

COVID-19 Vaccine Safety and Efficacy, Early Ambulatory Therapy, Rise of Autism and Transgenderism

Peter A. McCullough, MD, MPH, FACC, FAHA, FNI A



Author “Courage to Face COVID-19”
<https://couragetofacecovid.com/>
<http://petermcculloughmd.com>



Dr. McCullough is an internist, cardiologist, epidemiologist. He maintains ABIM certification in internal medicine and cardiovascular diseases. He practices both internal medicine including the management of common infectious diseases as well as the cardiovascular complications of both the viral infection and the injuries developing after the COVID-19 vaccine in Dallas TX, USA. Since the outset of the pandemic, Dr. McCullough has been a leader in the medical response to the COVID-19 disaster and has published “Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection” the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the *American Journal of Medicine* and subsequently updated in *Reviews in Cardiovascular Medicine*. He has numerous peer-reviewed publications on the infection and has commented extensively on the medical response to the COVID-19 crisis in *TheHill*, *FOX NEWS Channel*, *NewsMax*, *Real America*, *Victory Channel*, *ABC*, and *America Out Loud*. On November 19, 2020, June 27, 2022, and December 7, 2022, Dr. McCullough testified in the US Senate Committee on Homeland Security and Governmental Affairs and throughout 2021 in the Texas Senate Committee on Health and Human Services, Colorado General Assembly, Arizona Senate and House, Pennsylvania Senate, New Hampshire Senate, South Carolina Senate, and Mississippi House of Representatives concerning many aspects of the pandemic response. He has co-moderated two US Senate Panels on COVID-19 therapeutics and vaccines. Dr. McCullough has dedicated his academic and clinical efforts in combating the SARS-CoV-2 virus and in doing so, has reviewed thousands of reports, participated in scientific congresses, group discussions, press releases, and has been considered among the world’s experts on COVID-19.

Outline

- New biological products
- COVID-19 Vaccine Safety Review
- Real World Efficacy of COVID-19 Vaccines
- Pivot to Early Therapy for High-Risk COVID-19
- Natural Immunity
- Twin epidemics of autism and gender dysphoria
- Censorship of Scientific Discourse
- Conclusions

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September 17, 2021

Covid-19, Social Standing, and the New World Order

by [Wallace Garneau](#) | Sep 15, 2021

I have not had a Covid-19 vaccine. Let me open this article up right out of the gate by saying that. That does not mean I am anti-vaccine, or that I think the Covid-19 vaccines are unsafe or ineffective. I follow the science, and by that, I mean that I follow the...

COVID Q & A with Dr. Peter McCullough, #3

by [Malcolm Out Loud](#) | Sep 15, 2021

We, the general public are so

For New Biologic Products, Demand Safety, Safety, Safety

by [Dr. Peter McCullough](#) | Jun 5, 2021 | [Healthcare](#), [World](#)

This product of gain of function research in the Wuhan lab is what made SARS-CoV-2 super infectious and damaging to the body resulting in organ damage, respiratory failure, and blood clots. The CDC has verified a record 262,521 safety reports including 4,406 deaths, and 14,986 hospitalizations. These exceed the numbers for all previous vaccines in all years combined in history—making the COVID-19 the most dangerous vaccine of all time...





The great gamble of COVID-19 vaccine development

BY PETER A. MCCULLOUGH, OPINION CONTRIBUTOR — 08/17/20 10:30 AM EDT
THE VIEWS EXPRESSED BY CONTRIBUTORS ARE THEIR OWN AND NOT THE VIEW OF THE HILL

86 SHARES



Just In...

Extremely rare orange lobster saved from grocery store

CHANGING AMERICA
— 4M 43S AGO

Election denialists smacked down by Idaho Secretary of State

STATE WATCH — 9M 38S AGO

Leveling the playing field for recycled plastics

OPINION — 10M 39S AGO

Ocasio-Cortez blasts Texas abortion law defender: 'Sometimes it takes years' to recognize sexual assault

<https://thehill.com/opinion/healthcare/512191-the-great-gamble-of-covid-19-vaccine-development/>

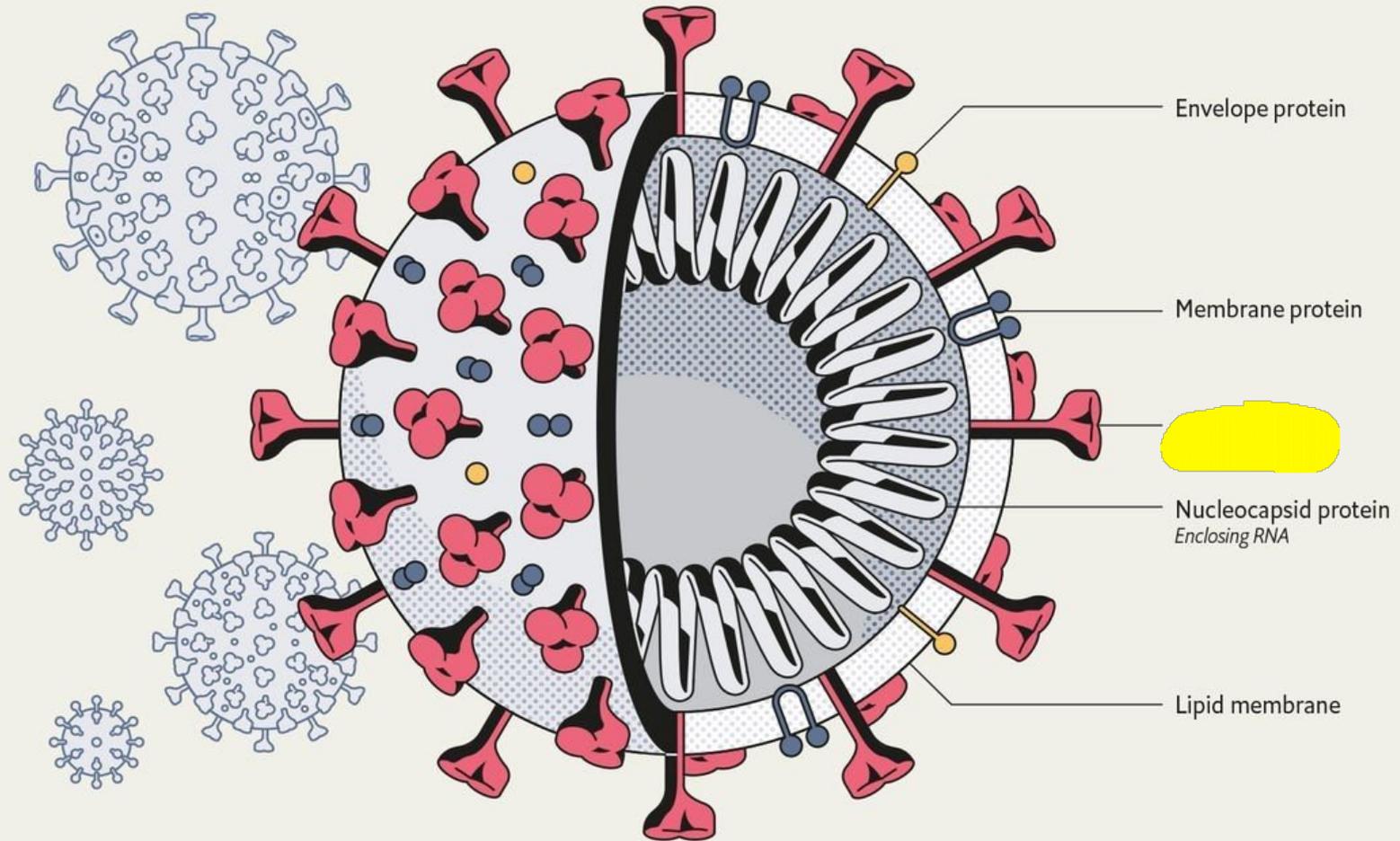


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We are over six months into the consequences of the SARS-Co-V2 pandemic in the United States. Patients, families and doctors are frightened, weary and frustrated by the lack of support from regulatory agencies — the National Institutes of Health, Food and Drug

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SARS-CoV-2 Structure



Manuel Bortoletti

Menachery VD, Yount BL Jr, Debbink K, Agnihothram S, Gralinski LE, Plante JA, Graham RL, Scobey T, Ge XY, Donaldson EF, Randell SH, Lanzavecchia A, Marasco WA, Shi ZL, Baric RS. A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence. *Nat Med*. 2015 Dec;21(12):1508-13. doi: 10.1038/nm.3985. Epub 2015 Nov 9. Erratum in: *Nat Med*. 2016 Apr;22(4):446. Erratum in: *Nat Med*. 2020 Jul;26(7):1146. PMID: 26552008; PMCID: PMC4797993

Menachery VD, Yount BL Jr, Sims AC, Debbink K, Agnihothram SS, Gralinski LE, Graham RL, Scobey T, Plante JA, Royal SR, Swanstrom J, Sheahan TP, Pickles RJ, Corti D, Randell SH, Lanzavecchia A, Marasco WA, Baric RS. SARS-like WIV1-CoV poised for human emergence. *Proc Natl Acad Sci U S A*. 2016 Mar 15;113(11):3048-53. doi: 10.1073/pnas.1517719113. Epub 2016 Mar 14. PMID: 26973027; PMCID: PMC4612644

Congress of the United States

Washington, DC 20515

MEMORANDUM

TO: Select Subcommittee on the Coronavirus Pandemic Members

FROM: Select Subcommittee on the Coronavirus Pandemic Majority Staff

DATE: March 5, 2023

RE: New Evidence Resulting from the Select Subcommittee’s Investigation into the Origins of COVID-19 – “The Proximal Origin of SARS-CoV-2”

On February 1, 2020, Dr. Anthony Fauci, Dr. Francis Collins, and at least eleven other scientists convened a conference call to discuss COVID-19.¹ It was on this conference call that Drs. Fauci and Collins were first warned that COVID-19 may have leaked from a lab in Wuhan, China and, further, may have been intentionally genetically manipulated.²

Only three days later, on February 4, 2020, four participants of the conference call authored a paper entitled “The Proximal Origin of SARS-CoV-2” (Proximal Origin) and sent a draft to Drs. Fauci and Collins.³ Prior to final publication in *Nature Medicine*, the paper was sent to Dr. Fauci for editing and approval.⁴

On April 16, 2020, slightly more than two months after the original conference call, Dr. Collins emailed Dr. Fauci expressing dismay that Proximal Origin—which they saw prior to publication and were given the opportunity to edit—did not squash the lab leak hypothesis and asks if the NIH can do more to “put down” the lab leak hypothesis.⁵ The next day—after Dr. Collins explicitly asked for more public pressure—Dr. Fauci cited Proximal Origin from the White House podium when asked if COVID-19 leaked from a lab.⁶

Creation of SARS Chimeric

LETTERS

nature
medicine

VOLUME 21 | NUMBER 12 | DECEMBER 2015 NATURE MEDICINE



A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence

Vineet D. Menachery¹, Boyd L. Yount Jr.², Kari Debbink^{1,2}, Sudhakar Agnihotram³, Lisa E. Gralinski¹, Jessica A. Plante¹, Rachel L. Graham¹, Trevor Scobey¹, Xing-Yi Ge⁴, Eric F. Donaldson¹, Scott H. Randell^{5,6}, Antonio Lanzavecchia⁷, Wayne A. Marasco⁸, Zhenqi-Li Shi⁹ & Ralph S. Baric^{1,2}

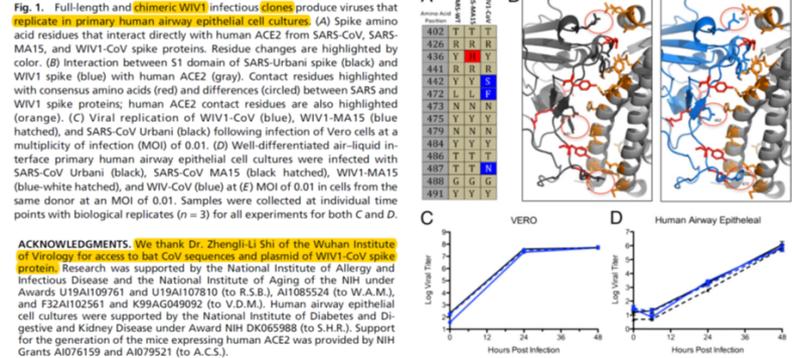
CoV, which is currently circulating in Chinese horseshoe bat populations¹. Using the SARS-CoV reverse genetics system², we generated and characterized a chimeric virus expressing the spike of bat coronavirus SHC014 in a mouse-adapted SARS-CoV backbone. The results indicate that group 2b viruses encoding the SHC014 spike in a wild-type backbone can efficiently use multiple orthologs of the SARS receptor human angiotensin converting enzyme II (ACE2), replicate efficiently in primary human airway cells and achieve *in vitro* titers equivalent to epidemic strains of SARS-CoV. Additionally, *in vivo* experiments demonstrate replication of the chimeric virus in mouse lung with notable pathogenesis. Evaluation of available SARS-based immune-therapeutic and prophylactic modalities revealed poor efficacy; both monoclonal antibody and vaccine approaches failed to neutralize and protect from infection with CoVs using the novel spike protein. On the basis

SARS-like WIV1-CoV poised for human emergence

Vineet D. Menachery¹, Boyd L. Yount Jr.², Amy C. Sims³, Kari Debbink^{4,5}, Sudhakar S. Agnihotram⁶, Lisa E. Gralinski¹, Rachel L. Graham¹, Trevor Scobey¹, Jessica A. Plante¹, Scott R. Royal⁷, Jessica Swanstrom⁸, Timothy P. Sheahan⁹, Raymond J. Pickles^{4,5}, Davide Corti¹⁰, Scott H. Randell¹¹, Antonio Lanzavecchia¹², Wayne A. Marasco¹³, and Ralph S. Baric^{1,2}

¹Department of Epidemiology, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599; ²Department of Microbiology and Immunology, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599; ³Division of Microbiology, National Center for Toxicological Research, Food and Drug Administration, Jefferson, AR 72079; ⁴Department of Cell Biology and Physiology and Maricopa Lung Institute/Cystic Fibrosis Center, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599; ⁵Institute for Research in Biomedicine, Bellinzona, Switzerland; ⁶Institute of Microbiology, Eidgenössische Technische Hochschule Zurich, Zurich, Switzerland; ⁷Humana BioMed SA, Bellinzona, Switzerland; ⁸Department of Cancer Immunology and AIDS, Dana-Farber Cancer Institute-Department of Medicine, Harvard Medical School, Boston MA 02215

Edited by Peter Palese, Icahn School of Medicine at Mount Sinai, New York, NY, and approved January 6, 2016 (received for review September 4, 2015)



Scientific Fraud to Cover Up Lab Origin

NATURE MEDICINE | VOL 26 | APRIL 2020 | 450-455 | www.nature.com/naturemedicine

correspondence



Kristian G. Andersen^{1,2,3}
Andrew Rambaut⁴, W. Ian Lipkin⁵,
Edward C. Holmes⁶ and Robert F. Garry⁷
¹Department of Immunology and Microbiology,
²The Scripps Research Institute, 124, India, CA, USA

The proximal origin of SARS-CoV-2

To the Editor — Since the first reports of novel pneumonia (COVID-19) in Wuhan, Hubei province, China^{1,2}, there has been considerable discussion on the origin of the causative virus, SARS-CoV-2 (also referred to as HCoV-19)³. Infections with SARS-CoV-2 are now widespread, and as of 11 March 2020, 121,564 cases have been confirmed in more than 110 countries, with 4,373 deaths⁴. SARS-CoV-2 is the seventh coronavirus known to infect humans; SARS-CoV, MERS-CoV and SARS-CoV-2 can cause severe disease, whereas HKU1, NL63, OC43 and 229E are associated with mild symptoms⁵. Here we review what can be deduced about the origin of SARS-CoV-2 from comparative analysis of genomic data. We offer a perspective on the notable features of the SARS-CoV-2 genome and discuss scenarios by which they could have arisen. Our analyses clearly show that SARS-CoV-2 is not a laboratory construct or a purposefully manipulated virus.

While the analyses above suggest that SARS-CoV-2 may bind human ACE2 with high affinity, computational analyses predict that the interaction is not ideal⁶ and that the RBD sequence is different from those shown in SARS-CoV to be optimal for receptor binding^{7,8}. Thus, the high-affinity binding of the SARS-CoV-2 spike protein to human ACE2 is most likely the result of natural selection on a human or human-like ACE2 that permits another optimal binding solution to arise. This is strong evidence that SARS-CoV-2 is not the product of purposeful manipulation.

2. Polybasic furin cleavage site and O-linked glycans. The second notable feature of SARS-CoV-2 is a polybasic cleavage site (RRAR) at the junction of S1 and S2, the two subunits of the spike⁹ (Fig. 1b). This allows effective cleavage by furin and other proteases and has a role in determining viral infectivity and host range¹⁰. In addition, a leading proline is also inserted at this site in SARS-CoV-2; thus,

low-pathogenicity avian influenza viruses into highly pathogenic forms¹¹. The acquisition of polybasic cleavage sites by HA has also been observed after repeated passage in cell culture or through animals¹². The function of the predicted O-linked glycans is unclear, but they could create a 'mucin-like domain' that shields epitopes or key residues on the SARS-CoV-2 spike protein¹³. Several viruses utilize mucin-like domains as glycan shields involved in immunoevasion¹⁴. Although prediction of O-linked glycosylation is robust, experimental studies are needed to determine if these sites are used in SARS-CoV-2.

Theories of SARS-CoV-2 origins It is improbable that SARS-CoV-2 emerged through laboratory manipulation of a related SARS-CoV-like coronavirus. As noted above, the RBD of SARS-CoV-2 is optimized for binding to human ACE2 with an efficient solution different from those previously predicted¹⁵. Furthermore, if

4852 Cell 184, September 16, 2021

OPEN ACCESS

Review

The origins of SARS-CoV-2: A critical review

Edward C. Holmes,^{1,*} Stephen A. Goldstein,² Angela L. Rasmussen,³ David L. Robertson,⁴ Alexander Crits-Christoph,⁵ Joel O. Wertheim,⁶ Simon J. Anthony,⁷ Wendy S. Barclay,⁸ Maciej F. Boni,⁹ Peter C. Doherty,¹⁰ Jeremy Farrar,¹¹ Jemma L. Geoghegan,^{12,13} Xiaowei Jiang,¹⁴ Julian L. Leibowitz,¹⁵ Stuart J.D. Neil,¹⁶ Tim Skern,¹⁷ Susan R. Weiss,¹⁸ Michael Worobey,¹⁹ Kristian G. Andersen,²⁰ Robert F. Garry,^{21,22} and Andrew Rambaut^{23,*}
¹Marie Bashir Institute for Infectious Diseases and Biosecurity, School of Life and Environmental Sciences and School of Medical Sciences, The University of Sydney, Sydney, NSW 2006, Australia

CONCLUSIONS

sen et al., 2020). There is no rational experimental reason why a new genetic system would be developed using an unknown and unpublished virus, with no evidence nor mention of a SARS-CoV-2-like virus in any prior publication or study from the WIV (Ge et al., 2012; Hu et al., 2017; Menachery et al., 2015), no evidence that the WIV sequenced a virus that is closer to SARS-CoV-2 than RaTG13, and no reason to hide research on a SARS-CoV-2-like virus prior to the COVID-19 pandemic. Under

As for the vast majority of human viruses, the most parsimonious explanation for the origin of SARS-CoV-2 is a zoonotic event. The documented epidemiological history of the virus is comparable to previous animal market-associated outbreaks of coronaviruses with a simple route for human exposure. The contact tracing of SARS-CoV-2 to markets in Wuhan exhibits striking similarities to the early spread of SARS-CoV to markets in Guangdong, where humans infected early in the epidemic lived near or worked in animal markets. Zoonotic spillover by definition selects for viruses able to infect humans. Although strong safeguards should be consistently employed to minimize the likelihood of laboratory accidents in virological research, those laboratory escapes documented to date have almost exclusively involved viruses brought into laboratories specifically because of their known human infectivity.

There is currently no evidence that SARS-CoV-2 has a laboratory origin. There is no evidence that any early cases had any connection to the WIV, in contrast to the clear epidemiological

Cell
Leading Edge

COVID-19 Vaccines: Characteristics, Mechanism of Production, Dosing, Storage

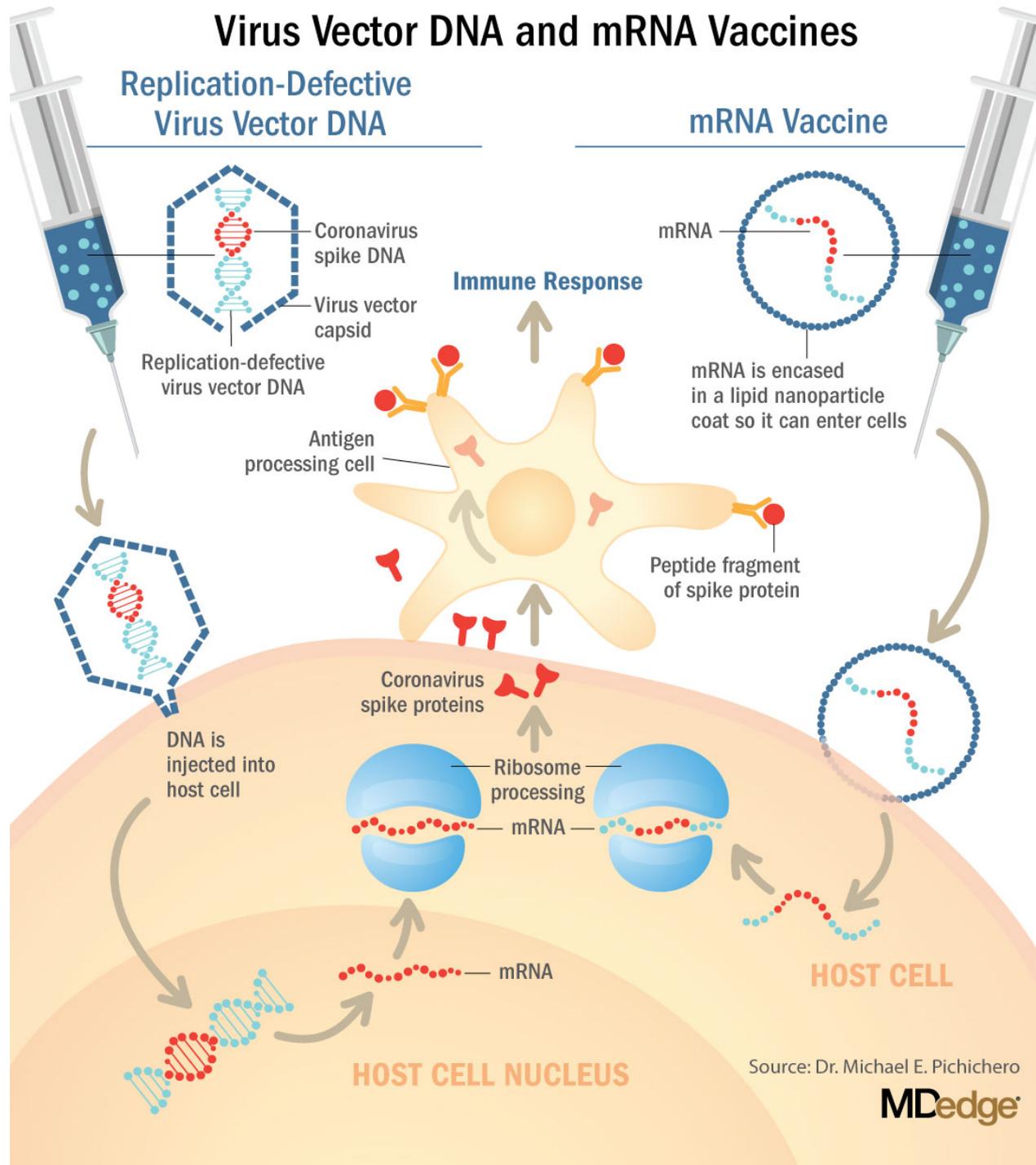
More than 100 vaccines have been developed against SARS-CoV-2, 26 of which have been evaluated in phase III clinical trials according to the World Health Organization (WHO) [1]. *Vaccines* 2022, 10, 961

Compound (Trade Name)	Manufacturer	Mechanism	Doses Needed	Interval	Storage (°C)
BNT162b2 (Comirnaty)	Pfizer/BioNTech	mRNA	2	21 d	-70
mRNA-1273 (Spikevax)	Moderna	mRNA	2	28 d	-20
ChAdOx1 nCoV-19 (Vaxzevria)	AstraZeneca/Oxford	AdV-vectored	2	4–12 wk	2–8
Ad26.CoV2.S	Johnson & Johnson	AdV-vectored	1	-	2–8
Gam-COVID-Vac (Sputnik V)	Gamaleya Research Institute	AdV-vectored	2	21 d	-18
Ad5-nCoV (Convidecia)	CanSino	AdV-vectored	1	-	-20
NVX-CoV2373 (Covovax)	Novavax	Protein subunit	2	21 d	-20
EpiVacCorona (Aurora-CoV)	Vector Institute	Protein subunit	2	21 d	2–8
BBIBP-CorV (Covilo)	Sinopharm (Beijing)	Inactivated virus	2	21–28 d	2–8
WIBP-CorV	Sinopharm (Wuhan)	Inactivated virus	2	14–21 d	2–8
Vero cell (CoronaVac)	Sinovac Biotech	Inactivated virus	2	28 d	2–8
BBV152 (Covaxin)	Bharat Biotech	Inactivated virus	2	28 d	2–8

AdV, adenovirus; d, days; n.a., not available; wk, weeks.

