physician responsible for many of these operations blithely explained they would save the state a great deal of money 'compared to what you save in welfare paying for these unwanted children—as they procreated more.'"
- "These revelations demonstrate that, **even in our age of bioethics and awareness of the wrongs of medical experimentation, we are not immune from the conditions that facilitated compulsory sterilization in the mid-20th century**: lack of institutional oversight, presumptions that certain members of society are not 'fit' to reproduce, ***and overzealous and biased physicians. The documents we found certainly contain historical lessons for the present and starkly remind us that we should never forget the past***."

"Bodily Integrity"

- *Lochner*'s Revenge
- *Washington v. Harper* (1990): "The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty."
- *United States v. Charters* (1987):"The right to be free of unwanted physical invasions has been recognized as an integral part of the individual's constitutional freedoms."
- Mariner, et al., *Am J. Public Health* (2005): "Public health and constitutional law have evolved to better protect both health and human rights. States' sovereign power to make laws of all kinds has not changed in the past century. What has changed is the Court's recognition of the importance of individual liberty and how it limits that power. Preserving the public's health in the 21st century requires preserving respect for personal liberty."
- Prisoner compassionate release cases recognize protection of natural immunity

Washington v. Harper (1990)

- "We hold that, *given the requirements of the prison environment*, the Due Process Clause permits the State to treat a prison inmate who has a serious mental illness with antipsychotic drugs against his will, if the inmate is dangerous to himself or others *and the treatment is in the inmate's medical interest*."

Sell v. United States (2003)

- "[The] Constitution permits the Government involuntarily to administer antipsychotic drugs to a mentally ill defendant facing serious criminal charges in order to render that defendant competent to stand trial, *but only if the treatment is medically appropriate*, *is unlikely to have side effects* that may undermine the fairness of the trial, and, *taking account of less intrusive alternatives*, is *necessary to further important governmental* trial-related interests."

Skinner v. OK (1942)

- "But the instant legislation runs afoul of the equal protection clause, though we give Oklahoma that large deference which the rule of the foregoing cases requires. Marriage and procreation are fundamental to the very existence and survival of the race. The power to sterilize, if exercised, may have subtle, far-reaching and devastating effects. In evil or reckless hands, it can cause races or types which are inimical to the dominant group to wither and disappear. *There is no redemption for the individual whom the law touches. Any experiment which the State conducts is to his irreparable injury. He is forever deprived of a basic liberty.*"
- "We mention these matters not to reexamine the scope of the police power of the States. We advert to them merely in emphasis of our view that *strict scrutiny of the classification* which a State makes in a sterilization law is essential, lest unwittingly, or otherwise, invidious discriminations are made against groups or types of individuals in violation of the constitutional guaranty of just and equal laws."
- "The equal protection clause would indeed be a formula of empty words if such conspicuously artificial lines could be drawn."

Skinner v. OK

- Stone, C.J. (concurring): "And so I think the real question we have to consider is not one of equal protection, but whether the wholesale condemnation of a class to such an invasion of personal liberty, without opportunity to any individual to show that his is not the type of case which would justify resort to it, satisfies the demands of due process. There are limits to the extent to which the presumption of constitutionality can be pressed, especially where the liberty of the person is concerned (*see United States v. Carolene Products Co.,* 304 U. S. 144, 304 U. S. 152, n. 4) and where the presumption is resorted to only to dispense with a procedure which the ordinary dictates of prudence would seem to demand for the protection of the individual from arbitrary action…..Undoubtedly, a state may, after appropriate inquiry, constitutionally interfere with the personal liberty of the individual to prevent the transmission by inheritance of his socially injurious tendencies. *Buck v. Bell,* 274 U. S. 200. But, until now, we have not been called upon to say that it may do so without giving him a hearing *and opportunity to challenge the existence as to him of the only facts which could justify so drastic a measure*."
- Jackson, J. (concurring): "There are limits to the extent to which a legislatively represented majority may conduct biological experiments at the expense of the dignity and personality and natural powers of a minority -- even those who have been guilty of what the majority define as crimes."

Union Pacific v. Botsford (1891)

- "The single question presented by this record is whether, in a civil action for an injury to the person, the court, on application of the defendant and in advance of the trial may order the plaintiff without his or her consent, to submit to a surgical examination as to the extent of the injury sued for. We concur with the circuit court in holding that it had no legal right or power to make and enforce such an order. ***No right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear and unquestionable authority of law.*** As well said by Judge Cooley: "The right to one's person may be said to be a right of complete immunity; to be let alone." Cooley on Torts 29."

Other State Problems

- *Jacobson*: Police Power resides in legislature or express delegation, not executive, school boards, or university presidents
- No evidence of delegation of authority to compel involuntary and unnecessary medical treatment
- University Presidents have a public health policy power?

Immunity Requirements

- 12 VAC5-110-80B. “Exemptions from Immunization Requirements”: Demonstration of existing immunity. **The demonstration in a student of antibodies against mumps, measles, rubella, or varicella in sufficient quantity to ensure protection of that student against that disease**, shall render that student exempt from the immunization requirements contained in 12VAC5-110-70 for the disease in question. **Such protection should be demonstrated by means of a serological testing method appropriate for measuring protective antibodies** against mumps, measles, rubella, or varicella respectively. Reliable history of chickenpox disease diagnosed or verified by a health care provider shall render students exempt from varicella requirements.

