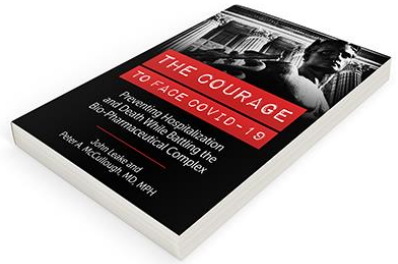
COVID-19 Vaccine Safety and Efficacy and Principles of Early Ambulatory Therapy

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

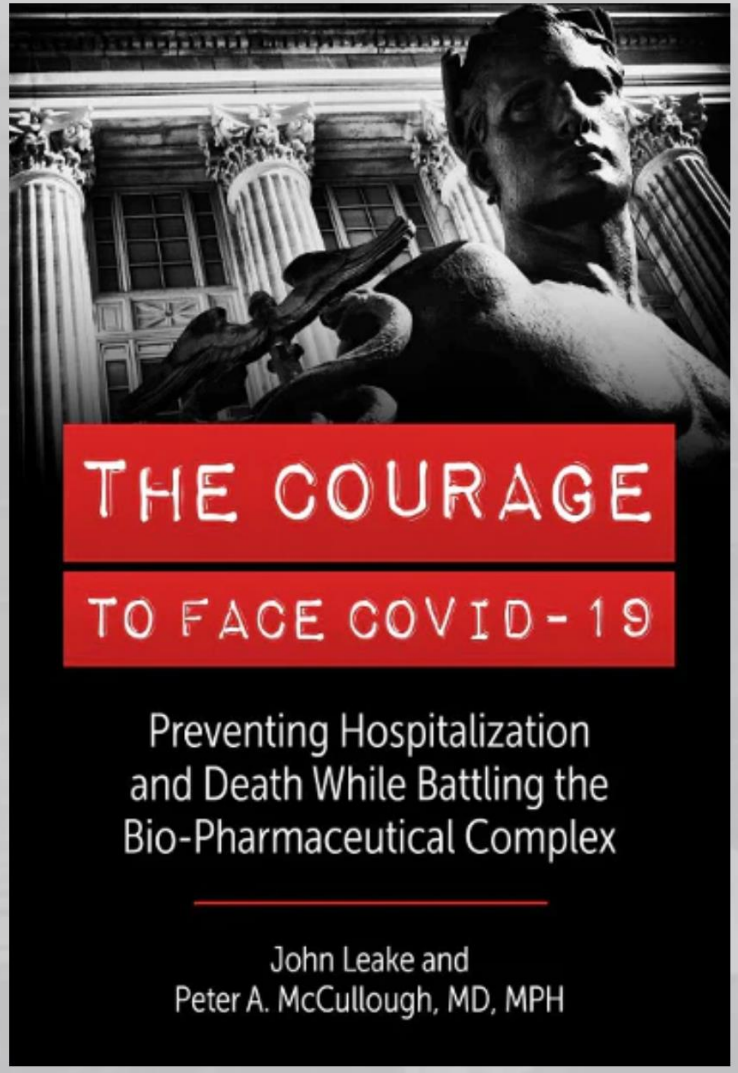
COURAGEOUS DISCOURSE

Author “Courage to Face COVID-19”
https://couragetofacecovid.com/
http://petermccloughmd.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, 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.

www.CourageToFaceCOVID.com



The Courage to Face COVID-19:

Preventing Hospitalization and Death While Battling the Bio-Pharmaceutical Complex

BUY NOW

Health

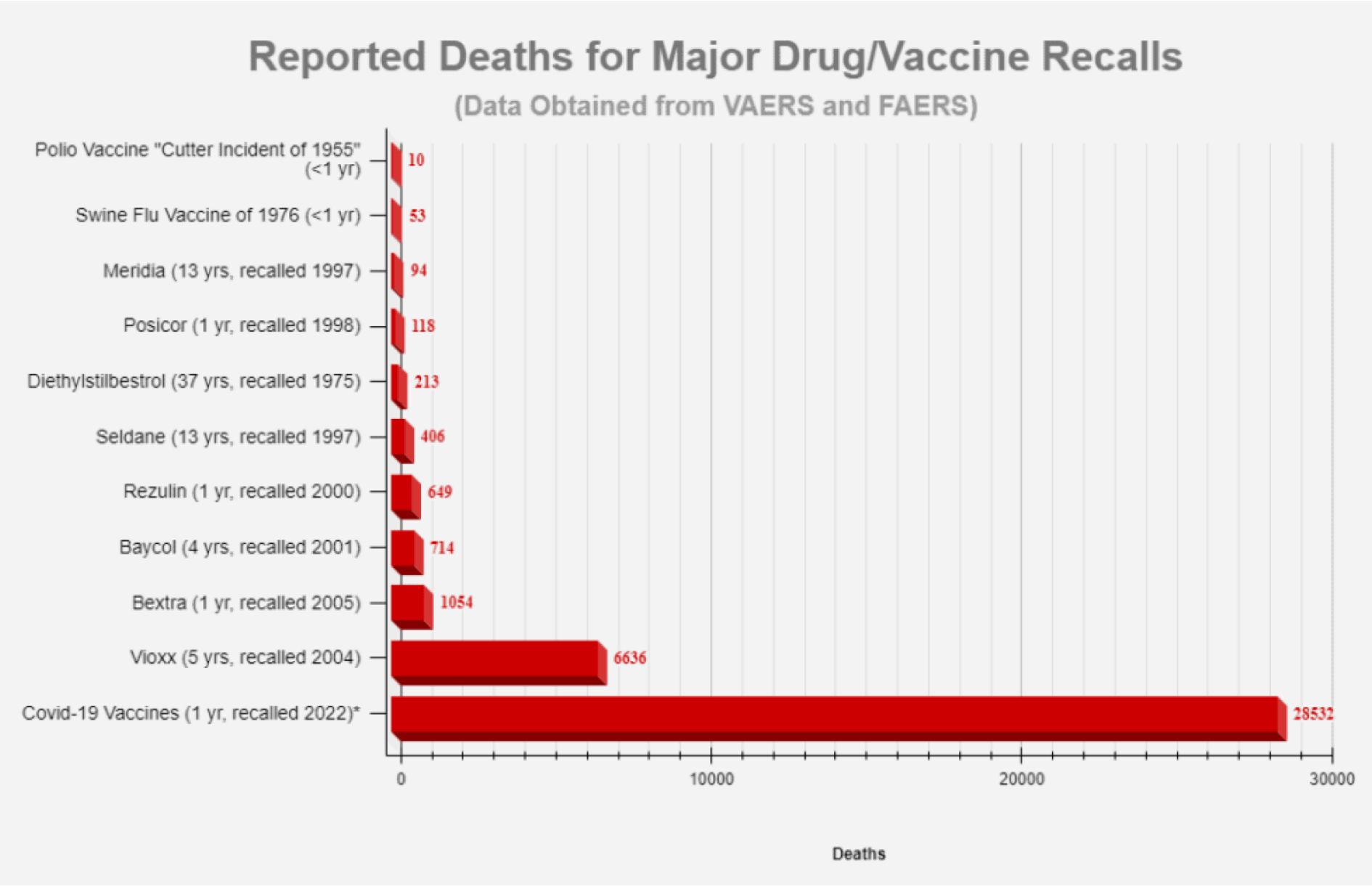
1976 U.S. swine flu vaccination program may offer lessons for COVID-19 pandemic

After months of negative media coverage, the Guillain-Barre reports brought an overdue end to the swine flu affair. Ford's programme was suspended in December 1976 with only some 20% of the US population (55M) vaccinated leaving 550 cases of Guillain-Barre and 25 deaths And since the US government had offered liability coverage to the pharmaceutical manufacturers that summer, **hundreds of compensation claims** from Guillain-Barre claimants followed for years afterward.

Before it was cut short, the program's goal was to vaccinate every American by the end of 1976

Mark Gollom · CBC News · Posted: Dec 03, 2020 4:00 AM ET | Last Updated: December 3, 2020

Covid-19 Vaccine Pharmacovigilance Report



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
- Freedom At Risk
- 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 HILL

The great gamble of COVID-19 vaccine development

BY PETER A. MCCULLOUGH, OPINION CONTRIBUTOR — 08/17/20 10:30 AM EDT

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

Just In...

Extremely rare orange lobster saved from grocery store
CHANGING AMERICA — 4M 43S AGO

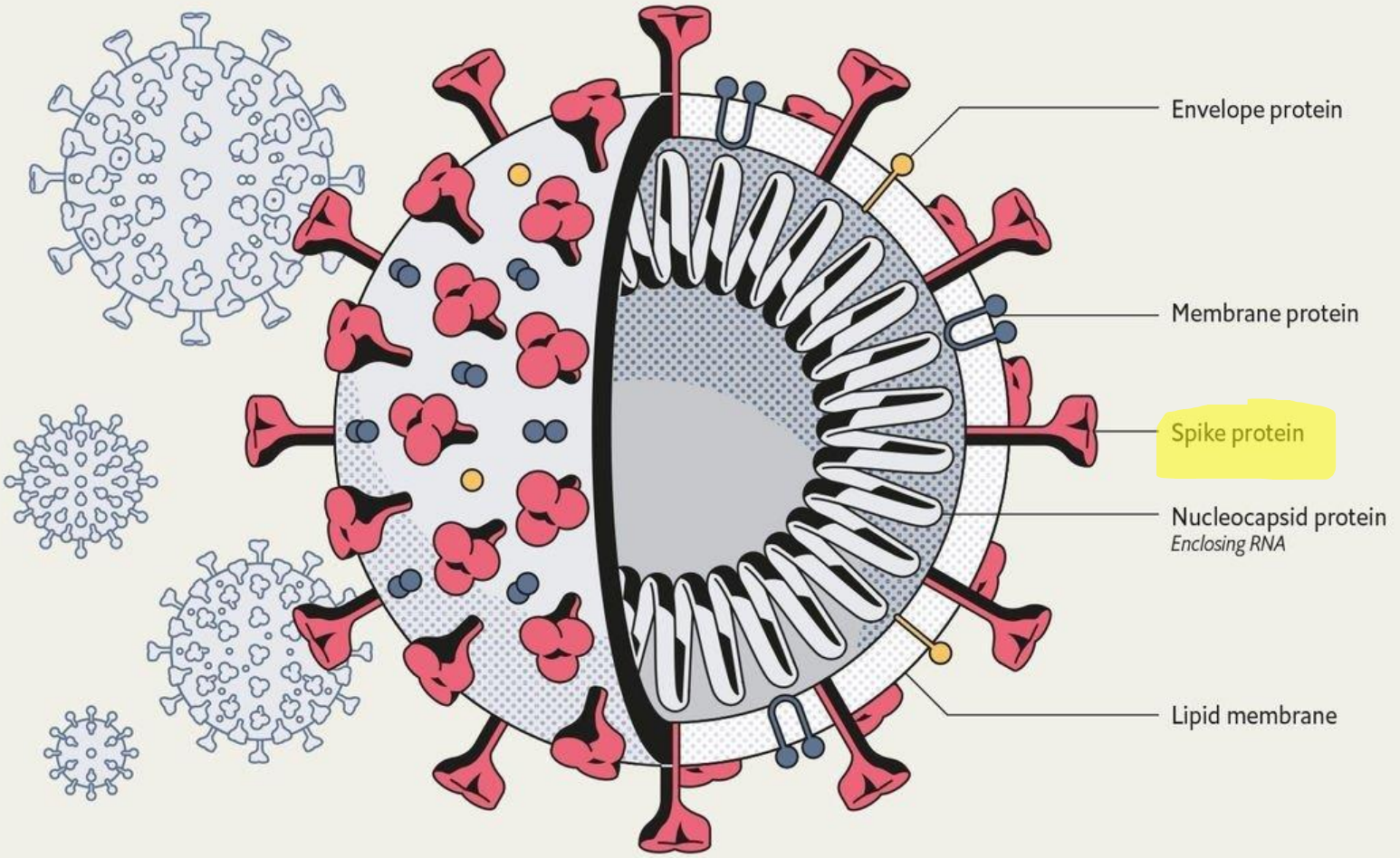
Election denialists smacked down by Idaho Secretary of State
STATE WATCH — 9M 38S AGO

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

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

SARS-CoV-2 Structure



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: 26976607; PMCID: PMC4801244.

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 Menachery[1], Boyd L Yount Jr[1], Kari Debbink[1,2], Sudhakar Agnihothram[3], Lisa E Gralinski[1], Jessica A Plante[1], Rachel L Graham[1], Trevor Scobey[1], Xing-Yi Ge[4], Eric F Donaldson[1], Scott H Randell[5,6], Antonio Lanzavecchia[7], Wayne A Marasco[8,9], Zhengli-Li Shi[4] & Ralph S Baric[1,2]

CoV, which is currently circulating in Chinese horseshoe bat populations[1]. Using the SARS-CoV reverse genetics system[2], 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

PNAS

SARS-like WIV1-CoV poised for human emergence

Vineet D. Menachery[a], Boyd L. Yount Jr.[a], Amy C. Sims[a], Kari Debbink[a,b], Sudhakar S. Agnihothram[c], Lisa E. Gralinski[a], Rachel L. Graham[a], Trevor Scobey[a], Jessica A. Plante[a], Scott R. Royal[a], Jesica Swanstrom[a], Timothy P. Sheahan[a], Raymond J. Pickles[d,e], Davide Corti[e,f,g], Scott H. Randell[d], Antonio Lanzavecchia[e,f], Wayne A. Marasco[h], and Ralph S. Baric[a,c,1]

[a]Department of Epidemiology, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599; [b]Department of Microbiology and Immunology, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599; [c]Division of Microbiology, National Center for Toxicological Research, Food and Drug Administration, Jefferson, AR 72079; [d]Department of Cell Biology and Physiology and Marsico Lung Institute/Cystic Fibrosis Center, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599; [e]Institute for Research in Biomedicine, Bellinzona, Switzerland; [f]Institute of Microbiology, Eidgenössische Technische Hochschule Zurich, Zurich, Switzerland; [g]Humabs BioMed SA, Bellinzona, Switzerland; and [h]Department 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)

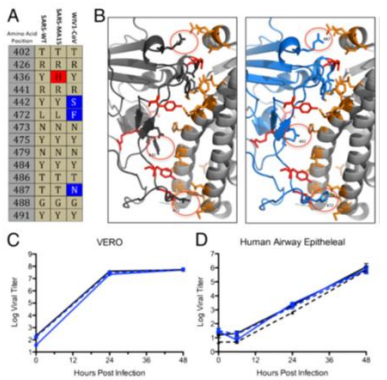


Fig. 1. Full-length and chimeric WIV1 infectious clones produce viruses that replicate in primary human airway epithelial cell cultures. (*A*) Spike amino acid residues that interact directly with human ACE2 from SARS-CoV, SARS-MA15, and WIV1-CoV spike proteins. Residue changes are highlighted by color. (*B*) Interaction between S1 domain of SARS-Urbani spike (black) and WIV1 spike (blue) with human ACE2 (gray). Contact residues highlighted with consensus amino acids (red) and differences (circled) between SARS and WIV1 spike proteins; human ACE2 contact residues are also highlighted (orange). (*C*) Viral replication of WIV1-CoV (blue), WIV1-MA15 (blue hatched), and SARS-CoV Urbani (black) following infection of Vero cells at a multiplicity of infection (MOI) of 0.01. (*D*) Well-differentiated air–liquid interface primary human airway epithelial cell cultures were infected with SARS-CoV Urbani (black), SARS-CoV MA15 (black hatched), WIV1-MA15 (blue-white hatched), and WIV-CoV (blue) at (*E*) MOI of 0.01 in cells from the same donor at an MOI of 0.01. Samples were collected at individual time points with biological replicates ($n = 3$) for all experiments for both *C* and *D*.

ACKNOWLEDGMENTS. We thank Dr. Zhengli-Li Shi of the Wuhan Institute of Virology for access to bat CoV sequences and plasmid of WIV1-CoV spike protein. Research was supported by the National Institute of Allergy and Infectious Disease and the National Institute of Aging of the NIH under Awards U19AI109761 and U19AI107810 (to R.S.B.), AI1085524 (to W.A.M.), and F32AI102561 and K99AG049092 (to V.D.M.). Human airway epithelial cell cultures were supported by the National Institute of Diabetes and Digestive and Kidney Disease under Award NIH DK065988 (to S.H.R.). Support for the generation of the mice expressing human ACE2 was provided by NIH Grants AI076159 and AI079521 (to A.C.S.).

Scientific Fraud to Cover Up Lab Origin

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

correspondence

Check for updates

The proximal origin of SARS-CoV-2

Kristian G. Andersen[1,✉], Andrew Rambaut[2], W. Ian Lipkin[3], Edward C. Holmes[4] and Robert F. Garry[5]

[1]Department of Immunology and Microbiology, The Scripps Research Institute, La Jolla, CA, USA.

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[3] (also referred to as HCoV-19)[4]. 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 deaths[5].

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 symptoms[6]. 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 ideal[7] and that the RBD sequence is different from those shown in SARS-CoV to be optimal for receptor binding[7,11]. 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 spike[8] (Fig. 1b). This allows effective cleavage by furin and other proteases and has a role in determining viral infectivity and host range[12]. In addition, a leading proline is also inserted at this site in SARS-CoV-2; thus, low-pathogenicity avian influenza viruses into highly pathogenic forms[16]. The acquisition of polybasic cleavage sites by HA has also been observed after repeated passage in cell culture or through animals[17].

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 protein[18]. Several viruses utilize mucin-like domains as glycan shields involved immunoevasion[18]. 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 predicted[7,11]. Furthermore, if

4852 Cell *184*, September 16, 2021

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Cell

Leading Edge

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,*]

[1]Marie 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

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

CONCLUSIONS

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

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

Vaccines **2022**, *10*, 961

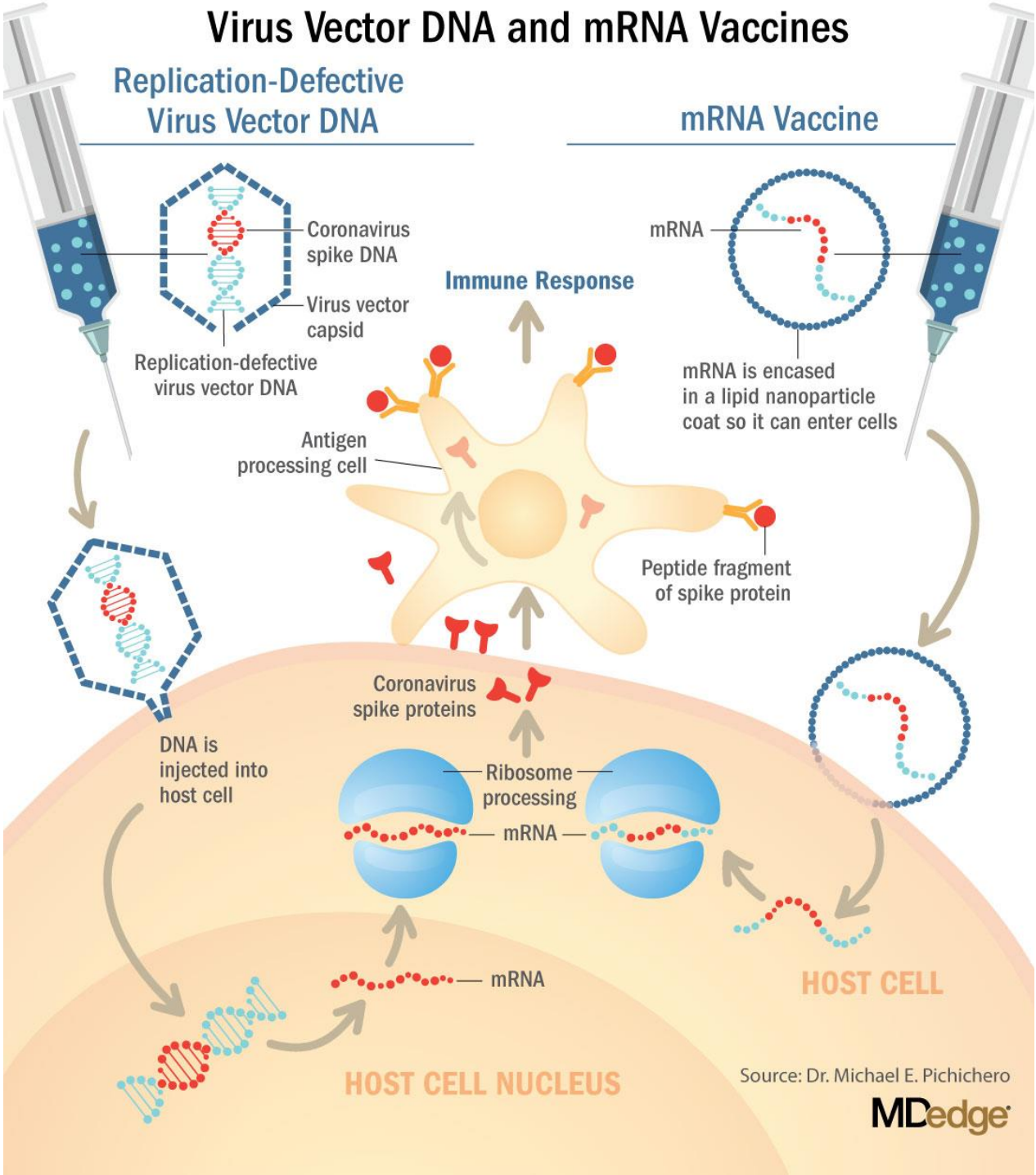
More than 100 vaccines have been developed against SARS-CoV-2, 26 of which have been evaluated in phase III clinical trials according to the World Health Organization (WHO) [1].

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



Source: Dr. Michael E. Pichichero

MDedge

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

EAC=events adjudication committee; DSMB=data safety monitoring board; EMA=European Medicines Agency

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,*]

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

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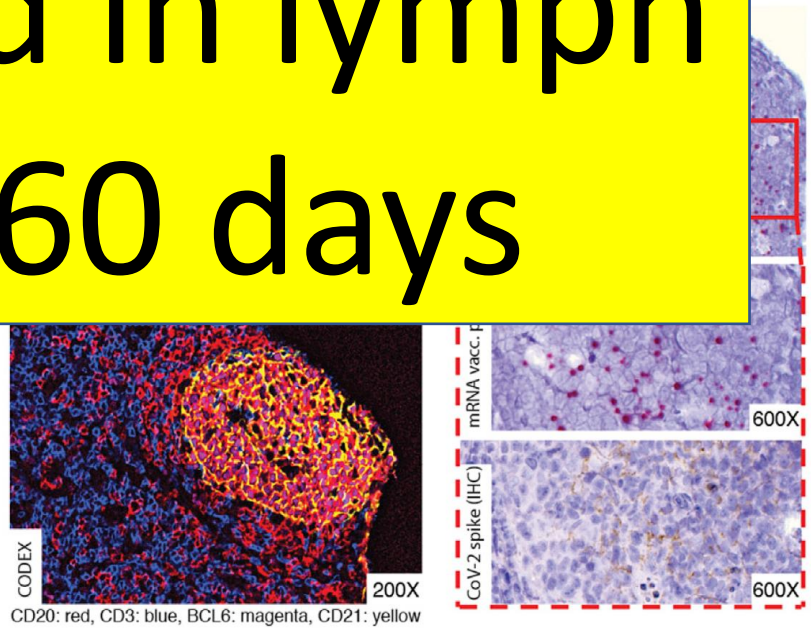
mRNA found in lymph nodes at 60 days

detected vaccine mRNA collected 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).