Fiolet, T.; Kherabi, Y.; MacDonald, C.J.; Ghosn, J.; Peiffer-Smadja, N. Comparing COVID-19 vaccines for their characteristics, efficacy and effectiveness against SARS-CoV-2 and variants of concern: A narrative review. *Clin. Microbiol. Infect.* **2022**, *28*, 202–221. [[CrossRef](#)] [[PubMed](#)]

Virus Vector DNA and mRNA Vaccines



Clinical Concerns

- mRNA or adenoviral DNA induce production of the Spike protein
 - Cell, tissue, organ endothelial damage
 - Spike protein in body fluids, donated blood
- No genotoxicity, teratogenicity, or oncogenicity studies
- Concerning ovarian biodistribution study (Pfizer, Japan)
- Concerning reduced fertility study (Moderna, EMA)
- No EAC, DSMB, Human Ethics Committee
- No restriction of properly excluded groups from RCTs
 - Pregnant women, women of childbearing potential
 - COVID survivors, previously immune
- No risk stratification for hospitalization and death
- No data transparency
- No mitigation of risks for public
- No assurances on long-term safety

practices, emphasizing critical questions that require urgent answers, particularly in
we wish to restore confidence in science and public health.

Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination

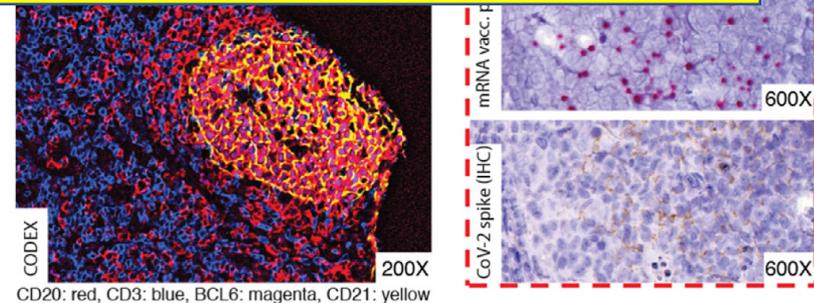
Katharina Röltgen,^{1,14} Sandra C.A. Nielsen,^{1,14} Oscar Silva,^{1,14} Sheren F. Younes,^{1,14} Maxim Zaslavsky,¹ Cristina Costales,¹ Fan Yang,¹ Oliver F. Wirz,¹ Daniel Solis,¹ Ramona A. Hoh,¹ Aihui Wang,¹ Prabhu S. Arunachalam,² Deana Colburg,¹ Shuchun Zhao,¹ Emily Haraguchi,¹ Alexandra S. Lee,³ Mihir M. Shah,³ Monali Manohar,³ Iris Chang,³ Fei Gao,² Vamsee Mallajosyula,² Chunfeng Li,² James Liu,⁴ Massa J. Shoura,¹ Sayantani B. Sindher,³ Ella Parsons,³ Naranjargal J. Dashdorj,^{5,6} Naranbaatar D. Dashdorj,⁵ Robert Monroe,⁷ Geidy E. Serrano,⁸ Thomas G. Beach,⁸ R. Sharon Chinthrajah,^{3,9} Gregory W. Charville,¹ James L. Wilbur,¹⁰ Jacob N. Wohlstadter,¹⁰ Mark M. Davis,^{2,11,12} Bali Pulendran,^{1,2,11} Megan L. Troxell,¹ George B. Sigal,¹⁰ Yasodha Natkunam,¹ Benjamin A. Pinsky,^{1,13} Kari C. Nadeau,^{3,9,15} and Scott D. Boyd^{1,3,15,16,*}

¹Department of Pathology, Stanford University, Stanford, CA, USA

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mRNA found in lymph nodes at 60 days

detected vaccine mRNA in the GCs of LNs on days 7, 16, and 37 postvaccination, with lower but still appreciable specific signal at day 60 (Figures 7A–7E). Only rare foci of vaccine mRNA were seen outside of GCs. Axillary LN core needle biopsies of nonvaccinees (n = 3) and COVID-19 patient specimens were negative for vaccine probe hybridization. Immunohistochemical staining for spike antigen in mRNA-vaccinated patient LNs varied between individuals but showed abundant spike protein in GCs 16 days post-second dose, with spike antigen still present as late as 60 days post-second dose. Spike antigen localized in a reticular pattern around the GC cells, similar to staining for follicular dendritic cell processes (Figure 7B).



*Correspondence: publications_scott_boyd@stanford.edu
<https://doi.org/10.1016/j.cell.2022.01.018>



SHORT COMMUNICATIONS

**SARS-CoV-2 spike mRNA vaccine sequences circulate
in blood up to 28 days after COVID-19 vaccination**

**Circulating mRNA in
blood 28 days after
injection**

RESEARCH LETTER

Detection of Messenger RNA COVID-19 Vaccines in Human Breast Milk

Author Affiliations: Division of Neonatology, Department of Pediatrics, NYU Langone Hospital-Long Island, NYU Long Island School of Medicine, Mineola, New York (Hanna, Heffes-Doon, Nayak); Women and Children's Research Laboratory, NYU Long Island School of Medicine, Mineola, New York (Lin, Manzano De Mejia, Botros, Gurzenda).

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Nazeeh Hanna, MD
Ari Heffes-Doon, MD
Xinhua Lin, PhD
Claudia Manzano De Mejia, MD
Bishoy Botros, BS
Ellen Gurzenda, BS
Amrita Nayak, MD



be transported to distant cells. Little has been reported on lipid nanoparticle biodistribution and localization in human tissues after COVID-19 mRNA vaccination. In rats, up to 3 days following intramuscular administration, low vaccine mRNA levels were detected in the heart, lung, testis, and brain tissues, indicating tissue biodistribution.⁴ We speculate that, following the vaccine administration, lipid nanoparticles containing the vaccine mRNA are carried to mammary glands via hematogenous and/or lymphatic routes.^{5,6} Furthermore,

Circulating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine Antigen Detected in the Plasma of mRNA-1273 Vaccine

and induced an immune response [2–5]. However, critical data demonstrating the direct production of spike protein via translation from the mRNA-1273 vaccine in these studies are missing, precluding a full understanding of the vaccine mechanism.

Here we provide evidence that circulating SARS-CoV-2

**Circulating Spike protein
in blood Day 1 to average
of 15 days after injection
(longest was 29 days)**

SARS-CoV-2 S1 Protein Persistence in SARS-CoV-2 Negative Post-Vaccination Individuals with Long COVID/ PASC-Like Symptoms

PASC=post acute sequelae of COVID-19 vaccination

We determined that post-vaccination individuals with PASC-like symptoms had similar symptoms to PASC patients. When analyzing their immune profile, post-vaccination individuals had statistically significant elevations of sCD40L, CCL5, IL-6, and IL-8. SARS-CoV-2 S1 and S2 protein were detected in CD16 + monocytes using flow cytometry and mass spectrometry on sorted cells.

Bruce (✉ brucep@incelldx.com)

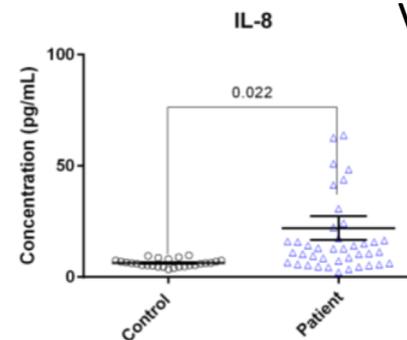
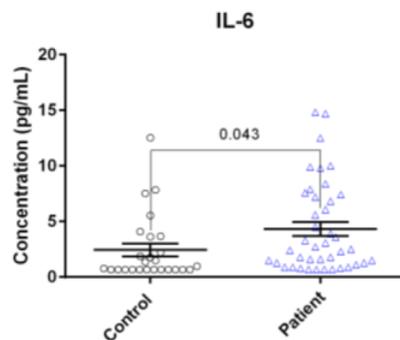
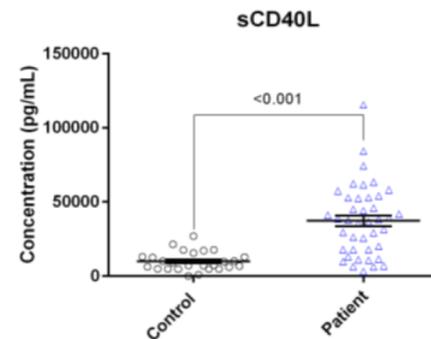
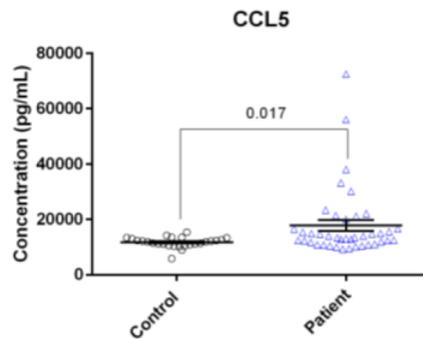
IncellDx

Edgar B. Francisco

IncellDx Inc

Ram Yogendra

Lawrence General Hospital, Lawrence, MA



Maximum duration after Vaccination=245 days

Outline

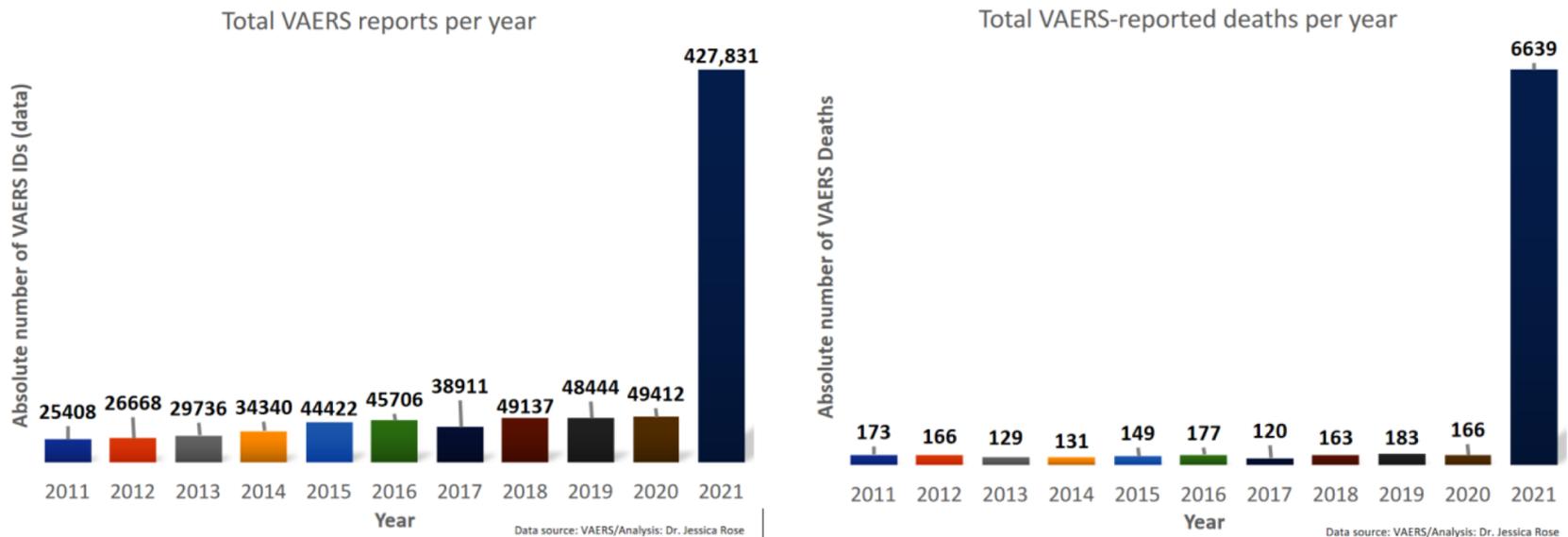
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Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System?

Jessica Rose, PhD, MSc, BSc

Figure 1: Bar plots showing the number of VAERS reports (left) and reported deaths (right) per year for the past decade. (2021 is partial data set.)

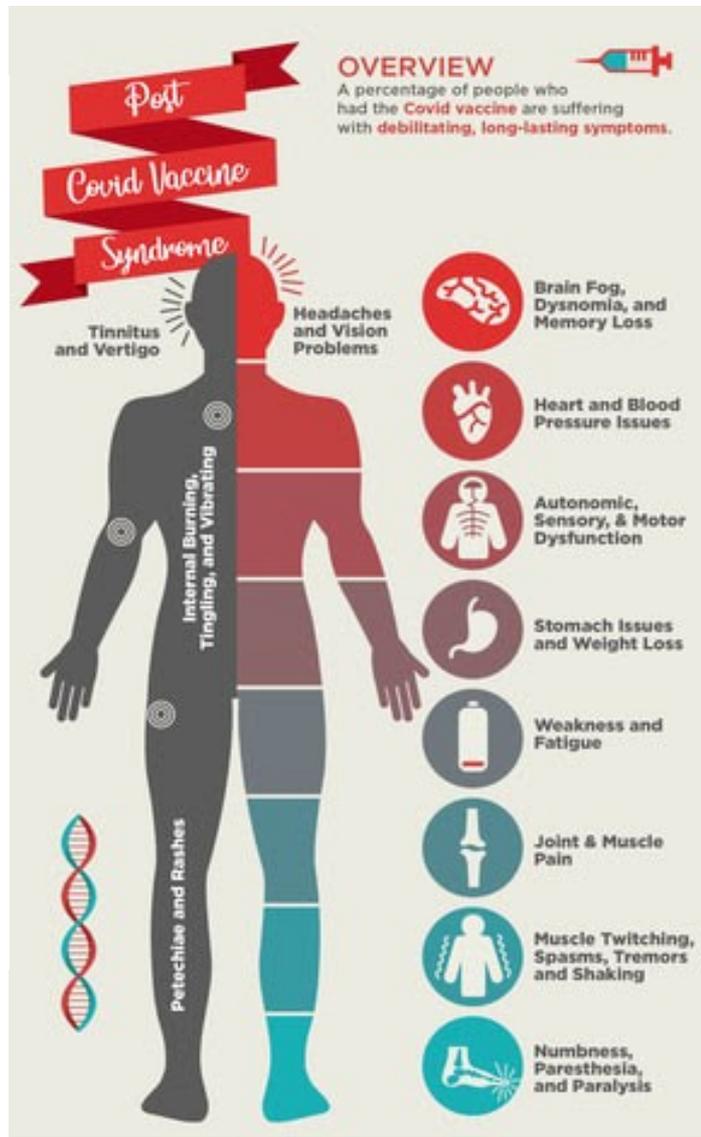
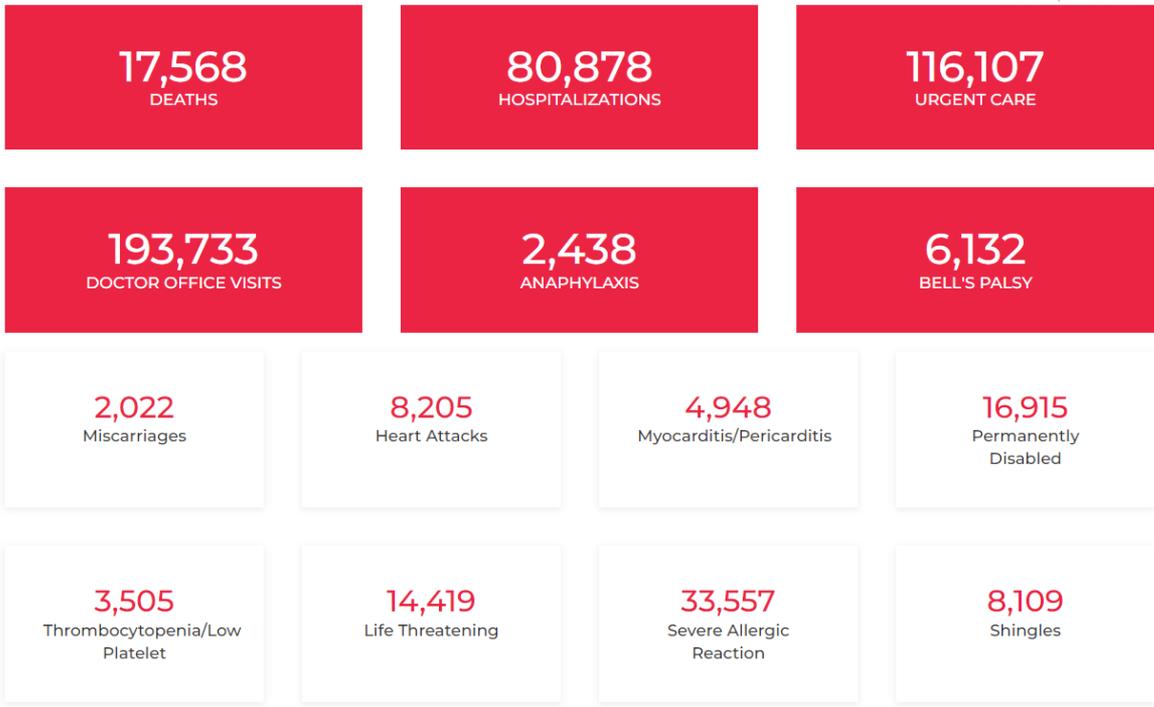




All VAERS COVID Reports US/Territories/Unknown

961,352 Reports Through May 12, 2023

source: OpenVAERS.com



Wiseman in FDA testimony estimates that the underreporting from VAERS on death after COVID-19 vaccination is 35.

<https://www.regulations.gov/comment/CDC-2021-0089-0023>

Historical PreCOVID ~280M Injections/year:

All ~70 vaccines average expected 16,320 VAERS total reports/yr, ~158 total deaths/yr

Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine

Max Schmeling¹ | Vibeke Manniche² | Peter Riis Hansen³ 

¹Innometric, Skørping, Denmark

²LIVA, Copenhagen, Denmark

Potential Explanations-Lot Variability

- 1) Hyper-concentration of mRNA (aggregation of LNP)
- 2) cDNA contamination
- 3) Other impurities

FIGURE 1. Safety events (SAEs) after BNT162b2 mRNA vaccination in Denmark (27 December 2020–11 January 2021) by number of doses per vaccine batch. Each dot represents a single vaccine batch. Trendlines are linear regression lines. Blue trendline: $R^2=0.68$, $\beta=0.000087$ (95% confidence interval [CI] 0.000056–0.000118), yellow: $R^2=0.89$, $\beta=0.0025$ (95% CI 0.0021–0.0029), green: $R^2=0.68$, $\beta=0.000087$ (95% CI 0.000056–0.000118). Vaccine batches representing the blue, green and yellow trendlines comprised 4.22%, 63.69% and 32.09% of all vaccine doses, respectively, with 70.78%, 27.49% and 47.15% (blue trendline), 28.84%, 71.50% and 51.99% (green trendline), and 0.38%, 1.01%, and 0.86% (yellow trendline) of all SAEs, serious SAEs, and SAE-related deaths, respectively.

HEALTH VIEWPOINTS

COVID-19 Vaccine Serious Adverse Events (SAE)

1. Cardiovascular

- Acceleration of atherosclerosis (heart, attack, stroke)
- Myocarditis
- Lethal arrhythmias (cardiac arrest)
- Heart rate/blood pressure problems (POTS, autonomic dysfunction)

2. Neurological

- Hemorrhagic stroke
- Neuropsychiatric/neurodegenerative diseases
- Seizures
- Peripheral neuropathy

3. Hematological

- Blood clots

4. Immunologic

- Immune blood disorders
- Multisystem inflammatory disorders

Blaylock RL. COVID UPDATE: What is the truth? Surg Neurol Int. 2022 Apr 22;13:167. doi: 10.25259/SNI_150_2022. PMID: 35509555; PMCID: PMC9062939.

[1250+ COVID Vaccine Publications and Case Reports](#), Scientific Publications & Case Reports Collection of peer reviewed case reports and studies citing adverse effects post COVID vaccination. Researching Covid vaccine adverse events can be daunting in part due to a broad myriad of factors. <https://react19.org/scientific-articles/>

Latest Bad News About COVID Vaccines

'Died Suddenly'? More Than 1-in-4 Think Someone They Know Died From COVID-19 Vaccines

Monday, January 02, 2023



Nearly half of Americans think COVID-19 vaccines may be to blame for many unexplained deaths, and more than a quarter say someone they know could be among the victims.

The latest Rasmussen Reports national telephone and online survey finds that (49%) of American Adults believe it is likely that side effects of COVID-19 vaccines have caused a significant number of unexplained deaths, including 28% who think it's Very Likely. Thirty-seven percent (37%) don't say a significant number of deaths have been caused by vaccine side effects, including 17% who believe it's Not At All Likely. Another 14% are not sure. (To see survey question wording, [click here](#).)

Spiro P. Pantazatos^{1,*} and Hervé Seligmann²

From 0-20 weeks post
injection there were
146-187k vaccine
associated deaths

... young adults, and older adults with low occupational risk or previous
... exposure. Our findings raise important questions about current COVID mass
vaccination strategies and warrant further investigation and review.

RESEARCH

Open Access

COVID-19 vaccine causalities may be as high as 278k in 2021

ination. With these sur... number of fatalities due to COVID-19 inoculation may be as high as 278,000
(95% CI 217,330–332,608) when... fatalities that may have occurred regardless of inoculation are removed.

Analysis of COVID-19 vaccine death reports from the Vaccine Adverse Events Reporting System (VAERS) Database

ResearchGate

Interim Results and Analysis

Scott McLachlan, Magda Osman, Kudakwashe Dube, Patience Chiketero, Yvonne Choi,
Norman Fenton

Risk and Information Management, Queen Mary University of London, UK

Birmingham Law School, University of Birmingham, UK

School of Biological and Chemical Sciences, Queen Mary University of London, UK

School of Fundamental Sciences, Massey University, NZ

Occupational Health and Wellbeing, Network Rail, UK

Health Informatics and Knowledge Engineering Research (HiKER) Group

McLachlan, Scott & Osman, Magda & Dube, Kudakwashe & Chiketero, Patience & Choi, Yvonne & Fenton, Norman. (2021). Analysis of COVID-19 vaccine death reports from the Vaccine Adverse Events Reporting System (VAERS) Database Interim Results and Analysis. 10.13140/RG.2.2.26987.26402.

