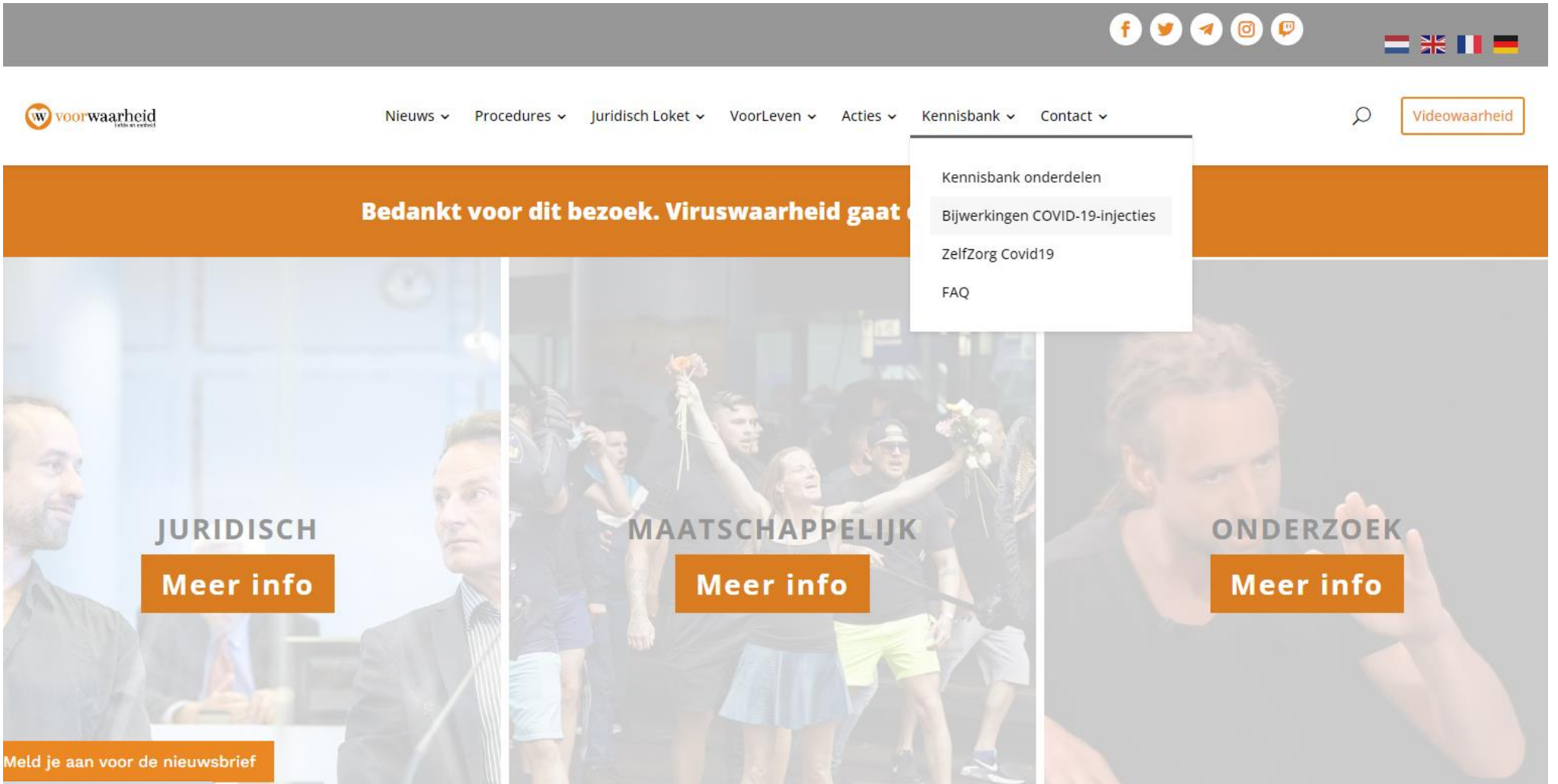
Update on the C19 injections


voorwaarheid
Nieuws
Procedures
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VoorLeven
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Kennisbank
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Videowaarheid
Kennisbank onderdelen
Bijwerkingen COVID-19-injecties
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FAQ
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Meld je aan voor de nieuwsbrief

Willem in gesprek met Jan Koning

19-07-2023

Jan Koning is zijn heel leven bezig geweest met andere mensen helpen.