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current issues in molecular biology

MDPI

Article

Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line

Markus Aldén [1], Francisko Olofsson Falla [1], Daowei Yang [1], Mohammad Barghouth [1], Cheng Luan [1], Magnus Rasmussen [2] and Yang De Marinis [1,*]

Citation: Aldén, M.; Olofsson Falla, F.; Yang, D.; Barghouth, M.; Luan, C.; Rasmussen, M.; De Marinis, Y. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* **2022**, *44*, 1115–1126. https://doi.org/10.3390/cimb44030073

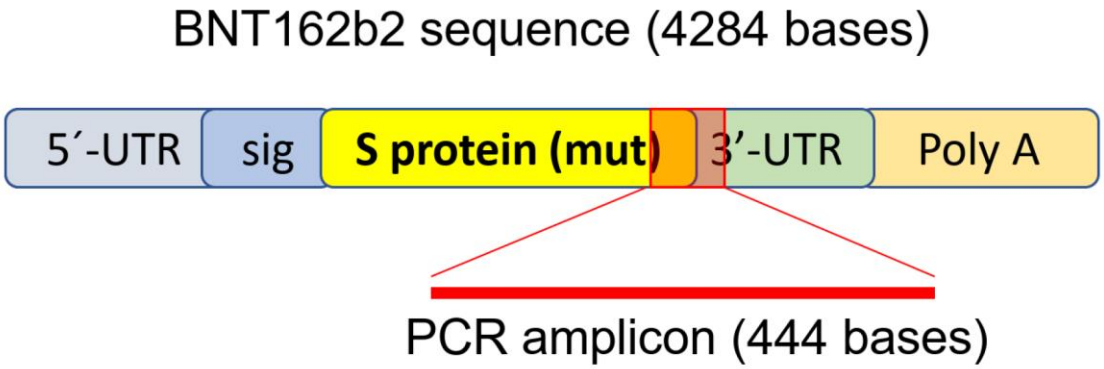
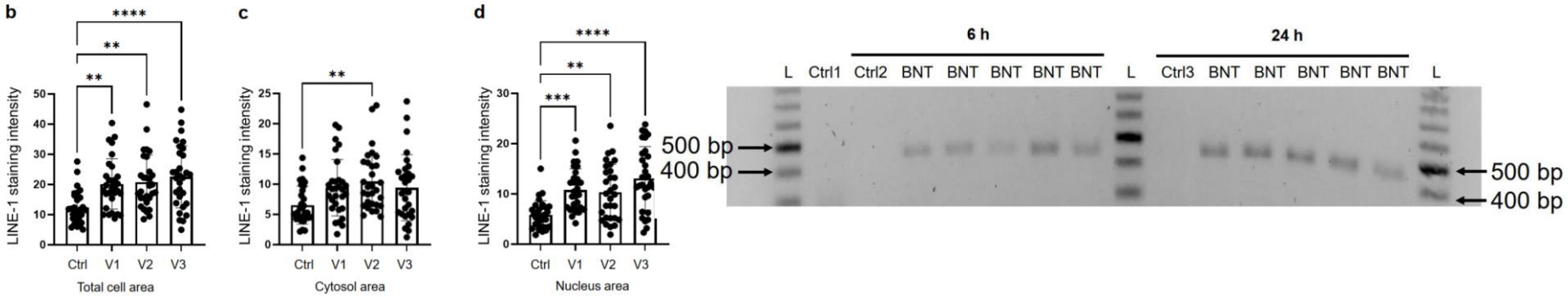


Figure 1. PCR primer set used to detect mRNA level and reverse-transcription of BNT162b2. Illustration of BNT162b2 was adapted from previously described literature [34].



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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

[illegible]@regionh.dk

RESEARCH LETTER

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

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

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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,

Clinical Infectious Diseases

BRIEF REPORT

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

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

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

antigens; immun

2020 to March 2021.Full description of study design are reported in the Supplementary Materials. SARS-CoV-2 antigens

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.

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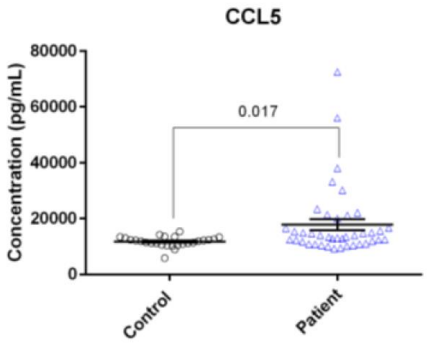
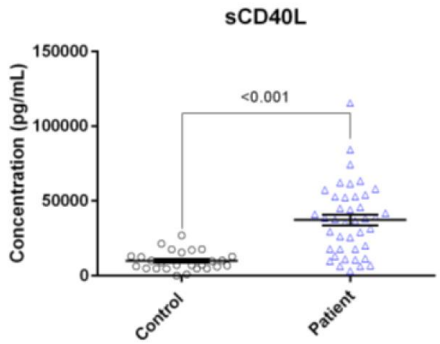
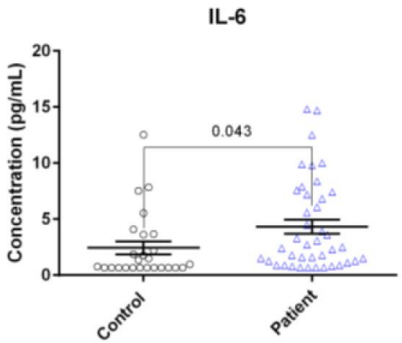
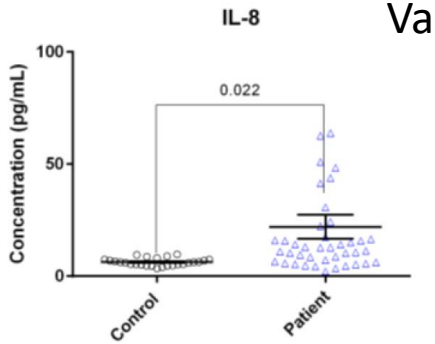




Maximum duration after Vaccination=245 days





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
- Freedom At Risk
- Censorship of Scientific Discourse
- Conclusions

September 17, 2021

Crushing the Lifeblood of Medical Science

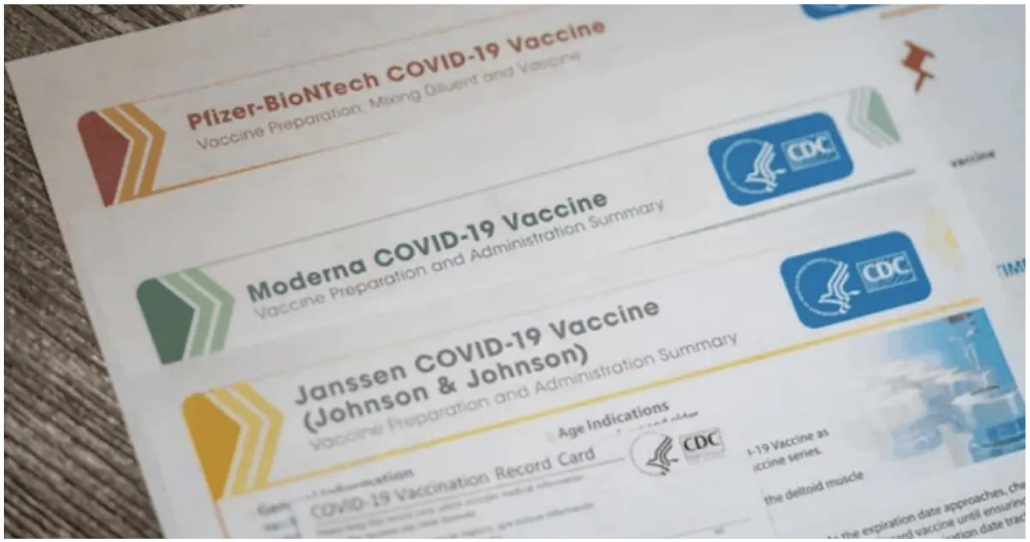
by Dr. Peter McCullough

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...

Vaccine Report Card From CDC/FDA is Long Overdue!

by Dr. Peter McCullough | Sep 6, 2021 | Healthcare, Politics,

The CDC/FDA holds all the data on differential efficacy of the vaccines and at 8 months into the public program, the agency's vaccine report card to America is long overdue. Americans are frustrated with the lack of transparency and want to make the most efficacious choice of vaccines and seek to understand how to take a shot and avoid the disastrous safety events of neurologic damage, myocarditis, blood clots, and paralysis...



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Science, Public Health Policy, and the Law

Volume 3:100-129
September, 2021
Clinical and Translational Research

An Institute for Pure and Applied Knowledge (IPAK)

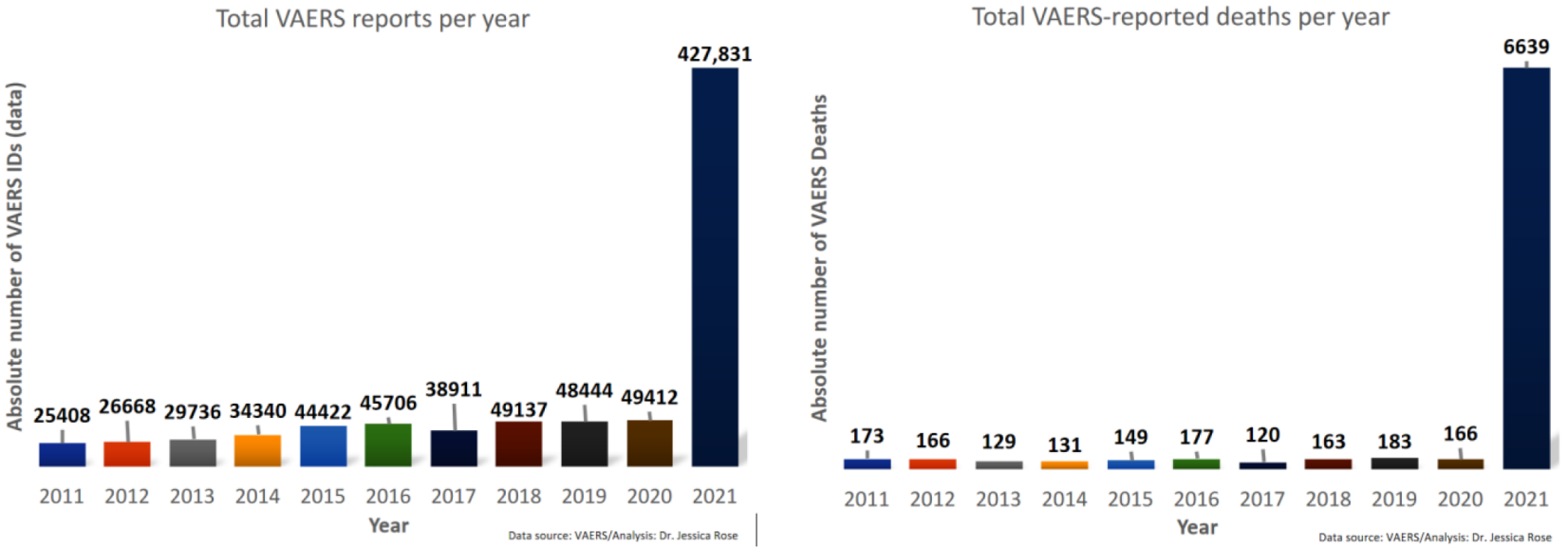
Public Health Policy Initiative (PHPI)

IPAK PHPI

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.)



VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports.

As of 11-18-2022 VAERS has stopped putting free text field information in the public data for Europe/UK.

All VAERS COVID Reports — US/Territories/Unknown

938,175 Reports Through February 17, 2023

source: OpenVAERS.com

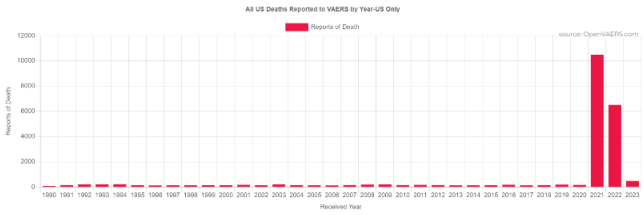
16,967 DEATHS	76,125 HOSPITALIZATIONS	112,714 URGENT CARE
185,931 DOCTOR OFFICE VISITS	2,430 ANAPHYLAXIS	6,073 BELL'S PALSY

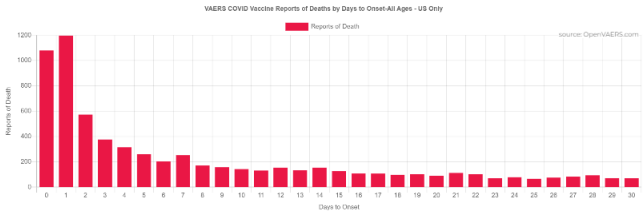
2,001 Miscarriages	7,569 Heart Attacks	4,859 Myocarditis/Pericarditis	16,342 Permanently Disabled
3,418 Thrombocytopenia/Low Platelet	14,132 Life Threatening	33,436 Severe Allergic Reaction	8,040 Shingles

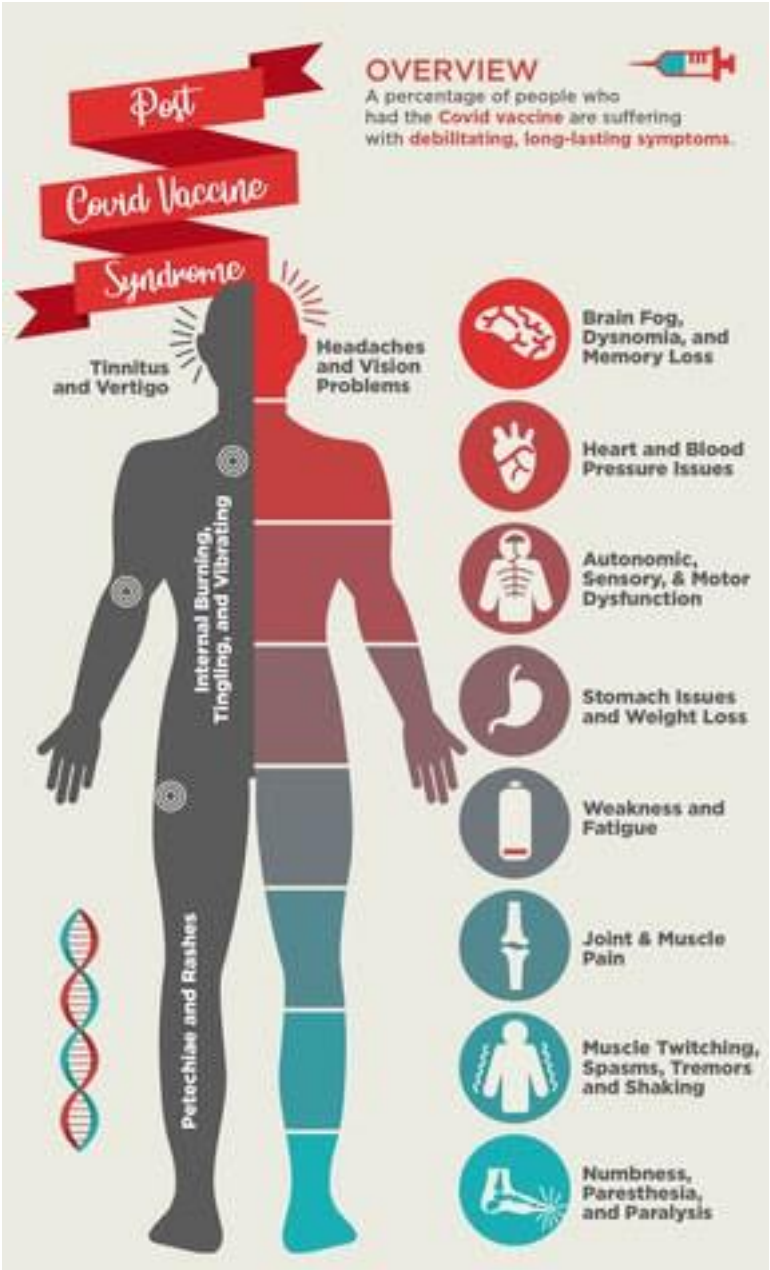
* As of November 18, 2022 VAERS has stopped putting free text field information in for Europe/UK.

Read More →

Read COVID Child Reports | Read VAERS COVID Reports | Read All VAERS Reports







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

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

RASMUSSEN™
REPORTS

IF IT'S IN THE NEWS, IT'S IN OUR POLLS. PUBLIC OPINION POLLING SINCE 2003.

‘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.)

COVID vaccination and age-stratified all-cause mortality risk

Spiro P. Pantazatos[1,*] and Hervé Seligmann[2]

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

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

Skidmore *BMC Infectious Diseases* (2023) 23:51
https://doi.org/10.1186/s12879-023-07998-3

COURAGEOUS DISCOURSE

BMC Infectious Diseases

RESEARCH **Open Access**

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

cination. With these su[illegible]mber of fatalities due to COVID-19 inoculation may be as high as 278,000 (95% CI 217,330–332,608) whe[illegible]ities 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

86% of deaths had no other explanation other than the vaccine

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.

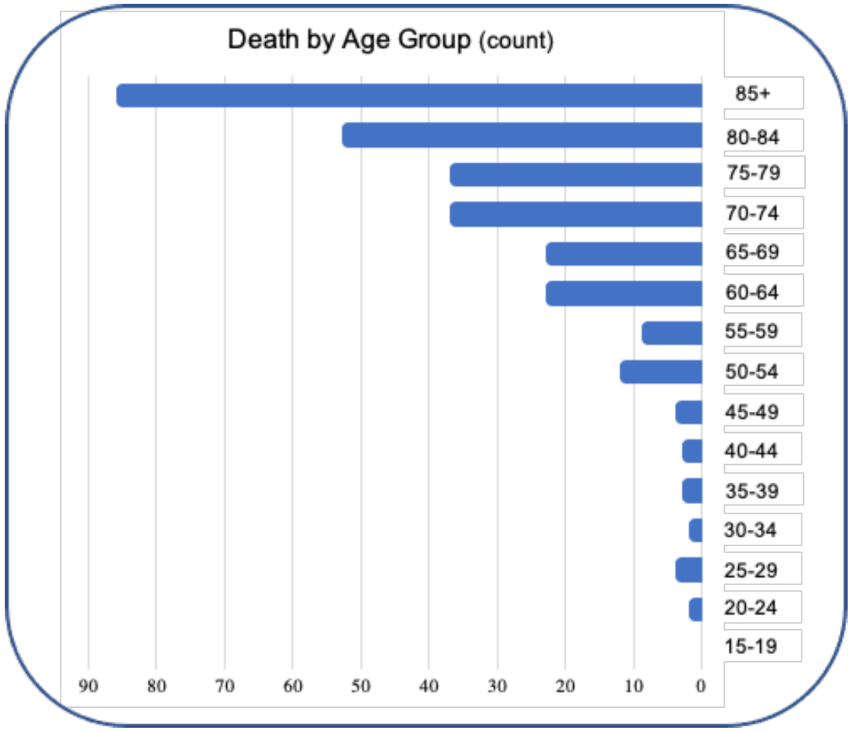


Figure 3: Death by Age Group

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.

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.

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)

dual cycle/Guillain-Barré/Bell's palsy

Reg escribing the conditions, 47% report mild, 43% report serious and 10% report severe/still recovering.

September 17, 2021

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

by Blaise Vanne | Sep 15, 2021

Today, Pharma companies underwrite three-quarters of the FDA's budget for scientific reviews (ProPublica) and fund nearly 50% of the FDA's total annual budget through PDUFA fees. In exchange, the agency increasingly fast-tracks expensive drugs and vaccines with...

The Taliban and the War on Terror

by Malcolm Out Loud | Sep 15,

Risks of Vaccines for Those Recovered from COVID-19 – Krammer, Raw & Mathioudakis

by Dr. Peter McCullough | Sep 12, 2021 | Healthcare, Politics

Received: 21 January 2022 | Revised: 8 March 2022 | Accepted: 13 March 2022

DOI: 10.1111/sji.13160

LETTER TO THE EDITOR

How to cite this article: Polykretis P. Role of the antigen presentation process in the immunization mechanism of the genetic vaccines against COVID-19 and the need for biodistribution evaluations. *Scand J Immunol*. 2022;00e1–3. doi:10.1111/sji.13160

SCANDINAVIAN JOURNAL OF Immunology AN INTERNATIONAL MONTHLY JOURNAL WILEY

Role of the antigen presentation process in the immunization mechanism of the genetic vaccines against COVID-19 and the need for biodistribution evaluations

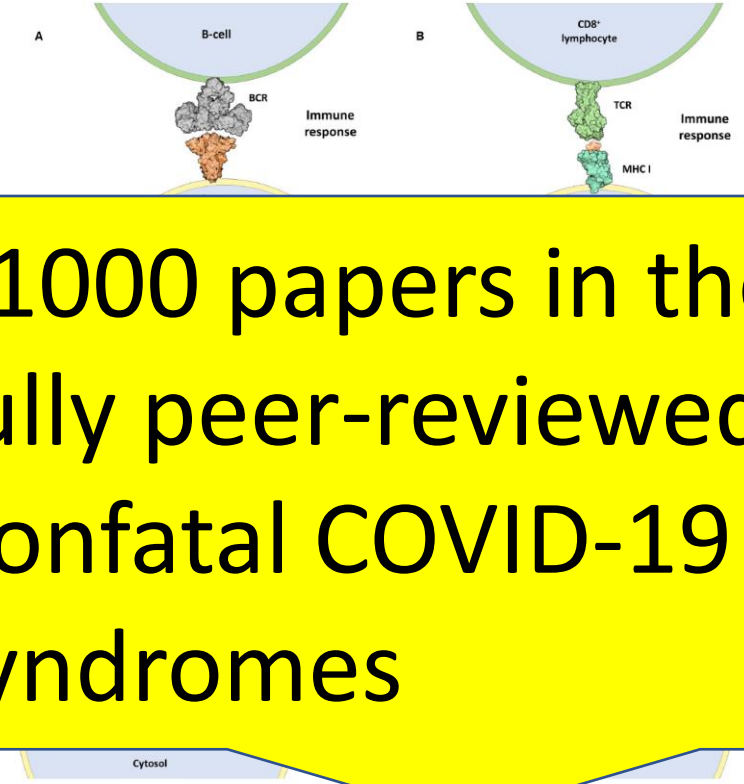


FIGURE 1 Schematic representation of: (A) A human cell intaking the lip… LNP) containing the mRNA, translating the SARS-CoV-2 spike protein and presenting it to the B-cell receptor (BCR) of a B cell. (B) A human cell intaking the LNP containing the mRNA, translating the spike protein and presenting it to the T-cell receptor (TCR) of a $CD8^+$ lymphocyte via the MHC I antigen presentation process. (C) MHC I presenting peptides deriving from the proteasomal degradation of endogenous proteins to the T-cell receptor (TCR) of a $CD8^+$ lymphocyte. (D) MHC II presenting peptides deriving from the proteasomal degradation of exogenous proteins to T-cell receptor (TCR) of a $CD4^+$ lymphocyte

Up to now, more than 1000 peer-reviewed studies evidence a multitude of adverse events in COVID-19 vaccine recipients.[9] Such studies report severe adverse reactions following vaccination, including thrombosis, thrombocytopenia, myocarditis, pericarditis, cardiac arrhythmias,

>1000 papers in the pre-print server and fully peer-reviewed literature on fatal and nonfatal COVID-19 vaccine injury syndromes

severity of the resulting damage and the consequences for health depend on the quantity of the cells involved, on the type of tissue and on the strength of the following autoimmune reaction. For instance, if the mRNA contained in the

SYMPTOMS OF HEART INFLAMMATION

Myocarditis and pericarditis cases being investigated

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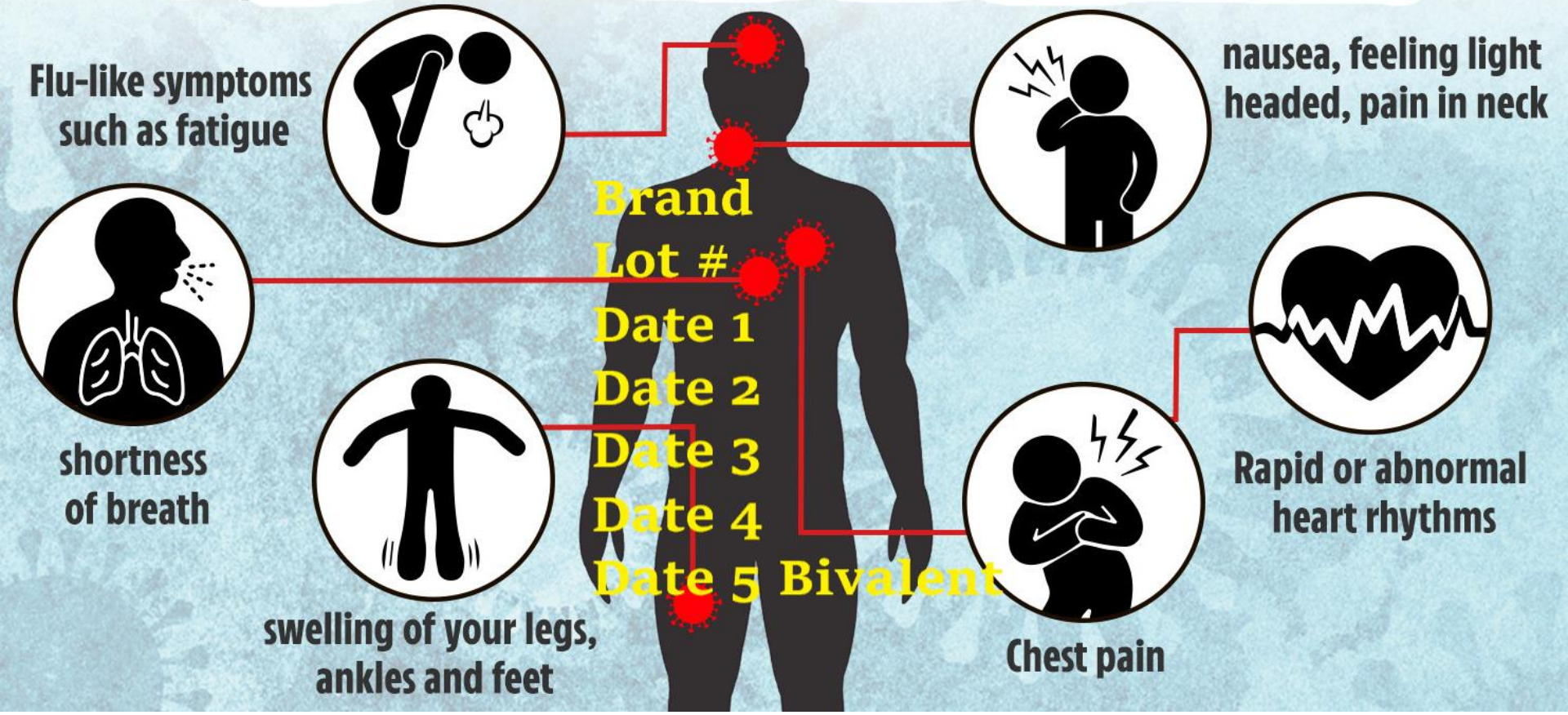


An Experimental Model for Dilated Cardiomyopathy after Rabbit Coronavirus Infection

Lorraine K. Alexander, J. David Small, Suzanne Edwards, and Ralph S. Baric

Program in Infectious Diseases, Department of Epidemiology, and Department of Microbiology and Immunology, University of North Carolina at Chapel Hill

Received 30 March 1992; revised 11 June 1992.