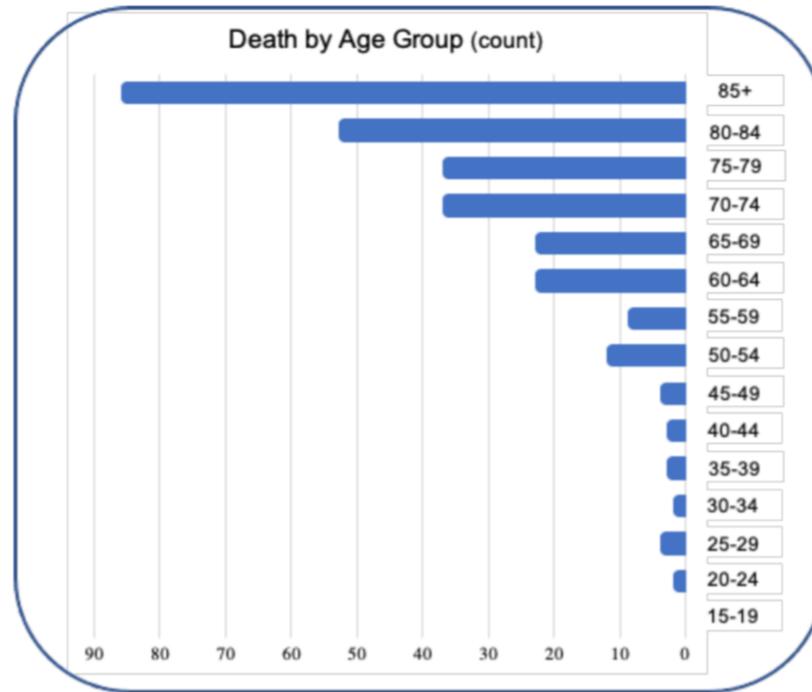


Figure 3: Death by Age Group

Much has been made in the media and academic literature about the need for protection and early vaccination of those aged 65 years and over. We believe this focus is the primary reason that 80% of the post-vaccination decedents reported are in this age group. Almost one-tenth (9%) expired within only 6 hours of their vaccination and 18% died in less than 12 hours. Over one third (36%) did not survive through to the following day.

Ml
fr
McLachlan, Scott & Osman, Magda & Dube, Kudakwashe & Chiketero, Patience & Choi, Yvonne & Fenton, Norman. (2021). Analysis of COVID-19 vaccine death reports from the Vaccine Adverse Events Reporting System (VAERS) Database Interim Results and Analysis. 10.13140/RG.2.2.26987.26402.

ht
352837543
https://www.researchgate.net/publication/352837543_Analysis_of_COVID-19_vaccine_death_reports_from_the_Vaccine_Adverse_Events_Reporting_System_VAERS_Database_Interim_Results_and_Analysis

JULY 27, 2022

15% of American Adults Diagnosed With New Condition After COVID Vaccine, Zogby Survey Finds



Press Release

[Return to Press Releases](#)

15% of vaccinated have
a new medical problem
(heart, blood clots,
autoimmune, menstrual, etc)

...ual cycle/Guillain-Barré/Bell's palsy
Regarding describing the conditions, 47% report mild, 43% report serious and 10% report
severe/still recovering.

3400 COVID Vaccine Publications and Case Reports

Are we missing a few? Please email us and let us know. This document is for informational purposes only. React 19 does not diagnose medical conditions, offer treatment advice, treat illnesses, or prescribe medicine or...

READ MORE



Article

Intramyocardial Inflammation after COVID-19 Vaccination: An Endomyocardial Biopsy-Proven Case Series

Christian Baumeier ^{1,*}, Ganna Aleshcheva ¹, Dominik Harms ¹, Ulrich Gross ¹, Christian Hamm ^{2,3}, Birgit Assmus ³ , Ralf Westenfeld ⁴, Malte Kelm ⁴, Spyros Rammos ⁵ , Philip Wenzel ⁶ , Thomas Münzel ⁶ , Albrecht Elsässer ⁷, Mudather Gailani ⁸, Christian Perings ⁹, Alae Bourakkadi ¹⁰, Markus Flesch ¹¹, Tibor Kempf ¹², Johann Bauersachs ¹², Felicitas Escher ^{1,13,14}  and Heinz-Peter Schultheiss ¹

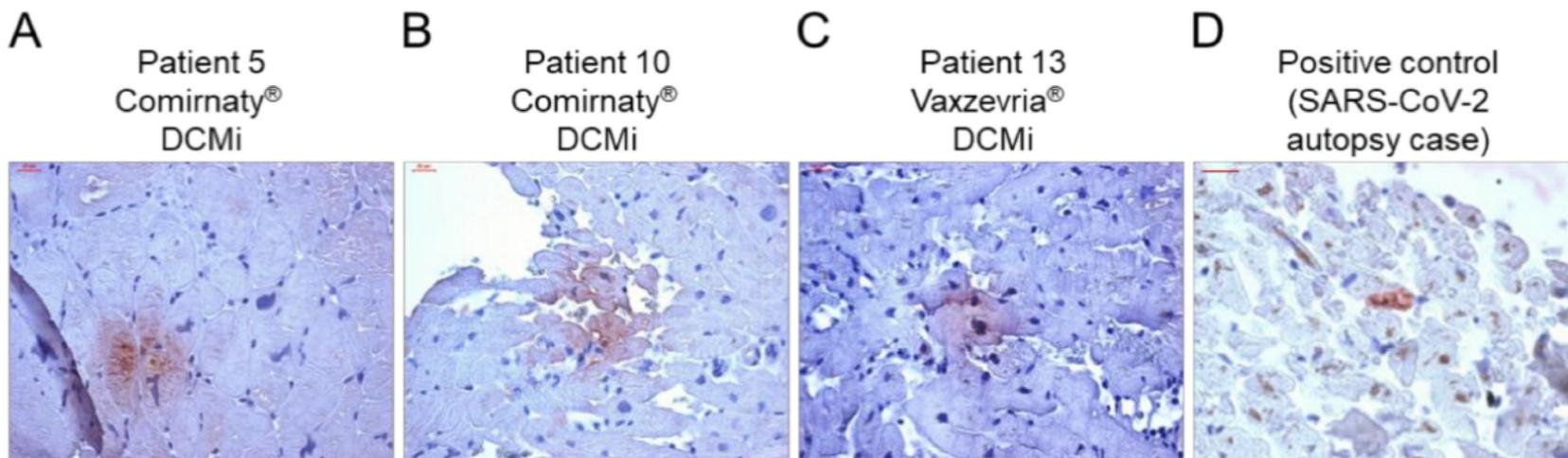


Figure 2. Evidence of SARS-CoV-2 spike protein in cardiac tissue after COVID-19 vaccination. (A–C) Representative immunohistochemical stainings of SARS-CoV-2 spike protein in EMBs from patients diagnosed with DCMi after receiving Comirnaty® (panel A and B, patients 5 and 10) or Vaxzevria® (panel C, patient 13). (D) SARS-CoV-2-positive cardiac tissue served as positive control. Magnification 400×. Scale bars 20 µm.

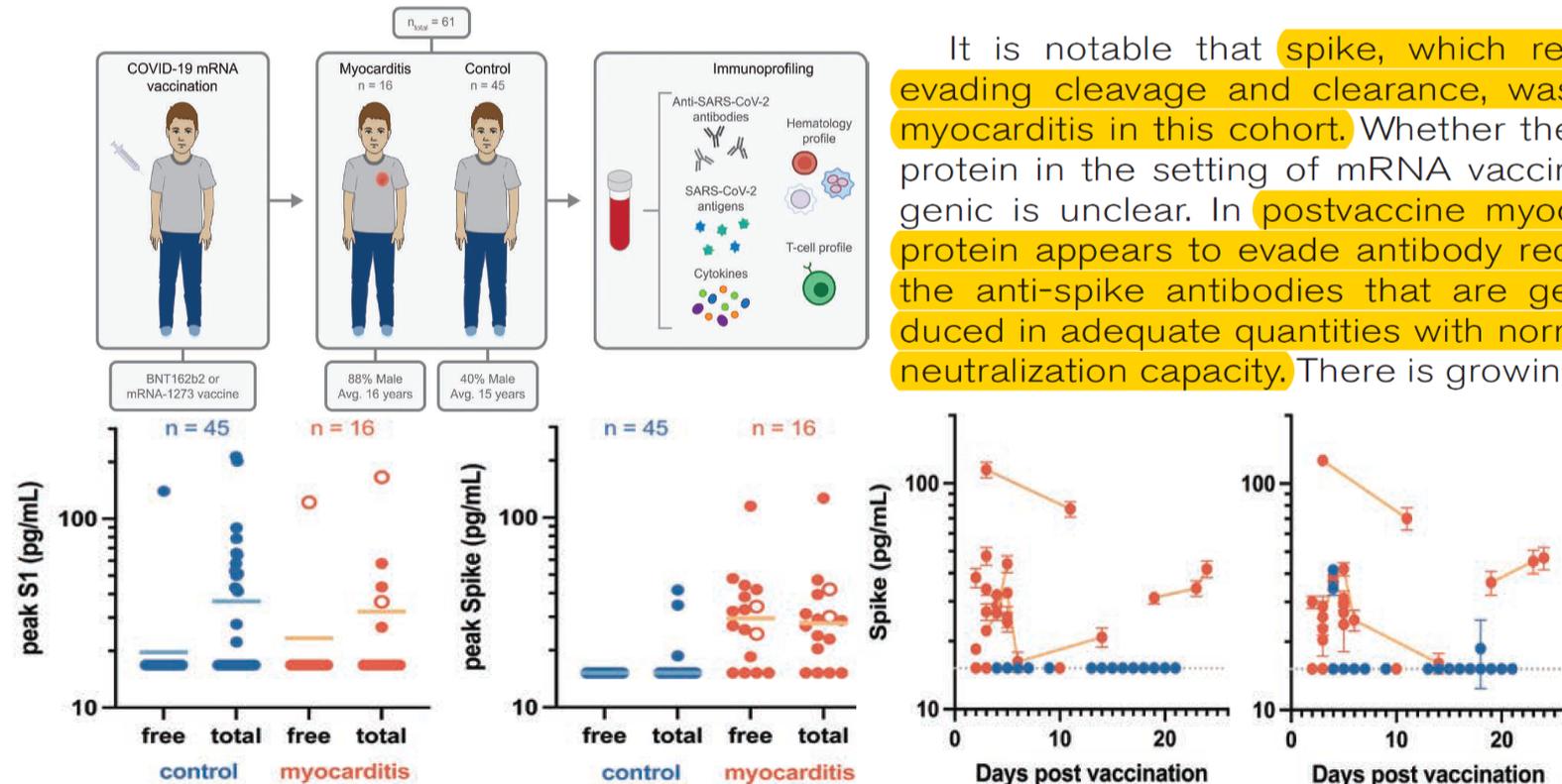
ORIGINAL RESEARCH ARTICLE

Circulating Spike Protein Detected in Post-COVID-19 mRNA Vaccine Myocarditis

Lael M. Yonker¹, MD*¹; Zoe Swank, PhD*¹; Yannic C. Bartsch, PhD*¹; Madeleine D. Burns¹, MS; Abigail Kane¹, MD; Brittany P. Boribong, PhD; Jameson P. Davis, BS; Maggie Loiselle, BS; Tanya Novak¹, PhD; Yasmeen Senussi¹, MBBS; Chi-An Cheng¹, PhD; Eleanor Burgess, MS; Andrea G. Edlow, MD; Janet Chou, MD; Audrey Dionne¹, MD; Duraisamy Balaguru¹, MD; Manuella Lahoud-Rahme¹, MD; Moshe Arditi¹, PhD; Boris Julg, MD, PhD; Adrienne G. Randolph¹, MD; Galit Alter, PhD; Alessio Fasano¹, MD†; David R. Walt¹, PhD†



It is notable that spike, which remained intact by evading cleavage and clearance, was associated with myocarditis in this cohort. Whether the circulating spike protein in the setting of mRNA vaccination was pathogenic is unclear. In postvaccine myocarditis, the spike protein appears to evade antibody recognition because the anti-spike antibodies that are generated are produced in adequate quantities with normal functional and neutralization capacity. There is growing in vitro evidence



Myocarditis in VAERS after mRNA injection by age and dose as of MARCH 18, 2022

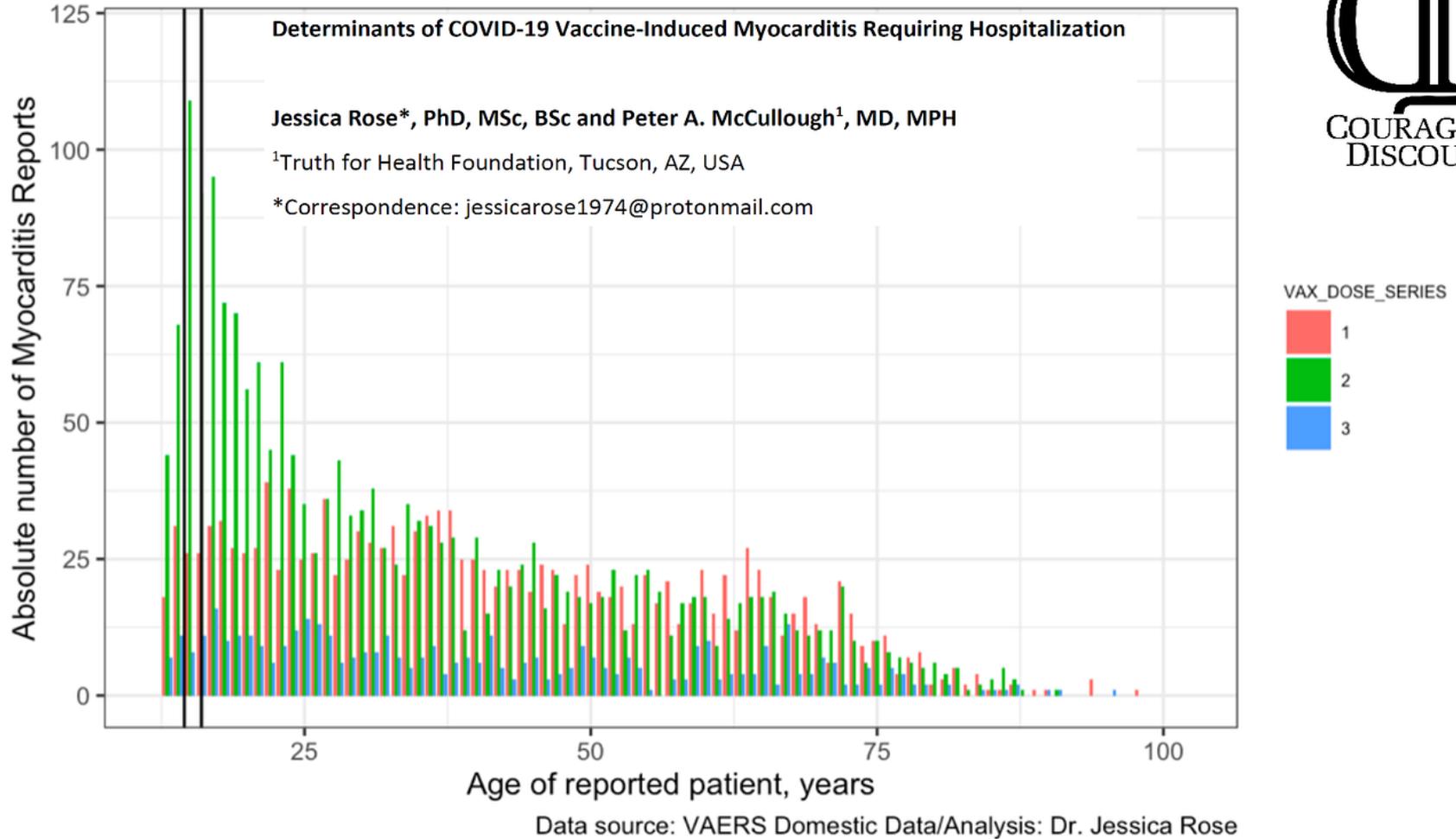


Figure 5: Myocarditis in VAERS Domestic data according to age and dose.



CORONAVIRUS

Cytokineopathy with aberrant cytotoxic lymphocytes and profibrotic myeloid response in SARS-CoV-2 mRNA vaccine-associated myocarditis

Anis Barmada^{1†}, Jon Klein^{1†}, Anjali Ramaswamy^{1‡}, Nina N. Brodsky^{1,2‡}, Jillian R. Jaycox¹, Hassan Sheikh^{1,2}, Kate M. Jones¹, Victoria Habet², Melissa Campbell², Tomokazu S. Sumida³, Amy Kontorovich⁴, Dusan Bogunovic^{4,5}, Carlos R. Oliveira², Jeremy Steele², E. Kevin Hall², Mario Pena-Hernandez¹, Valter Monteiro¹, Carolina Lucas^{1,6}, Aaron M. Ring¹, Saad B. Omer^{7,8,9}, Akiko Iwasaki^{1,6,10*}, Inci Yildirim^{2,6,8,9*}, Carrie L. Lucas^{1*}

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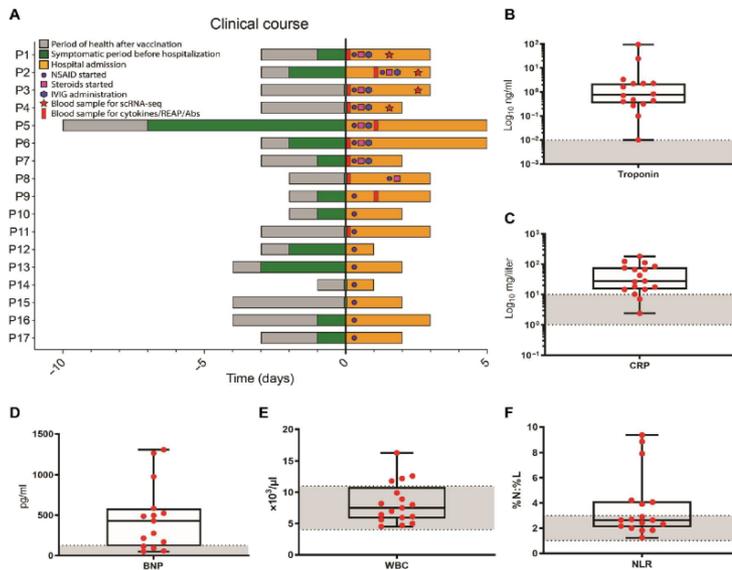


Fig. 1. Clinical parameters of the SARS-CoV-2 vaccine-associated myocarditis cohort. (A) Time course for patients showing the day of vaccine administration, symptom onset, treatment, and sample collection relative to hospital admission (day 0). (B to F) Maximum values of selected blood markers in patients tested during hospital admission. Boxes depict the interquartile range (IQR), horizontal bars represent the median, whiskers extend to 1.5 × IQR, and red dots show the value of each patient. Dashed lines and gray area represent normal reference ranges used at Yale New Haven Hospital. CRP, C-reactive protein; BNP, B-type natriuretic peptide; WBC, white blood cell; NLR, neutrophil-to-lymphocyte ratio; REAP, rapid extracellular antigen profiling; Abs, antibodies; IVIG, intravenous immunoglobulin; NSAID, nonsteroidal anti-inflammatory drug.

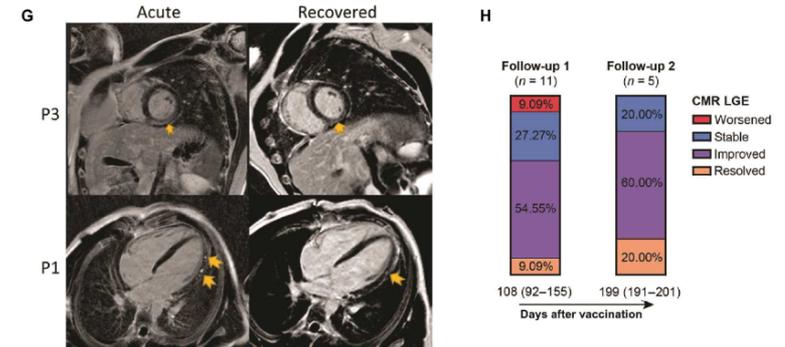


Fig. 5. Inflammatory and profibrotic signatures of monocytes in myocarditis. (A and B) Box plots showing the average proportions of nonclassical (CD14^{dim} CD16⁺) and classical (CD14⁺ CD16⁻) monocyte subsets across the groups. The boxes denote the IQR, horizontal bars represent the median, whiskers extend to 1.5 × IQR, and dots show the values of each donor. Statistical significance was determined using the Bayesian model scCODA (49) accounting for the compositional dependencies between cell subsets in the scRNA-seq data while controlling for false discoveries (FDR < 0.05 in myocarditis versus E-YVCs). (C and D) Average expression score of (C) inflammatory genes from the S100A family of alarmins (S100A8-12; FDR < 0.05, logFC > 0.1 in myocarditis versus E-YVCs) and (D) 238 genes from a published dataset of extracellular matrix (ECM) remodeling (GSEA MSigDB M3468) in the same classical monocyte subset shown in (B) across groups. Statistical significance between scores was determined using the unpaired two-sided Wilcoxon rank-sum test comparing the E-YVC and myocarditis groups. (E) Dot plot showing top differentially expressed and up-regulated genes in the same classical monocyte subset shown in (B) across donors (FDR < 0.05, logFC > 0.1 in myocarditis versus E-YVCs). (F) ELISA measurement of sCD163 in serum across the groups. Statistical significance was determined using the unpaired two-tailed t test between the E-YVC and myocarditis groups, and error bars represent the SE. (G) Representative CMR images of acute myocarditis and follow-up/recovery (191 days for P1 and 82 days for P3 after vaccination) showing persistent LGE (yellow arrows) seen in a subset of patients (from 17 patients included in our cohort, at admission, 11 were LGE positive, 4 were LGE negative, and 2 had no CMR). Particularly, for P1, four-chamber phase sequence inversion recovery (PSIR) demonstrating patch subepicardial LGE along the left ventricular lateral wall from base to apex (acute), with improvement in both quantity and intensity at follow-up (recovered). For P3, mid-ventricle short axis PSIR demonstrating subepicardial to nearly transmural LGE sparing the subendocardial region (acute), which was mildly improved in intensity and quantity at follow-up (recovered). (H) Stacked bar plots depicting the percentage of patients categorized by CMR LGE changes at two follow-ups after vaccination/first admission [median days (IQR)]. Additional details of imaging findings and patients with LGE at admission and follow-up are in table S1.

Case Report
Infectious Diseases,
Microbiology & Parasitology



Myocarditis-induced Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report Focusing on Histopathological Findings

Sangjoon Choi ,¹ SangHan Lee ,¹ Jeong-Wook Seo ,² Min-ju Kim ,²
Yo Han Jeon ,¹ Ji Hyun Park ,¹ Jong Kyu Lee ,¹ and Nam Seok Yeo ,¹

We present autopsy findings of a 22-year-old man who developed chest pain 5 days after the first dose of the BNT162b2 mRNA vaccine and died 7 hours later. Histological examination of

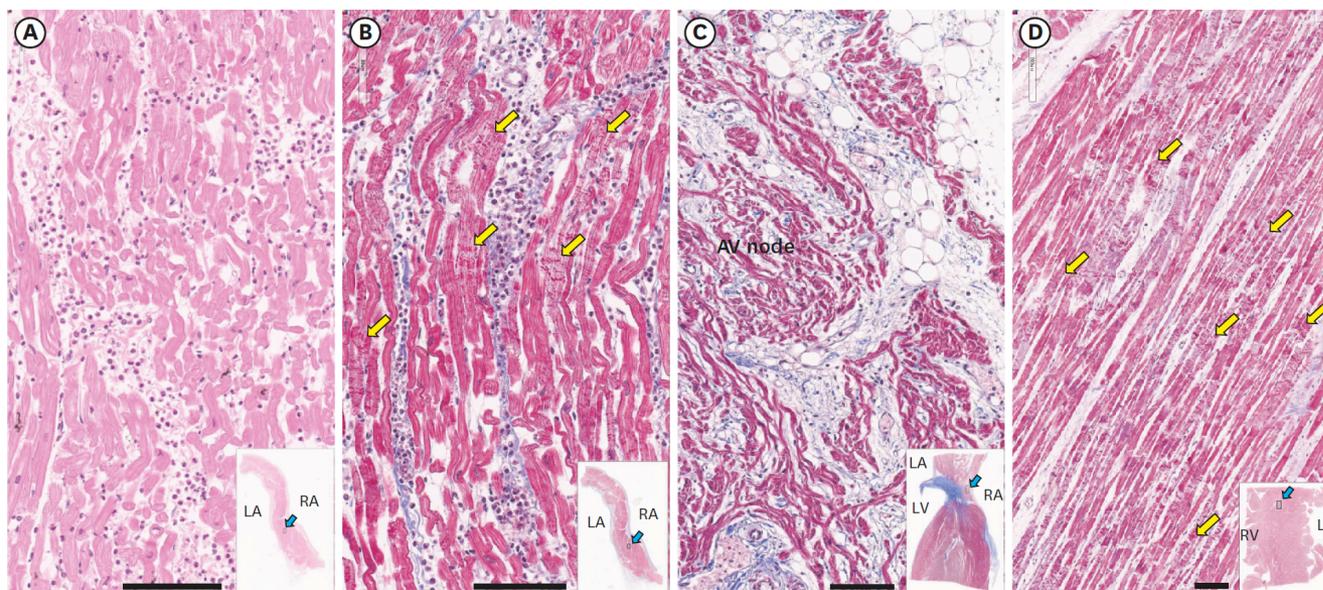


Fig. 1. Histopathology of the heart. (A) Hematoxylin and eosin stains of atrial septum shows massive inflammatory infiltration with neutrophil predominance. (B) The myocytes often show contraction band necrosis (yellow arrows), which were highlighted by Masson's trichrome staining. (C) The atrioventricular node area shows extension of atrial myocarditis to the superficial layer of the node. (D) The ventricular myocardium is free of inflammatory infiltrates, but there are multiple large foci of contraction band necrosis (yellow arrows) particularly in the left ventricular wall and the ventricular septum. Bars represent 100 μ m. The blue arrows in insets show where the section was taken from the low magnification views. Hematoxylin and eosin stain was used for the specimen shown in (A) and Masson's trichrome stain was used for the specimen shown in (B-D).
RA = right atrium, LA = left atrium, RV = right ventricle, LV = left ventricle.