Eerst als verpleegkundige en na zijn tijd in Kenya ook als verloskundige. Tijdens de C19 crisis werd hij al snel bewust van de fouten in het beleid.

Nu slaat hij de noodklok aangaande miskramen en complicaties bij zwangerschappen.

Excuses voor het slechte geluid.

NEWS FEATURE | 18 July 2023

Medicine is plagued by untrustworthy clinical trials. How many studies are faked or flawed?

Investigations suggest that, in some fields, at least one-quarter of clinical trials might be problematic or even entirely made up, warn some researchers. They urge stronger scrutiny.

Richard Van Noorden

https://www.nature.com/articles/d41586-023-02299-w

Key Takeaways

Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)

- **Definitive Diagnosis** (must meet all five criteria):

  1. COVID vaccine 4 to 42 days prior to symptom onset[#]
  2. Any venous or arterial thrombosis (often cerebral or abdominal)
  3. Thrombocytopenia (platelet count < 150 x 10^9/L)[*]
  4. Positive PF4 "HIT" (heparin-induced thrombocytopenia) ELISA
  5. Markedly elevated D-dimer (> 4 times upper limit of normal)

- **Incidence is extremely low**. Risk of death and serious outcomes of COVID-19, including thrombosis, far outweigh risk of VITT possibly associated with highly efficacious vaccines.
- **Urgent medical evaluation for VITT** is indicated if any of the following develop 4 to 42 days after vaccination:
  - Severe headache
  - Visual changes
  - Abdominal pain
  - Nausea and vomiting
  - Back pain
  - Shortness of breath
  - Leg pain or swelling
  - Petechiae, easy bruising, or bleeding

https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

Case Rep Hematol. 2022; 2022: 6013321.
Published online 2022 Jun 25. doi: 10.1155/2022/6013321
PMCID: PMC9252767
PMID: 35795543

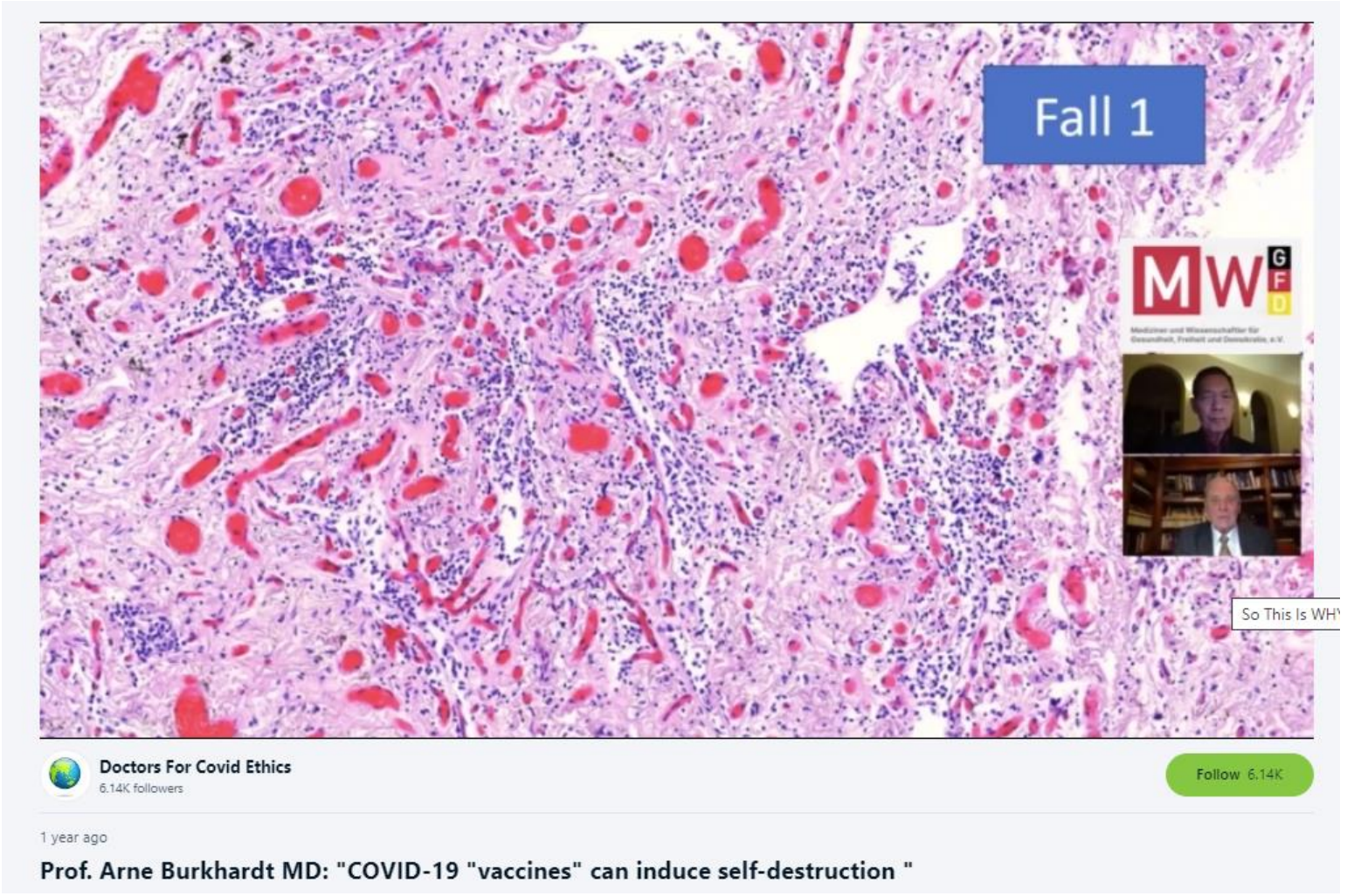
Immune Thrombocytopenia following COVID-19 Vaccine