Financial support: National Institutes of Health (AI-23946); American Heart Association (AHA 901112; Established Investigator Award AHA 890192 to R.S.B.).

Reprints or correspondence: Dr. Ralph S. Baric, Department of Epidemiology, School of Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599-7400.

The Journal of Infectious Diseases 1992;166:978–85

0022-1899/92/6605-0005$01.00

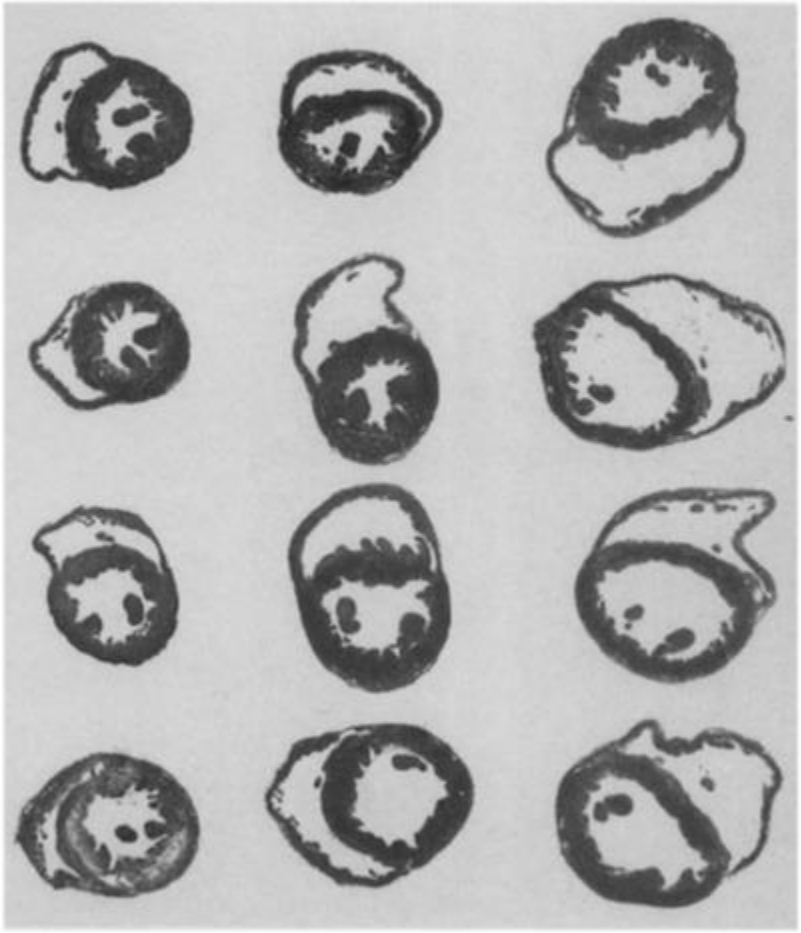


Figure 3. Cardiac dilation in survivors of rabbit coronavirus infection: representative sections from slight (S) and moderate (M) groups at 30–111 days after infection. Uninfected control (C) animals were sacrificed on similar days (36–106).

Isolation of infectious virus. Between 30 and 111 days after infection, the heart muscle of 7 animals was examined by in vivo infectivity assay for the presence of virus. Infectious virus was isolated from the hearts of 4 of the 7 animals. Clinical signs of RbCV infection were not observed in animals inoculated with the heart homogenate. However, previous exposure to RbCV was demonstrated by protection from subsequent challenge with an RbCV stock of 10^3–10^4 RID_{50}/mL.

A model system for DCM after infection with RbCV has been described. Studies in this laboratory and others demonstrate that viral infection of the heart results in degeneration and necrosis of myocytes, myocarditis, and CHF [15, 17, 18, 34]. Acute infection of the heart may also lead to DCM at a later stage in life [14–16, 34]. Such findings support the theory that viral infection of the heart may lead to dilated cardiomyopathy in humans.

JAMA Cardiology | Original Investigation

Prevalence of Clinical and Subclinical Myocarditis in Competitive Athletes With Recent SARS-CoV-2 Infection

Results From the Big Ten COVID-19 Cardiac Registry

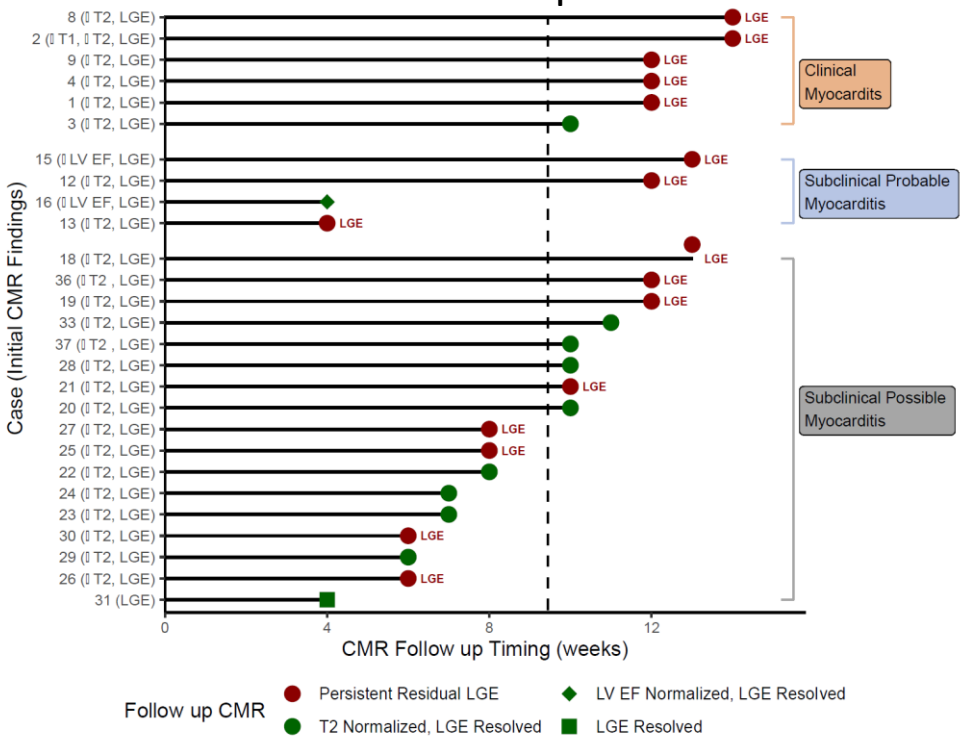
Curt J. Daniels, MD; Saurabh Rajpal, MBBS, MD; Joel T. Greenshields, MS; Geoffrey L. Rosenthal, MD; Eugene H. Chung, MD; Michael Terrin, MD; Jean Jeudy, MD; Scott E. Mattson, DO; Ian H. Law, MD; James Borchers, MD; Richard Kovacs, MD; Jeffrey Kovan, DO; Sami F. Rifat, MD; Jennifer Albrecht, PhD; Ana I. Bento, PhD; Lonnie Albers, MD; David Bernhardt, MD; Carly Day, MD; Suzanne Hecht, MD; Andrew Hipskind, MD; Jeffrey Mjaanes, MD; David Olson, MD; Yvette L. Rooks, MD; Emily C. Somers, PhD; Matthew S. Tong, DO; Jeffrey Wisinski, DO; Jason Womack, MD; Carrie Esopenko, PhD; Christopher J. Kratochvil, MD; Lawrence D. Rink, MD; for the Big Ten COVID-19 Cardiac Registry Investigators

Table. Demographic, Imaging, and Biomarker Data for Athletes Diagnosed With Myocarditis[a]

Athlete	Cardiac symptoms	Troponin level	ECG findings	ECHO findings	Time from COVID-19 diagnosis, d	CMR imaging findings	Follow-up CMR imaging time and findings
Clinical myocarditis							
1	Chest pain, palpitations	Elevated	Abnormal	Abnormal	46	↑T2, LGE	12 wk; Residual LGE
2	Chest pain	Elevated	Abnormal	NCM	Unknown	↑T1, ↑T2, LGE	14 wk; Residual LGE
3	Chest pain, dyspnea	Normal	Abnormal	NCM	15	↑T2, LGE	10 wk; Resolved[b]
4	Chest pain, dyspnea	Normal	Abnormal	NCM	13	↑T2, LGE	12 wk; Residual LGE
5	Dyspnea	Normal	NCM	Abnormal	77	↓LVEF + pericarditis	Pending[c]
6	Chest pain, palpitations	Normal	NCM	NCM	25	LGE	Pending[c]
7	Chest pain	Normal	NCM	NCM	50	LGE	Pending[c]
8	Chest pain	Normal	NCM	NCM	25	↑T2, LGE	14 wk; Residual LGE
9	Chest pain, palpitations	Normal	NCM	NCM	45	↑T2, LGE	12 wk; Residual LGE
Subclinical probable myocarditis							
10	None	Elevated	NCM	NCM	30	↑T1,↑ T2, LGE	Pending[c]
11	None	Elevated	NCM	NCM	14	↑ T2, LGE	Pending[c]
12	None	Elevated	NCM	NCM	14	↑T2, LGE	12 wk; Residual LGE
13	None	Elevated	NCM	NCM	11	↑T2, LGE	4 wk; Residual LGE
14	None	Normal	Abnormal	NCM	13	↑T1,↑ T2, LGE	Pending[c]
15	None	Normal	NCM	Abnormal	42	↓LVEF, LGE	13 wk; Residual LGE
16	None	Normal	NCM	Abnormal	12	↓LVEF, LGE	4 wk; Resolved[b]
17	None	Normal	NCM	Abnormal	25	↑T1, ↑T2, LGE	Pending[c]
Subclinical possible myocarditis							
18	None	Normal	NCM	NCM	36	↑T2, LGE	13 wk; Residual LGE
19	None	Normal	NCM	NCM	20	↑T2, LGE	12 wk; Residual LGE
20	None	Normal	NCM	NCM	71	↑T2, LGE	10 wk; Resolved[b]
21	None	Normal	NCM	NCM	10	↑T2, LGE	10 wk; Residual LGE
22	None	Normal	NCM	NCM	14	↑T2, LGE	8 wk; Resolved[b]
23	None	Normal	NCM	NCM	11	↑T2, LGE	7 wk; Resolved[b]
24	None	Normal	NCM	NCM	11	↑T2, LGE	7 wk; Resolved[b]
25	None	Normal	NCM	NCM	15	↑T2, LGE	8 wk; Residual LGE
26	None	Normal	NCM	NCM	44	↑T2, LGE	6 wk; Residual LGE
27	None	Normal	NCM	NCM	21	↑T2, LGE	8 wk; Residual LGE
28	None	Normal	NCM	NCM	49	↑T2, LGE	10 wk; Resolved[b]
29	None	Normal	NCM	NCM	35	↑T2, LGE	6 wk; Resolved[b]
30	None	Normal	NCM	NCM	24	↑T2, LGE	6 wk; Residual LGE
31	None	Normal	NCM	NCM	51	LGE	4 wk; Resolved[b]
32	None	Normal	NCM	NCM	25	↑ T2, LGE	Pending[c]
33	None	Normal	NCM	NCM	20	↑T2, LGE	11 wk; Resolved[b]
34	None	Normal	NCM	NCM	48	↑T2, LGE	Pending[c]
35	None	Normal	NCM	NCM	14	↑T1, ↑T2, LGE	Pending[c]
36	None	Normal	NCM	NCM	11	↑T2, LGE	12 wk; Residual LGE
37	None	Normal	NCM	NCM	19	↑T2, LGE	10 wk; Resolved[b]

>9600 athletes offered survey+testing in 2020

30% tested COVID-19 positive



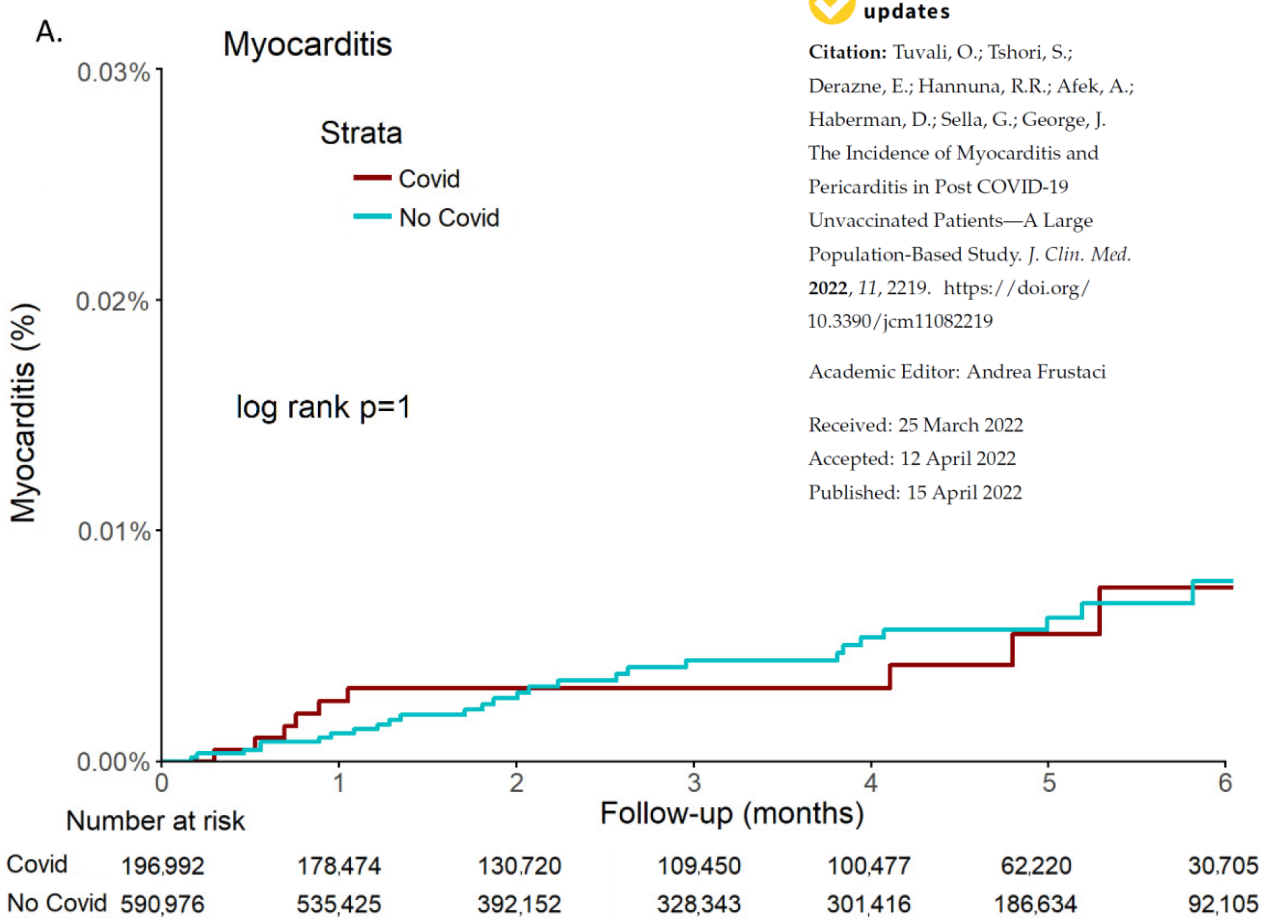
Journal of
Clinical Medicine

MDPI

Article

The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients—A Large Population-Based Study

Ortal Tuvali [1,†], Sagi Tshori [2,†], Estela Derazne [3], Rebecca Regina Hannuna [2], Arnon Afek [3,4], Dan Haberman [1], Gal Sella [1] and Jacob George [1,*]



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Citation: Tuvali, O.; Tshori, S.; Derazne, E.; Hannuna, R.R.; Afek, A.; Haberman, D.; Sella, G.; George, J. The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients—A Large Population-Based Study. *J. Clin. Med.* **2022**, *11*, 2219. https://doi.org/10.3390/jcm11082219

Academic Editor: Andrea Frustaci

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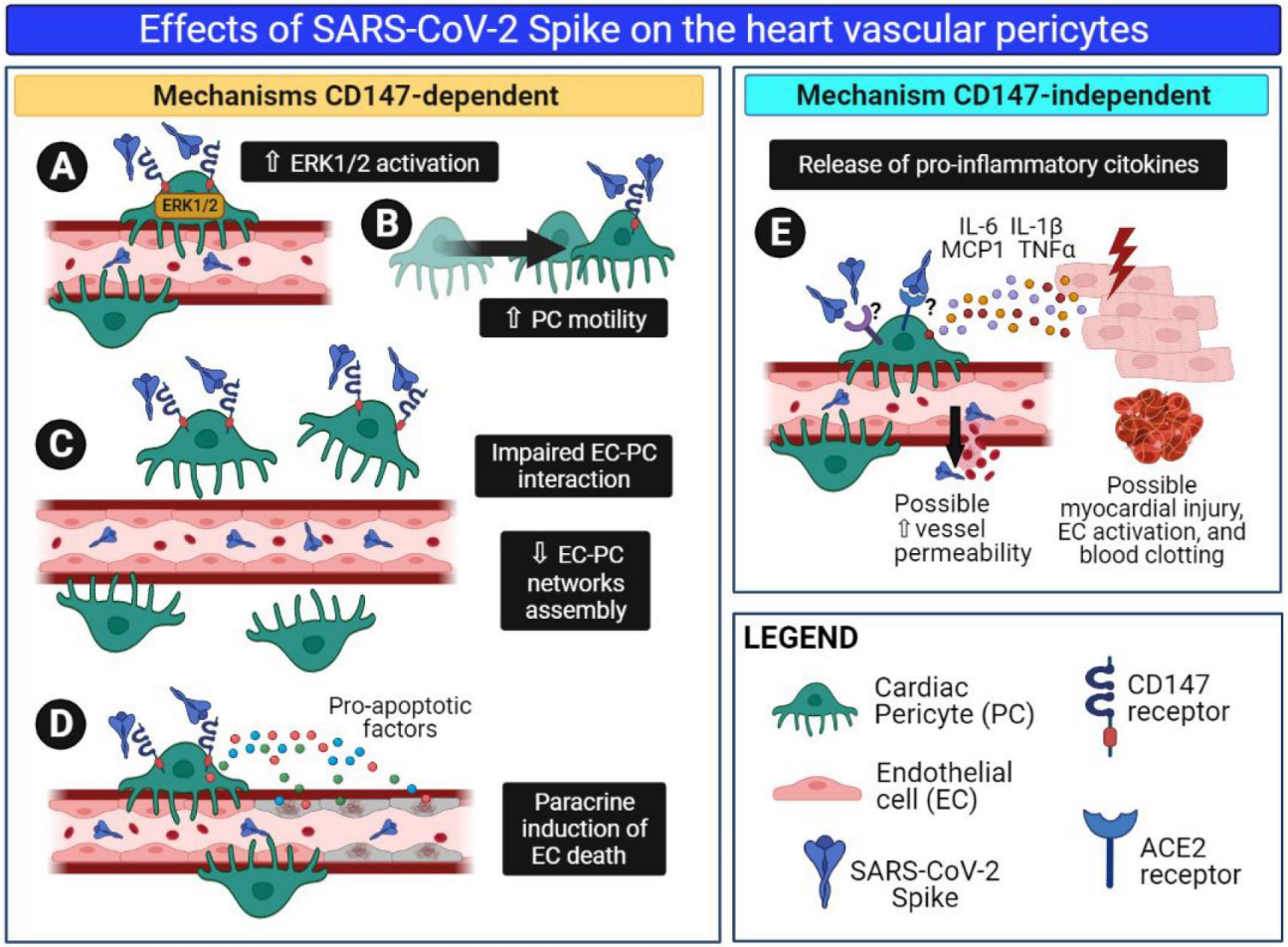
Accepted: 12 April 2022
Published: 15 April 2022

Original research article

The SARS-CoV-2 Spike protein disrupts human cardiac pericytes function through CD147-receptor-mediated signalling: a potential non-infective mechanism of COVID-19 microvascular disease

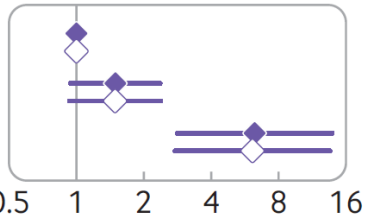
Elisa Avolio, PhD[1]; Michele Carrabba, PhD[1]; Rachel Milligan, PhD[2]; Maia Kavanagh Williamson, PhD[2]; Antonio P Beltrami, MD PhD[3]; Kapil Gupta, PhD[4]; Karen T Elvers, PhD[5]; Monica Gamez, PhD[1]; Rebecca Foster, PhD[1]; Kathleen Gillespie, PhD[1]; Fergus Hamilton, PhD[1]; David Arnold, PhD[1]; Imre Berger, PhD[4,6]; Massimo Caputo, MD[1]; Andrew D Davidson, PhD[2]; Darryl Hill, PhD[2]; Paolo Madeddu, MD[1]