Autopsy Histopathologic Cardiac Findings in Two Adolescents Following the Second

COVID-19 Vaccine Dose

doi: 10.5858/arpa.2021-0435-SA

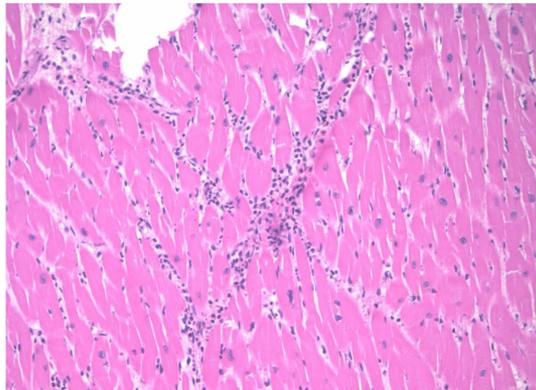
James R. Gill, MD; Randy Tashjian, MD; Emily Duncanson, MD

RESULTS

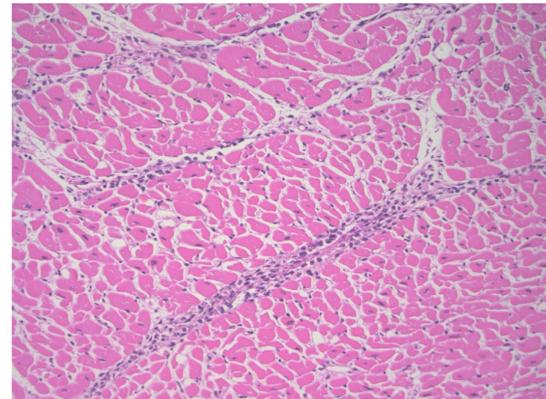
The results of autopsies for **two teenage boys** who were found **dead in bed 3 and 4 days** after receiving the **second dose of the Pfizer-BioNTech COVID-19 vaccine** are presented (Table

1). Both boys were pronounced dead at home without attempted resuscitation.

Figure 2: Case A. Heart. Interstitial inflammation adjacent to fibrosis. H&E 200X



Figures 4: Case B. Heart. Perivascular inflammation. H&E 200X



Fabienne Schlumpf: Triple-Vaccinated Olympic Athlete Develops Myocarditis, Possible End Of Career



The COVID World post date: January 7th, 2022

Swiss marathon record holder and Olympic athlete Fabienne Schlumpf has been diagnosed with myocarditis shortly after being vaccinated with the COVID-19 booster shot.

Schlumpf, who finished 12th in the marathon race at the recent Olympic Games in Tokyo, is now unable to compete for the foreseeable future.



Fabienne Schlumpf, 31, has developed myocarditis shortly after receiving the COVID-19 booster



The runner made the news public on Thursday, writing in a [post](#) on Instagram:

"BAD NEWS

Unfortunately myocarditis is holding me back right now. It's definitely not an easy time for me but I'm not giving up. I hope to be back soon, chasing my dreams... and competitors"

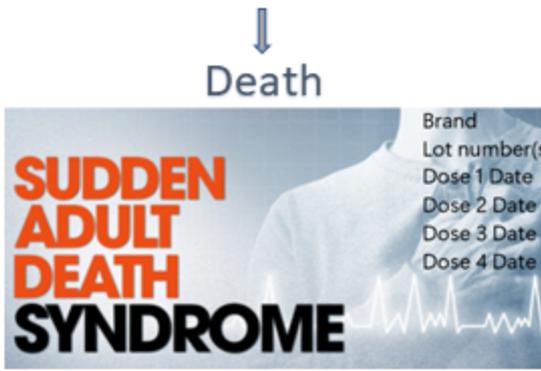
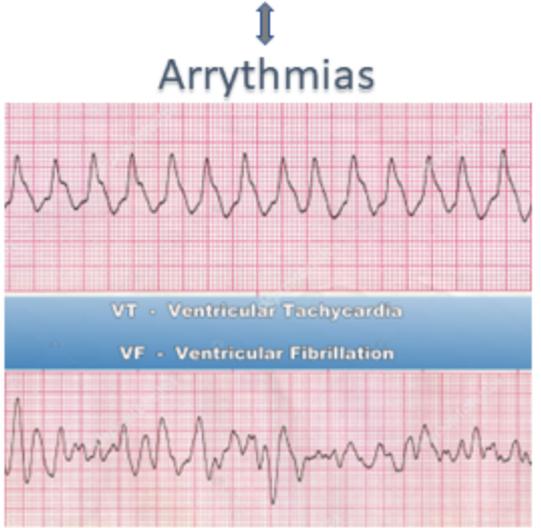
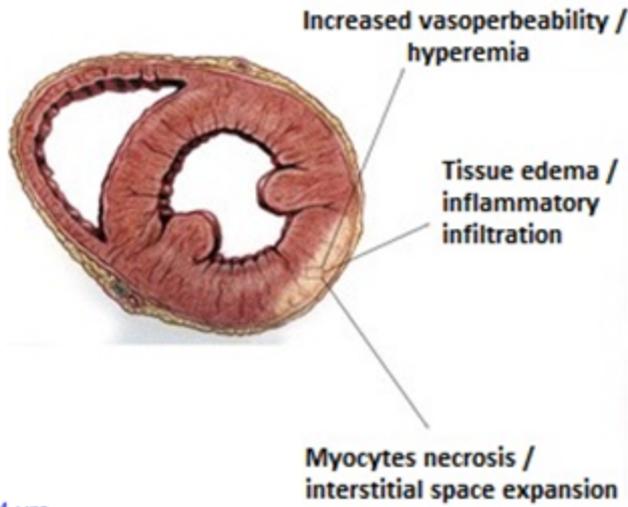
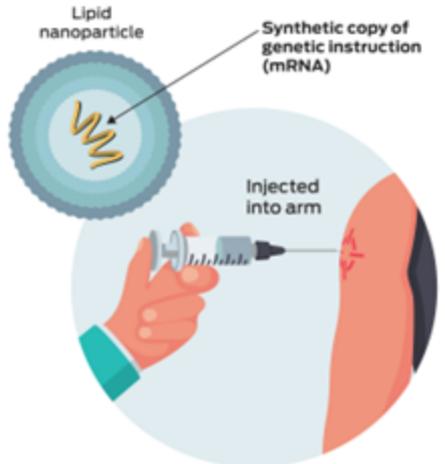
The 31-year-old was reported to be feeling **'fatigued'** in everyday life and after her heart rate skyrocketed during an easy endurance run last month, she sought out a doctor who diagnosed her with **myocarditis**.

The experienced runner had planned to go on a **training camp in Portugal** at the beginning of this year but this was cancelled after her diagnosis.

"Nobody can say for how long I have to put my career on hold."

Schlumpf confirmed to a Swiss newspaper that she has been **triple-vaccinated** and that she hasn't had **COVID**.

COVID-19 Vaccination → Myocarditis → Outcomes



Risk Factors

- Young men 90%, women 10% peak risk group age 18-24 yrs
- Genetic predisposition SCN5A mutation
- Hot lots of well-manufactured, high purity mRNA adenviral DNA
- Cumulative Spike-protein exposure "priming" COVID-19+shots
- Hemodynamic distribution to myocardium
- Pericyte uptake of genetic code and production of Spike-protein
- Spike-protein mediated myocardial inflammation

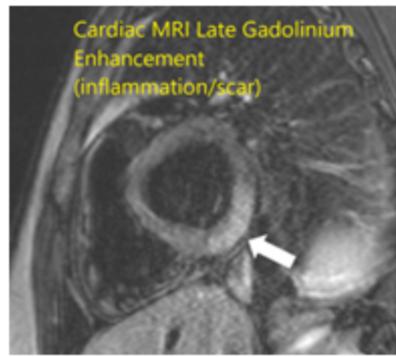
Symptoms

- 57% subclinical
- 43% symptoms
 - Chest pain
 - Effort intolerance
 - Palpitations
 - Near syncope
 - Fever, malaise, myalgia

Detection

- If detected: treatment calls for no exercise, medications, defibrillator in high risk, repeat testing for resolution
- If undetected
 - First manifestation can be sudden death
 - During athletic exertion
 - While asleep in the early morning hours

Diagnosis



- Presenting, ~90% hospitalized
- ECG changes
- 1 Blood Troponin, BNP, ST2, Galectin-3
- Arrhythmias
- Ventricular dysfunction
- Positive MRI for LGE
- Biopsy shows Spike-protein+ Inflammation

ARTICLE OPEN

Check for updates

Risk assessment of retinal vascular occlusion after COVID-19 vaccination

Jing-Xing Li^{1,2,3}, Yu-Hsun Wang⁴, Henry Bai^{5,6}, Shu-Bai Hsu^{7,8}, Connie Chen^{9,10}, James Cheng-Chung Wei^{1,11,12,13,14} and Chun-Ju Lin^{1,2,5,14,15}

Coronavirus disease 2019 (COVID-19) vaccines are associated with several ocular manifestations. Emerging evidence has been reported; however, the causality between the two is debatable. We aimed to investigate the risk of retinal vascular occlusion after COVID-19 vaccination. This retrospective cohort study used the TriNetX global network and included individuals vaccinated with COVID-19 vaccines between January 2020 and December 2022. We excluded individuals with a history of retinal vascular occlusion or those who used any systemic medication that could potentially affect blood coagulation prior to vaccination. To compare the risk of retinal vascular occlusion, we employed multivariable-adjusted Cox proportional hazards models after performing a 1:1 propensity score matching between the vaccinated and unvaccinated cohorts. Individuals with COVID-19 vaccination had a higher risk of all forms of retinal vascular occlusion in 2 years after vaccination, with an overall hazard ratio of 2.19 (95% confidence interval 2.00–2.39). The cumulative incidence of retinal vascular occlusion was significantly higher in the vaccinated cohort compared to the

Table 3. The risk of retinal vascular occlusion significantly increased in individuals receiving the first and second doses of BNT162b2 and mRNA-1273 within 2 years.

	Vaccinated		Unvaccinated		HR (95% CI)
	Number of events	Incidence (%)	Number of events	Incidence (%)	
2 years					
BNT162b2					
First dose	111,491		111,491		
	120	0.036	92	0.021	1.48 (1.12–1.94)
Second dose	96,135		96,135		
	116	0.042	107	0.030	1.36 (1.04–1.77)
mRNA-1273					
First dose	50,382		50,382		
	114	0.064	79	0.044	1.48 (1.10–1.97)
Second dose	47,536		47,536		
	106	0.069	75	0.048	1.50 (1.11–2.02)
Ad26.COV2.S*					
First dose	7158		7158		
	<10*	0.140	<10*	0.140	2.35 (0.74–7.39)
Second dose	162		162		
	0	-	0	-	NA
12 weeks					
BNT162b2					
First dose	111,491		111,491		

After 2 injections, ~4x increased rates of arterial and venous embolism 2 years later

CCB	86635 (11.6)			160913 (21.8)	0.016
Metformin	55369 (7.4)	112269 (15.1)		158061 (21.4)	0.002
Lipid lowering agents	164276 (22.0)	329242 (8.5)		188800 (25.5)	0.004
Corticosteroids	163232 (21.9)	333649 (8.6)	0.37	158061 (21.4)	<0.001
NSAIDs	191038 (25.6)	507084 (13.1)	0.322	188800 (25.5)	0.008
Antipsychotics	61980 (8.3)	137901 (3.6)	0.202	57996 (7.8)	0.008
Previous hospitalization	106573 (14.3)	224481 (5.8)	0.286	102014 (13.8)	0.018

ACEI angiotensin converting enzyme inhibitor, ARB Angiotensin II receptor blockers, CCB Calcium-channel blockers, N number, NSAIDs non-steroidal anti-inflammatory drugs, PSM propensity score matching, SMD standardized mean difference.





September 8, 2021

News Highlights

The War Between Nationalists and Globalists

by [Karen Schoen](#)



COVID-19 Investigation: Empirical

Without Protection from Pharmaceutical Laws, Vaccines Will Do More Harm

by [Dr. Peter McCullough](#) | Jul 5, 2021 | [Healthcare](#), [Politics](#),





- <90 days on market Pfizer notified of 1223 deaths and 1291 adverse events of interest
- FDA attempted in court to block public release for 55 yrs

September 17, 2021

Covid-19, Social Standing, and the New World Order

by **Wallace Garneau**



The Unholy Alliance Between Big Pharma's Vaccines and Drugs and the FDA

by **Blaise Vanne**



COVID-19 Vaccines Not Safe for Human Use on Either Side of the Atlantic

by **Dr. Peter McCullough** | Jun 19, 2021 | [Healthcare](#), [Politics](#)

Since the majority of the deaths occur within a few days of the vaccine administration, if the vaccine did not directly “cause” the death, it was undoubtedly in the causal pathway of these temporally related fatalities. Common narratives include vaccine-induced fatal heart attacks, strokes, blood clots, and blood disorders. 5,888 Americans have died and confirmed by the CDC, and possibly tens of thousands not reported or still backlogged at the CDC...



June 11, 2022

Press Release

Independent Pharmacovigilance Report Confirms Evidence for Recall of Covid-19 Vaccines



NEWS

NEWS RELEASES

Press Release: Independent Pharmacovigilance Report Confirms Evidence for Recall of Covid-19 Vaccines

June 11, 2022 • 20 Comments

To Save Lives COVID-19 Vaccines Must be Taken off Market



Outline

- New biological products
- COVID-19 Vaccine Safety Review
- **Real World Efficacy of COVID-19 Vaccines**
- Pivot to Early Therapy for High-Risk COVID-19
- Natural Immunity
- Twin epidemics of autism and gender dysphoria
- Censorship of Scientific Discourse
- Conclusions

September 2, 2022

COVID-19 Vaccine

Unsupportable Claims

- 1) Prevent infection with current strains
- 2) Stop transmission
- 3) Reduce hospitalization/death (No RCT evidence)
- 4) *Prevent outbreak reoccurrence

*anticipated



Vaccine Efficacy Overestimated In Non-Randomized Studies

- 1) Milder mutations as more vaccinated over time
- 2) Hospital EMR's default is "unvaccinated"
- 3) No linkage to CDC vaccine data
- 4) No control for early RX and natural immunity
- 5) No adjudication of hospital COVID illness
- 6) COI with universities, funders, pushing vaccines

rates introduced into these observational datasets. Our contribution is to size up these important biases, the magnitude of which surprised us and may surprise you. We conclude that "real-world" studies using methodologies popular in early 2021 overstate vaccine effectiveness. Our finding highlights how difficult it is to conduct high-quality observational studies during a pandemic.

**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
ABOUT COMIRNATY (COVID-19 VACCINE, mRNA), THE PFIZER-BIONTECH
COVID-19 VACCINE, AND THE PFIZER-BIONTECH COVID-19 VACCINE,
BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND
OLDER**



FOR 12 YEARS OF AGE AND OLDER

WHAT ARE THE BENEFITS OF THESE VACCINES?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine have been **shown to prevent COVID-19**. FDA has authorized Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide better protection against COVID-19 caused by the Omicron variant of SARS-CoV-2.

The duration of protection against COVID-19 is currently unknown.

An EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

BIONTECH
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany



Manufactured by
Pfizer Inc., New York, NY 10017

LAB-1451-21.6f

Revised: 31 August 2022

Association Between mRNA Vaccination and COVID-19 Hospitalization and Disease Severity

Mark W. Tenforde, MD, PhD; Wesley H. Self, MD, MPH; Katherine Adams, MPH; Manjusha Gaglani, MBBS; Adit A. Ginde, MD, MPH; Tresa McNeal, MD; Shekhar Ghamande, MD; David J. Douin, MD; H. Keipp Talbot, MD, MPH; Jonathan D. Casey, MD, MSc; Nicholas M. Mohr, MD, MS; Anne Zepeski, PharmD; Nathan I. Shapiro, MD, MPH; Kevin W. Gibbs, MD; D. Clark Files, MD; David N. Hager, MD, PhD; Arber Shehu, MD; Matthew E. Prekker, MD, MPH; Heidi L. Erickson, MD; Matthew C. Exline, MD, MPH; Michelle N. Gong, MD; Amira Mohamed, MD; Daniel J. Henning, MD, MPH; Jay S. Steingrub, MD; Ithan D. Peltan, MD, MSc; Samuel M. Brown, MD, MS; Emily T. Martin, PhD; Arnold S. Monto, MD; Akram Khan, MD; Catherine L. Hough, MD; Laurence W. Busse, MD; Caitlin C. ten Lohuis, ACNP-BC; Abhijit Duggal, MD; Jennifer G. Wilson, MD; Alexandra June Gordon, MD; Nida Qadir, MD; Steven Y. Chang, MD, PhD; Christopher Mallow, MD, MHS; Carolina Rivas, BS; Hilary M. Babcock, MD, MPH; Jennie H. Kwon, DO, MSc; Natasha Halasa, MD, MPH; James D. Chappell, MD, PhD; Adam S. Luring, MD, PhD; Carlos G. Grijalva, MD, MPH; Todd W. Rice, MD, MSc; Ian D. Jones, MD; William B. Stubblefield, MD, MPH; Adrienne Baughman, BS; Kelsey N. Womack, PhD; Jillian P. Rhoads, PhD; Christopher J. Lindsell, PhD; Kimberly W. Hart, MA; Yuwei Zhu, MD, MS; Samantha M. Olson, MPH; Miwako Kobayashi, MD; Jennifer R. Verani, MD, MPH; Manish M. Patel, MD; for the Influenza and Other Viruses in the Acutely Ill (IVY) Network

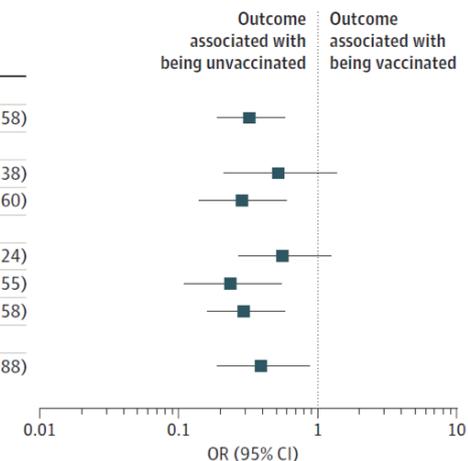
Participants

During March 11, 2021, to August 15, 2021, 5479 patients were enrolled from 21 hospitals; 966 patients were excluded from this analysis, with the most common reasons for exclusion being receipt of at least 1 mRNA vaccine but not being fully vaccinated (n = 547) and receipt of a COVID-19 vaccine other than an mRNA vaccine (n = 194) (Figure 1). The analytic population included 4513 patients (median age, 59 years [IQR, 45-69]; 2202 [48.8%] women; 23.0% non-Hispanic Black individuals, 15.9% Hispanic individuals, and 20.1% with an immunocompromising condition), including 1983 cases with COVID-19 and 2530 controls without it (1359 test-negative controls and 1171 syndrome-negative controls).

3/21 to 8/21 45% Delta

Figure 3. Association Between Progression to Severe Disease and Prior Vaccination Among Adults Hospitalized With COVID-19

Subgroup	Fully vaccinated case patients/total breakthrough cases (%)	Unvaccinated case patients/total unvaccinated (%)	Absolute difference (95% CI), %	Adjusted odds ratio (95% CI) ^a
Progression to death or invasive mechanical ventilation				
Overall	17/142 (12.0)	261/1055 (24.7)	-12.8 (-18.7 to -6.8)	0.33 (0.19 to 0.58)
By immunocompromising condition ^b				
Yes (immunocompromised)	8/61 (13.1)	31/146 (21.2)	-8.1 (-18.9 to 2.6)	0.54 (0.21 to 1.38)
No (immunocompetent)	9/81 (11.1)	230/909 (25.3)	-14.2 (-21.6 to -6.8)	0.29 (0.14 to 0.60)
By age group, y				
18-64	9/57 (15.8)	188/814 (23.1)	-7.3 (-17.2 to 2.6)	0.57 (0.27 to 1.24)
≥65	8/85 (9.4)	73/241 (30.3)	-20.9 (-29.4 to -12.4)	0.24 (0.11 to 0.55)
Hypoxemic within 24 h of admission ^c				
Overall	13/96 (13.5)	227/806 (28.2)	-14.6 (-22.1 to -7.1)	0.30 (0.16 to 0.58)
Progression to death				
Overall	9/142 (6.3)	91/1055 (8.6)	-2.3 (-6.6 to 2.1)	0.41 (0.19 to 0.88)



Death occurred 9 of 142 (6.3%) vaccine break-through cases and 91 of 1055 (8.6%) unvaccinated cases, p=0.36

An adjusted odds ratio (aOR) less than 1.0 indicated that progression to death or invasive mechanical ventilation after hospital admission for COVID-19 was associated with being unvaccinated compared with being vaccinated.

^a Models were adjusted for age group (18-49, 50-64, and ≥65 years), sex, self-reported race and ethnicity, and number of chronic medical comorbidities (0, 1, 2, 3, and ≥4). Models stratified by age group were adjusted for continuous age in years.

^b Immunocompromising conditions are defined in the Table.

^c Analysis restricted to COVID-19 case patients with hypoxemia within 24 hours of admission, defined as receiving supplemental oxygen or having an oxygen saturation less than 92% as measured by pulse oximetry.

September 17, 2021

Iran's Brewing Christian Volcano

by [Malcolm Out Loud](#) | Sep 17, 2021

The turning point of the Middle East may very well center around the Iranian people. Iran's population is about 85,000,000, of whom 58,000,000 (almost 70%) are below the age of 42 years who have not known any rule except the tyrannical theocracy of Islamic Sharia....

Governments Have Lost the War Against the Virus

by [Bryan Hyde](#) | Sep 17, 2021

The idea that the political class has leveraged fear over the Covid-19 pandemic into control over the public isn't just a conspiracy theory. Scott

Column

Don't Fool with the Diversity of Mother Nature

by [Dr. Peter McCullough](#) | Jul 10, 2021 | [Healthcare](#), [Politics](#)

Anytime diversity is reduced in biological systems, it leads to instability in ecological systems. It can be the breeding ground for large evolutionary changes, including large mutations and more aggressive variants. The Niesen report found that there was a much greater degree of immunity or "epitopes" on B-cells and T-cells among those unvaccinated, implying that immunity was far more robust than those vaccinated...