Sonal Prasad, [1] Roopam Jariwal, [2] Moujidin Adebayo, [2] Sara Jaka, [2] Greti Petersen, [2] and Everardo Cobos [2]

> adverse reactions have been reported including rare instances of thrombocytopenia and thrombosis. More specifically, there have been reported cases of both vaccine-induced immune thrombocytopenia (VIT) and vaccine-induced immune thrombotic thrombocytopenia (VITT). VITT presents within 4–30 days of vaccination with symptoms of thrombocytopenia and thrombosis including cerebral venous sinus thrombosis, splanchnic thrombosis [1], pulmonary embolism, and deep vein thrombosis. Significant laboratory findings in VITT include low fibrinogen, elevated d-dimer, and low platelets [3]. VIT has been noted to present with thrombocytopenia within 1–23 days with symptoms of bleeding, bruising, and petechiae [1]. Laboratory findings in VIT are only remarkable for severely low platelet count.

There is confounding evidence whether VIT and VITT occur via the same mechanism or if they are the same reaction with a spectrum of manifestations. A review of the literature shows that VITT has been the predominantly reported thrombocytopenia in adenoviral vector-based vaccines such as AstraZeneca [1, 3, 4] and Johnson & Johnson [1], whereas VIT has mostly been reported in mRNA-based vaccines such as Pfizer and Moderna [4]. However, more research is needed to establish a correlation between the occurrence of VIT and VITT with the type of COVID-19 vaccine being administered.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9252767/



https://rumble.com/vr8zfm-prof.-arne-burkhardt-md-covid-19-vaccines-can-induce-self-destruction-.html