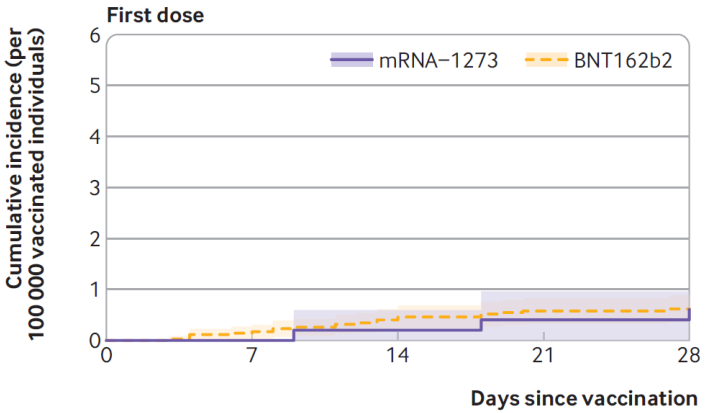


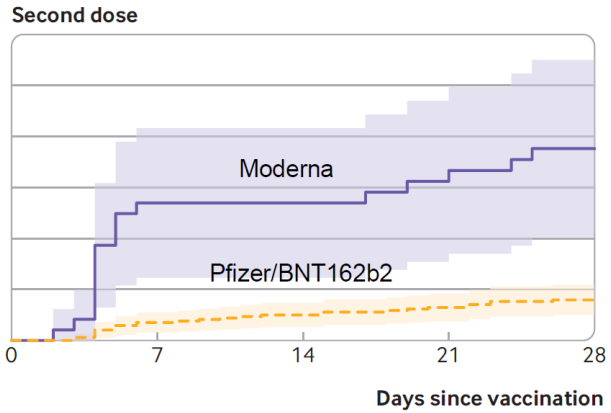
SARS-CoV-2 vaccination and myocarditis or myopericarditis: population based cohort study

Anders Husby,[1,2] Jørgen Vinsløv Hansen,[2] Emil Fosbøl,[3] Emilia Myrup Thiesson,[2] Morten Madsen,[4] Reimar W Thomsen,[4] Henrik T Sørensen,[4] Morten Andersen,[5] Jan Wohlfahrt,[2] Gunnar Gislason,[6,7,8] Christian Torp-Pedersen,[9,10,11] Lars Køber,[3] Anders Hviid[2,5]

Outcome	No	Rate ratio (95% CI)	Rate ratio (95% CI)	Firth rate ratio (95% CI)
Myocarditis or myopericarditis				
Unvaccinated (reference)	145		1	1
BNT162b2 (Pfizer-BioNTech)	43		1.48 (0.93 to 2.36)	1.49 (0.94 to 2.37)
mRNA-1273 (Moderna)	21		6.25 (2.83 to 13.82)	6.12 (2.76 to 13.61)







International Journal of
Molecular Sciences

MDPI

check for updates

Citation: Baumeier, C.; Aleshcheva, G.; Harms, D.; Gross, U.; Hamm, C.; Assmus, B.; Westenfeld, R.; Kelm, M.; Rammos, S.; Wenzel, P.; et al. Intramyocardial Inflammation after COVID-19 Vaccination: An Endomyocardial Biopsy-Proven Case Series. *Int. J. Mol. Sci.* **2022**, *23*, 6940. https://doi.org/10.3390/ijms23136940

Academic Editors: Loredana Frasca and Steven Fiering

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Accepted: 21 June 2022
Published: 22 June 2022

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]

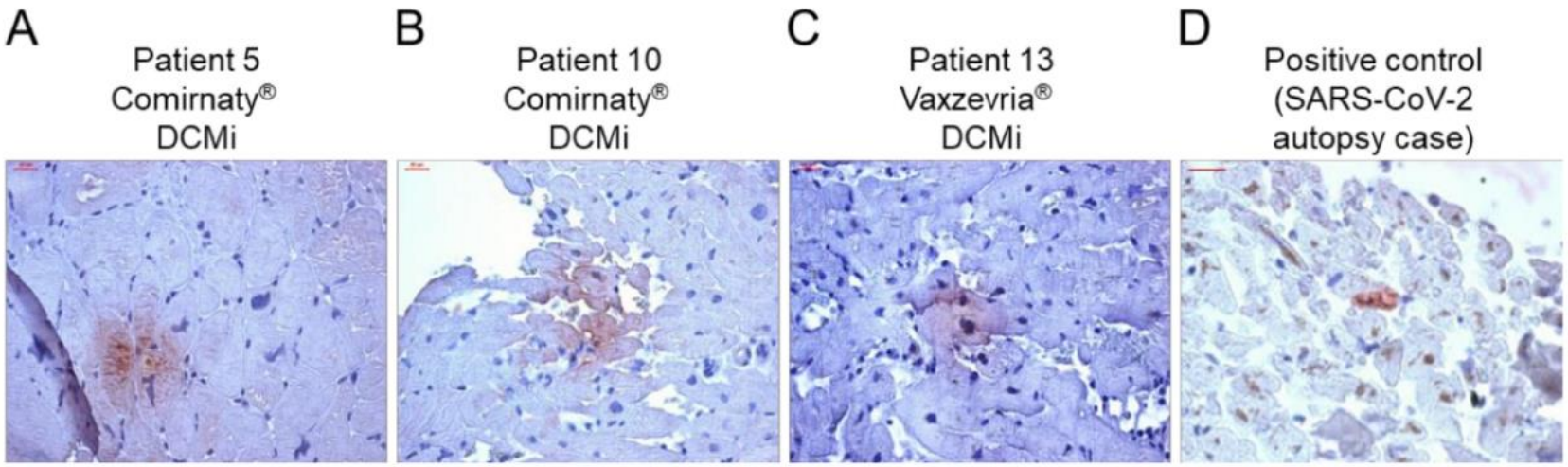


Figure 2. Evidence of SARS-CoV-2 spike protein in cardiac tissue after COVID-19 vaccination. (**A**–**C**) Representative immunohistochemical stainings of SARS-CoV-2 spike protein in EMBs from patients diagnosed with DCMi after receiving Comirnaty® (panel A and B, patients 5 and 10) or Vaxzevria® (panel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

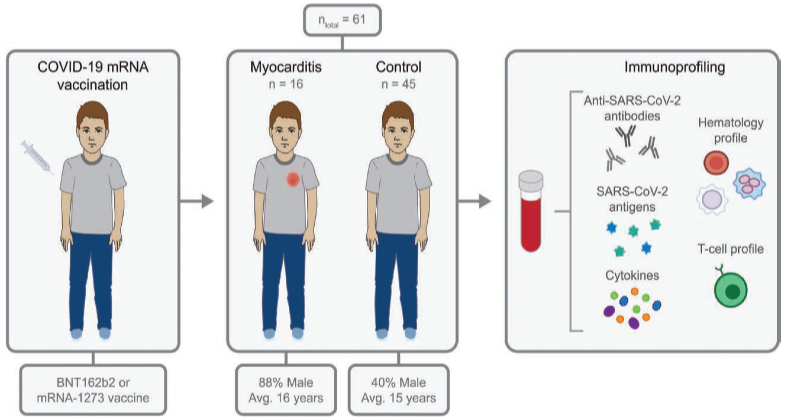
Circulation

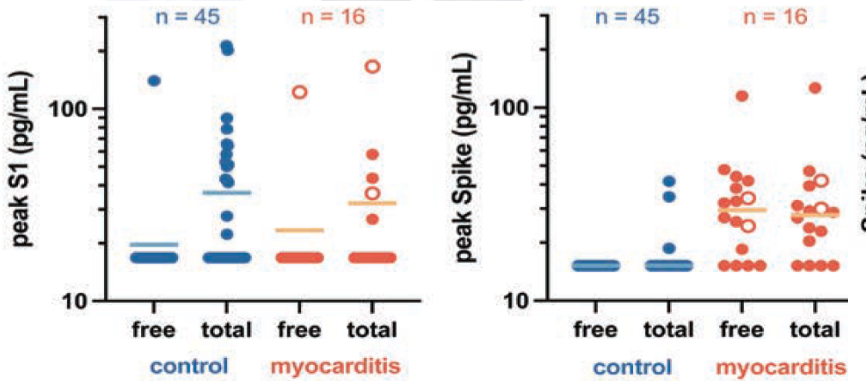
Circulation. 2023;147:00–00. DOI: 10.1161/CIRCULATIONAHA.122.061025

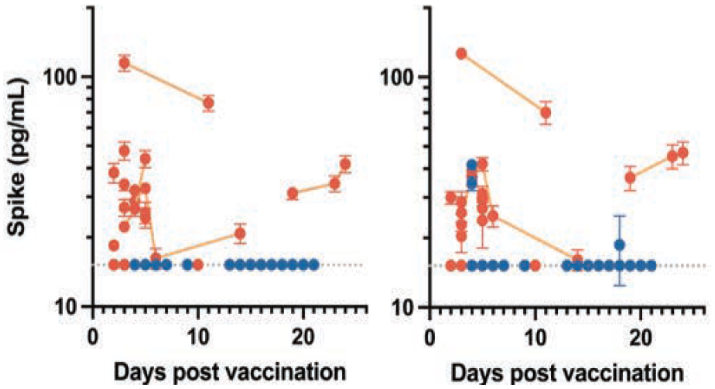
ORIGINAL RESEARCH ARTICLE

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

Lael M. Yonker, MD*; Zoe Swank, PhD*; Yannic C. Bartsch, PhD*; Madeleine D. Burns, MS; Abigail Kane, MD; Brittany P. Boribong, PhD; Jameson P. Davis, BS; Maggie Loiselle, BS; Tanya Novak, PhD; Yasmeen Senussi, MBBS; Chi-An Cheng, PhD; Eleanor Burgess, MS; Andrea G. Edlow, MD; Janet Chou, MD; Audrey Dionne, MD; Duraisamy Balaguru, MD; Manuella Lahoud-Rahme, MD; Moshe Arditi, PhD; Boris Julg, MD, PhD; Adrienne G. Randolph, MD; Galit Alter, PhD; Alessio Fasano, MD†; David R. Walt, 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

Received: 30 December 2021 | Accepted: 9 February 2022

DOI: 10.1111/eci.13759

ORIGINAL ARTICLE

WILEY

BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis

Allison Krug[1] | Josh Stevenson[2] | Tracy Beth Høeg[3,4]

- 86% required hospitalization
- Healthy boys have considerably higher chances of hospitalization with myocarditis than with COVID-19 respiratory illness even at peak prevalence

…ion myo/pericarditis against COVID-19 hospitalization during delta, our risk-benefit analysis suggests that among 12–17-year-olds, two-dose vaccination was uniformly favourable only in nonimmune girls with a comorbidity. In boys with prior infection and no comorbidities, even one dose carried more risk than benefit according to international estimates. In the setting of omicron, one dose may be protective in nonimmune children, but dose two does not appear to confer additional benefit at a population level.

Diagnosis of Myocarditis Caused by COVID-19 Vaccination

Guidance

Myocarditis and pericarditis after COVID-19 vaccination: clinical management guidance for healthcare professionals

Updated 21 March 2022

Contents

Print this page

The UK Health Security Agency (UKHSA), in partnership with the Royal College of General Practitioners (RCGP) and the Royal College of Emergency Medicine (RCEM), has produced this clinical guidance to support the detection and management of clinical cases of myocarditis and pericarditis associated with coronavirus (COVID-19) vaccination.

It is a living document and will be reviewed and updated as further data becomes available.

Background

COURAGEOUS DISCOURSE

Background to myocarditis and pericarditis after COVID-19 vaccination and guidelines:

- this is a very rare condition following vaccination (see the Medicines and Healthcare products Regulatory Agency's (MHRA) weekly summary for the latest data)
- most patients who develop symptoms do so within a week of vaccination
- patients who develop symptoms have usually been vaccinated with a mRNA vaccine (Pfizer or Moderna)

Australian Government
Department of Health

New item for cardiac magnetic resonance imaging (MRI) for myocarditis associated with mRNA COVID-19 vaccination - factsheet

Last updated: 16 December 2021

What are the changes?

From 1 January 2022, Medicare Benefits Schedule (MBS) item 63399 is being introduced for cardiac magnetic resonance imaging (MRI) to assist in diagnosing myocarditis that may occur after vaccination with the mRNA COVID-19 vaccines Comirnaty (Pfizer) and Spikevax (Moderna).

The item is for use in circumstances where myocarditis cannot be definitively diagnosed using conventional imaging and other diagnostic tests.

This is a temporary item. It is being made available pending a full health technology assessment by the Medical Services Advisory Committee (MSAC) on the use of cardiac MRI in diagnosing myocarditis more broadly.

Item 63399 will be available for use from 1 January 2022 to 30 June 2022.

Service/Descriptor

MRI–scan of cardiovascular system for the assessment of myocardial structure and function, if the service is requested by a consultant physician who has assessed the patient, and the request for the scan indicates:

(a) the patient has suspected myocarditis after receiving a mRNA COVID-19 vaccine; and

(b) the patient had symptom onset within 21 days of a mRNA COVID-19 vaccine administration; and

(c) the results from the following examinations are inconclusive to form a diagnosis of myocarditis:

(i) echocardiogram; and

(ii) troponin; and

(iii) chest X-ray.

Screening tests can include: hs-troponin I/T, BNP/NT-proBNP, ST2, Galectin-2, D-dimer, hs-CRP ECG, echocardiogram, cMRI

tomography

MDPI

Review

Myocarditis Following COVID-19 Vaccination: Cardiac Imaging Findings in 118 Studies

Pedram Keshavarz [1,2], Fereshteh Yazdanpanah [3], Maryam Emad [4], Azadeh Hajati [4], Seyed Faraz Nejati [4], Faranak Ebrahimian Sadabad [4], Tamta Azrumelashvili [5], Malkhaz Mizandari [5,*] and Steven S. Raman [1]

-94% hospitalized
-91% positive MRI
-Long-term outcomes unknown

Abstract: We reviewed the reported imaging findings of myocarditis in the literature following COVID-19 vaccination on cardiac imaging by a literature search in online databases, including Scopus, Medline (PubMed), Web of Science, Embase (Elsevier), and Google Scholar. In total, 532 cases of myocarditis after COVID-19 vaccination were reported (462, 86.8% men and 70, 13.2% women, age range 12 to 80) with the following distribution: Pfizer-BioNTech: 367 (69%), Moderna: 137 (25.8%), AstraZeneca: 12 (2.3%), Janssen/Johnson & Johnson: 6 (1.1%), COVAXIN: 1 (0.1%), and unknown mRNA vaccine: 9 (1.7%). The distribution of patients receiving vaccine dosage was investigated. On cardiac MR Imaging, late intravenous gadolinium enhancement (LGE) was observed mainly in the epicardial/subepicardial segments (90.8%, 318 of 350 enhancing segments), with the dominance of inferolateral segment and inferior walls. Pericardial effusion was reported in 13.1% of cases. The vast majority of patients (94%, 500 of 532) were discharged from the hospital except for 4 (0.7%) cases. Post-COVID-19 myocarditis was most commonly reported in symptomatic men after the second or third dose, with CMRI findings including LGE in 90.8% of inferior and inferolateral epicardial/subepicardial segments. Most cases were self-limited.

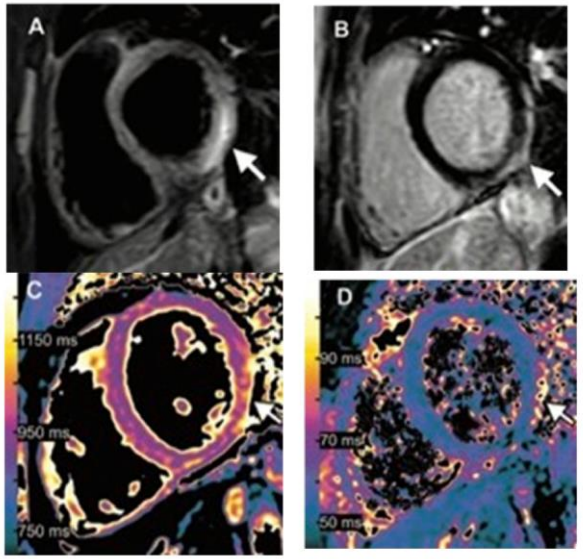


Figure 3. Images of a 15-year-old boy with myocarditis after COVID-19 vaccination. One day after receiving his second vaccination dose, he developed fever, myalgia, and intermittent tachycardia. (**A**) T2-weighted short inversion time inversion recovery MRI scans at 1.5 T in short-axis view show focal high-signal intensities (arrow) at the basal lateral and inferior wall, indicating myocardial edema. (**B**) Late gadolinium enhancement image in short-axis view shows corresponding linear subepicardial enhancement (arrow), indicating inflammatory myocardial necrosis. (**C**) T1 mapping and (**D**) T2 mapping in the short-axis view show elevated T1 and T2 at the mid-ventricular lateral and infero-lateral wall (arrow in (**C**,**D**)), indicating acute myocardial injury (focal T1, 1165 ms; focal T2, 70 ms; institution-specific cut-off values for acute myocarditis: T1 global ≥ 1000 ms, T2 global ≥ 55.9 ms). Reprinted/adapted with permission from Ref. [8], 2021, RSNA.

Citation: Keshavarz, P.; Yazdanpanah, F.; Emad, M.; Hajati, A.; Nejati, S.F.; Ebrahimian Sadabad, F.; Azrumelashvili, T.; Mizandari, M.; Raman, S.S. Myocarditis Following COVID-19 Vaccination: Cardiac Imaging Findings in 118 Studies. *Tomography* **2022**, *8*, 1959–1973. https://doi.org/10.3390/tomography8040164

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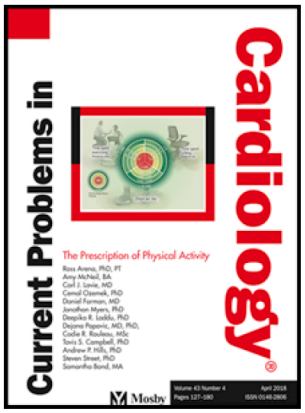
Journal Pre-proof



A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products

Jessica Rose PhD, MSc, BSc , Peter A. McCullough MD, MPH

PII: S0146-2806(21)00226-7
DOI: https://doi.org/10.1016/j.cpcardiol.2021.101011
Reference: YMCD 101011

To appear in: *Current Problems in Cardiology*

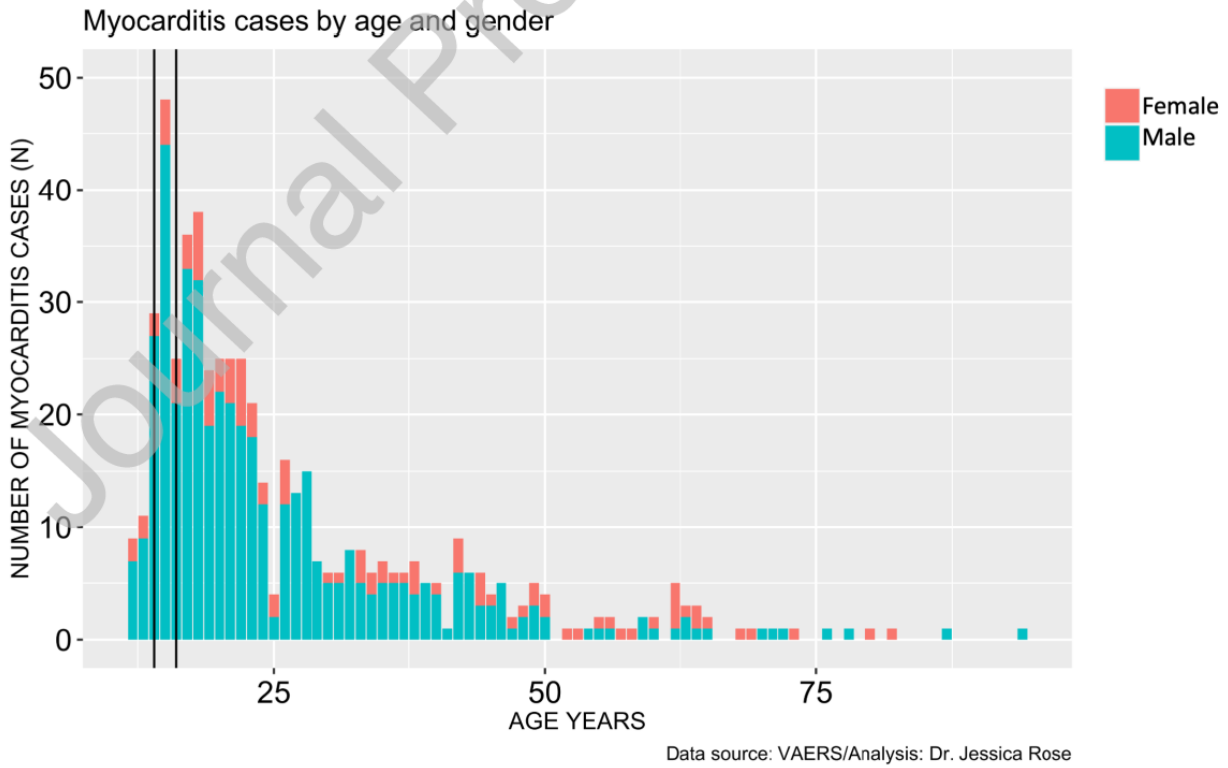


Figure 4. Histogram showing Myocarditis cases reported in VAERS following injection with COVID-19 products according to age and gender.

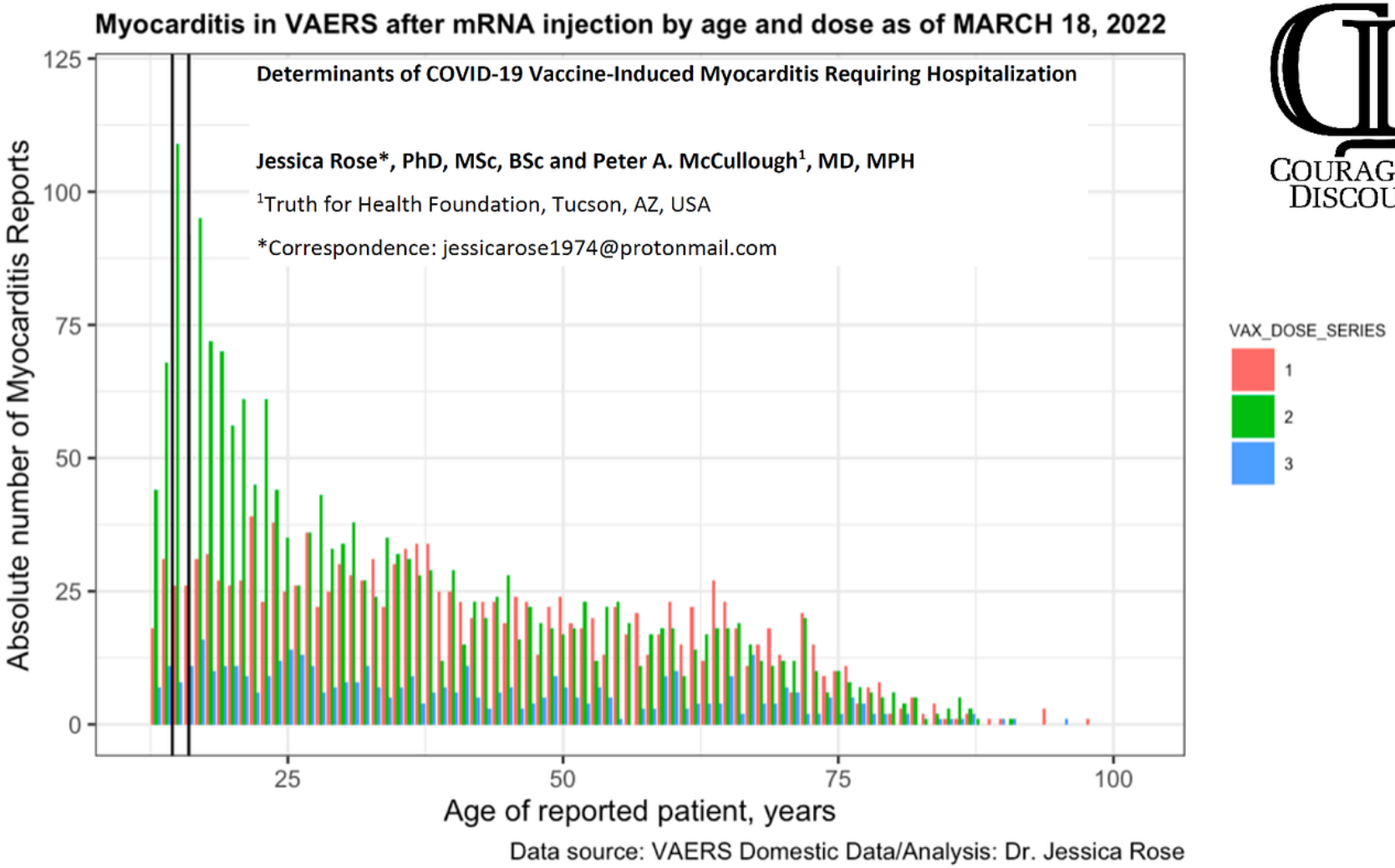


Figure 5: Myocarditis in VAERS Domestic data according to age and dose.