...ast off one's chains, but to live in a way that respects and enhances the freedom of others." Nelson Mandela. The APPS are free...Apple, Android, or Alexa, t

January 1, 2022



Column

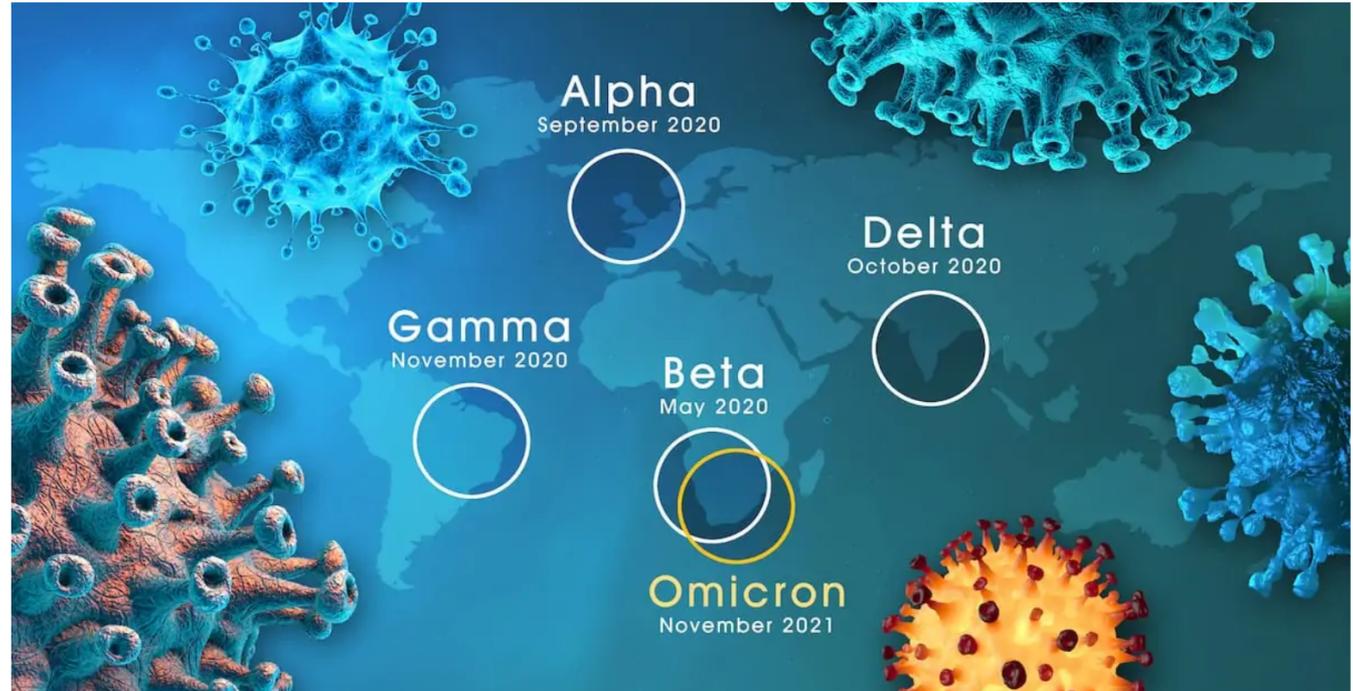
Omicron Breaks Through Natural and Vaccine Immunity in a Battle Against Delta

by Dr. Peter McCullough | Dec 31, 2021 | Healthcare, Politics

I've always thought New Year's Day was an especially American tradition, full of the optimism and hope we're famous for in our daily lives -- an energy and confidence we call the American spirit. Perhaps because we know we control our own destiny, we believe deep down inside that working together we can make each new year better than the old. - Ronald Reagan

If you don't like something, change it. If you can't change it, change your attitude. - Maya Angelou

Be at war with your vices, at peace with your neighbors, and let every new year find you a better man. - Benjamin Franklin



COVID Resources

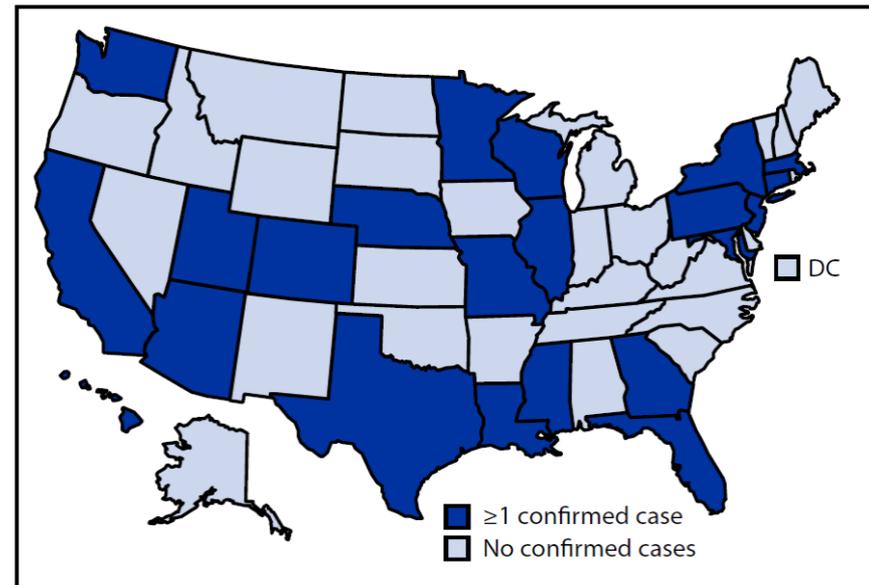
SARS-CoV-2 B.1.1.529 (Omicron) Variant — United States, December 1–8, 2021

CDC COVID-19 Response Team

Characteristics of the First Investigated U.S. COVID-19 Cases Attributed to the Omicron Variant

Details are available for 43 cases of COVID-19 attributed to the Omicron variant; 25 (58%) were in persons aged 18–39 years (Table). The earliest date of symptom onset was November 15 in a person with a history of international travel. Fourteen (33%) persons reported international travel during the 14 days preceding symptom onset or receipt of a positive test result. Among these cases of COVID-19 attributed to the Omicron variant, 34 (79%) occurred in persons who completed the primary series of an FDA-authorized or approved COVID-19 vaccine ≥ 14 days before symptom onset or receipt of a positive SARS-CoV-2 test result, including 14 who had received an additional or booster dose; five of the 14 persons had received the additional dose < 14 days before symptom onset. Six (14%) persons had a documented previous SARS-CoV-2 infection. The most commonly reported symptoms were cough, fatigue, and congestion or runny nose. One vaccinated patient was hospitalized for 2 days, and no deaths

FIGURE. States reporting at least one confirmed SARS-CoV-2 B.1.1.529 (Omicron) variant COVID-19 case — United States, December 1–8, 2021

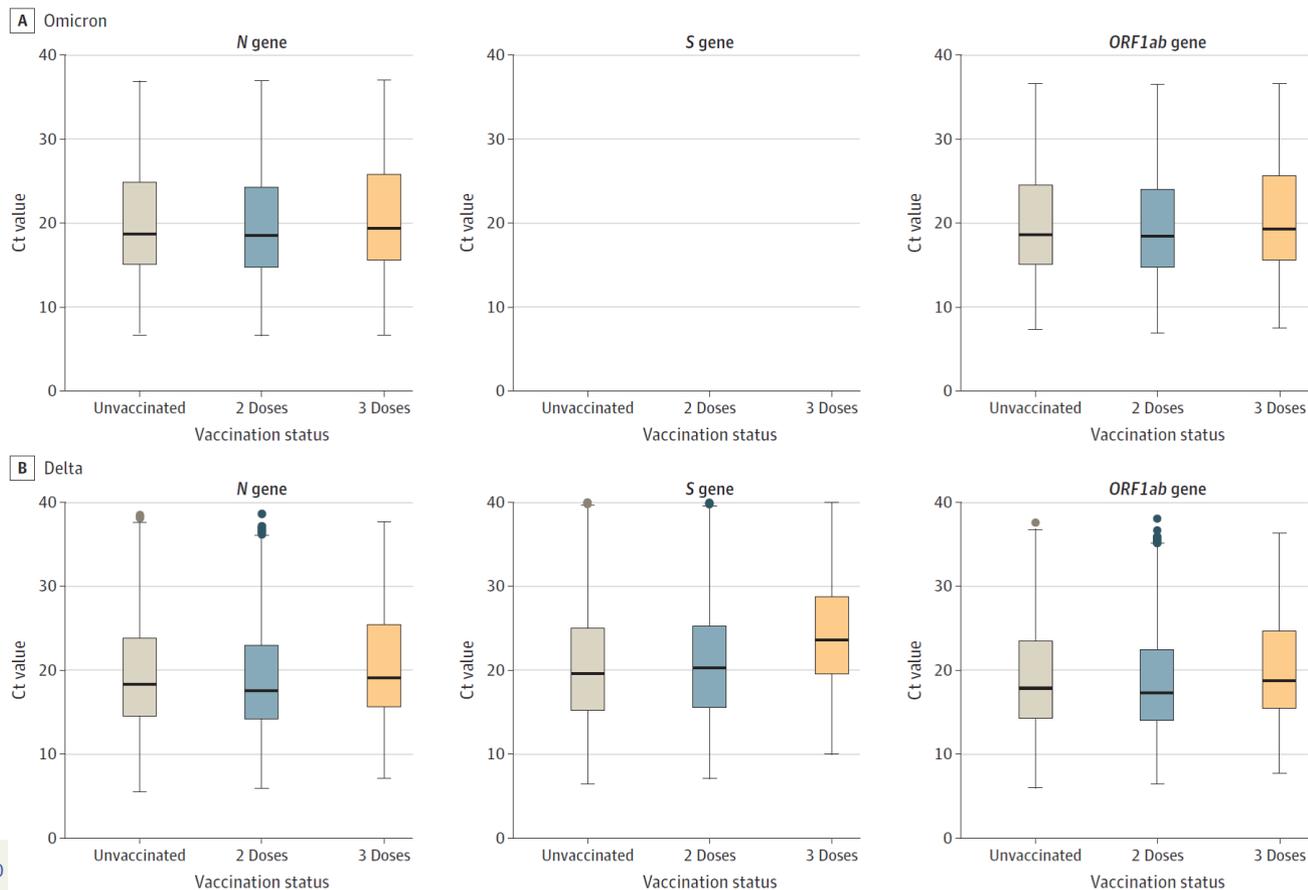


Association Between 3 Doses of mRNA COVID-19 Vaccine and Symptomatic Infection Caused by the SARS-CoV-2 Omicron and Delta Variants

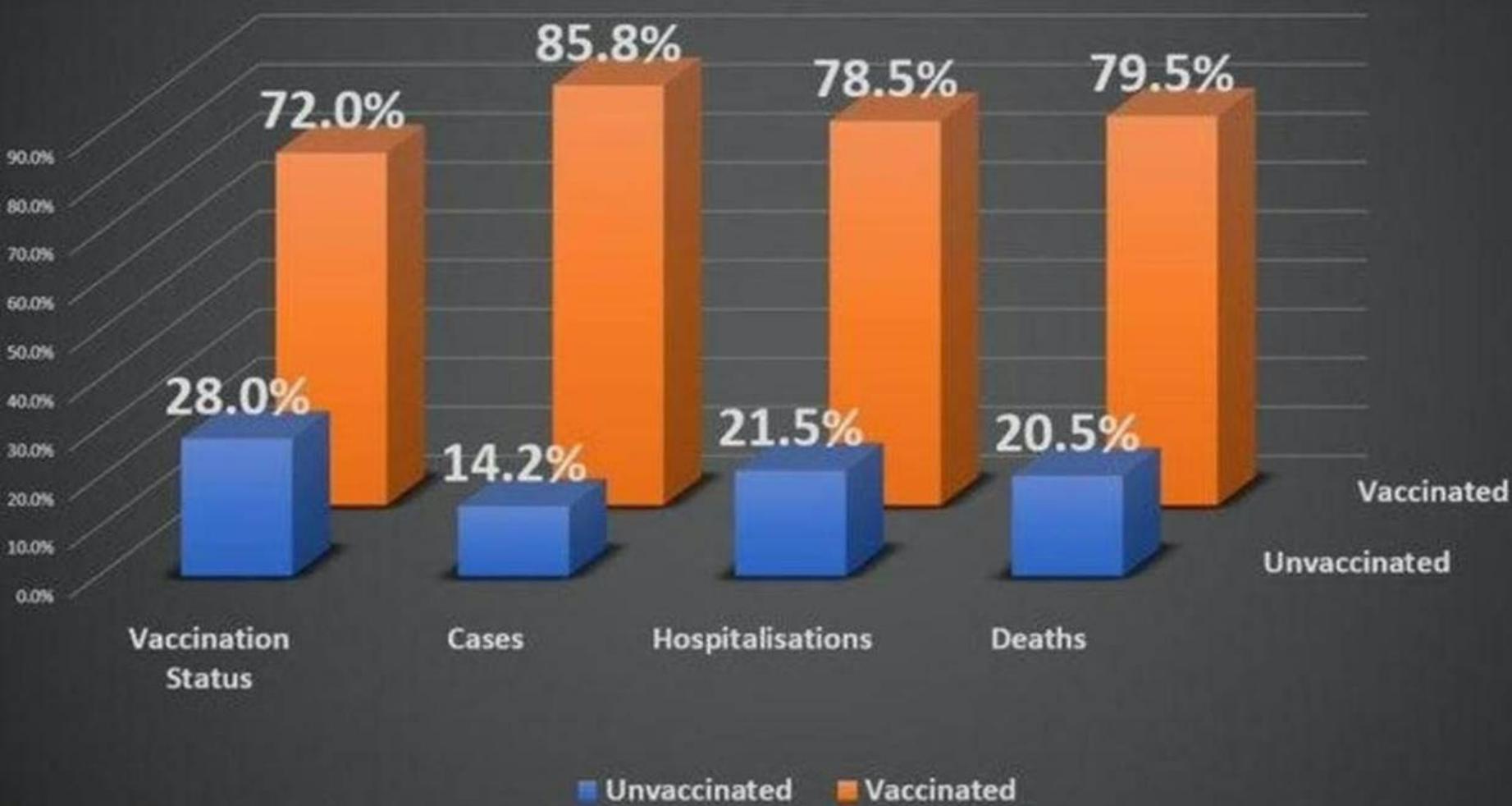
Emma K. Accorsi, PhD; Amadea Britton, MD; Katherine E. Fleming-Dutra, MD; Zachary R. Smith, MA; Nong Shang, PhD; Gordana Derado, PhD; Joseph Miller, PhD; Stephanie J. Schrag, DPhil; Jennifer R. Verani, MD, MPH



Figure 3. Cycle Threshold Values for the *N*, *ORF1ab*, and *S* genes by Variant and Vaccination Status Among SARS-CoV-2-Positive Cases Tested by the TaqPath COVID-19 Combo Kit Assay in the Increasing Community Access to Testing Platform, December 10, 2021, to January 1, 2022



SCOTTISH COVID-19 Statistics
As Public Health Scotland WEEKLY report 12/01/2022



WORLDWIDE BAYESIAN CAUSAL IMPACT ANALYSIS OF
VACCINE ADMINISTRATION ON DEATHS AND CASES
ASSOCIATED WITH COVID-19: A BIGDATA ANALYSIS OF
145 COUNTRIES

A PREPRINT

Kyle A. Beattie *
Department of Political Science
University of Alberta
Alberta, Canada
kbeattie@ualberta.ca



Abstract

89% of countries showed an increase in deaths per million directly due to the causal impact of mass vaccination

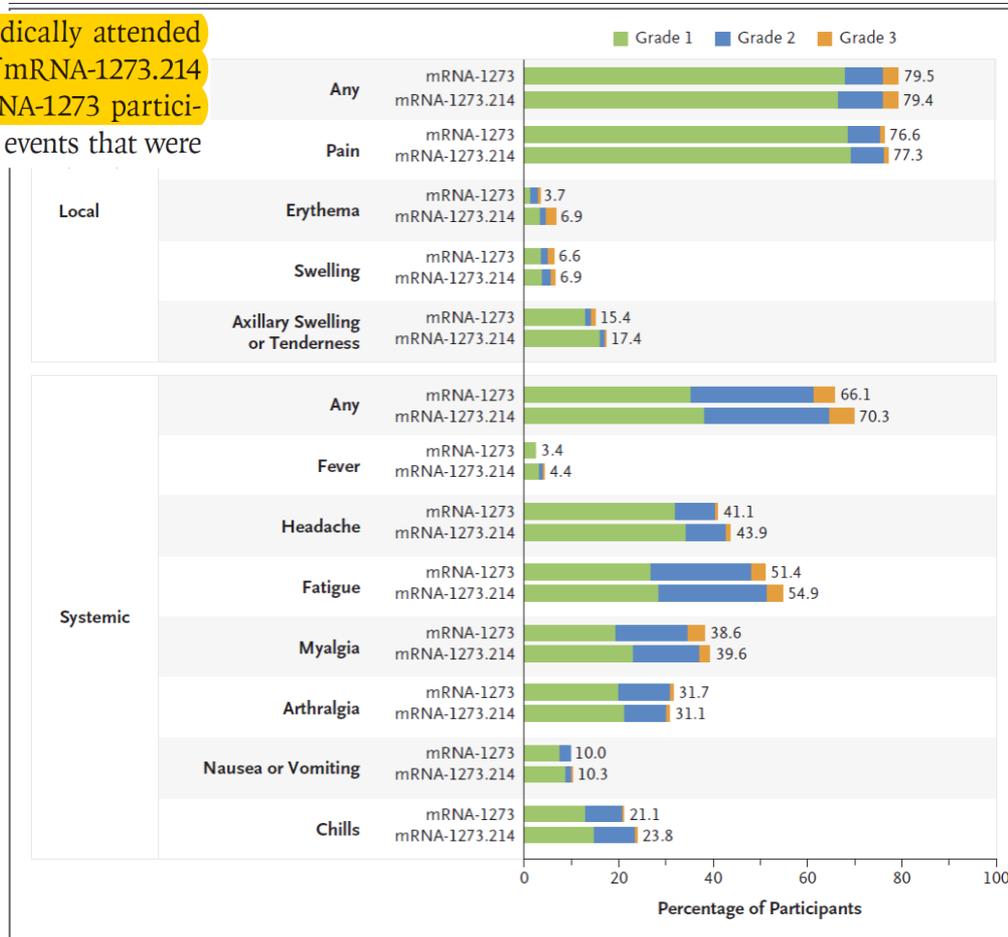
... increase the values in either y_1 or y_2 over and above what was expected with no treatment. y_1 showed an increase/decrease ratio of (+113/-13), which means 89.84% of statistically significant countries showed an increase in total deaths per million associated with COVID-19 due directly to the causal impact of treatment initiation. y_2 showed an increase/decrease ratio of (+105/-16) which means 86.78% of statistically significant countries showed an increase in total cases per million of COVID-19 due directly to the causal impact of treatment initiation. Causal impacts of the treatment on y_1 ranges from -19% to +19015% with an average causal impact of +463.13%. Causal impacts of the treatment on y_2 ranges from -46% to +12240% with an average causal impact of +260.88%. Hypothesis 1 Null can be rejected for a large majority of countries.

This study subsequently performed correlational analyses on the causal impact results, whose effect variables can be represented as $y_1.E$ and $y_2.E$ respectively, with the independent numeric variables of: *days elapsed since vaccine rollout began* (n_1), *total vaccination doses per hundred* (n_2), *total vaccine brands/types in use* (n_3) and the independent

A Bivalent Omicron-Containing Booster Vaccine against Covid-19

Spyros Chalkias, M.D., Charles Harper, M.D., Keith Vrbicky, M.D.,

related to study vaccination. Medically attended adverse events occurred in 9.8% of mRNA-1273.214 participants and in 13.8% of mRNA-1273 participants. Medically attended adverse events that were



From Moderna, Cambridge (S.C., N.M., J.E.T., X.C., Y.C., A.S., B.G., D.K.E., J.F., H.Z., J.M.M., R.D.), and Brigham and Women's Hospital, Boston (S.R.W., L.R.B.) — both in Massachusetts; Meridian Clinical Research, Norfolk (C.H., K.V.), Meridian Clinical Research, Omaha (B.E.), and Meridian Clinical Research, Grand Island (A.B.) — all in Nebraska; and the Department of Surgery, Duke University Medical Center, Durham, NC (D.C.M.). Dr. Chalkias can be contacted at spyros.chalkias@modernatx.com, or at Moderna, 200 Technology Sq., Cambridge, MA 02139.

A list of the investigators is provided in the Supplementary Appendix, available at [NEJM.org](https://www.nejm.org).

This article was published on September 16, 2022, at [NEJM.org](https://www.nejm.org).

DOI: 10.1056/NEJMoa2208343
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Vaccine Manufacturers Railroad Products through FDA while Raking in Pre-Purchase Revenue

by **Dr. Peter McCullough** | Sep 3, 2022 | Health, Politics



Outline

- New biological products
- COVID-19 Vaccine Safety Review
- Real World Efficacy of COVID-19 Vaccines
- **Pivot to Early Therapy for High-Risk COVID-19**
- Natural Immunity
- Twin epidemics of autism and gender dysphoria
- Censorship of Scientific Discourse
- Conclusions

Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19)



Contagion Control
"Stop the Spread"

Early Home
Treatment
Via Telemedicine "Safety Net for Survival"

Late-Stage
Hospitalization

Vaccination
"Herd Immunity"

↓ Hospitalizations/Death"

September 8, 2021

News Highlights

The War Between Nationalists and Globalists

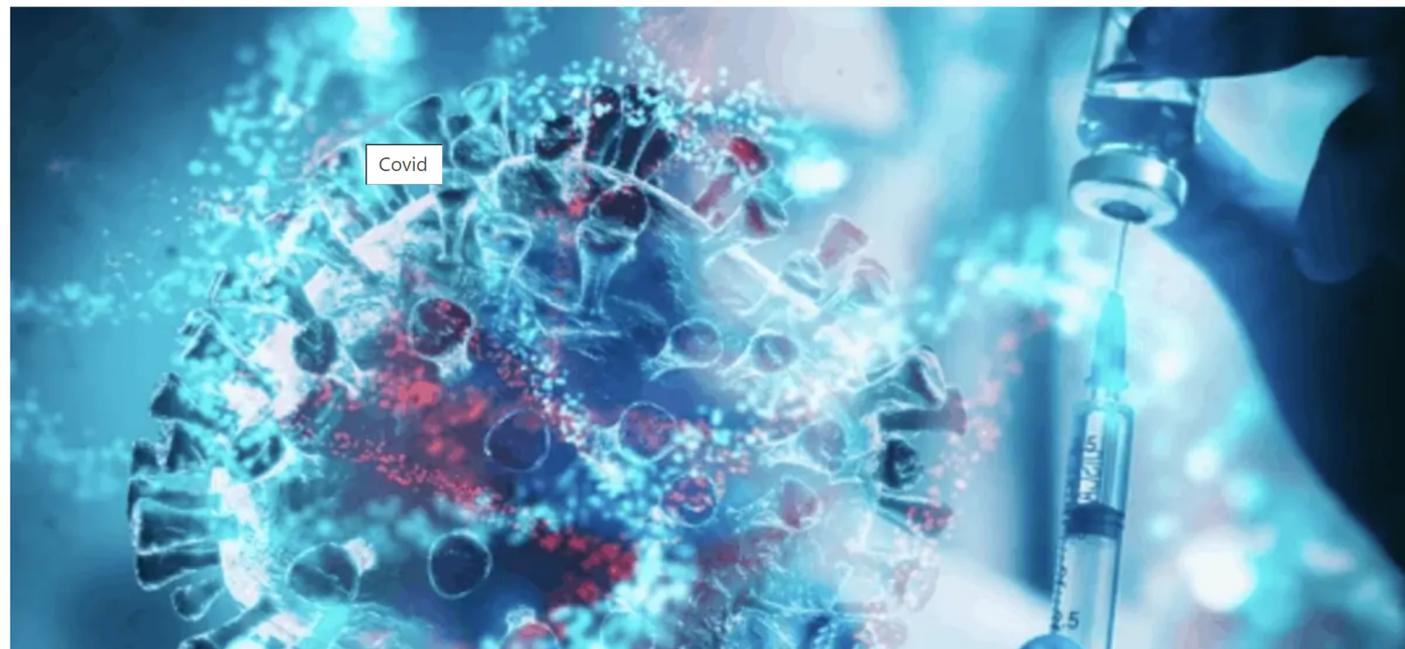
by [Karen Schoen](#)