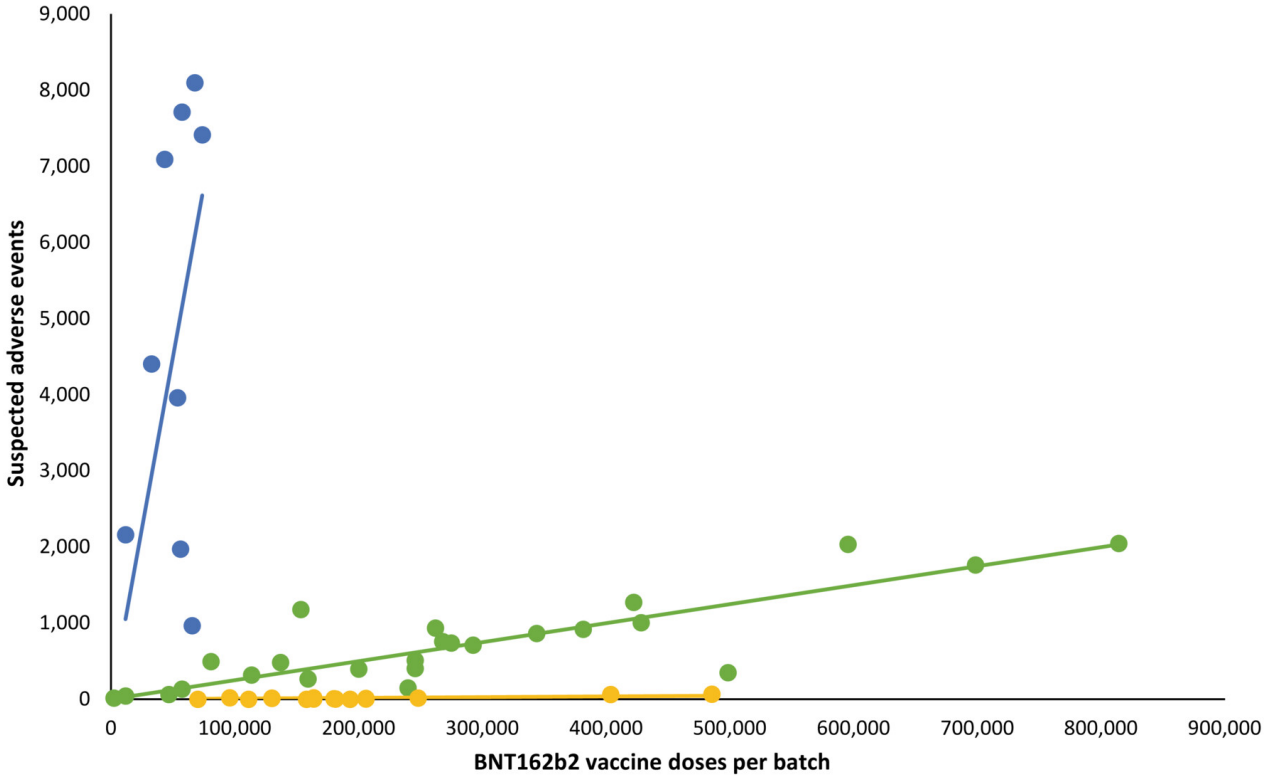
RESEARCH LETTER | Open Access

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

Max Schmeling, Vibeke Manniche, Peter Riis Hansen

First published: 30 March 2023 | https://doi.org/10.1111/eci.13998 | Citations: 1

[Correction added on 13 April 2023, after first online publication: The corresponding author's affiliation was updated in this version]



https://onlinelibrary.wiley.com/doi/10.1111/eci.13998

Doctors for COVID Ethics

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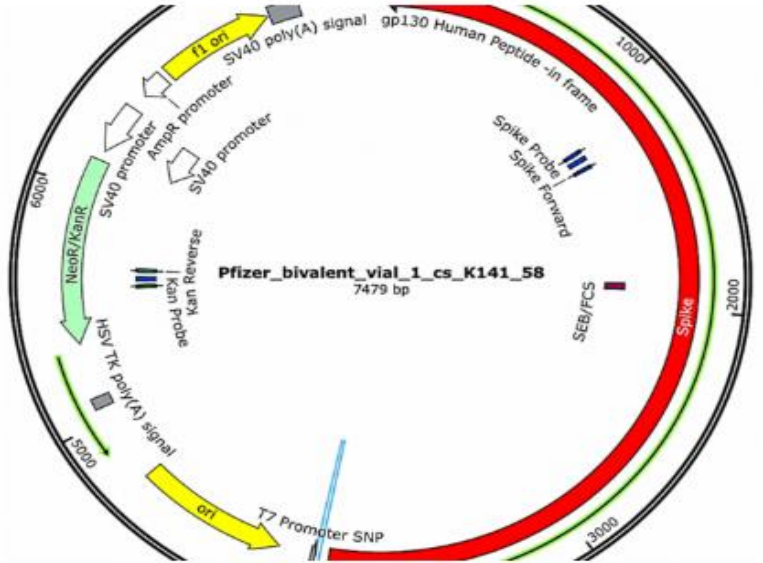