The JOURNAL of PEDIATRICS

BRIEF REPORTS | ARTICLES IN PRESS

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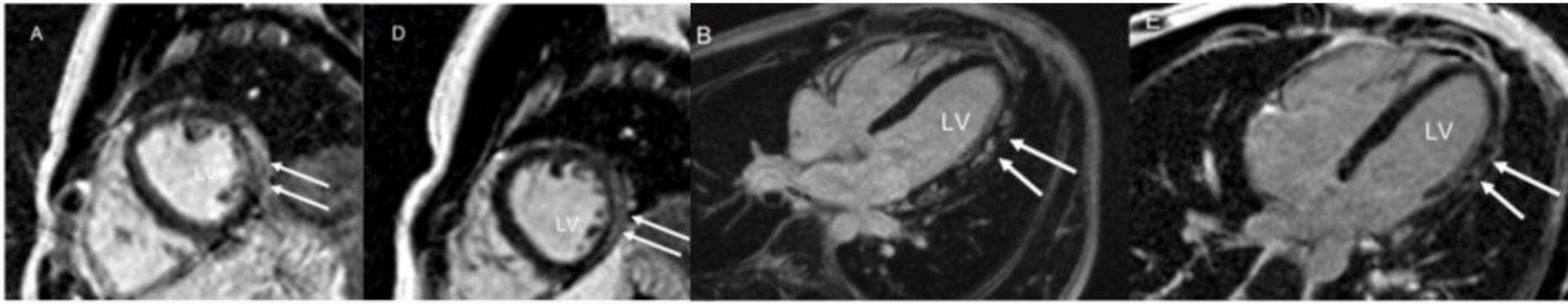
Persistent Cardiac MRI Findings in a Cohort of Adolescents with post COVID-19 mRNA vaccine myopericarditis

Jenna Schauer, MD • Sujatha Buddhe, MD, MS • Avanti Gulhane, MD, DNB, FSCMR • ...
Sathish Mallenahalli Chikkabyrappa, MD • Yuk Law, MD • Michael A. Portman, MD • Show all authors

Published: March 25, 2022 • DOI: https://doi.org/10.1016/j.jpeds.2022.03.032

PlumX Metrics

Figure 2. CMR images from 3 days after admission of a 16-year-old male who presented to emergency room with chest pain and elevated troponin 3 days after receiving Pfizer COVID-19 mRNA vaccine. Initial CMR. 1a and 1b. subepicardial to midmyocardial LGE in inferior and inferolateral LV wall from base to apex (arrows). 1c shows T2 hyper-intensity in similar segments, consistent with edema. 1d, 1e and 1f. Follow up CMR 4.4 months later. LGE still persistent but decreased from 26% to 19.84% (arrows), LVEF remained stable at 58%. There is improved T2 hyperintensity.



J Korean Med Sci. 2021 Oct 18;36(40):e286
https://doi.org/10.3346/jkms.2021.36.e286
eISSN 1598-6357·pISSN 1011-8934

JKMS

Case Report

Infectious Diseases, Microbiology & Parasitology

Check for updates

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

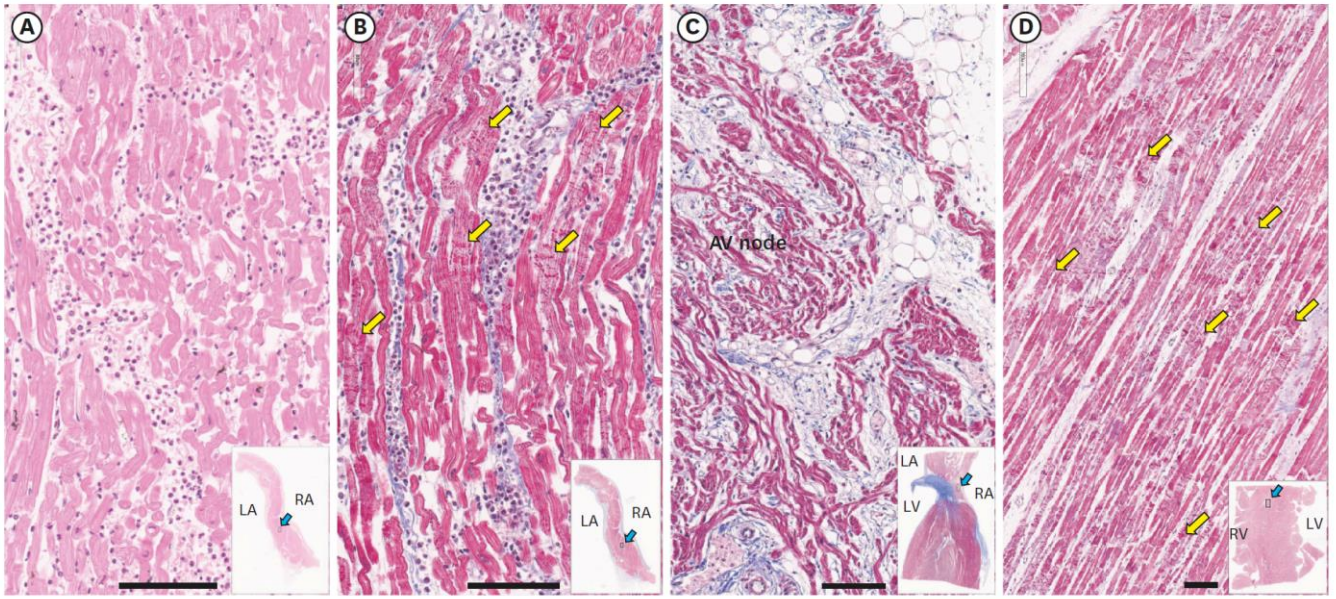


Fig. 1. Histopathology of the heart. (**A**) Hematoxylin and eosin stains of atrial septum shows massive inflammatory infiltration with neutrophil predominance. (**B**) The myocytes often show contraction band necrosis (yellow arrows), which were highlighted by Masson's trichrome staining. (**C**) The 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 μm. 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.

COLLEGE of AMERICAN PATHOLOGISTS

ARCHIVES of Pathology & Laboratory Medicine

Autopsy Histopathologic Cardiac Findings in Two Adolescents Following the Second COVID-19 Vaccine Dose

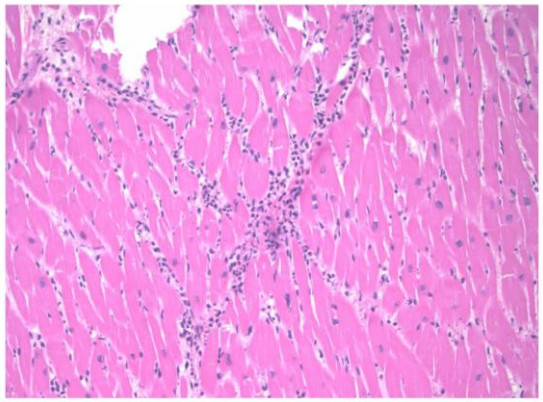
doi: 10.5858/arpa.2021-0435-SA

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

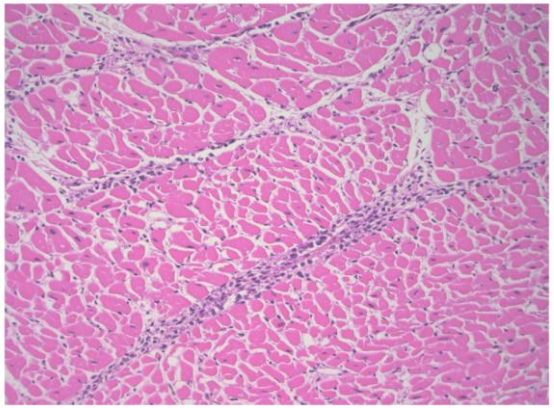
RESULTS

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



Circulation *Circulation.* 2022;146:743–754. DOI: 10.1161/CIRCULATIONAHA.122.059970

ORIGINAL RESEARCH ARTICLE

Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex

Martina Patone, PhD; Xue W. Mei, PhD; Lahiru Handunnetthi, PhD; Sharon Dixon, MD; Francesco Zaccardi, PhD; Manu Shankar-Hari, PhD; Peter Watkinson, MD; Kamlesh Khunti, PhD; Anthony Harnden, PhD; Carol A.C. Coupland, PhD; Keith M. Channon, MD; Nicholas L. Mills, PhD; Aziz Sheikh, MD; Julia Hippisley-Cox, MD

Vaccine-Associated Myocarditis

In the study period, we observed 140 and 90 patients who were admitted to the hospital or died of myocarditis after a first and second dose of ChAdOx1 vaccine, respectively. Of these, 40 (28.6%) and 11 (12.2%), respectively, died with myocarditis or within 28 days from hospital admission. Similarly, there were 124, 119, and 85 patients who were admitted to the hospital or died of myocarditis after a first, second, and third dose of BNT162b2 vaccine, respectively. Of these, 22 (17.7%), 14 (11.8%), and 13 (15.3%) patients died with myocarditis or within 28 days from hospital admission. Last,

N=100 fatal cases

N=51 AstraZeneca

N=49 Pfizer

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"*

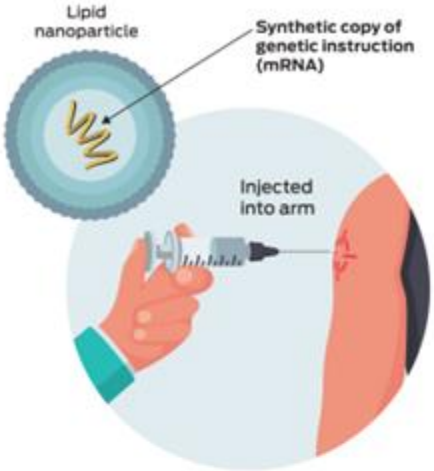
The 31-year-old was reported to be feeling '**fatigued**' in everyday life and after her heart rate skyrocketed during an easy endurance run last month, she sought out a doctor who diagnosed her with **myocarditis.**

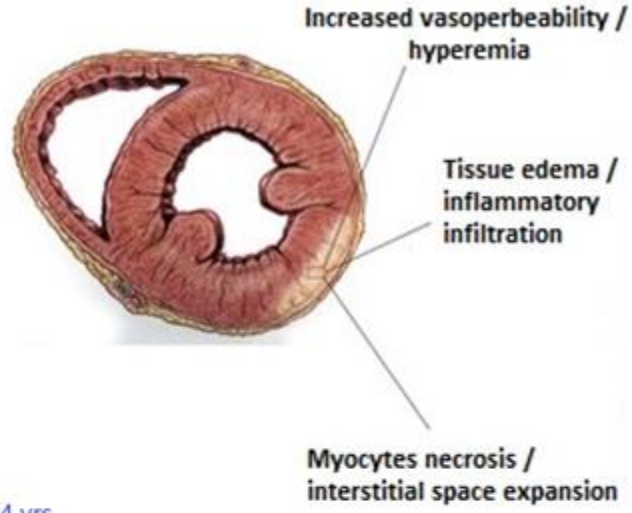
The experienced runner had planned to go on a **training camp in Portugal** at the beginning of this year but this was cancelled after her diagnosis.

> *"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% sublinical
-43% symptoms
  -Chest pain
  -Effort intolerance
  -Palpitations
  -Near syncope
  -Fever, malaise, myalgia

Detection

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

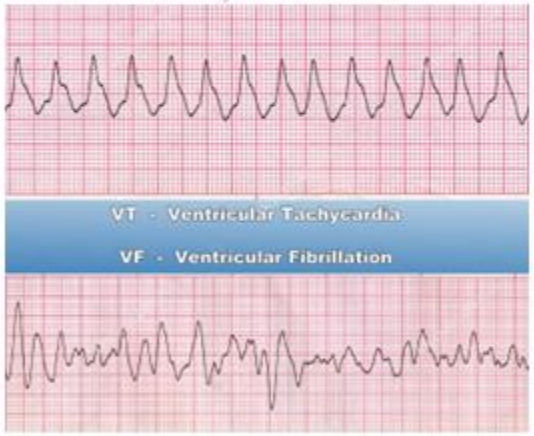
Diagnosis

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

Outcomes

Collapse

Arrythmias



Death

Received: 11 May 2022 | Revised: 29 July 2022 | Accepted: 5 August 2022

DOI: 10.1002/pds.5523

ORIGINAL ARTICLE

WILEY

Thromboembolic events after Ad.26.COV2.S COVID-19 vaccine: Reports to the Vaccine Adverse Event Reporting System

Emily Jane Woo | Adamma Mba-Jonas | Alisha Thomas | Bethany Baer | Brendan Day | Yeowon Kim | Margarita Gomez-Lorenzo | Narayan Nair

Plain language summary

As part of routine public health activities, the Food and Drug Administration reviews side effects that have been reported to the Vaccine Adverse Event Reporting System (VAERS). From February 27, 2021 to February 28, 2022, VAERS received 3790 reports of blood clots in people who had received Janssen COVID-19 Vaccine. Most cases were serious (e.g., life-threatening, fatal, or required hospitalization). Some of the clots were very severe (e.g., extending from the ankle to the groin, or involving both lungs at the same time). Some people had abnormal levels of platelets (blood cells that help the body stop bleeding), but many did not. Reports in VAERS do not prove that a vaccine caused an adverse event. More research is needed to understand whether Janssen COVID-19 Vaccine can cause blood clots.

Without Protection from Pharmaceutical Laws, Vaccines Will Do More Harm

by Dr. Peter McCullough | Jul 5, 2021 | Healthcare, Politics,

The War Between Nationalists and Globalists

by Karen Schoen

COVID-19 Investigation: Empirical

https://phmpt.org/

- <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

https://phmpt.org/

rge tranche of Pfizer documents some 10,000 pages was
by the FDA March 1, 2022. Included are nine pages of recorded side
ffects, about 158,000 different health problems in all

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...

“Current COVID-19 Vaccination Must Stop”

Dr. Aseem Malhotra, UK, Sept 2022

Journal of Insulin Resistance
ISSN: (Online) 2519-7533, (Print) 2412-2785

AOSIS

Page 1 of 8 Review Article

Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 1

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Malhotra A. Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 1. J. insul. resist. 2022;5(1), a71. https://doi.org/10.4102/jir.v5i1.71

Background: In response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), several new pharmaceutical agents have been administered to billions of people worldwide, including the young and healthy at little risk from the virus. Considerable leeway has been afforded in terms of the pre-clinical and clinical testing of these agents, despite an entirely novel mechanism of action and concerning biodistribution characteristics.

Aim: To gain a better understanding of the true benefits and potential harms of the messenger ribonucleic acid (mRNA) coronavirus disease (COVID) vaccines.

Methods: A narrative review of the evidence from randomised trials and real world data of the COVID mRNA products with special emphasis on BionTech/Pfizer vaccine.

Results: In the non-elderly population the “number needed to treat” to prevent a single death runs into the thousands. Re-analysis of randomised controlled trials using the messenger ribonucleic acid (mRNA) technology suggests a greater risk of serious adverse events from the vaccines than being hospitalised from COVID-19. Pharmacovigilance systems and real-world safety data, coupled with plausible mechanisms of harm, are deeply concerning, especially in relation to cardiovascular safety. Mirroring a potential signal from the Pfizer Phase 3 trial, a significant rise in cardiac arrest calls to ambulances in England was seen in 2021, with similar data emerging from Israel in the 16–39-year-old age group.

Conclusion: It cannot be said that the consent to receive these agents was fully informed, as is required ethically and legally. A pause and reappraisal of global vaccination policies for COVID-19 is long overdue.

Contribution: This article highlights the importance of addressing metabolic health to reduce chronic disease and that insulin resistance is also a major risk factor for poor outcomes from COVID-19.

Keywords: COVID-19; mRNA vaccine; cardiac arrests; real evidence-based medicine; shared decision-making.

www.PeterMcCulloughMD.com

Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 2

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Background: Authorities and sections of the medical profession have supported unethical, coercive, and misinformed policies such as vaccine mandates and vaccine passports, undermining the principles of ethical evidence-based medical practice and informed consent. These regrettable actions are a symptom of the ‘medical information mess’: The tip of a mortality iceberg where prescribed medications are estimated to be the third most common cause of death globally after heart disease and cancer.

Aim: To identify the major root causes of these public health failures.

Methods: A narrative review of both current and historical driving factors that underpin the pandemic of medical misinformation.

Results: Underlying causes for this failure include regulatory capture – guardians that are supposed to protect the public are in fact funded by the corporations that stand to gain from the sale of those medications. A failure of public health messaging has also resulted in wanton waste of resources and a missed opportunity to help individuals lead healthier lives with relatively simple – and low cost – lifestyle changes.

Conclusion: There is a strong scientific, ethical and moral case to be made that the current COVID vaccine administration must stop until all the raw data has been subjected to fully independent scrutiny. Looking to the future the medical and public health professions must recognise these failings and eschew the tainted dollar of the medical-industrial complex. It will take a lot of time and effort to rebuild trust in these institutions, but the health – of both humanity and the medical profession – depends on it.

Contribution: This article highlights the importance of addressing metabolic health to reduce chronic disease and that insulin resistance is also a major risk factor for poor outcomes from COVID-19.

Keywords: COVID-19; mRNA vaccine; cardiac arrests; real evidence-based medicine; shared decision making.

June 11, 2022

Press Release

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

World Council For Health

NEWS NEWS RELEASES

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

June 11, 2022 • 20 Comments

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
- Freedom At Risk
- 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
4) *Prevent outbreak reoccurrence

*anticipated

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

COURAGEOUS DISCOURSE

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.

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

Pfizer
Manufactured by
Pfizer Inc., New York, NY 10017

LAB-1451-21.6f

Revised: 31 August 2022

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).

JAMA | Original Investigation

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, MSci; 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, MSci; Natasha Halasa, MD, MPH; James D. Chappell, MD, PhD; Adam S. Lauring, MD, PhD; Carlos G. Grijalva, MD, MPH; Todd W. Rice, MD, MSci; 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

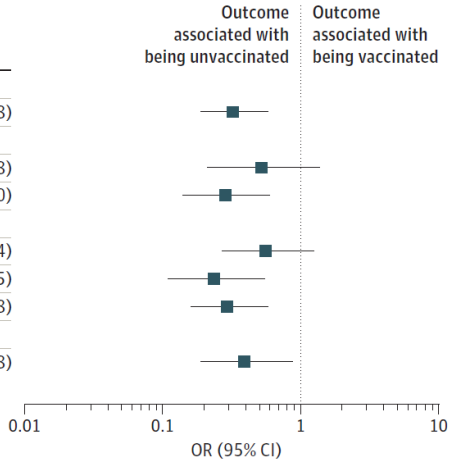
Participants

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]	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 occured 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.

Effectiveness of Covid-19 vaccination against risk of symptomatic infection, hospitalization, and death up to 9 months: a Swedish total-population cohort study

842,974 pairs (N=1,684,958)

Preprints with THE LANCET

Peter Nordström, MD, PhD, Marcel Ballin, MSc., Anna Nordström, MD, PhD

Pfizer/BNT 30 mcg mRNA/injection

Symptomatic Infection
Fully Vaccinated (VE)

22 studies show waning vaccine efficacy over 3-6 months for all vaccines against all variants

Dr. Paul Alexander, Brownstone Institute Oct 29 2021

>180 days (N=22,755)	32	0·8	15	2·4	69 (44-83)	59 (18-79)

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...

Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study

Anika Singanayagam*, Seran Hakki*, Jake Dunning*, Kieran J Madon, Michael A Crone, Aleksandra Koycheva, Nieves Derqui-Fernandez, Jack L Barnett, Michael G Whitfield, Robert Varro, Andre Charlett, Rhia Kundu, Joe Fenn, Jessica Cutajar, Valerie Quinn, Emily Conibear, Wendy Barclay, Paul S Freemont, Graham P Taylor, Shazaad Ahmad, Maria Zambon, Neil M Ferguson†, Ajit Lalvani†, on behalf of the ATACCC Study Investigators‡

Lancet Infect Dis 2021
Published Online
October 28, 2021
https://doi.org/10.1016/

Summary

Background The SARS-CoV-2 delta (B.1.617.2) variant is highly transmissible and spreading globally, including in populations with high vaccination rates. We aimed to investigate transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild delta variant infection in the community.

39% of transmission from fully vaccinated to fully vaccinated

for uninfected individ… 001). SAR among household contacts exposed to fully vaccinated index cases was similar to household c… exposed to unvaccinated index cases (25% [95% CI 15–35] for vaccinated *vs* 23% [15–31] for unvaccinated). 12 (39%) of 31 infections in fully vaccinated household contacts arose from fully vaccinated epidemiologically linked index cases, further confirmed by genomic and virological analysis in three index case–contact pairs. Although peak viral load did not differ by vaccination status or variant type, it increased modestly with age (difference of 0·39 [95% credible interval –0·03 to 0·79] in peak $\log_{10}$ viral load per mL between those aged 10 years and 50 years). Fully vaccinated individuals with delta variant infection had a faster (posterior probability >0·84) mean rate of viral load decline (0·95 $\log_{10}$ copies per mL per day) than did unvaccinated individuals with pre-alpha (0·69), alpha (0·82), or delta (0·79) variant infections. Within individuals, faster viral load growth was correlated with higher peak viral load (correlation 0·42 [95% credible interval 0·13 to 0·65]) and slower decline (–0·44 [–0·67 to –0·18]).

Interpretation Vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts. Host–virus interactions early in infection may shape the entire viral trajectory.