COVID-19 Investigation: Empirical

Vaccinated or Not, Acute COVID-19 in High-Risk Patients Demands Early Treatment

by [Dr. Peter McCullough](#) | Aug 17, 2021 | [Healthcare](#), [Politics](#),



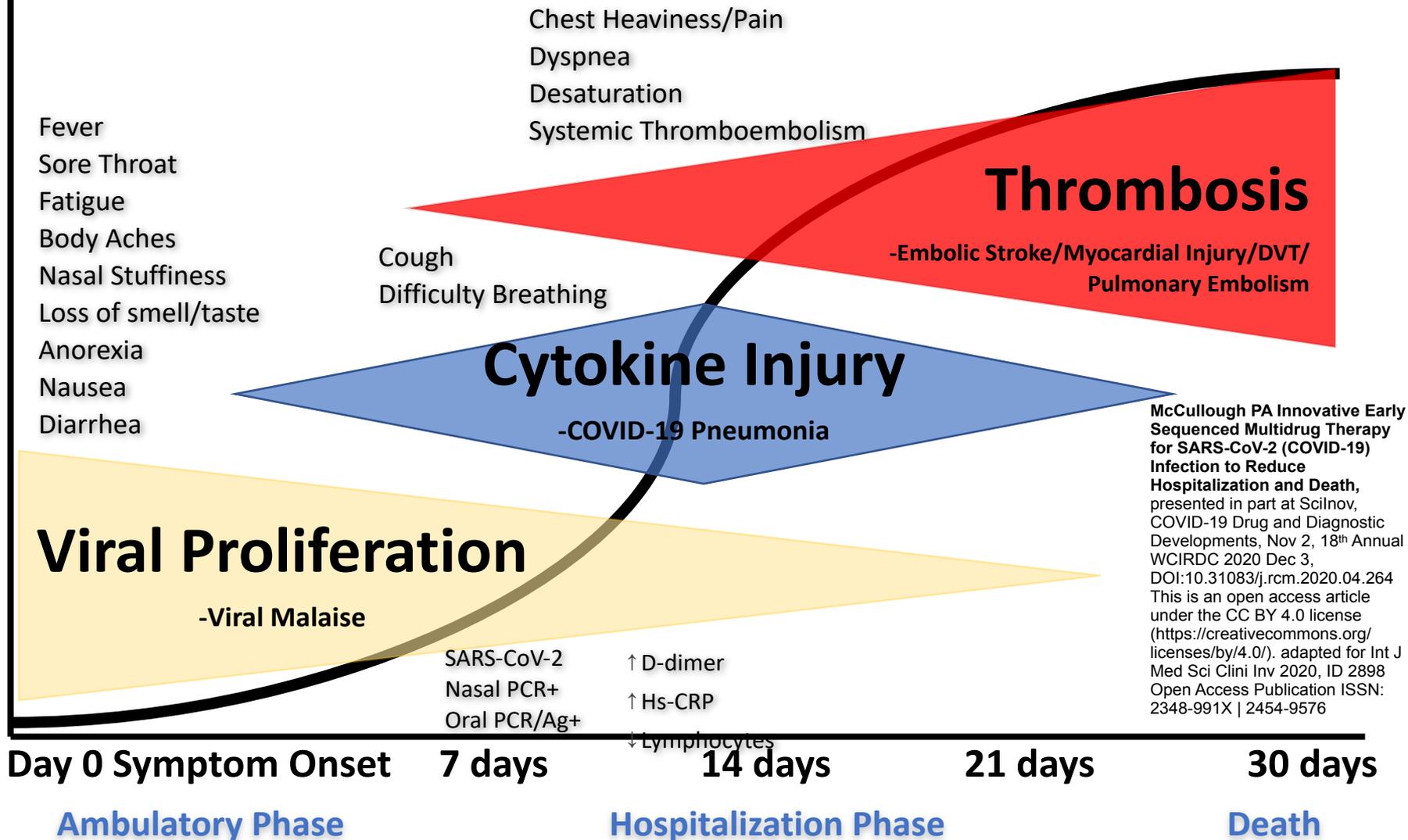
Therapeutic Response

Intracellular anti-infectives/antiviral antibodies

Corticosteroids/immunomodulators

Antiplatelet agents/anticoagulants

Untreated Mortality Risk



McCullough PA Innovative Early Sequenced Multidrug Therapy for SARS-CoV-2 (COVID-19) Infection to Reduce Hospitalization and Death, presented in part at Scilnov, COVID-19 Drug and Diagnostic Developments, Nov 2, 18th Annual WCIRDC 2020 Dec 3, DOI:10.31083/j.rcm.2020.04.264 This is an open access article under the CC BY 4.0 license (<https://creativecommons.org/licenses/by/4.0/>). adapted for Int J Med Sci Clin Inv 2020, ID 2898 Open Access Publication ISSN: 2348-991X | 2454-9576

Adapted from McCullough PA Innovative Early Sequenced Multidrug Therapy for SARS-CoV-2 (COVID-19) Infection to Reduce Hospitalization and Death, presented in part at Scilnov, COVID-19 Drug and Diagnostic Developments, Nov 2, 18th Annual WCIRDC 2020 Dec 3, DOI:10.31083/j.rcm.2020.04.264 This is an open access article under the CC BY 4.0 license (<https://creativecommons.org/licenses/by/4.0/>), adapted for Int J Med Sci Clin Inv 2020, ID 2898 Open Access Publication ISSN: 2348-991X | 2454-9576

COVID-19-like or COVID-19-confirmed illness:

- Self-quarantine at home
- Povidone iodine or Peroxide oral/nasal washes 6x day
- Contagion control
- Ventilate fresh air-reduce reinoculation

Room Air

Age < 50 yr.
Healthy

Age ≥ 50 yr. or a
Single Comorbidity
BMI > 30 kg/m², Pulmonary Dz, DM, CVD, CKD, Cancer

Age ≥ 50 yr. with
≥1 Comorbidities

OTC bundle: Zinc 50 mg, vitamin D₃ 20,000 IU, Vitamin C 3000 mg, Quercetin 500 mg po bid, Famotidine 80 mg (5-30 days)

If feasible: Monoclonal Antibody Infusion/Injection EUA Dosing

Watchful Waiting

Immediately ≥ 2 Anti-Infective Agents (5-30 days)

HCO 200 mg po bid
+ AZM 250 mg po bid or
+DOXY 100 mg po bid

IVM 600 mcg/kg po qd x 5 doses
+ AZM 250 mg po bid or
+DOXY 100 mg po bid

Paxlovid bid or
Molnupiravir bid EUA dosing
+ AZM 250 mg po bid or
+DOXY 100 mg po bid

Pulse Ox
Deliver
Home O₂
If Needed

If Symptoms
Worsen

Respiratory Symptoms Develop or Day 5 of illness

Inhaled budesonide 1 mg/2 mL nebulization/Dexamethasone 6 mg/Prednisone 1 mg/kg qd x 5 days ± taper/Colchicine 0.6 (0.5) mg po bid x 3 d then qd x 30 d

Complete Self-quarantine

Underlying Serious Medical Condition, ↑VTE Risk,
Suspect micro- or overt thrombosis

Aspirin 325 mg po qd ± Low-molecular weight heparin or
Apixaban, Rivaroxaban, Dabigatran, Edoxaban in Standard doses (5-30 days)

Re-evaluate
Hospitalize

Escalate Clinically

Consolidate

Received: 2021.11.05
Accepted: 2021.11.25
Available online: 2021.12.08
Published: 2021.12.30

Retrospective Study of Outcomes and Hospitalization Rates of Patients in Italy with a Confirmed Diagnosis of Early COVID-19 and Treated at Home Within 3 Days or After 3 Days of Symptom Onset with Prescribed and Non-Prescribed Treatments Between November 2020 and August 2021

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABDEF 1 **Serafino Fazio**
AE 2 **Paolo Bellavite**
CD 3 **Elisabetta Zanolin**
DE 4 **Peter A. McCullough** 
AD 5 **Sergio Pandolfi**
ABF 6 **Flora Affuso**

1 Retired Professor of Internal Medicine, Medical School University Federico II, Naples, Italy
2 Physiopathology Chair, Homeopathic Medical School of Verona, Verona, Italy
3 Unit of Epidemiology and Medical Statistics, Department of Diagnostics and Public Health, University of Verona, Verona, Italy
4 Department of Cardiology, Truth for Health Foundation, Tucson, AZ, USA
5 Department of Neurosurgery, Villa Mafalda Clinics, Rome, Italy
6 Independent Researcher, Gallipoli, Italy

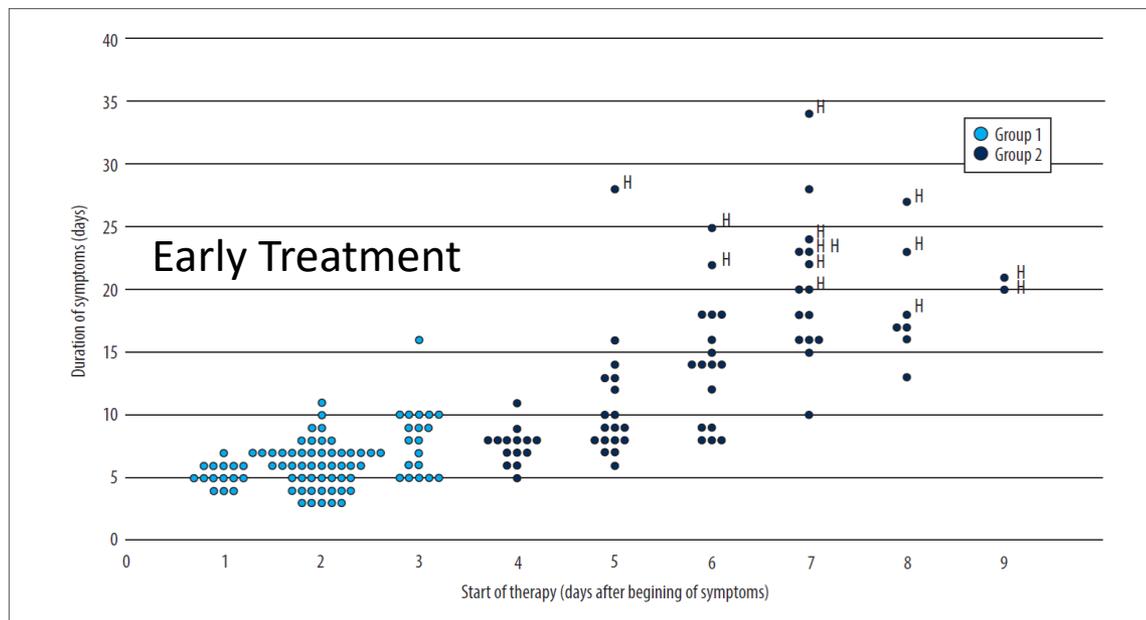


Figure 2. Duration of symptoms in relation to the delay in start of therapy. The symbol “H” specifies the patients who were hospitalized. The figure was created with Excel software and the “H” labels were added where indicated with PowerPoint software (Microsoft Office 2019).

On now
The McCullough Report
 At Home Management of
 Dr. Peter A. McCullough
 The McCullough Report

Listen live 

The Weekend

Listen on **iHeart Radio** or our **Media Player**.

The McCullough Report
At-Home Management of COVID-19, Everyone Can Do 2 pm ET

Energetic Health Radio
The CDC's Dirty Little Secret w/ Dr. Henry Ealy 3 pm ET

The Frankly Daniel Show
A Fractured Biden COVID-19 Fairy Tale w/ Daniel Baranowski 4 pm ET

Dr. Henry Ealy
This Week In COVID: Vaccine Breakthrough Increases By 78.8% In Only 1 Month

Dr. Peter McCullough
Omicron Unleashes Mass Illness and a New Reality on podcast

A New Year Begins

New Year Brings New Hope

by **DrLee4America**

It is a New Year, and with that comes a feeling of new potential, new hope, and optimism – if you choose to change your outlook on what role you play in how you view each day.

Column

Dilute Povidone-Iodine Nasal/Oral Washes for the Prevention and Treatment of COVID-19

by **Dr. Peter McCullough** | Dec 30, 2021 | Feature 3, Healthcare



  PDF

The SARS-CoV-2 virus is transmitted in the air and settles in the nose, and multiplies for days before it invades the body. When sick with nasal congestion, headache, fever, and body aches, the source of symptoms is the virus in the nose.

The virus must be killed in the nasal cavity at least twice a day after coming back home for prevention and up to every four hours during active treatment. This is very important with the Omicron variant, which multiplies 70 times faster than the prior strains of the virus.

Early treatment using this approach is associated with a 71% improvement, as shown in the figure. Also shown is a quick set up at home with povidone-iodine, which costs under \$10 a bottle online.

Take 1/2 tsp mix in a shot glass 1.5 oz of water, squirt up nose, sniff back to the back of the throat and spit out. Do twice in each nostril, then gargle with the rest for 30 sec. Do not swallow. If iodine allergic or intolerant, can substitute hydrogen peroxide.

Arefin MK, Rumi SKNF, Uddin AKMN, Banu SS, Khan M, Kaiser A, Chowdhury JA, Khan MAS, Hasan MJ. Virucidal effect of povidone iodine on COVID-19 in the nasopharynx: an open-label randomized clinical trial. Indian J Otolaryngol Head Neck Surg. 2021 May 18:1-5. doi: 10.1007/s12070-021-02616-7. Epub ahead of print. PMID: 34026595; PMCID: PMC8130786

Effect of 1% Povidone Iodine Mouthwash/Gargle, Nasal and Eye Drop in COVID-19 patient

Md. Iqbal Mahmud Choudhury¹, Nilufar Shabnam², Tazin Ahsan³, Md. Saiful kabir⁴, Rashed Md. Khan⁵, S.M. Abu Ahsan⁶

¹Assistant professor, Plastic Surgery Unit, Department of Surgery, Bangabandhu Sheikh Mujib Medical University, Shahbag, Dhaka, Bangladesh. ²Assistant professor, Department of Surgery, BIRDEM Hospital & Ibrahim Medical College, Shahbag, Dhaka, Bangladesh. ³Medical officer, Upazila Health Complex, Chowgacha, Jessore, Bangladesh. ⁴Professor and Head, Department of Dermatology and Venereology, National Medical College, Dhaka, Bangladesh. ⁵Professor and Head, Department of Dermatology and Venereology, Dhaka Medical College, Dhaka, Bangladesh. ⁶Associate Professor and Head, Ad-din Sakina Medical college, Jessore, Bangladesh.

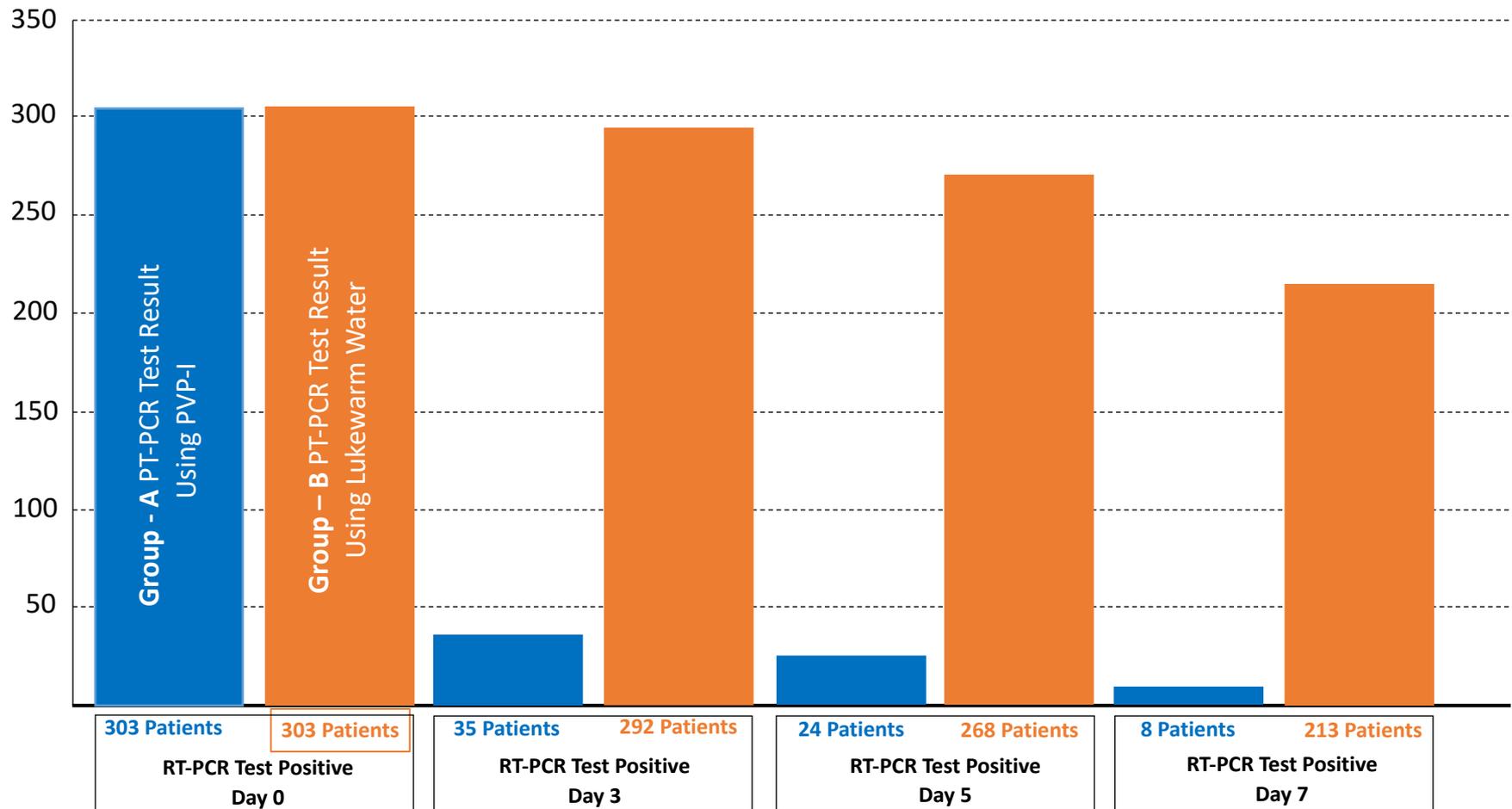
Bioresearch Communications
Volume 7, Issue 1, January 2021



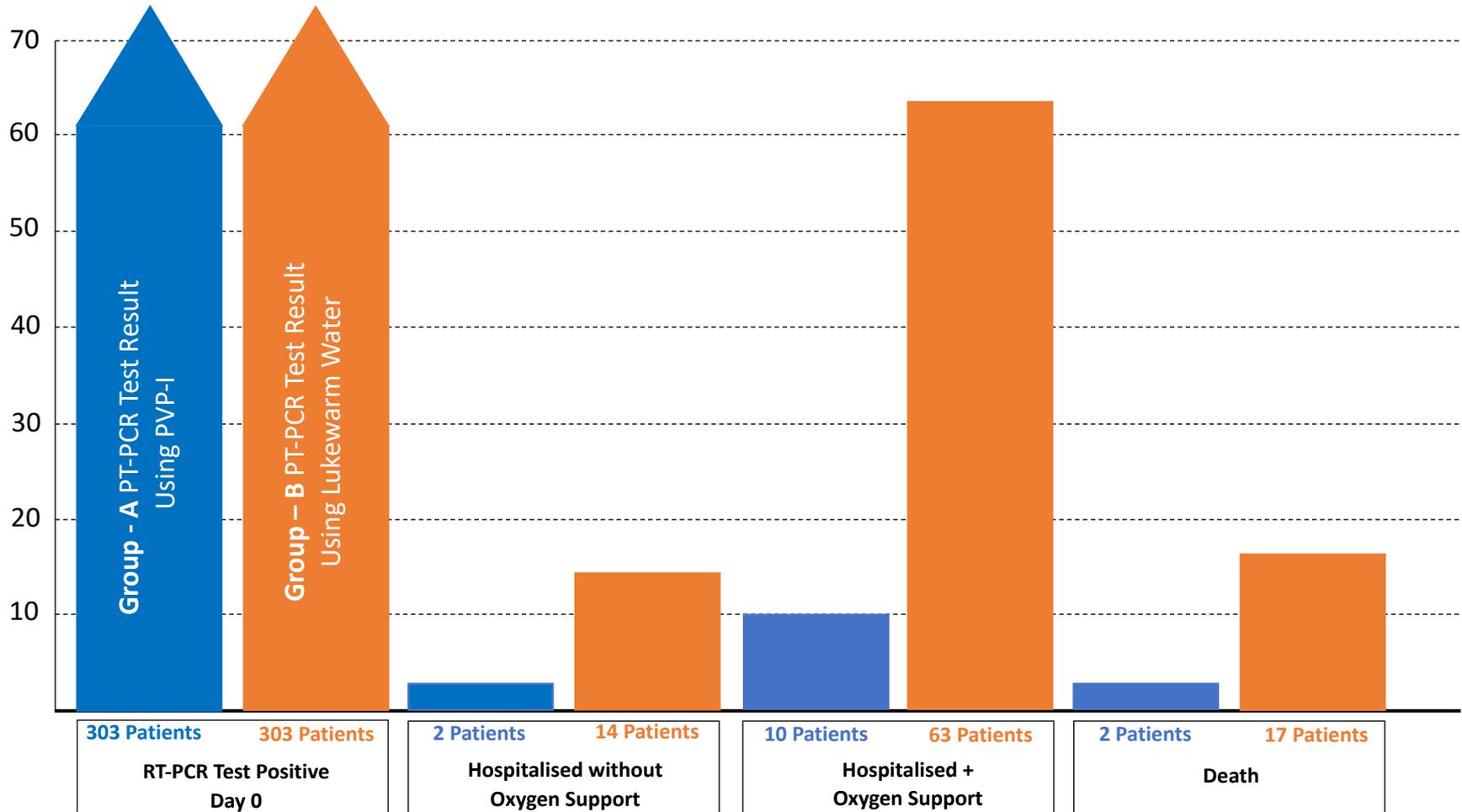
ABSTRACT: Background: The sudden onset of COVID-19 began in late 2019 caused by a novel coronavirus (SARS-COV2) and on 11th March, WHO declared it to have developed pandemic status. There is still no specific treatment and vaccine available for COVID-19; causing wide spread health problem and concern of the globe. Povidone iodine (PVP-I) is an antiseptic that has been used for over 150 years. It is already proved that different concentration of PVP-I can deactivate COVID-19 virus. **Methodology:** In this randomized controlled clinical trial, out of 1113 patients 606 patients were enrolled and divided in 2 groups by randomization after taken consents. In Gr-A, 303 patients underwent mouthwash/gargle, nasal drops and eye drops with 1% povidone iodine 4 hourly for 4 weeks as well as symptomatic treatment according to need. In Gr-B 303 patients were advised mouthwash/gargle, nasal cavity and eye wash with lukewarm water 4 hourly for 4 weeks and symptomatic treatment according to need. RT-PCR test done every 3rd, 5th and 7th day and Thyroid hormone level (TSH, T₃, T₄, FT₄) at 4th week for follow up. **Results:** The group of patients used 1% PVP-I have shown tremendously reduced mortality, morbidity and hospital as well as financial burden in this covid situation. **Conclusion:** Administration of 1% PVP-I as mouthwash/gargle, nasal or eye drop is simple, rapid and cost effective in reduction of mortality and morbidity by COVID-19.

KEYWORDS: Povidone Iodine, 1Pq.s, COVID-19.