April 5, 2023

COVID-19 mRNA vaccines contain excessive quantities of bacterial DNA: evidence and implications

In Depth

https://doctors4covidethics.org/covid-19-mrna-vaccines-contain-excessive-quantities-of-bacterial-dna-evidence-and-implications/

Dr. Denis Rancourt: COVID Injections Have Killed 13 Million People Worldwide

By Rhoda Wilson

Theme: Law and Justice, Science and Medicine

Global Research, July 06, 2023
The Expose 26 June 2023

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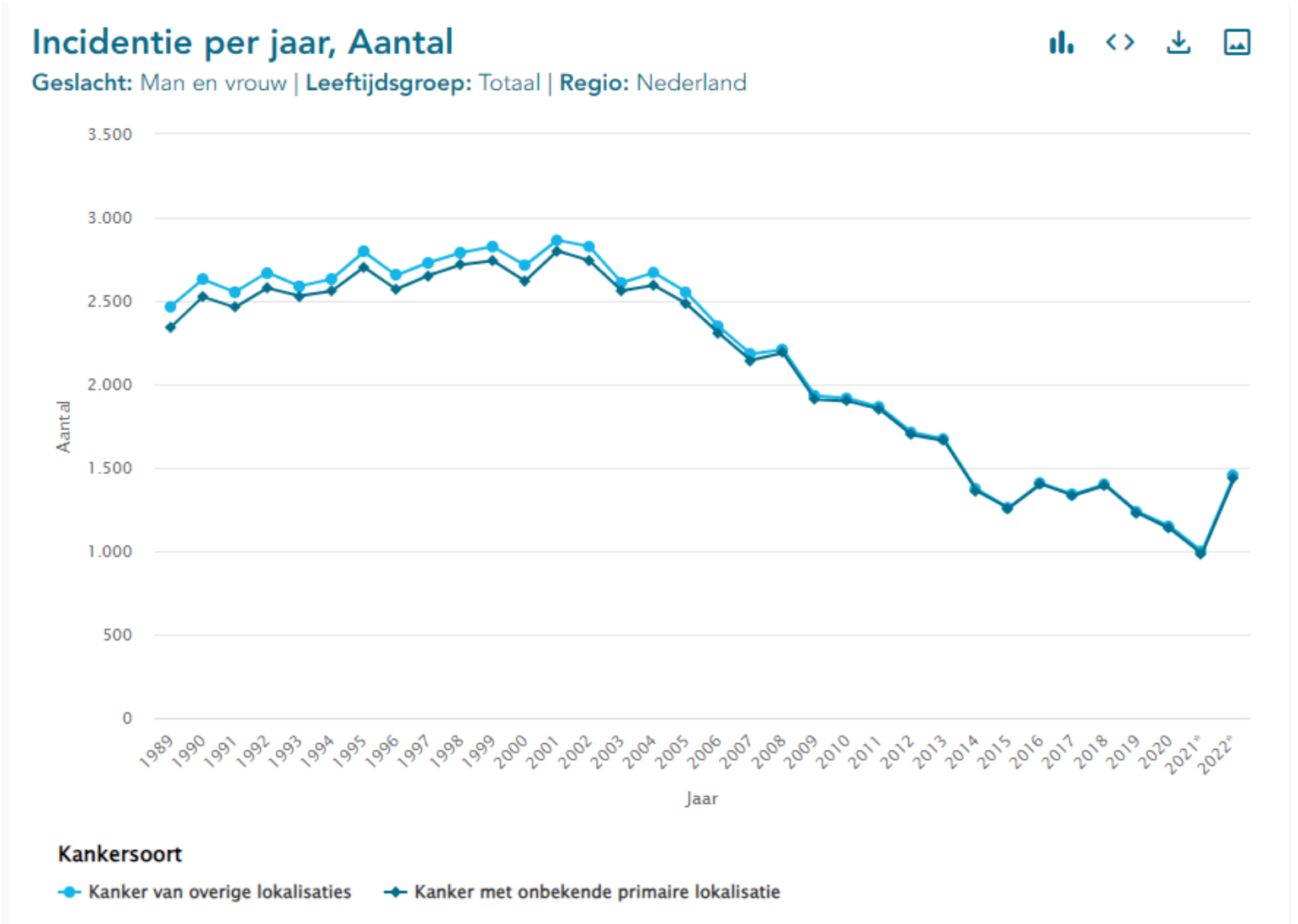
Dr. Denis Rancourt's research has shown that the vaccination campaign in India caused the deaths of 3.7 million fragile residents. And, "in Western countries, we quantified the average all-ages rate of death to be 1 death for every 2,000 injections, to increase exponentially with age … We estimated that the vaccines had killed 13 million worldwide," he said.