J Cutajar BSc, V Quinn BSc, E Conibear MSc, Prof A Lalvani DM), **Department of Infectious Disease** (A Singanayagam, Prof W Barclay PhD, Prof G P Taylor DSc, M A Crone MBBCh, Prof P S Freemont PhD), **NIHR Health Protection Research Unit in Modelling and Health Economics, MRC Centre for Global Infectious Disease Analysis, Jameel Institute** (Prof N M Ferguson DPhil), **and UK Dementia Research Institute Centre for Care Research and Technology** (M A Crone, Prof P S Freemont),

January 1, 2022

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

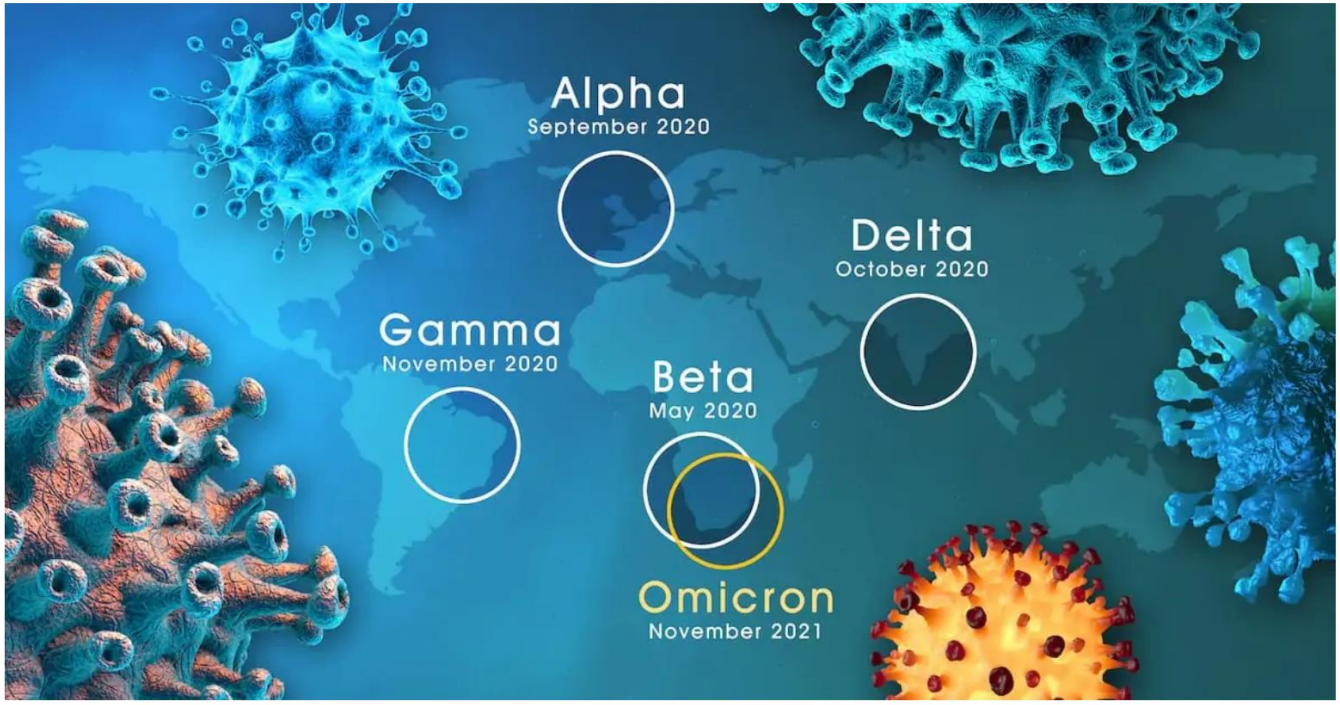
COVID Resources

Column

C19 EXPERT PANEL @PeterMcCulloughMD

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

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



Omicron variant of SARS-CoV-2 harbors a unique insertion mutation of putative viral or human genomic origin

A.J. Venkatakrishnan[1], Praveen Anand[2], Patrick J. Lenehan[1], Rohit Suratekar[2], Bharathwaj Raghunathan[3], Michiel J.M. Niesen[1], Venky Soundararajan[1,2,3]*

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[3] nference, Toronto, ON M5V 1M1, Canada
*Correspondence to: Venky Soundararajan (venky@nference.net)

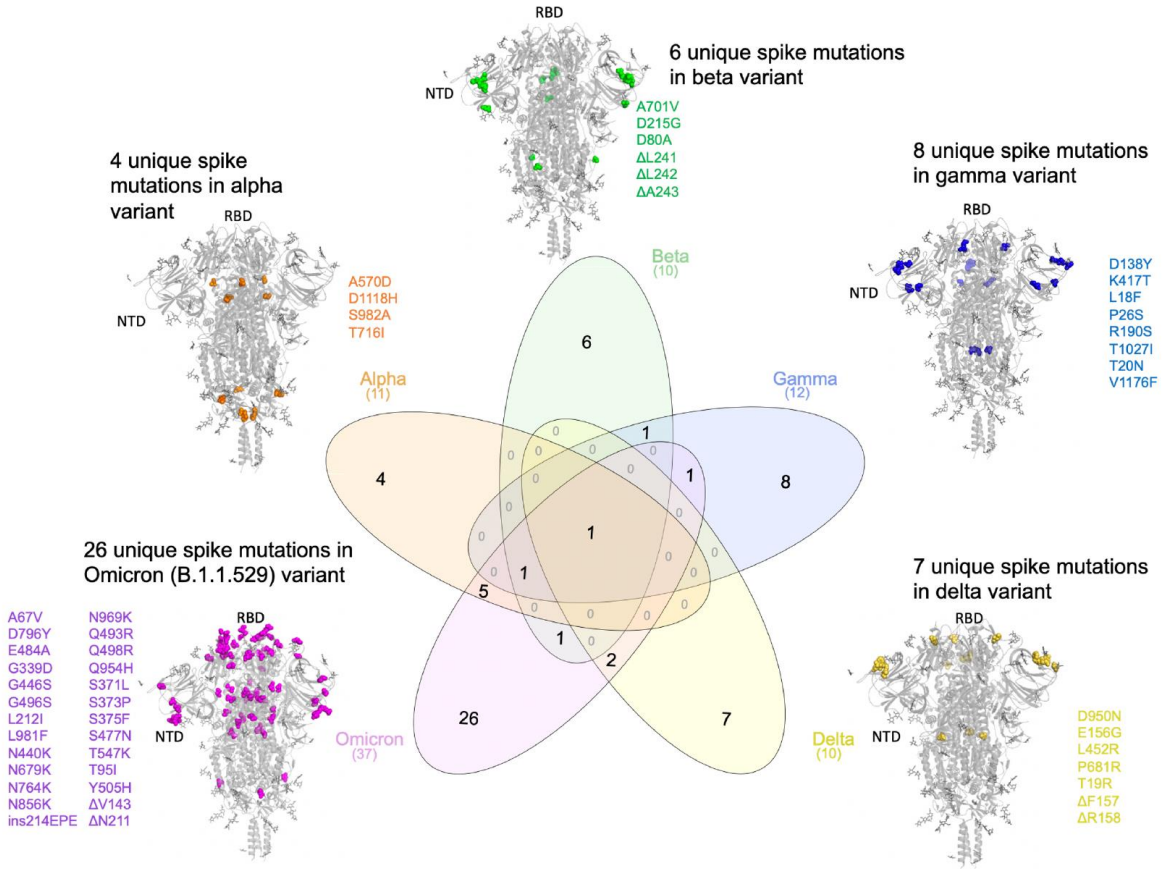


Figure 1. Venn diagram depicting the overlap of lineage specific spike mutations in the SARS-CoV-2 variants of concern. The unique key mutations observed in the spike protein for each of the variants are highlighted (spheres) on the homo-trimeric Spike protein of SARS-CoV-2. The B.1.1.529 (Omicron) variant has the highest number (26) of unique mutations in the spike protein from this perspective, making its emergence a “step function” in evolution of SARS-CoV-2 strains.

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
December 10, 2021

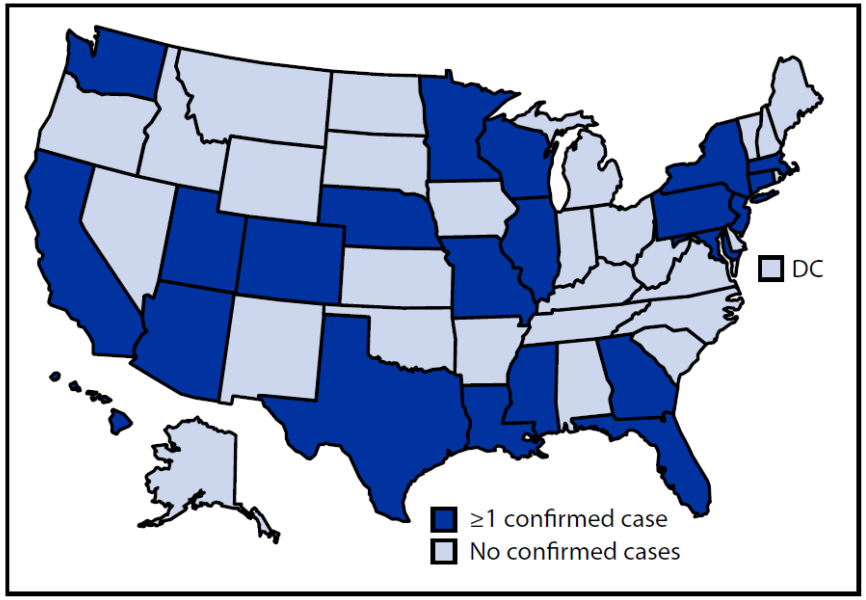
SARS-CoV-2 B.1.1.529 (Omicron) Variant — United States, December 1–8, 2021

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



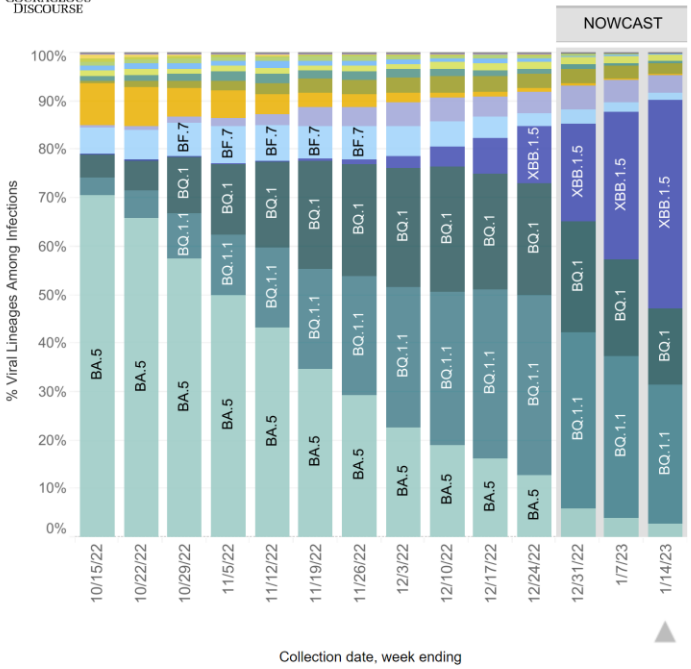
United States: 1/8/2023 – 1/14/2023 NOWCAST

USA

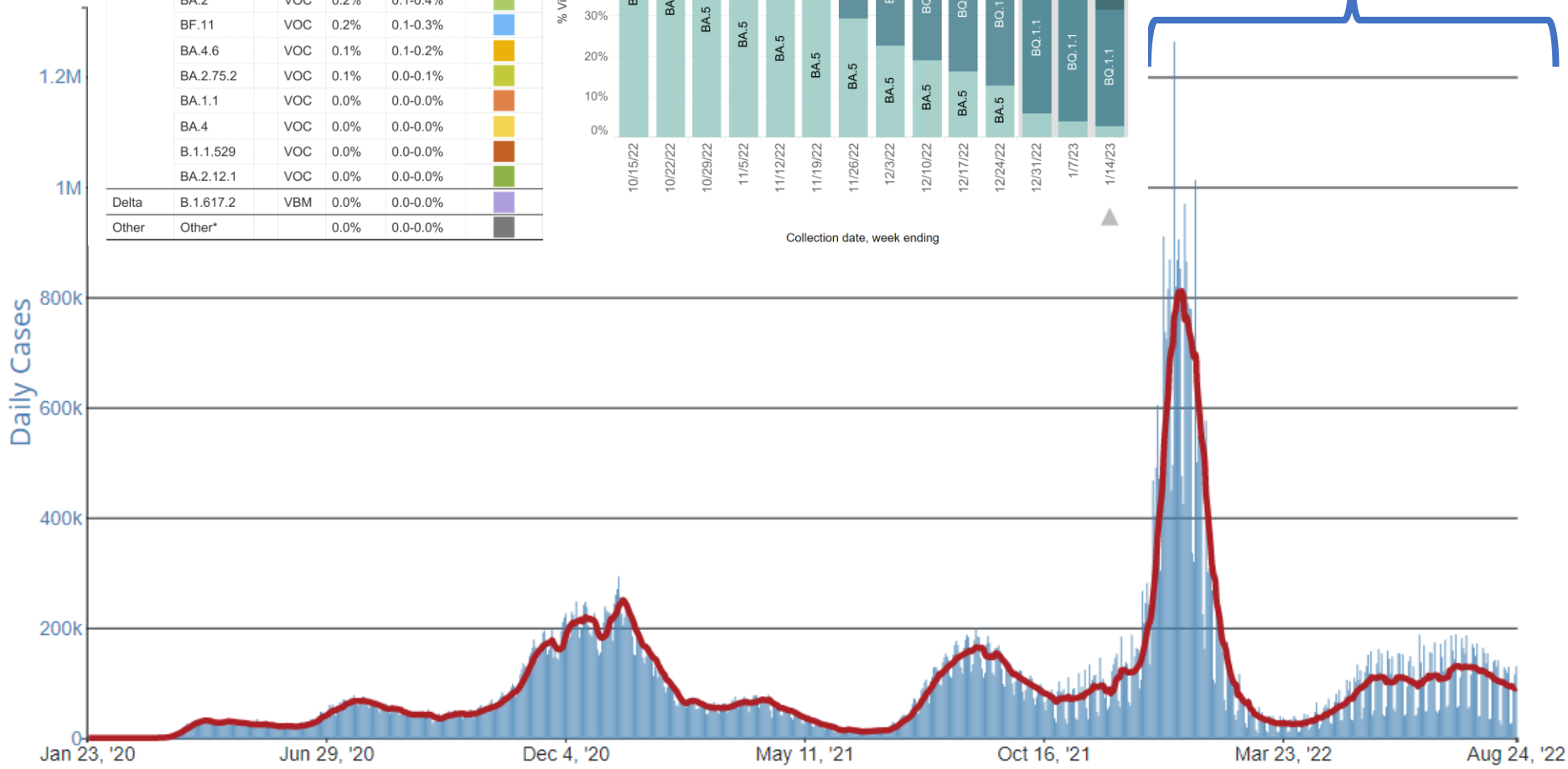
WHO label	Lineage #	US Class	%Total	95%PI
Omicron	XBB.1.5	VOC	43.0%	26.4-61.1%
	BQ.1.1	VOC	28.8%	20.5-38.7%
	BQ.1	VOC	15.9%	11.0-22.2%
	XBB	VOC	3.9%	3.0-5.1%
	BA.5	VOC	2.6%	1.8-3.7%
	BN.1	VOC	2.1%	1.5-3.1%
	BF.7	VOC	1.4%	0.9-2.1%
	BA.2.75	VOC	1.3%	0.8-1.9%
	BA.5.2.6	VOC	0.5%	0.3-0.8%
	BA.2	VOC	0.2%	0.1-0.4%
	BF.11	VOC	0.2%	0.1-0.3%
	BA.4.6	VOC	0.1%	0.1-0.2%
	BA.2.75.2	VOC	0.1%	0.0-0.1%
	BA.1.1	VOC	0.0%	0.0-0.0%
	BA.4	VOC	0.0%	0.0-0.0%
	B.1.1.529	VOC	0.0%	0.0-0.0%
	BA.2.12.1	VOC	0.0%	0.0-0.0%
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.0%

COURAGEOUS DISCOURSE

United States: 10/9/2022 – 1/14/2023



Omicron

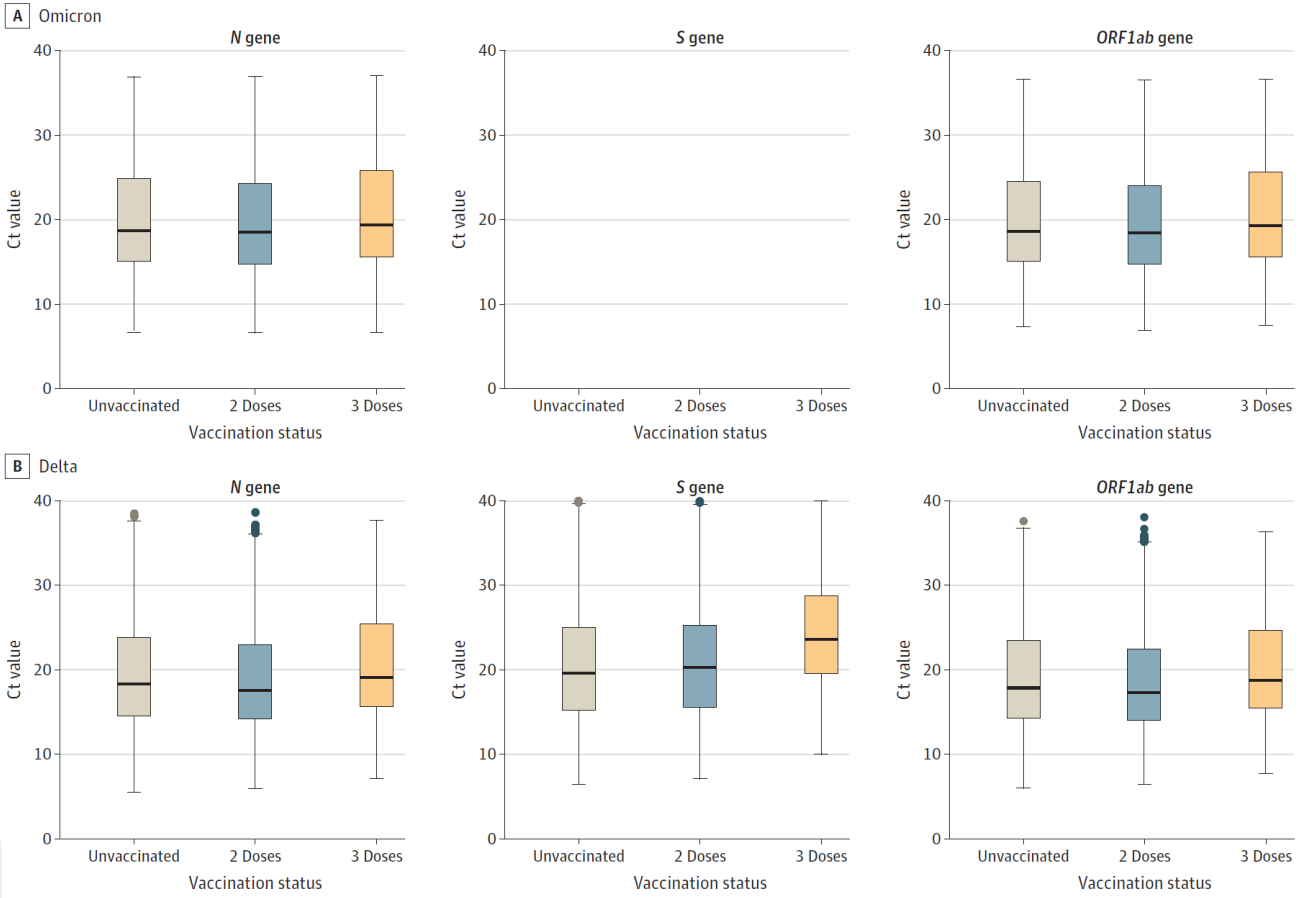


JAMA | Original Investigation

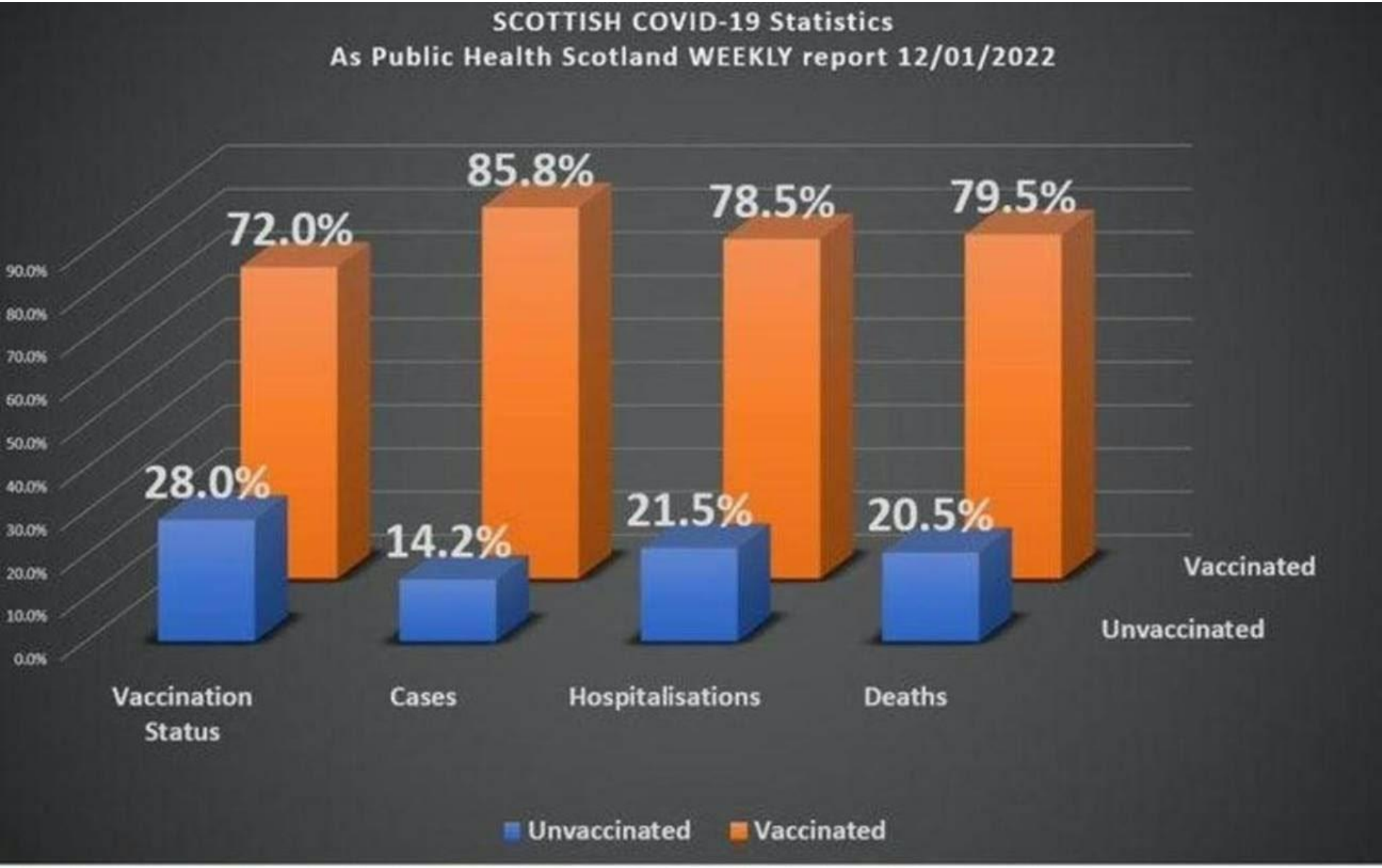
Association Between 3 Doses of mRNA COVID-19 Vaccine and Symptomatic Infection Caused by the SARS-CoV-2 Omicron and Delta Variants

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



JAMA. doi:10.1001/jama.2022.0470
Published online January 21, 2022.



https://www.publichealthscotland.scot/media/11076/22-01-12-covid19-winter_publication_report.pdf

Worldwide Bayesian Causal Impact Analysis of Vaccine Administration on Deaths and Cases Associated with COVID-19: A BigData Analysis of 145 Countries

A Preprint

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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 $y1$ or $y2$ over and above what ...expected with no treatment. $y1$ 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. $y2$ 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 $y1$ ranges from -19% to +19015% with an average causal impact of +463.13%. Causal impacts of the treatment on $y2$ 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.