RCT: EFFECT OF 1% POVIDONE IODINE MOUTHWASH/GARGLE, NASAL AND EYE DROP IN COVID-19 PATIENTS



RCT: EFFECT OF 1% POVIDONE IODINE MOUTHWASH/GARGLE, NASAL AND EYE DROP IN COVID-19 PATIENTS (OUTCOMES)



Safe, Effective Antimicrobial Nasal/Oral Rinses



Rep. Nancy Mace (R-S.C.) speaks with reporters in Washington, D.C. on Oct. 21, 2021. (Anna Moneymaker/Getty Images)

PREMIUM US NEWS

GOP Congresswoman Wants to Know Why Feds Have Not Promoted Nasal Spray to Treat COVID-19

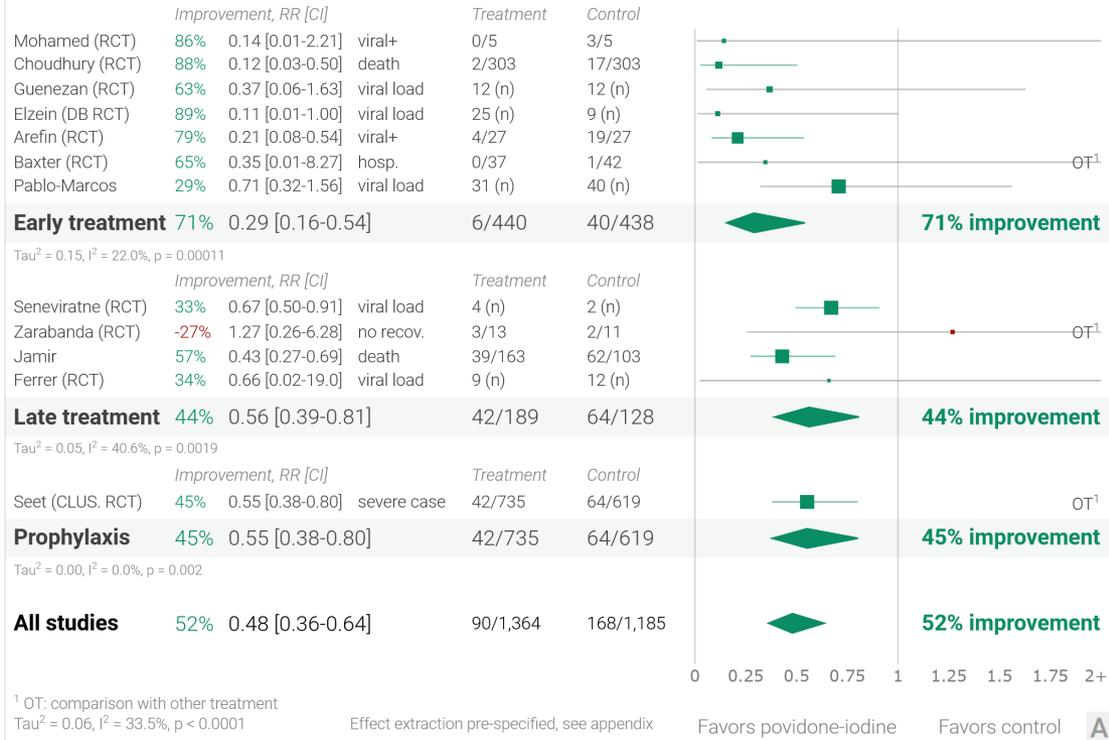
By [Alice Giordano](#) February 21, 2022 Updated: February 22, 2022

Print

Republican Congresswoman [Nancy Mace](#) is demanding answers from the Health and Human Services Department (HHS) about why the federal agency has not promoted nasal sprays as a treatment and prevention of COVID-19.

12 povidone-iodine COVID-19 studies

c19pvpi.com Dec 29, 2021



Understanding Unapproved Use of Approved Drugs "Off Label"



Understanding Unapproved Use of Approved Drugs "Off Label"

Has your healthcare provider ever talked to you about using an FDA-approved drug for an unapproved use (sometimes called an "off-label" use) to treat your disease or medical condition?



Content current as of: 02/05/2018

Why might an approved drug be used for an unapproved use?

From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient. You may be asking yourself why your healthcare provider would want to prescribe a drug to treat a disease or medical condition that the drug is not approved for. One reason is that there might not be an approved drug to treat your disease or medical condition. Another is that you may have tried all approved treatments without seeing any benefits. In situations like these, you and your healthcare provider may talk about using an approved drug for an unapproved use to treat your disease or medical condition.

A Guide to Home-Based COVID Treatment

Step-By-Step Doctors' Plan
That Could Save Your Life

Editors: Jane M. Orient, M.D. &
Elizabeth Lee Vliet, M.D.



September 17, 2021

Crushing the Lifeblood of Medical Science

by [Dr. Peter McCullough](#)

In this issue of The McCullough Report, we have some grave news about a concerning set of developments that have taken the COVID-19 crisis response and its consequences to the world to a whole new level. With the backdrop that free speech and scientific discourse is...

MCCULLOUGH REPORT

Treat the Viral Infection, Handle the Pandemic Crisis

by [Dr. Peter McCullough](#) | May 11, 2021 | [Healthcare](#), [Politics](#),

Sick COVID-19 patients don't feel better with masks and it's either too late or they have been failed by the vaccination. We need real doctors helping frightened patients in need to get through the crisis. We need to cut through all the fear, panic, hubris, and false narrative and getting to the truth of what is really going on during the pandemic...



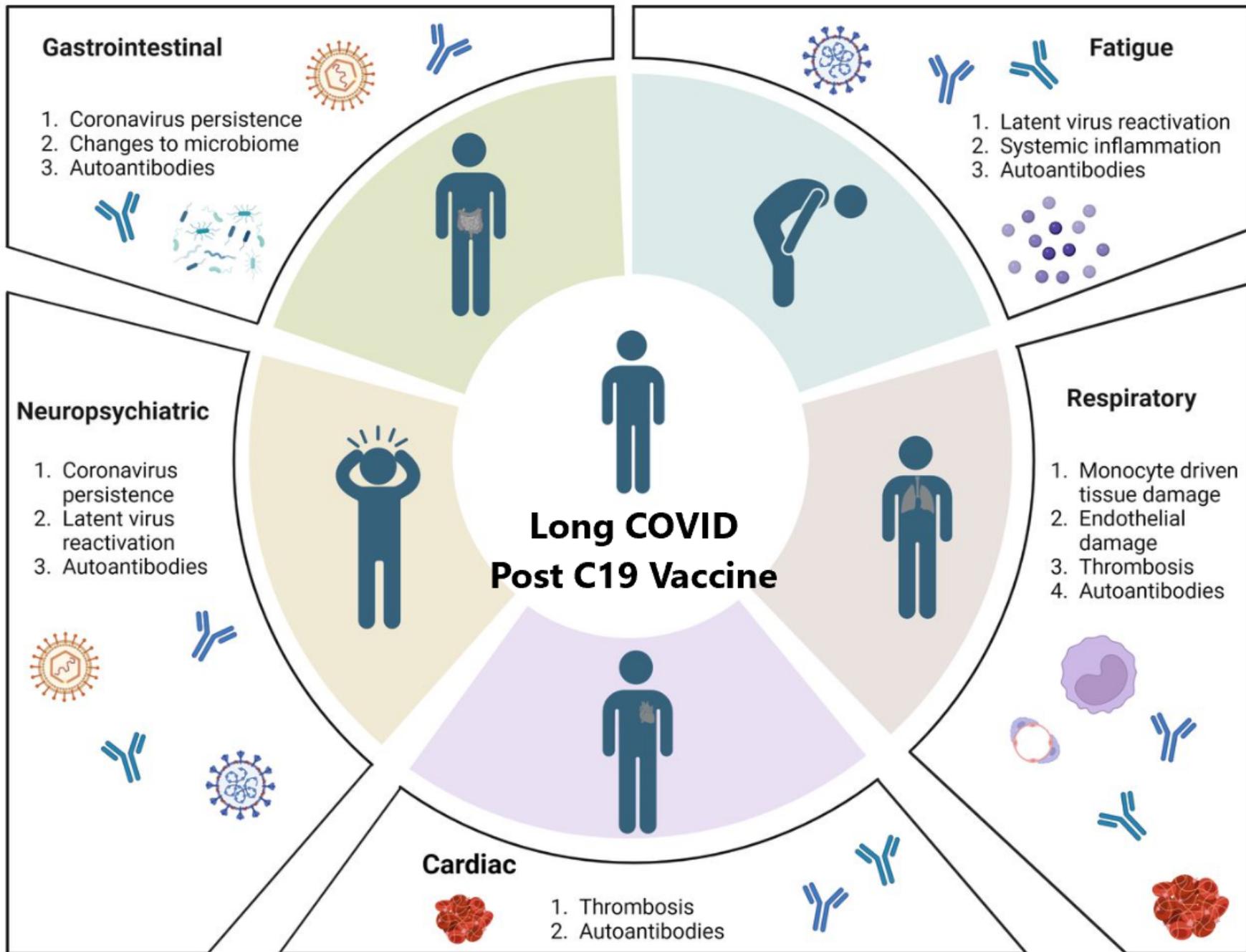


Article

Statistical Analysis Methods Applied to Early Outpatient COVID-19 Treatment Case Series Data

Eleftherios Gkioulekas ^{1,*}, Peter A. McCullough ² and Vladimir Zelenko ^{3,†}

By December 2020, there was “clear and convincing evidence” ($p < 0.01$) that early therapy was reducing COVID-19 hospitalizations and deaths



OPEN

A single-dose of oral nattokinase potentiates thrombolysis and anti-coagulation profiles

SCIENTIFIC REPORTS | 5:11601 | DOI: 10.1038/srep11601

Received: 28 August 2014
Accepted: 29 May 2015
Published: 25 June 2015

Yuko Kurosawa¹, Shinsuke Nirengi², Toshiyuki Homma², Kazuki Esaki², Mitsuhiro Ohta³, Joseph F. Clark⁴ & Takafumi Hamaoka¹

1st visit

Informed consent, Health checkup, Questionnaire

2nd visit and 3rd visit
(wash out period; > 2 weeks)

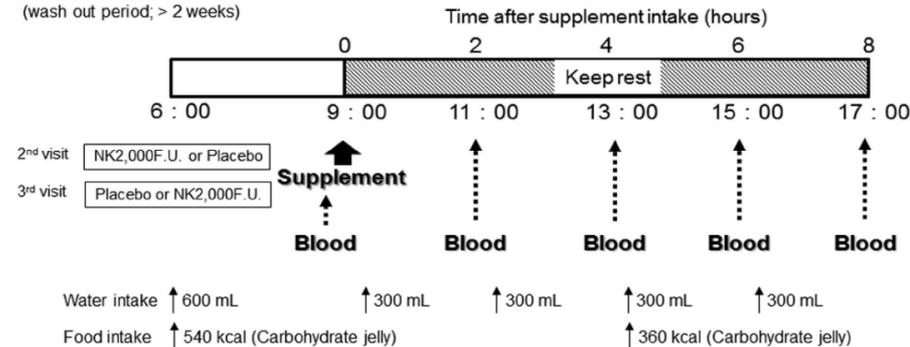


Figure 1. This figure shows the study design and the experimental procedures.

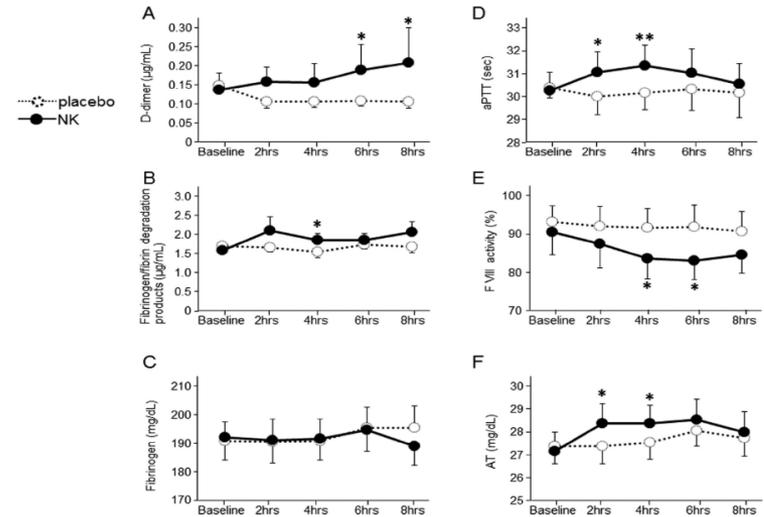


Figure 2. The figures show the fibrinolysis/coagulation parameters before and after a 2,000 FU of NK administration or placebo in twelve healthy young male, double blind crossover placebo-controlled design. Data are expressed as mean \pm SEM. Statistically significant when compared with placebo: *P < 0.05, **P < 0.01.

Nattokinase: A Promising Alternative in Prevention and Treatment of Cardiovascular Diseases

Hongjie Chen¹, Eileen M McGowan², Nina Ren³, Sara Lal², Najah Nassif², Fatima Shad-Kaneez², Xianqin Qu² and Yiguang Lin²

¹Department of Traditional Chinese Medicine, The Third Affiliated Hospital, Sun Yat-Sen University, Guangzhou, China. ²School of Life Sciences, University of Technology Sydney, Broadway, NSW, Australia. ³Guangdong Online Hospital Clinic, Guangdong No.2 Provincial People's Hospital, Guangzhou, China.

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ABSTRACT: Cardiovascular disease (CVD) is the leading cause of death in the world and our approach to the control and management of CVD mortality is limited. Nattokinase (NK), the most active ingredient of natto, possesses a variety of favourable cardiovascular effects and the consumption of Natto has been linked to a reduction in CVD mortality. Recent research has demonstrated that NK has potent fibrinolytic activity, antihypertensive, anti-atherosclerotic, and lipid-lowering, antiplatelet, and neuroprotective effects. This review covers the major pharmacologic effects of NK with a focus on its clinical relevance to CVD. It outlines the advantages of NK and the outstanding issues pertaining to NK pharmacokinetics. Available evidence suggests that NK is a unique natural compound that possesses several key cardiovascular beneficial effects for patients with CVD and is therefore an ideal drug candidate for the prevention and treatment of CVD. Nattokinase is a promising alternative in the management of CVD.

KEYWORDS: Nattokinase, natto, cardiovascular disease, antithrombotic agents, antihypertensive drugs, atherosclerosis

Table 1.

YEAR	LOCATION OF STUDY	SIZE OF STUDY	CLINICAL CONDITION OBSERVED	SUMMARY OF FINDINGS	REFERENCES
1990	Japan	12	Fibrinolytic activity	3x NK daily oral administration resulted in enhanced fibrinolytic activity in the plasma and production of tissue plasminogen activator	Sumi et al ⁶
2004	Japan	24	Ischaemic stroke	NK demonstrated a clear neuroprotective effect in patients with acute ischaemic stroke	Shah et al ⁵⁶
2008	Korea	86	Hypertension	NK supplementation resulted in a reduction in both systolic and diastolic BP ($P < .05$)	Kim et al ⁸
2009	Taiwan	45	Blood coagulation factors	2 mo of NK treatment significantly decreased fibrinogen, factor VII, and factor confirming a promising cardiovascular benefit	Hsia et al ¹⁷
2009	Taiwan	30	Hyperglycaemia	A decrease in serum cholesterol, LDL-C, and HDL-C in the NK group was observed following 8 wk of treatment (4000 FU), but the difference was not statistically significant	Wu et al ⁴²
2013	USA	11	Pharmacokinetics	NK can be measured directly in the human blood after single dosing. Serum levels of NK peaked at approximately 13.3h \pm 2.5 h	Ero et al ⁶⁰
2015	Japan	12	Thrombolysis and anticoagulation	Blood fibrin/fibrinogen degradation products (thrombolysis and anticoagulation profile) were significantly increased 4 h after NK administration following a single dose of 2000 FU ($P < .05$), supporting NK as a useful fibrinolytic/anticoagulant agent to reduce the risk of thrombosis and CVDs in humans	Kurosawa et al ¹⁶
2016	USA	79	Hypertension and von Willebrand factor	NK consumption for 8 wk led to beneficial changes to BP in hypertensive patients. A decrease in vWF was seen in the female population consuming NK	Jensen et al ¹⁵
2016	USA	11	Toxicology/toxicity	NK consumption of 10 mg/kg/day for 4 wk was well tolerated in healthy human volunteers suggesting that the oral consumption of NK is of low toxicological concern	Lampe and English ⁶¹
2017	China	76	Atherosclerosis and hyperglycaemia	Daily NK treatment (6500 FU for 26 wk) effectively suppressed the progression of atherosclerosis in patients with atherosclerotic plaques by reducing CCA-IMT and carotid plaque size significantly. NK treatment reduced total cholesterol, LDL-C, and triglyceride and increased HDL-C in hyperlipidaemic patients	Ren et al ⁹

Abbreviations: BP, blood pressure; CCA-IMT, common carotid artery; CVD, cardiovascular disease; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; NK, nattokinase.

Degradative Effect of Nattokinase on Spike Protein of SARS-CoV-2

Takashi Tanikawa ^{1,*}, Yuka Kiba ^{2,†}, James Yu ³, Kate Hsu ³, Shinder Chen ³, Ayako Ishii ⁴, Takami Yokogawa ², Ryuichiro Suzuki ⁵, Yutaka Inoue ¹ and Masashi Kitamura ^{2,*}

Citation: Tanikawa, T.; Kiba, Y.; Yu, J.; Hsu, K.; Chen, S.; Ishii, A.; Yokogawa, T.; Suzuki, R.; Inoue, Y.; Kitamura, M. Degradative Effect of Nattokinase on Spike Protein of SARS-CoV-2. *Molecules* **2022**, *27*, 5405. <https://doi.org/10.3390/molecules27175405>

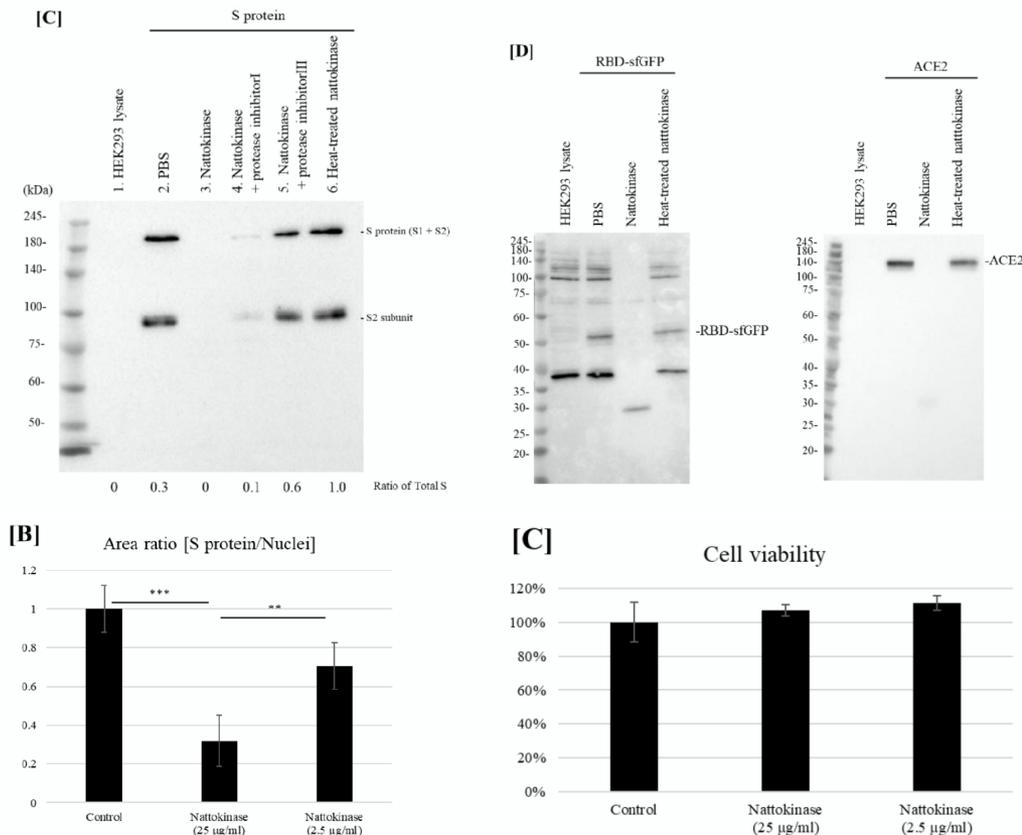


Figure 2. (A) Degradative effect of nattokinase on S protein on the cell surface. Spike-pcDNA3.1 was transfected with HEK293 cells and incubated for 9 h. After incubation, nattokinase (25 and 2.5 µg/mL) were added to culture medium and further incubated for 13 h. Cells were fixed and immunofluorescent analysis was performed. S protein on the cell surface was stained with anti-spike protein antibody (Red) and nucleus was stained with DAPI (Blue). (B) Ratio of S protein area to nucleus positive area. Three images per sample were captured and S protein/nucleus positive areas were calculated. Data are shown as mean + SD, and *p*-value was determined by one-way analysis of variance (ANOVA) with Tukey's post-hoc test using R software (R-3.3.3 for windows) (** *p* < 0.01; *** *p* < 0.001). (C) Cell viability was evaluated by MTT assay. Indicated nattokinase was added to culture medium and incubated for 13 h; MTT assay was performed.

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- **Natural Immunity**
- Twin epidemics of autism and gender dysphoria
- Censorship of Scientific Discourse
- Conclusions

Duration of immune protection of SARS-CoV-2 natural infection against reinfection in Qatar



Hiam Chemaitelly, PhD^{1,2,3*}, Nico Nagelkerke PhD¹, Houssein H. Ayoub, PhD⁴, Peter Coyle, MD^{5,6,7}, Patrick Tang, MD PhD⁸, Hadi M. Yassine, PhD^{6,9}, Hebah A. Al-Khatib, PhD^{6,9}, Maria K. Smatti, MSc^{6,9}, Mohammad R. Hasan, PhD⁸, Zaina Al-Kanaani, PhD⁵, Einas Al-Kuwari, MD⁵, Andrew Jeremijenko, MD⁵, Anvar Hassan Kaleeckal, MSc⁵, Ali Nizar Latif, MD⁵, Riyazuddin Mohammad Shaik, MSc⁵, Hanan F. Abdul-Rahim, PhD¹⁰, Gheyath K. Nasrallah, PhD^{6,9}, Mohamed Ghaith Al-Kuwari, MD¹¹, Adeel A. Butt, MBBS MS^{3,5,12}, Hamad Eid Al-Romaihi, MD¹³, Mohamed H. Al-Thani, MD¹³, Abdullatif Al-Khal, MD⁵, Roberto Bertollini, MD MPH¹³, and Laith J. Abu-Raddad, PhD^{1,2,3,10*}

- Natural immunity 97.3% protection against severe, critical, or fatal COVID-19
- No waning over 15 months

Protection against Omicron from Vaccination and Previous Infection in a Prison System

Elizabeth T. Chin, Ph.D., David Leidner, Ph.D., Lauren Lamson, M.S.,
 Kimberley Lucas, M.P.H., David M. Studdert, Sc.D.,
 Jeremy D. Goldhaber-Fiebert, Ph.D., Jason R. Andrews, M.D.,
 and Joshua A. Salomon, Ph.D.

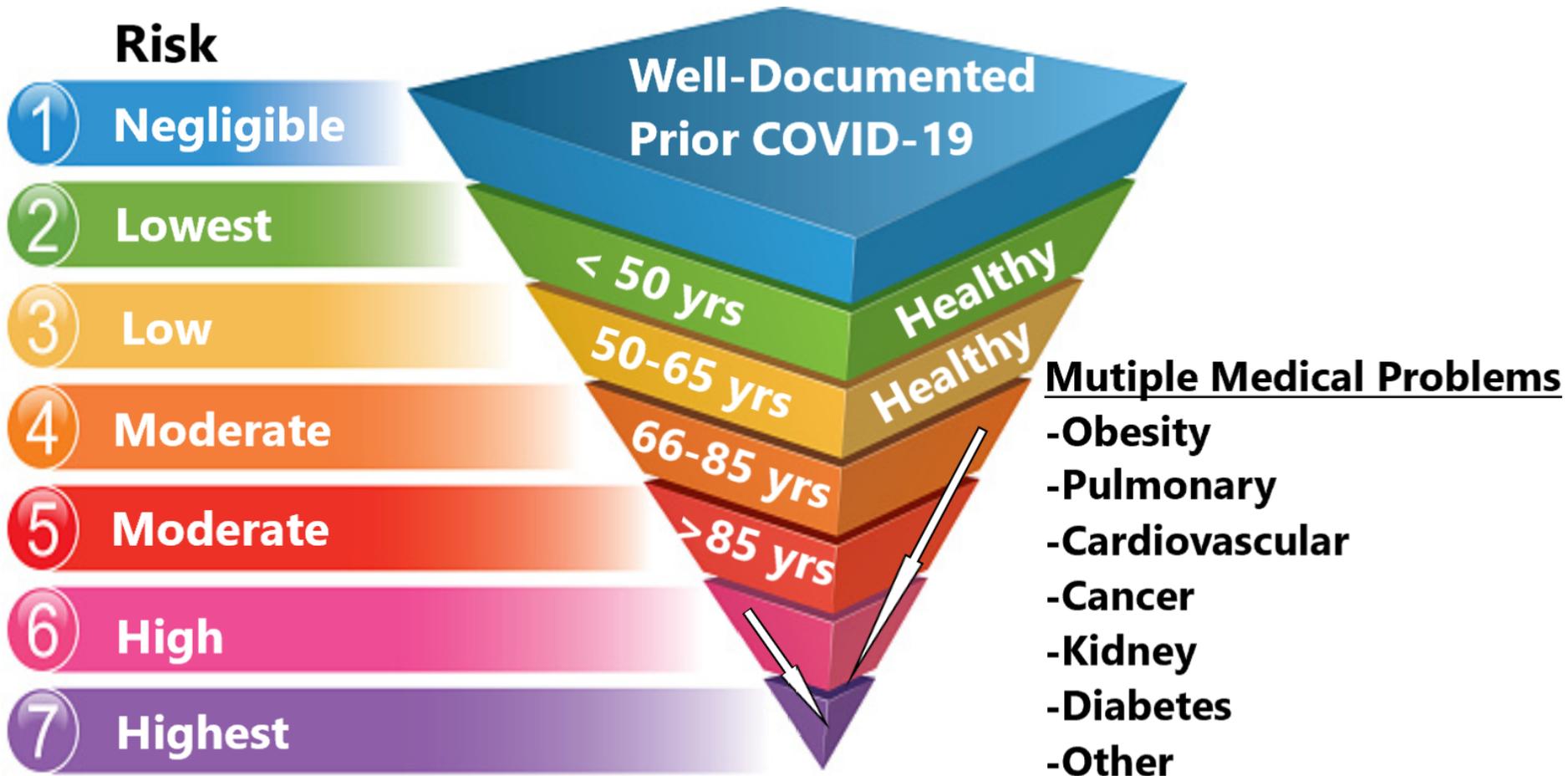
This article was published on October 26, 2022, at NEJM.org.