https://www.globalresearch.ca/dr-denis-rancourt-covid-injections-have-killed-13-million-people-worldwide/5824868



https://nkr-cijfers.iknl.nl/#/viewer/bb7f9e36-11ef-42c8-8754-

Adverse Effects

Original Investigation

ONLINE FIRST FREE

May 22, 2023

Safety of the BNT162b2 COVID-19 Vaccine in Children Aged 5 to 17 Years

Mao Hu, BS[1]; Hui Lee Wong, PhD, MSc[2]; Yuhui Feng, MS[1]; et al

» Author Affiliations | Article Information

JAMA Pediatr. Published online May 22, 2023. doi:10.1001/jamapediatrics.2023.1440

COVID-19 Resource Center

Key Points

Question Does active monitoring detect potentially elevated risk of health outcomes after BNT162b2 COVID-19 vaccination in the US pediatric population aged 5 to 17 years?

Findings In this cohort study of more than 3 million children (aged 5-17 years) who received BNT162b2 COVID-19 vaccination through mid-2022 using data from 3 US commercial claims databases, only myocarditis or pericarditis met the statistical threshold for a signal after BNT162b2 COVID-19 vaccination via near–real-time monitoring.

https://jamanetwork.com/journals/jamapediatrics/fullarticle/2805184

Article | Open Access | Published: 27 March 2023

Risk of death following COVID-19 vaccination or positive SARS-CoV-2 test in young people in England

Vahé Nafilyan, Charlotte R. Bermingham, Isobel L. Ward, Jasper Morgan, Francesco Zaccardi, Kamlesh Khunti, Julie Stanborough, Amitava Banerjee & James C. Doidge

Whilst COVID-19 vaccination has been linked to an increased risk of myocarditis and other cardiac events in young people, we found no evidence of substantially increased mortality risk, either due to cardiac events or overall, from mRNA vaccines, which suggest that cases of myocarditis or myopericarditis due to mRNA COVID-19 vaccines are unlikely to be fatal. We do, however, find evidence of an increased risk of cardiac death after a first dose of a non mRNA vaccine among females. It should also be noted that non mRNA vaccines are no longer used in the UK vaccination programme[28]. This provides reassurance that mRNA vaccines pose minimal risk of increased mortality in the first twelve weeks post-vaccination in young individuals. However, it is important to continue to monitor mortality after vaccination as more deaths are being registered, and extend the surveillance to other age groups and deaths from other causes.

https://www.nature.com/articles/s41467-023-36494-0

Serious harms of the COVID-19 vaccines: a systematic review

Peter C Gøtzsche, Maryanne Demasi

doi: https://doi.org/10.1101/2022.12.06.22283145

Discussion Serious and severe harms of the COVID-19 vaccines have been ignored or downplayed, and sometimes been deliberately excluded by the study sponsors in high impact medical journals. This area needs further study. Authorities have recommended virtually everyone get vaccinated and receive booster doses. They fail to consider that the balance between benefits and harms becomes negative in low-risk groups such as children and people who have already acquired natural immunity.

https://www.medrxiv.org/content/10.1101/2022.12.06.22283145v1

ISSN: 2475-6296

Review Article

Journal of Clinical & Experimental Immunology

COVID-19 vaccines – An Australian Review

Conny Turni[1] and Astrid Lefringhausen[2]

[1]*Queensland Alliance for Agriculture and Food Innovation, the University of Queensland, St Lucia, Queensland 4067, Australia.*

[2]*Albany Creek, Queensland 4035*

Corresponding author
Conny Turni, Queensland Alliance for Agriculture and Food Innovation, the University of Queensland, St Lucia, Queensland 4067, Australia.