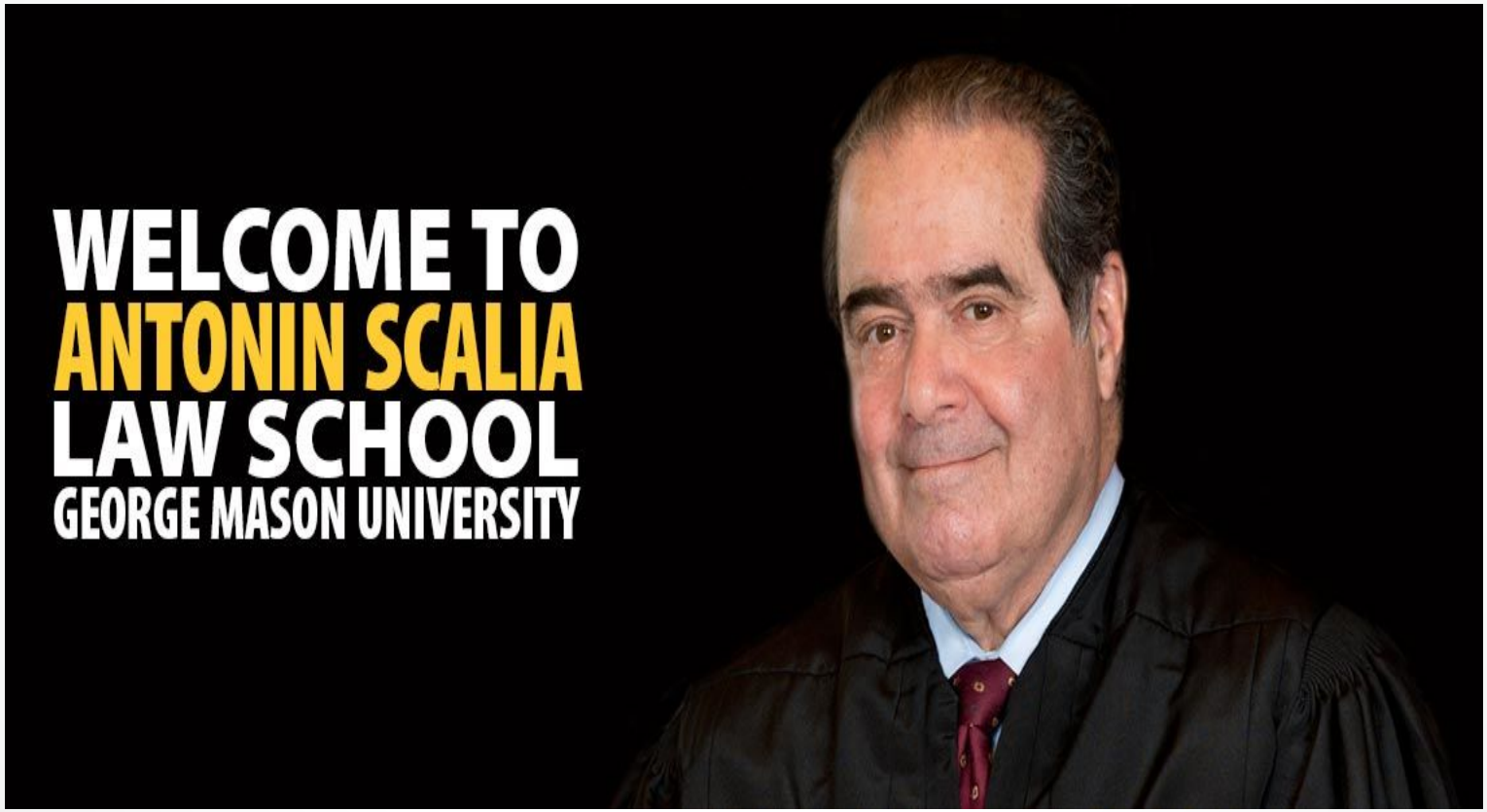
OSHA Rule

- No federal police power (*Jacobson*): "Although, therefore, one of the declared objects of the Constitution was to secure the blessings of liberty to all under the sovereign jurisdiction and authority of the United States, no power can be exerted to that end by the United States unless, apart from the Preamble, it be found in some express delegation of power or in some power to be properly implied therefrom. 1 Story's Const. § 462."
- OSHA "Emergency Temporary Standards": "necessary" to protect employees against "grave danger"from exposure to "substances or agents determined to be toxic or physically harmful or from new hazards"
- ETS can take effect immediately upon publication in the Federal Register but expires after 6 months and must be replaced by a permanent rule
- OSHA issued 9 ETSs between 1971-1983: 6 challenged and only 1 upheld
- Largely unused since invalidation of 1983 asbestos ETS

29 U.S.C. 655

- (6)(b)(5): “toxic materials or harmful physical agents”
- A “virus” is not a “toxic material” or “harmful physical agent” under any reasonable construction of OSH Act
- *Might* authorize requiring employers to provide adequate personal protective equipment especially in high-risk settings but a mask is different from a compelled medical treatment that might kill or injure you permanently

Thank You!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