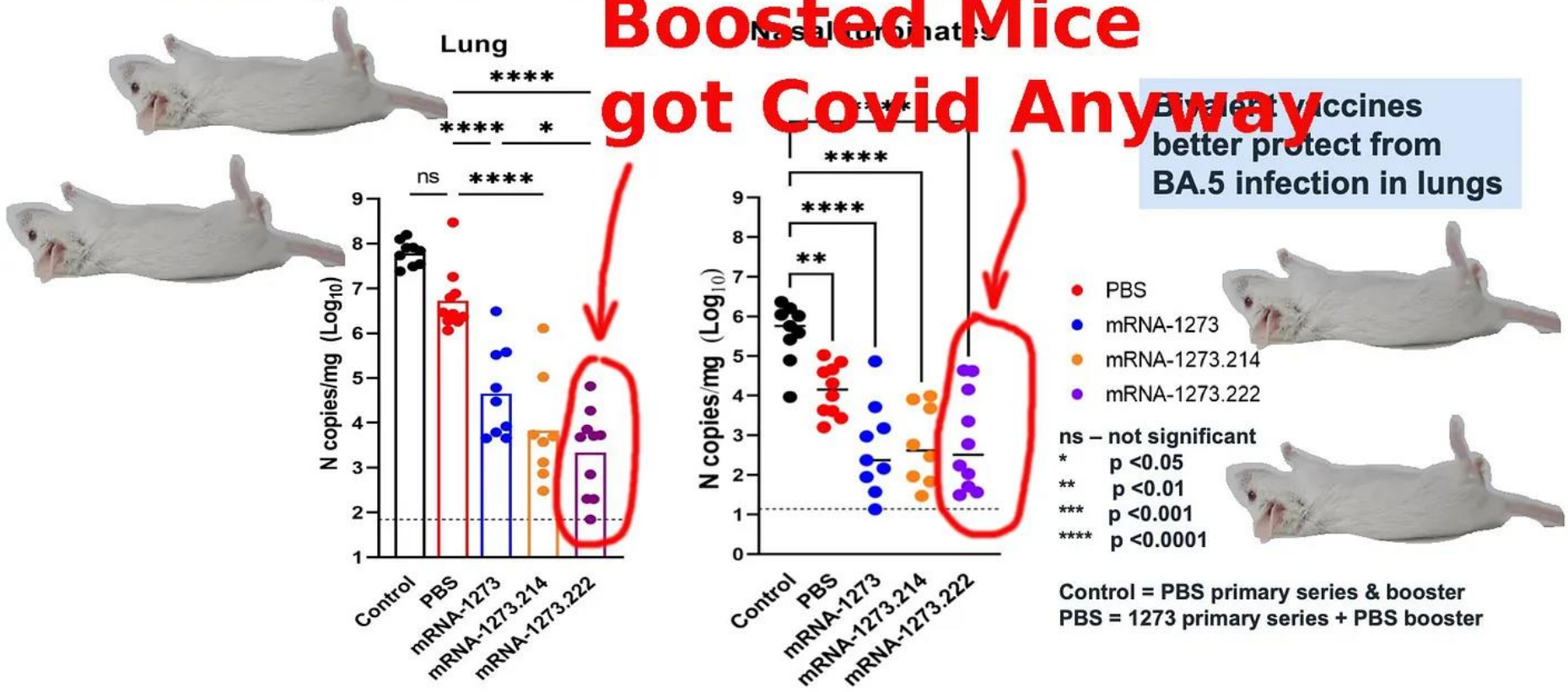
This study subsequently performed correlational analyses on the causal impact results, whose effect variables can be represented as $y1.E$ and $y2.E$ respectively, with the independent numeric variables of: *days elapsed since vaccine rollout began* ($n1$), *total vaccination doses per hundred* ($n2$), *total vaccine brands/types in use* ($n3$) and the independent

BA4/5 Bivalent Vaccines Failed to Reduce Nasal Turbinate Viral Load

Increased Protection from BA.5 Challenge after Booster Dose of BA.4/BA.5 & BA.1 Omicron Vaccines (mRNA-1273.214 & mRNA-1273.222) in Mice

- Mice challenged with 10^4 PFU of BA.5 virus 4 weeks after booster dose

Boosted Mice got Covid Anyway



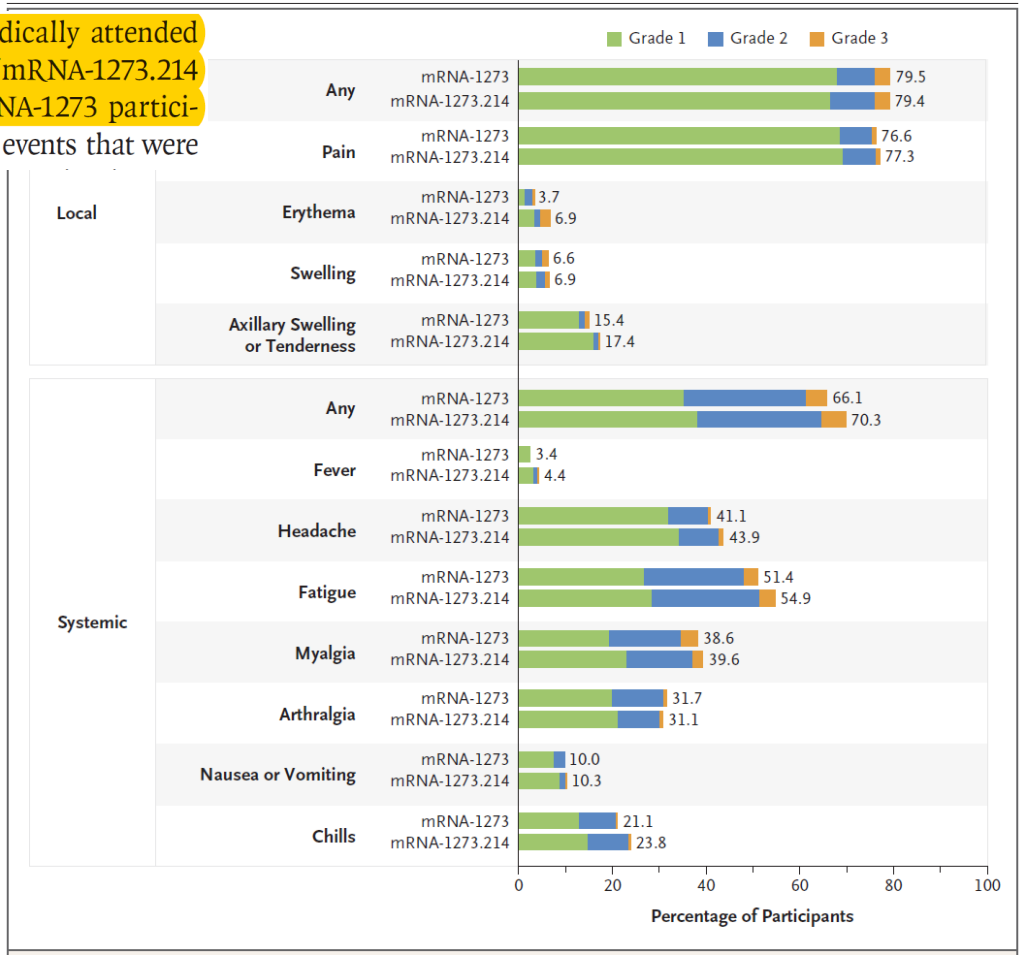
Scheaffer et al, manuscript under preparation

ORIGINAL ARTICLE

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.

This article was published on September 16, 2022, at NEJM.org.

DOI: 10.1056/NEJMoa2208343

Column

Vaccine Manufacturers Railroad Products through FDA while Raking in Pre-Purchase Revenue

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

www.PeterMcCulloughMD.com

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
- Freedom At Risk
- Censorship of Scientific Discourse
- Conclusions

Review

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
"↓Hospitalizations/Death"

Late-Stage
Hospitalization
"Safety Net for Survival"

Vaccination
"Herd Immunity"

*Correspondence: peteramccullough@gmail.com (Peter A. McCullough)
DOI: 10.31083/j.rcm.2020.04.264

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,

REVIEW

THE AMERICAN JOURNAL of MEDICINE®

Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection

Peter A. McCullough, MD, MPH,[a,b,c] Ronan J. Kelly, MD,[a] Gaetano Ruocco, MD,[d] Edgar Lerma, MD,[e] James Tumlin, MD,[f] Kevin R. Wheelan, MD,[a,b,c] Nevin Katz, MD,[g] Norman E. Lepor, MD,[h] Kris Vijay, MD,[i] Harvey Carter, MD,[j] Bhupinder Singh, MD,[k] Sean P. McCullough, BS,[l] Brijesh K. Bhambi, MD,[m] Alberto Palazzuoli, MD, PhD,[n] Gaetano M. De Ferrari, MD, PhD,[o] Gregory P. Milligan, MD, MPH,[a] Taimur Safder, MD, MPH,[a] Kristen M. Tecson, PhD,[b] Dee Dee Wang, MD,[p] John E. McKinnon, MD,[p] William W. O'Neill, MD,[p] Marcus Zervos, MD,[p] Harvey A. Risch, MD, PhD[q]

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1. Precautionary principle—mass casualty event
2. Signal of benefit—from all evidence
3. Acceptable safety
4. Drugs in combination

KEYWORDS: Ambulatory treatment; Anticoagulant; [illegible]; COVID-19; Critical care; Epidemiology; Hospitalization; Mortality; SARS-CoV-2

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Conflicts of Interest: None.
Authorship: All authors had access to the data and a role in writing this manuscript.

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The pandemic of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2 [COVID-19]) is rapidly expanding across the world with each country and region developing distinct epidemiologic patterns in terms of frequency, hospitalization, and death. There has been considerable focus on 2 major areas of response to the pandemic: containment of the spread of infection and reducing inpatient mortality.

https://doi.org/10.1016/j.amjmed.2020.07.003

Published online: ?? xx, xxxx

IMR Press

Review

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

Peter A. McCullough[1,*], Paul E. Alexander[2], Robin Armstrong[3], Cristian Arvinte[4], Alan F. Bain[5], Richard P. Bartlett[6], Robert L. Berkowitz[7], Andrew C. Berry[8], Thomas J. Borody[9], Joseph H. Brewer[10], Adam M. Brufsky[11], Teryn Clarke[12], Roland Derwand[13], Alieta Eck[14], John Eck[14], Richard A. Eisner[15], George C. Fareed[16], Angelina Farella[17], Silvia N. S. Fonseca[18], Charles E. Geyer, Jr.[19], Russell S. Gonnering[20], Karladine E. Graves[21], Kenneth B. V. Gross[22], Sabine Hazan[23], Kristin S. Held[24], H. Thomas Hight[25], Stella Immanuel[26], Michael M. Jacobs[27], Joseph A. Ladapo[28], Lionel H. Lee[29], John Littell[30], Ivette Lozano[31], Harpal S. Mangat[32], Ben Marble[33], John E. McKinnon[34], Lee D. Merritt[35], Jane M. Orient[36], Ramin Oskoui[37], Donald C. Pompan[38], Brian C. Procter[39], Chad Prodromos[40], Juliana Cepelowicz Rajter[41], Jean-Jacques Rajter[41], C. Venkata S. Ram[42], Salete S. Rios[43], Harvey A. Risch[44], Michael J. A. Robb[45], Molly Rutherford[46], Martin Scholz[47], Marilyn M. Singleton[48], James A. Tumlin[49], Brian M. Tyson[50], Richard G. Urso[51], Kelly Victory[52], Elizabeth Lee Vliet[53], Craig M. Wax[54], Alexandre G. Wolkoff[55], Vicki Wooll[56] and Vladimir Zelenko[57]

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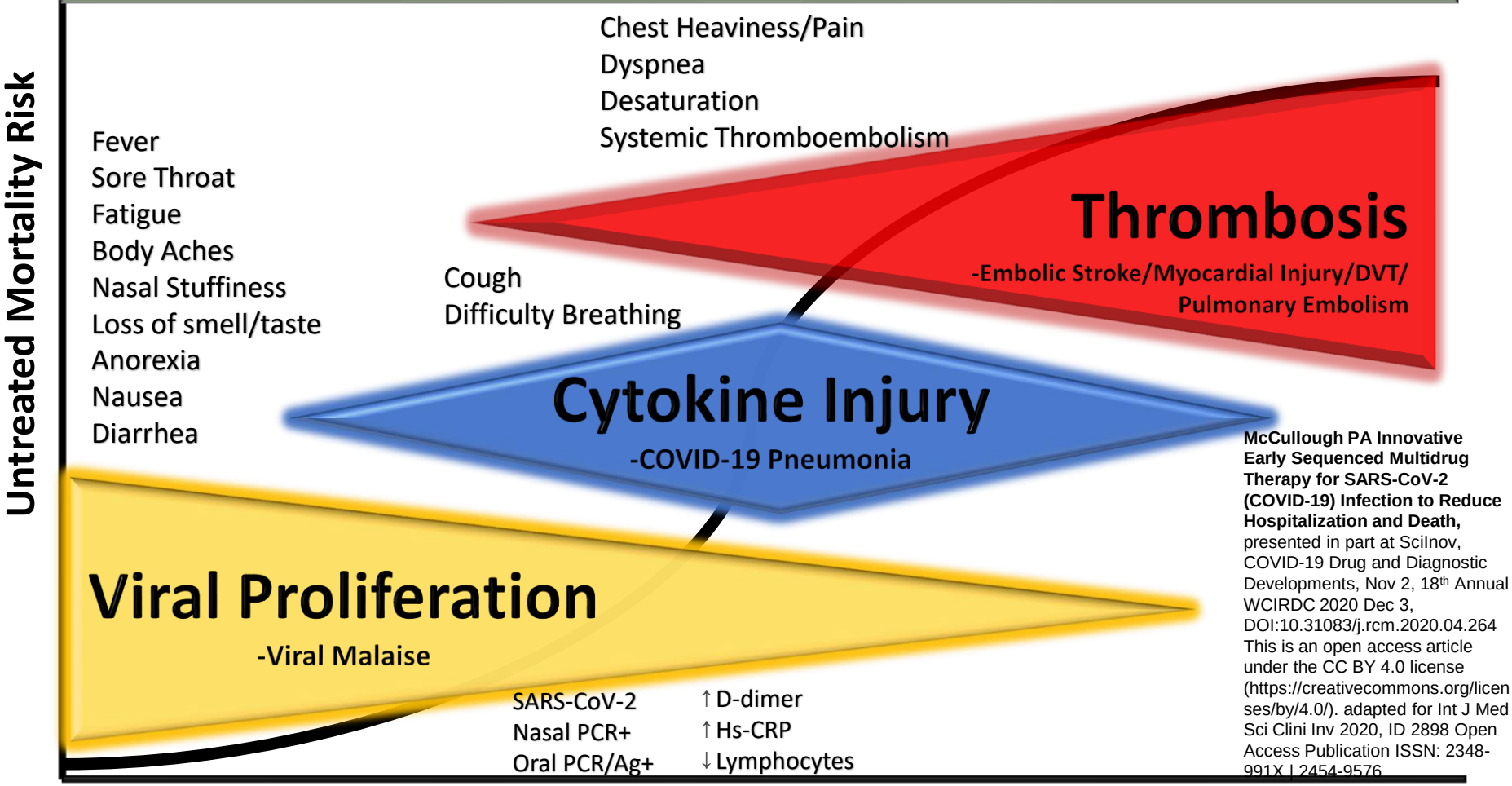
DOI:10.31083/j.

Therapeutic Response

Intracellular anti-infectives/antiviral antibodies
Corticosteroids/immunomodulators
Antiplatelet agents/anticoagulants



McCullough PA Innovative Early Sequenced Multidrug Therapy for SARS-CoV-2 (COVID-19) Infection to Reduce Hospitalization and Death, presented in part at SciInov, COVID-19 Drug and Diagnostic Developments, Nov 2, 18th Annual WCIRDC 2020 Dec 3, DOI:10.31083/j.rcm.2020.04.264

Changes in population immunity against infection and severe disease from SARS-CoV-2 Omicron variants in the United States between December 2021 and November 2022.

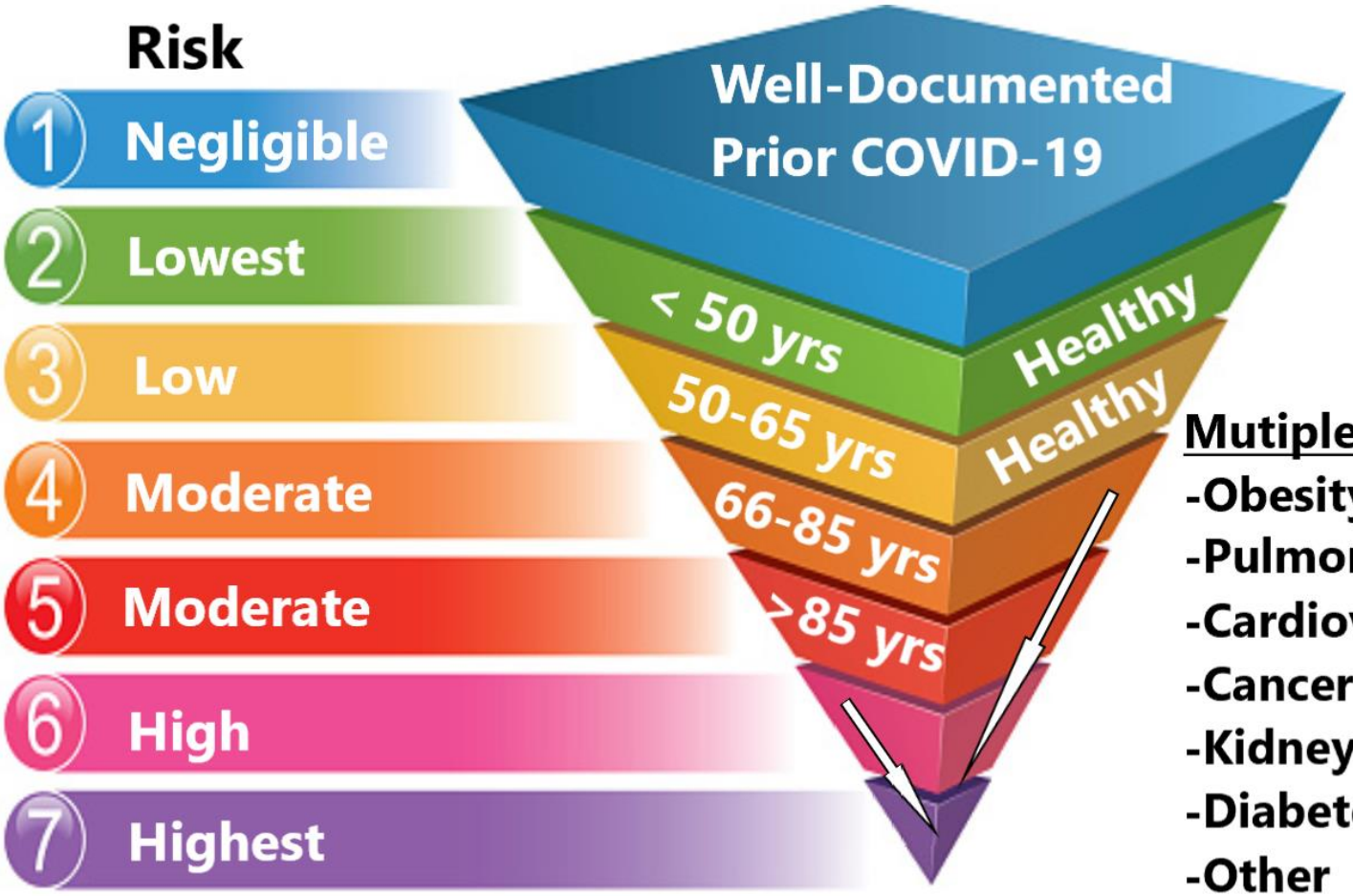
Authors: Fayette Klaassen [1], Melanie H. Chitwood [2], Ted Cohen [2], Virginia E. Pitzer [2], Marcus Russi [2], Nicole A. Swartwood [1], Joshua A. Salomon [3], and Nicolas A. Menzies [1]

94% of Americans have been infected with SARS-CoV-2 and 97% have some form of immunity

to have bee… at least once. Combined with vaccination, 97% (95%–

99%) were estimated … some prior immunological exposure to SARS-CoV-2. Between

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



Mutiple Medical Problems

- -Obesity
- -Pulmonary
- -Cardiovascular
- -Cancer
- -Kidney
- -Diabetes
- -Other

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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 adapted for Int J Med Sci Clini 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/m^2, Pulmonary Dz, DM, CVD, CKD, Cancer

Age ≥ 50 yr. with ≥1 Comorbidities

OTC bundle: Zinc 50 mg, vitamin D_3 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)

HCQ 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 0_2
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

BMI=body mass index, Dz=disease, DM=diabetes mellitus, CVD=cardiovascular disease, CKD=chronic kidney disease, yr=years, HCQ=hydroxychloroquine, AZM=azithromycin, DOXY=doxycycline, IVM=Ivermectin, VTE=venous thrombo-embolic, EUA=Emergency Use Authorization (U.S. administration)

MEDICAL SCIENCE MONITOR

CLINICAL RESEARCH

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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

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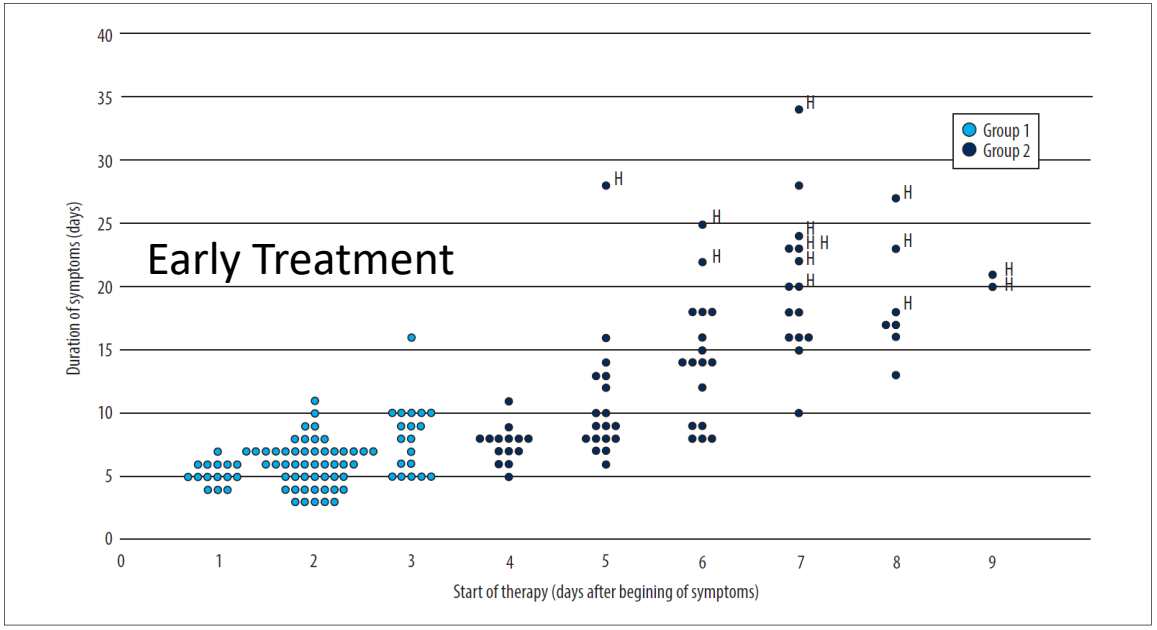

Figure 2. Duration of symptoms in relation to the delay in start of therapy. The symbol "H" specifies the patients who were hospitalized. The figure was created with Excel software and the "H" labels were added where indicated with PowerPoint software (Microsoft Office 2019).

Fazio S, Bellavite P, Zanolin E, McCullough PA, Pandolfi S, Affuso F. 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. Med Sci Monit. 2021 Dec 30;27:e935379. doi: 10.12659/MSM.935379. PMID: 34966165; PMCID: PMC8725339.

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

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.

Print 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.