N Engl J Med 2022;387:1770-82.

Prior infection during Delta or Omicron periods, next SARS-CoV-2 infection had zero risk of hospitalization/death

Variant predominance	Two doses	Three doses	5.2%	0	0	0.7 (0.4)	[126-162]	[127.5-146]	[66-291]	[53.25-296]
				0	0	0.7 (0.4)	145	143	37	38.5
							[127-158]	[120.5-149.5]	[28-58]	[26.75-53.25]
Total	59794	9992	16.7%	96	1	0.6 (0.6)	393	396	59	70
							[372-435]	[372-470]	[33-243]	[35-255]

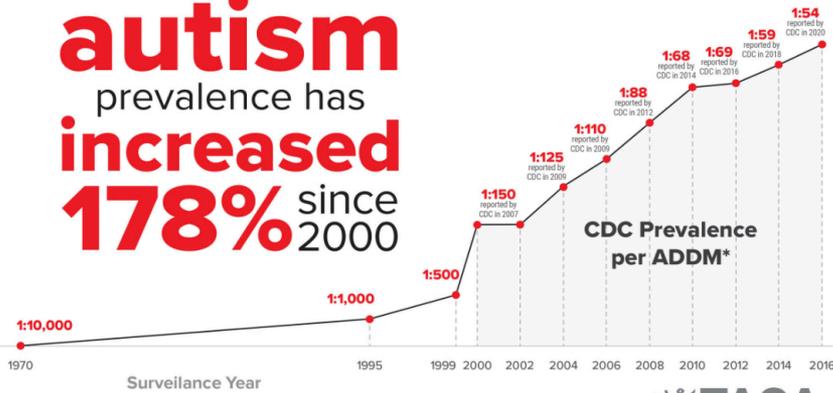
Acute COVID-19 Risk for Hospitalization or Death in Omicron Era



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autism prevalence has increased 178% since 2000



*ADDM (Autism and Developmental Disabilities Monitoring Network)



Journal of Toxicology and Environmental Health, Part A, 74:903-916, 2011
 Copyright © Taylor & Francis Group, LLC
 ISSN: 1528-7394 print / 1087-2620 online
 DOI: 10.1080/15287394.2011.573736

A POSITIVE ASSOCIATION FOUND BETWEEN AUTISM PREVALENCE AND CHILDHOOD VACCINATION UPTAKE ACROSS THE U.S. POPULATION

Gayle DeLong

Department of Economics and Finance, Baruch College/City University of New York, New York, New York, USA

The reason for the rapid rise of autism in the United States that began in the 1990s is a mystery. Although individuals probably have a genetic predisposition to develop autism, researchers suspect that one or more environmental triggers are also needed. One of those triggers might be the battery of vaccinations that young children receive. Using regression analysis and controlling for family income and ethnicity, the relationship between the proportion of children who received the recommended vaccines by age 2 years and the prevalence of autism (AUT) or speech or language impairment (SLI) in each U.S. state from 2001 and 2007 was determined. A positive and statistically significant relationship was found: The higher the proportion of children receiving recommended vaccinations, the higher was the prevalence of AUT or SLI. A 1% increase in vaccination was associated with an additional 680 children having AUT or SLI. Neither parental behavior nor access to care affected the results, since vaccination proportions were not significantly related (statistically) to any other disability or to the number of pediatricians in a U.S. state. The results suggest that although mercury has been removed from many vaccines, other culprits may link vaccines to autism. Further study into the relationship between vaccines and autism is warranted.

TABLE 2. Analysis of Learning Disabilities, United States, 2001–2007, Fixed Effects Model

	Autism or speech or language impairment	Emotional disturbance	Hearing impairment	Mental retardation	Orthopedic impairment	Other health impairment	Specific learning disability	Traumatic brain injury	Visual impairment
Proportion of children receiving 4:3:1:3:3 vaccination series	0.0166*** (0.00)	0.0010 (0.31)	0.0026 (0.70)	0.0008 (0.69)	-0.0008 (0.42)	0.0018 (0.32)	0.0064* (0.09)	0.0006 (0.17)	0.0003* (0.10)
Loghousehold Income	-0.0029 (0.70)	0.0006 (0.72)	-0.0081 (0.31)	0.0008 (0.34)	-0.0014 (0.46)	-0.0011 (0.73)	0.0004 (0.95)	-0.0014*** (0.01)	-0.0001 (0.71)
Hispanic (%)	0.0213 (0.13)	0.0006 (0.83)	-0.0269* (0.06)	0.0117*** (0.00)	-0.0042 (0.20)	-0.0029 (0.56)	-0.0061 (0.72)	-0.0008 (0.41)	0.0005 (0.29)
African American, not Hispanic (%)	0.0216 (0.13)	0.0108 (0.15)	-0.0443 (0.12)	0.0053 (0.97)	-0.0073 (0.19)	0.0055 (0.29)	0.0231 (0.23)	-0.0001 (0.90)	0.0001 (0.79)
Other, not Hispanic (%)	-0.0208 (0.41)	-0.0124** (0.03)	-0.0074 (0.64)	0.0024 (0.69)	-0.0025 (0.60)	-0.0078 (0.26)	-0.0479*** (0.01)	-0.0009 (-0.77)	0.0013** (0.04)
Adjusted R ²	.9636	.9358	.1803	.9536	.7935	.9090	.9006	.9280	.5312
n	354	354	348	354	327	352	356	231	302

Note. Standard errors are heteroskedastic-robust using White's method. Time dummy variables included; p values are in parentheses. The maximum number of observations is 357. Not every state reports each disability for every year so the number of observations could be less than 357. Significance indicated as *** (*) (†) p < .01 (.05) (.10).

VACCINES DOSES for U.S. CHILDREN

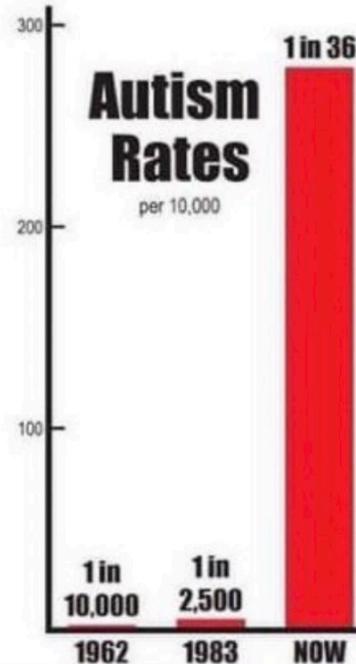
1962
OPV
Smallpox
DTP
5 Doses

1983
DTP (2 months)
OPV (2 months)
DTP (4 months)
OPV (4 months)
DTP (6 months)
MMR (15 months)
DTP (18 months)
OPV (18 months)
DTP (4 years)
OPV (4 years)
Td (15 years)
24 Doses

NOW
Influenza (pregnancy)
Tdap (pregnancy)
Hep B (birth)
Hep B (2 months)
Rotavirus (2 months)
DTaP (2 months)
HIB (2 months)
PCV (2 months)
IPV (2 months)
Rotavirus (4 months)
DTaP (4 months)
HIB (4 months)
PCV (4 months)
IPV (4 months)
Hep B (6 months)
Rotavirus (6 months)
DTaP (6 months)
HIB (6 months)
PCV (6 months)
IPV (6 months)
Influenza (6 months)
Influenza (7 months)
HIB (12 months)
PCV (12 months)
MMR (12 months)
Varicella (12 months)
Hep A (12 months)
DTaP (18 months)
Influenza (18 months)
Hep A (18 months)

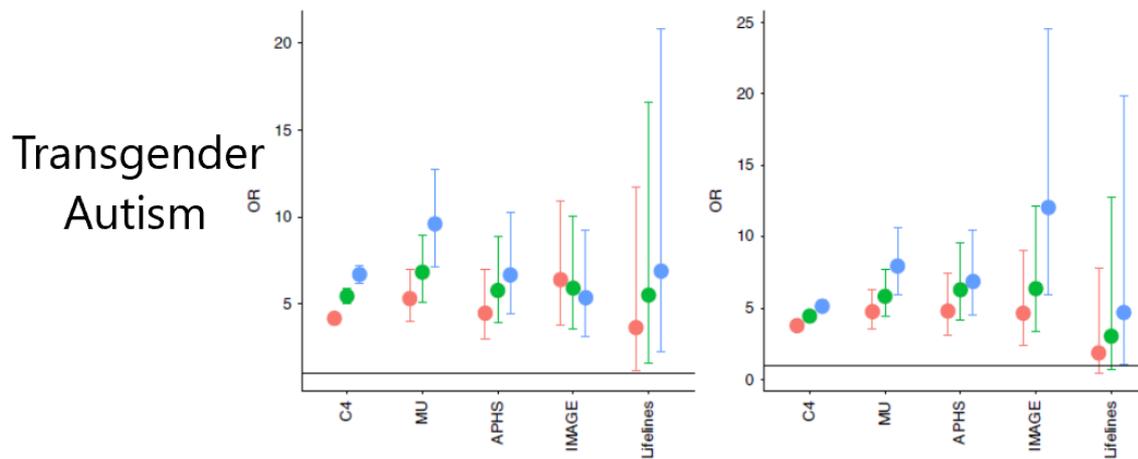
Influenza (30 months)
Influenza (42 months)
DTaP (4 years)
IPV (4 years)
MMR (4 years)
Varicella (4 years)
Influenza (5 years)
Influenza (6 years)
Influenza (7 years)
Influenza (8 years)
Influenza (9 years)
HPV (9 years)
Influenza (10 years)
HPV (10 years)
Influenza (11 years)
HPV (11 years)
Tdap (12 years)
Influenza (12 years)
Meningococcal (12 years)
Influenza (13 years)
Influenza (14 years)
Influenza (15 years)
Influenza (16 years)
Meningococcal (16 years)
Influenza (17 years)
Influenza (18 years)

72 Doses



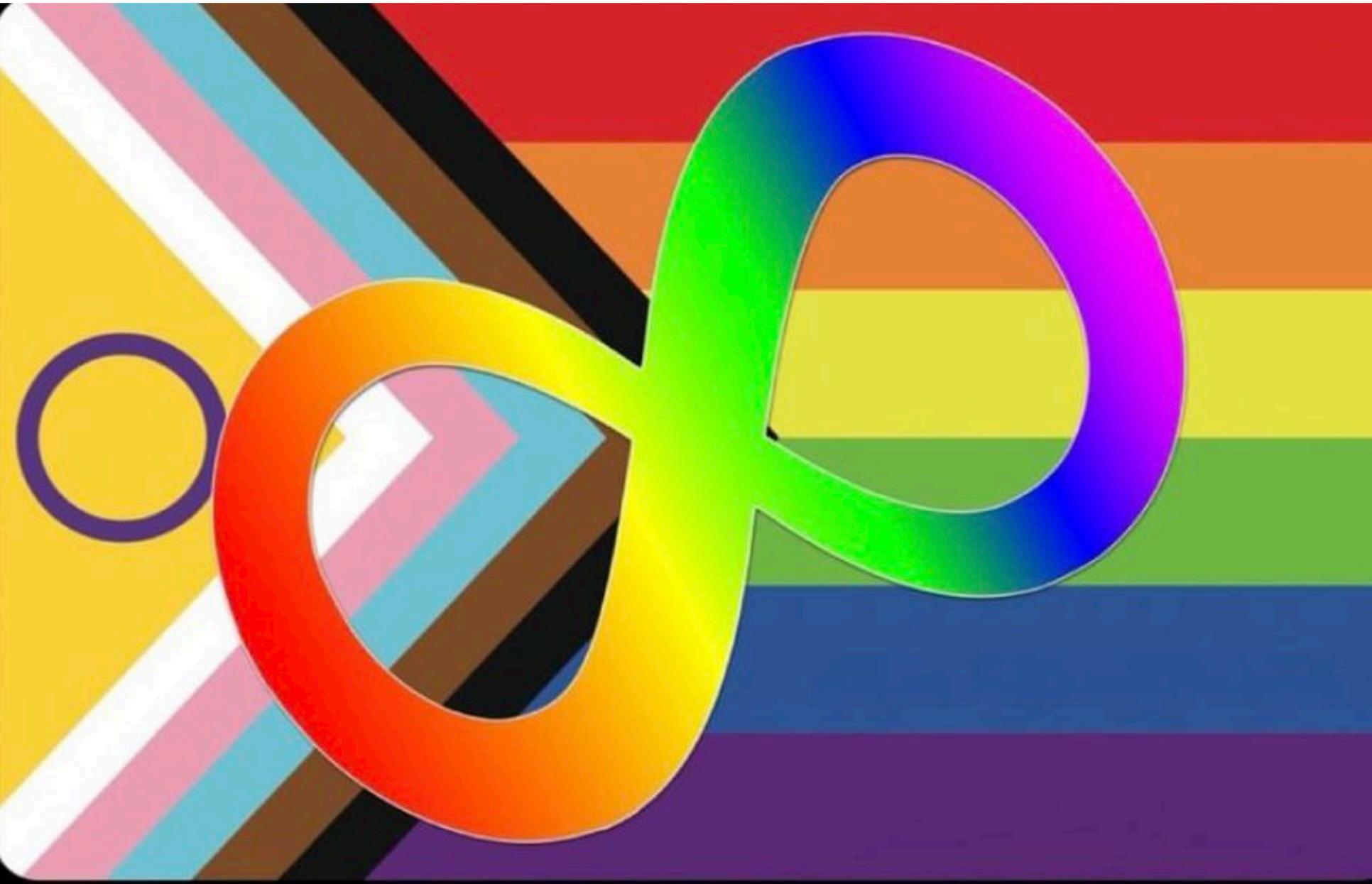
Elevated rates of autism, other neurodevelopmental and psychiatric diagnoses, and autistic traits in transgender and gender-diverse individuals

Varun Warriar¹, David M. Greenberg^{1,2}, Elizabeth Weir¹, Clara Buckingham¹, Paula Smith¹, Meng-Chuan Lai^{1,3,4}, Carrie Allison¹ & Simon Baron-Cohen¹



Compared to reference group Reference category ● Cisgender male ● Cisgender ● Cisgender female

Fig. 2 ORs and 95% CIs for autism in transgender and gender-diverse individuals compared to cisgender males, cisgender females, and cisgender individuals altogether. **a** This figure provides the unadjusted Odds Ratios (ORs, point) and 95% CIs for autism in transgender and gender-diverse individuals compared to either cisgender males, cisgender females, or cisgender (cisgender males and cisgender females) individuals in five datasets (C4: $N = 514,100$; MU: $N = 85,670$; APHS: $N = 2312$; IMAGE: $N = 1803$; and Lifelines: $N = 37,975$). **b** This figure provides adjusted ORs (point) and 95% CIs for autism in transgender and gender-diverse individuals compared to cisgender males, cisgender females, or all cisgender individuals in five datasets (C4: $N = 514,100$; MU: $N = 85,670$; APHS: $N = 2312$; IMAGE: $N = 1803$; and Lifelines: $N = 37,975$). ORs have been adjusted for age, educational attainment, and in the case of IMAGE dataset, an additional dummy variable for study (see “Supplementary Methods”). The y-axis is on the same scale for both panels. The differences in ORs for the IMAGE dataset between Models 1 and 2 is primarily due to the inclusion of “study” group as a covariate. Specifically, the IMAGE dataset consists of individuals recruited into a study of mathematics and autism (“Methods”). Whilst the mathematics group is predominantly male and have higher educational attainment (all have at least an undergraduate degree), the case-control group had a more balanced ratio and a wider range of educational attainment. Covarying for the study the participants have been recruited into (mathematics or autism case-control) changes the ORs.





Volume 18, Issue 8
August 2021

JOURNAL ARTICLE

Mental Healthcare Utilization of Transgender Youth Before and After Affirming Treatment [Get access](#)

Elizabeth Hisle-Gorman, MSW, PhD , Natasha A. Schvey, PhD, Terry A. Adirim, MD, MPH, Anna K. Rayne, MD, Apryl Susi, MS, Timothy A. Roberts, MD, MPH, David A. Klein, MD, MPH

The Journal of Sexual Medicine, Volume 18, Issue 8, August 2021, Pages 1444–1454.

<https://doi.org/10.1016/j.jsxm.2021.05.014>

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“Pronounced increases in mental healthcare for adjustment, anxiety, mood, personality, psychotic disorders, and suicide”

medical affirmation on mental health, including family and social factors associated with the persistence and discontinuation of mental healthcare needs among TGD youth.

Keywords: Transgender, Gender-Diverse, Mental Health, Adolescent, Youth

Issue Section: Transgender Health



Original Investigation | Equity, Diversity, and Inclusion

Analysis of Mortality Among Transgender and Gender Diverse Adults in England

Sarah S. Jackson, PhD, MPH; Jalen Brown, BS; Ruth M. Pfeiffer, PhD; Duncan Shrewsbury, PhD; Stewart O'Callaghan, MSc; Alison M. Berner, MSc; Shahinaz M. Gadalla, PhD; Meredith S. Shiels, PhD

Table 3. MRRs for Select Causes Among Transgender and Gender Diverse Individuals Compared With Cisgender Individuals in the UK's Clinical Practice Research Datalink^a

Cause of death	All transgender and gender diverse individuals		
	No. who died	MRR (95% CI)	
		Compared with cisgender men	Compared with cisgender women
External causes of mortality			
Suicide or homicide	10	3.34 (1.70-6.54)	5.62 (2.65-11.91)
Accidental poisoning	7	2.28 (1.04-5.02)	5.20 (2.22-12.18)
Neoplasms			
Gastrointestinal	9	1.15 (0.50-2.66)	1.14 (0.50-2.63)
Lung	14	1.28 (0.65-2.52)	1.22 (0.62-2.41)
Endocrine, nutritional, and metabolic diseases	≤5 ^b	1.80 (0.69-4.66)	2.95 (1.08-8.07)
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified; other ill-defined and unspecified causes of mortality	≤5 ^b	5.27 (1.95-14.26)	18.63 (5.39-64.37)

Abbreviation: MRR, mortality rate ratio.

^a Missing covariate data were imputed using multiple imputation. Models were estimated using Poisson regression adjusted for continuous index age, continuous index year, race and ethnicity (White, Black, Asian, or another or unknown race or ethnicity), Index of Multiple Deprivation (quintiles), smoking status (current, former, never), alcohol use (current, former, never), body mass index (weight in kilograms divided by height in meters squared: underweight or healthy weight [<18.5 - 24.9], overweight [25.0 - 29.9], or obese [≥ 30.0]), and practice.

^b Clinical Practice Research Datalink requires suppression of counts ≤ 5 .

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Medical Freedom

Social Freedom

Economic Freedom

Podcast

A Second Opinion on US COVID-19 Pandemic Response

by [Dr. Peter McCullough](#) | Feb 7, 2022 | [Healthcare](#), [Politics](#),



Top US health agency admits major mistakes in COVID-19 pandemic response

Director of Centers for Disease Control and Prevention announces plans to overhaul agency because 'we fell short in many ways'

Darren Lyn | 18.08.2022



CDC Implodes as False Narrative Crumbles

by [Dr. Peter McCullough](#) | Aug 27, 2022 | [Health](#), [Politics](#)



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Conclusions

- COVID-19 pandemic response has been a global disaster
- Safety profile and expected serious adverse events after COVID-19 vaccination are well characterized
- Limitations of theoretical efficacy have evolved over time
- Prehospital phase is a therapeutic opportunity for acute COVID-19
 - Reduce the risk of hospitalization and death
 - More safely temporize to close the crisis with herd immunity
- Twin epidemics of autism and related transgenderism
 - Amplifies psychiatric burden of disease
 - Increases in mortality
- Censorship and reprisal are working to crush freedom of speech, scientific discourse, and medical progress

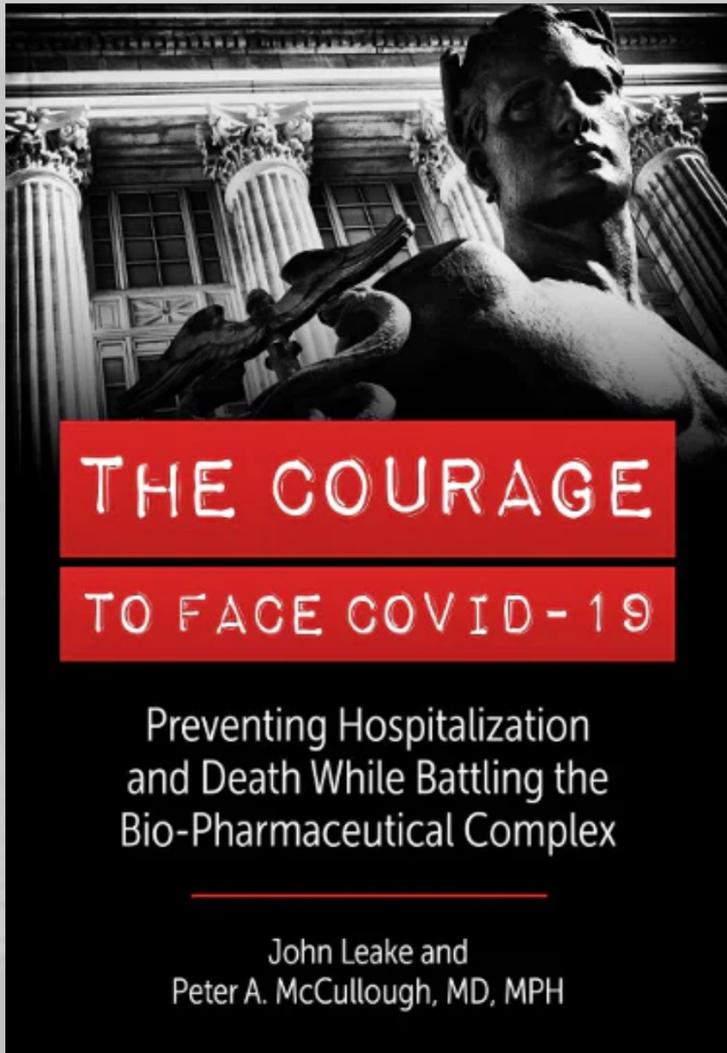


Courtesy of Jan Aleson, Independence, KS

Call to Action

- **Drop** all vaccine mandates immediately
- **Prohibit** forms of pressure, coercion, or threat of reprisal for vaccination
- **Ban** all forms of vaccine discrimination
- **Pause** Pfizer/Moderna/JNJ vaccines and thorough safety review
- **Begin** vaccine-injury treatment centers at major medical centers
- **Pivot** to early COVID-19 treatment at community and academic medical centers
- **Ban** transgender programs for youth and drop funding for adult elective procedures

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