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

Bioresearch Communications
Volume 7, Issue 1, January 2021

Md. Iqbal Mahmud Choudhury[1], Nilufar Shabnam[2], Tazin Ahsan[3], Md. Saiful kabir[4], Rashed Md. Khan[5], S.M. Abu Ahsan[6]

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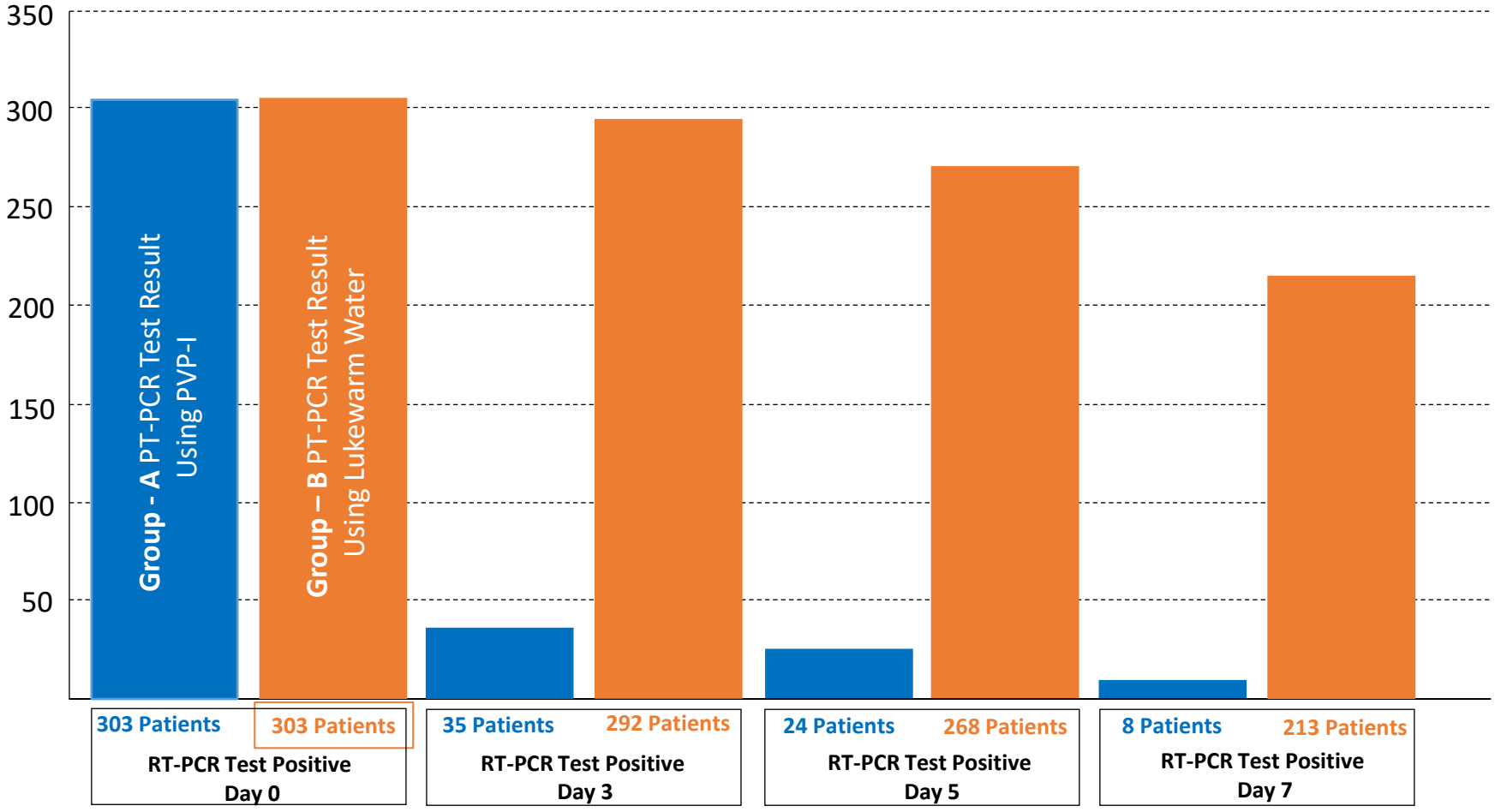
ABSTRACT: Background: The sudden onset of COVID-19 began in late 2019 caused by a novel coronavirus (SARS-COV2) and on 11th March, WHO declared it to have developed pandemic status. There is still no specific treatment and vaccine available for COVID-19; causing wide spread health problem and concern 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,T_3, T_4, FT_4) 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.

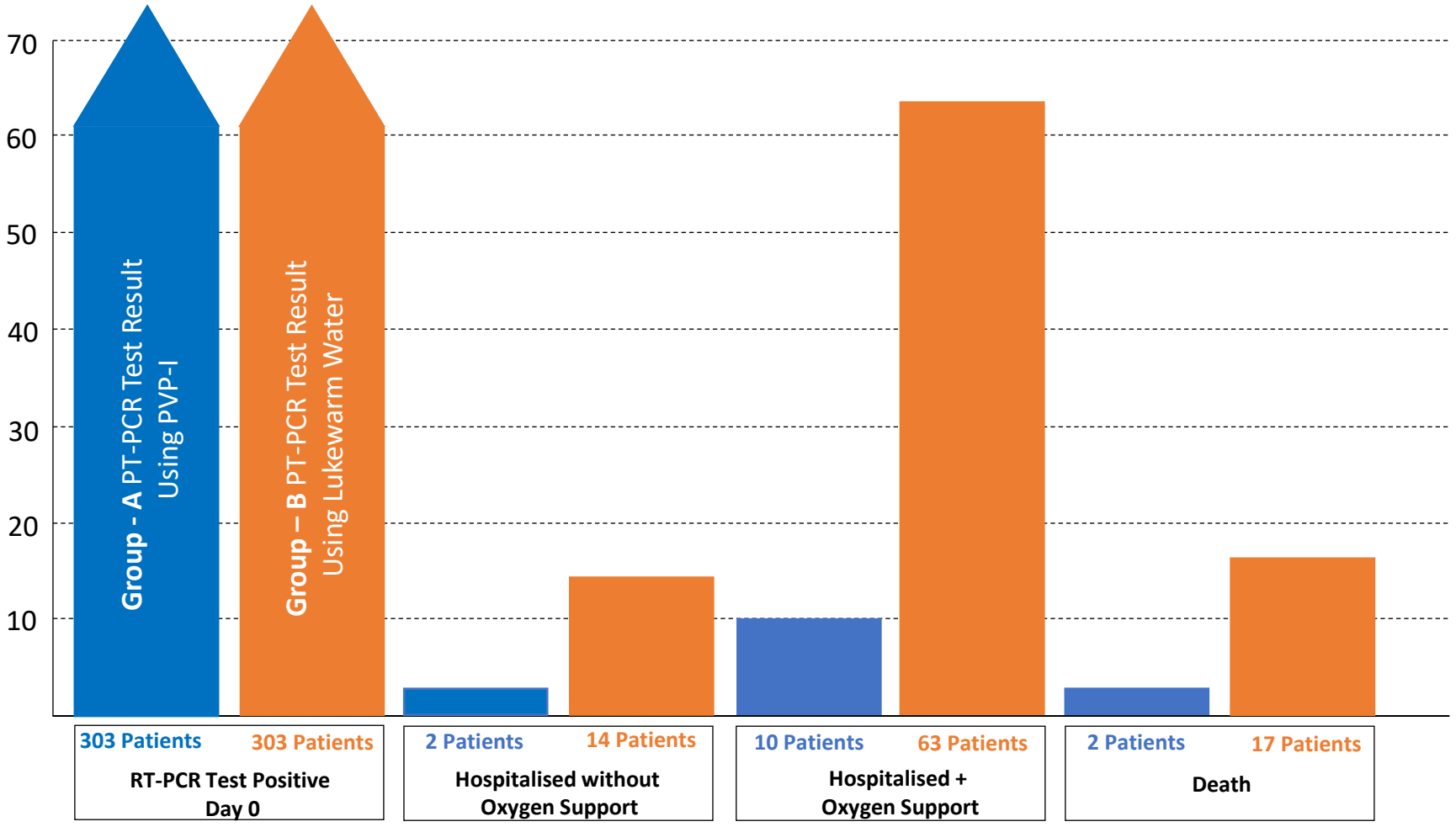
KEYWORDS: Povidone Iodine, 1Pq.s, COVID-19.

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



Bioresearch Communications
Volume 7, Issue 1, January 2021

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



Bioresearch Communications
Volume 7, Issue 1, January 2021

Safe, Effective Antimicrobial Nasal/Oral Rinses

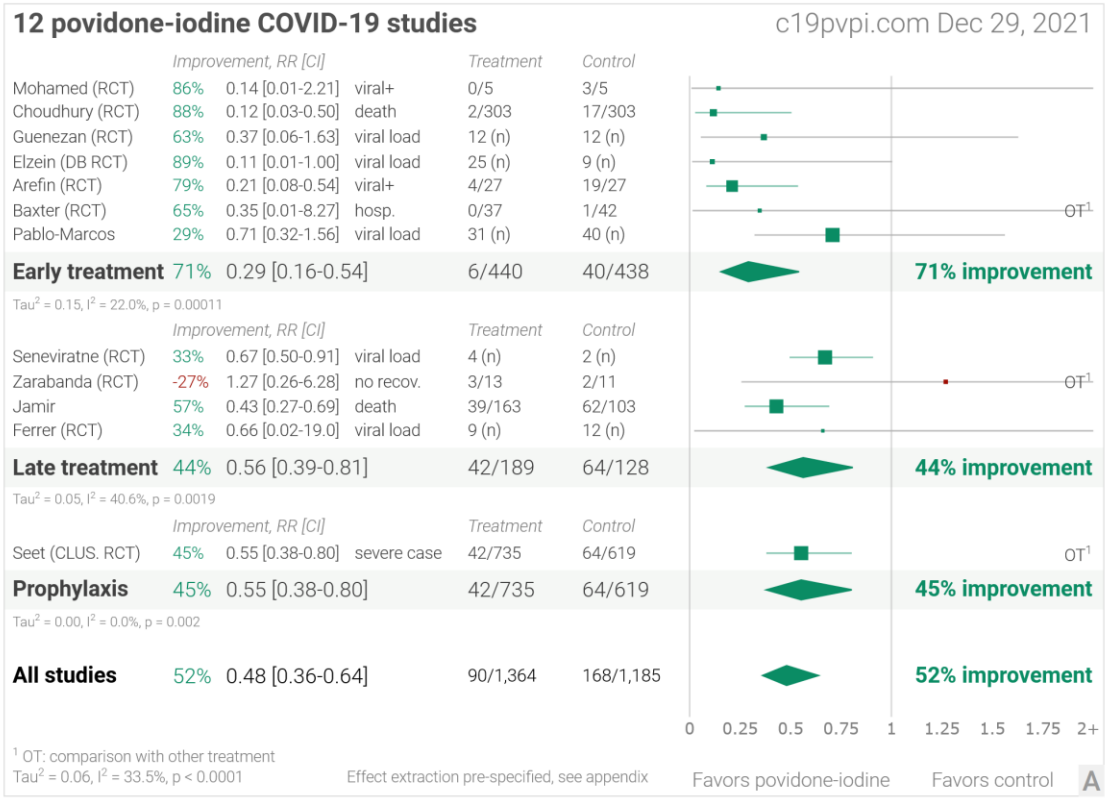
Rep. Nancy Mace (R-S.C.) speaks with reporters in Washington, D.C. on Oct. 21, 2021. (Anna Moneymaker/Getty Images)

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.



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.

https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label

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.

A voice for private physicians since 1943

AAPS

Association of American Physicians & Surgeons

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...

Treat the Viral Infection, Handle the Pandemic Crisis

by Dr. Peter McCullough | May 11, 2021 | Healthcare, Politics,

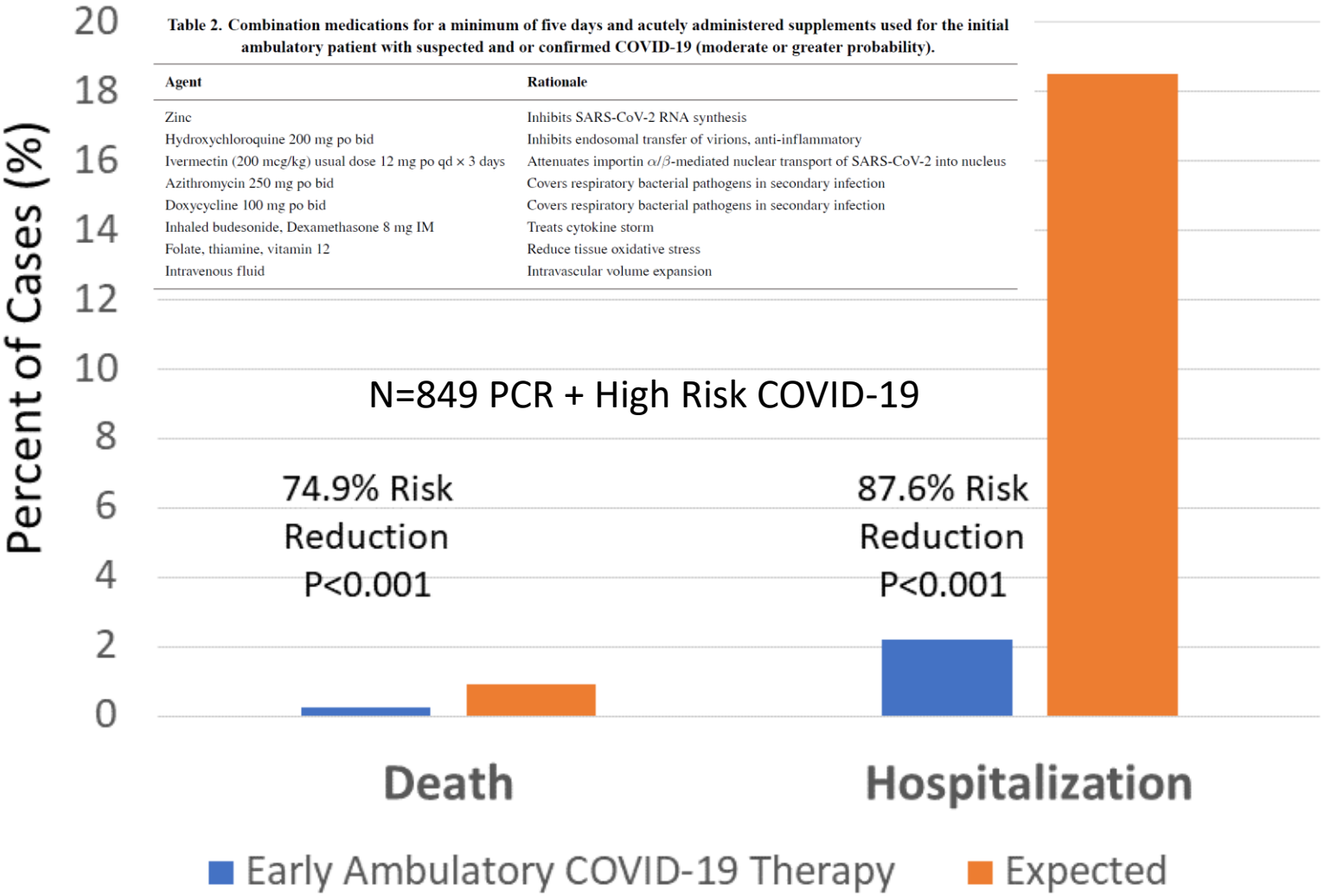
Sick COVID-19 patients don't feel better with masks and it's either too late or they have been failed by the vaccination. We need real doctors helping frightened patients in need to get through the crisis. We need to cut through all the fear, panic, hubris, and false narrative and getting to the truth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

Early Ambulatory Multidrug Therapy Reduces Hospitalization and Death in High-Risk Patients with SARS-CoV-2 (COVID-19)

Brian Procter[1], Casey Ross[1], Vaness Pickard[1], Erica Smith[1], Cortney Hanson[1], and Peter A. McCullough[2]

Table 2. Combination medications for a minimum of five days and acutely administered supplements used for the initial ambulatory patient with suspected and or confirmed COVID-19 (moderate or greater probability).

Agent	Rationale
Zinc	Inhibits SARS-CoV-2 RNA synthesis
Hydroxychloroquine 200 mg po bid	Inhibits endosomal transfer of virions, anti-inflammatory
Ivermectin (200 mcg/kg) usual dose 12 mg po qd × 3 days	Attenuates importin α/β-mediated nuclear transport of SARS-CoV-2 into nucleus
Azithromycin 250 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Doxycycline 100 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Inhaled budesonide, Dexamethasone 8 mg IM	Treats cytokine storm
Folate, thiamine, vitamin 12	Reduce tissue oxidative stress
Intravenous fluid	Intravascular volume expansion



Procter BC, Ross C, Pickard V, Smith E, Hanson C, McCullough PA. Clinical outcomes after early ambulatory multidrug therapy for high-risk SARS-CoV-2 (COVID-19) infection. Rev Cardiovasc Med. 2020 Dec 30;21(4):611-614. doi: 10.31083/j.rcm.2020.04.260. PMID: 33388006.

Permanent link to preprint on Authorea: https://doi.org/10.22541/au.161000355.54720791/v1

COVID

MDPI

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

2022, 2, 1139–11

10.3390/covid2080084

Academic Editor: Anton Civit

words: COVID-19; SARS-CoV-2; ambulatory treatment; early treatment; mortality; hospitalization; epidemiology; biostatistics; drug repurposing

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
- Freedom At Risk
- 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 PhD[1], Houssein H. Ayoub, PhD[4], Peter Coyle, MD[5,6,7], Patrick Tang, MD PhD[8], Hadi M. Yassine, PhD[6,9], Hebah A. Al-Khatib, PhD[6,9], Maria K. Smatti, MSc[6,9], Mohammad R. Hasan, PhD[8], Zaina Al-Kanaani, PhD[5], Einas Al-Kuwari, MD[5], Andrew Jeremijenko, MD[5], Anvar Hassan Kaleeckal, MSc[5], Ali Nizar Latif, MD[5], Riyazuddin Mohammad Shaik, MSc[5], Hanan F. Abdul-Rahim, PhD[10], Gheyath K. Nasrallah, PhD[6,9], Mohamed Ghaith Al-Kuwari, MD[11], Adeel A. Butt, MBBS MS[3,5,12], Hamad Eid Al-Romaihi, MD[13], Mohamed H. Al-Thani, MD[13], Abdullatif Al-Khal, MD[5], Roberto Bertollini, MD MPH[13], 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

medRxiv preprint doi: https://doi.org/10.1101/2022.07.06.22277306; this version posted July 7, 2022.

ORIGINAL ARTICLE

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

Outline

- New biological products
- COVID-19 Vaccine Safety Review
- Real World Efficacy of COVID-19 Vaccines
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- Natural Immunity
- Freedom At Risk
- Censorship of Scientific Discourse
- Conclusions

September 17, 2021

America's Uniqueness Starts and Ends with the US Constitution

by **Paul Engel** | Sep 17, 2021

Decades of ignorance and apathy by the American people have reduced the supreme law of the land to an anachronism, a throwback to a time when rights, freedom, and liberty were important to them. Today, Americans seem more interested in being taken care of than...

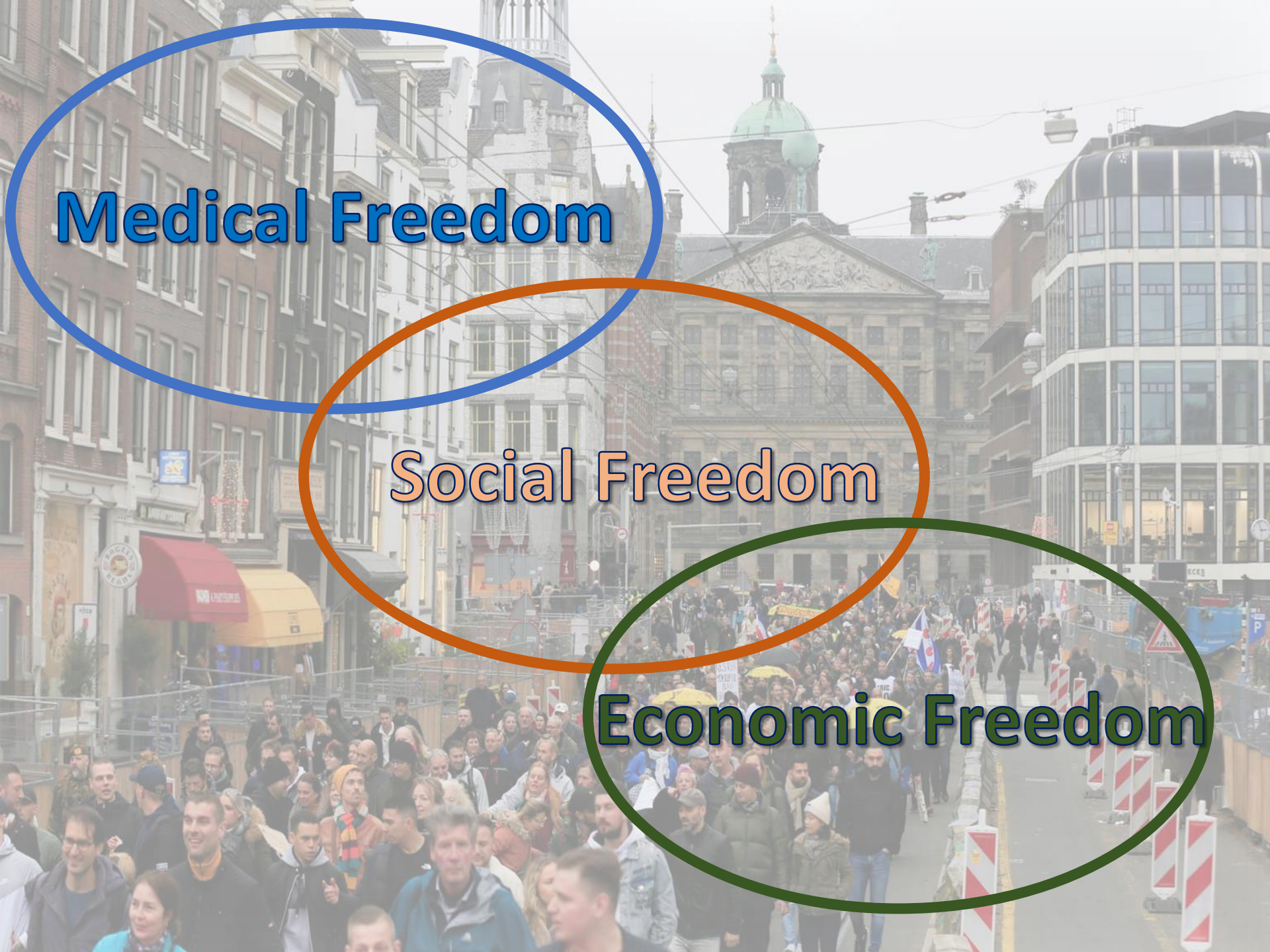
COVID and Your Health

COVID Investigation: CDC Profits Off of the Chaos They

Your Freedom Can be Won Back at the End of a Hypodermic Needle

by **Dr. Peter McCullough** | Jun 12, 2021 | Healthcare, Politics

This sounds like a science fiction movie, but it is happening in real life before our very eyes. The line of truth appears to be the vaccine, who will succumb and take it, and who will not. The first wave of either intentional or accidental bioterrorism was with the COVID-19 respiratory illness. The second wave is more insidious and broadly applied to a population prepared by months of fear and isolation...


Medical Freedom
Social Freedom
Economic Freedom

September 17, 2021

What to Expect if the Tyranny in Australia Hits Home

by Cathi Chamberlain | Sep 17, 2021

If you aren't stockpiling food and supplies right now, you may be in for a very uncomfortable future. Just ask Australians. Like a thief in the night, their western freedoms, once the envy of the world, have been stripped away. Tens of thousands of Aussies are...

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

Public and Private Outrage Over Ineffective, Unsafe, Forced Vaccination

by Dr. Peter McCullough | Sep 3, 2021 | Healthcare, Politics

When more than 25% of the population takes the ill-advised COVID-19 vaccine, this promotes a super-dominant mutant that can easily evade the vaccines' weak protection, which has happened with Delta. India has shown the world the only way to deal with Delta is not more vaccination, but early multidrug treatment...

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
- Freedom At Risk
- Censorship of Scientific Discourse
- Conclusions

Podcast

A Second Opinion on US COVID-19 Pandemic Response

by **Dr. Peter McCullough** | Feb 7, 2022 | Healthcare, Politics,

AMERICAS

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

Outline

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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
- The prehospital phase is the therapeutic opportunity for acute COVID-19
- Early ambulatory therapy with a sequenced, multi-drug regimen is supported by available sources of evidence and has a positive benefit-to-risk profile
  - Reduce the risk of hospitalization and death
  - More safely temporize to close the crisis with herd immunity
- 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