Submitted: 10 Sep 2022; **Accepted:** 12 Sep 2022; **Published:** 21 Sep 2022

Citation: *Conny Turni and Astrid Lefringhausen (2022) COVID-19 vaccines – An Australian Review. Journal of Clinical & Experimental Immunology. 7(3):491-508.*

Abstract

After millions of people have been vaccinated as often as four times within a year, the effects of these vaccinations are slowly becoming apparent. This review has been written from an Australian perspective with the main focus on the COVID-19 mRNA vaccines. We will look at the promises/predictions originally made and the actual facts. We will evaluate the safety and efficacy by looking at the literature and the data from government agencies. The literature review will be summed up in a table listing the so far reported side effects of which many are very serious including death, with this data coming from 1011 case reports. Long term side effects will also be covered and the risk benefit ratio will be explored. The review is ending with some very critical question that need further discussion.

https://www.opastpublishers.com/open-access-articles/covid19-vaccinesan-australian-review.pdf

Myocarditis

Clinical outcomes of myocarditis after SARS-CoV-2 mRNA vaccination in four Nordic countries: population based cohort study

Anders Husby ,[1] Hanne Løvdal Gulseth,[2] Petteri Hovi,[3,4] Jørgen Vinsløv Hansen,[1] Nicklas Pihlström,[5] Nina Gunnes,[2] Tommi Härkänen ,[6] Jesper Dahl,[7] Øystein Karlstad,[8] Tiina Heliö,[9] Lars Køber,[10] Rickard Ljung ,[11,12] Anders Hviid [1]

More myocarditis than covid19

Table 1 | Characteristics of 7292 individuals with new onset myocarditis (myocarditis associated with SARS-CoV-2 mRNA vaccination, myocarditis associated with covid-19 disease, and conventional myocarditis), in Denmark, Finland, Norway, and Sweden, 2018-22 (Nordic myocarditis cohort)

	Type of myocarditis		
Characteristics	Vaccination	Covid-19	Conventional
Total No of patients	530 (100.0)	109 (100.0)	6653 (100.0)
No of patients by country:			
Denmark	98 (18.5)	8 (7.3)	695 (10.4)
Finland	140 (26.4)	25 (22.9)	2059 (30.9)
Norway	109 (20.6)	18 (16.5)	1161 (17.5)
Sweden	183 (34.5)	58 (53.2)	2738 (41.2)
Time period:			
2018-19	0	0	3820 (57.4)
2020-22	530 (100.0)	109 (100)	2833 (42.6)

https://bmjmedicine.bmj.com/content/2/1/e000373

COVID REPORTS

Ventricular Arrhythmia and COVID-19 Vaccine-associated Myocarditis

Sheth, Saloni P. MD; Gandhi, Rupali MD, JD

Author Information

The Pediatric Infectious Disease Journal ():10.1097/INF.0000000000003833, January 19, 2023. | **DOI:** 10.1097/INF.0000000000003833

FREE PAP

Metrics

Abstract

A 17-year-old male presented with COVID-19 vaccine-associated myocarditis. Six months later, due to chest discomfort with exercise, the patient underwent an exercise stress test that revealed a 3-beat run of nonsustained ventricular tachycardia at 230 bpm at peak exercise. The long-term outcomes of COVID-19 vaccine-associated myocarditis are unclear. This patient had nonsustained ventricular tachycardia over 6 months after diagnosis.

https://journals.lww.com/pidj/fulltext/9900/ventricular_arrhythmia_and_covid_19.319.aspx

Catecholamines Are the Key Trigger of COVID-19 mRNA Vaccine-Induced Myocarditis: A Compelling Hypothesis Supported by Epidemiological, Anatomopathological, Molecular, and Physiological Findings

Flavio A Cadegiani [1] [2]

Affiliations + expand

PMID: 35971401 PMCID: PMC9372380 DOI: 10.7759/cureus.27883

Free PMC article

Abstract

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine-induced myocarditis is a rare but well-documented complication in young males. The increased incidence of sudden death among athletes following vaccination has been reported and requires further investigation. Whether the risk of myocarditis, a known major cause of sudden death in young male athletes, also increases after coronavirus disease 2019 (COVID-19) infection is unknown. The severity and implications of these critical adverse effects require a thorough analysis to elucidate their key triggering mechanisms. The present review aimed to evaluate whether there is a justification to hypothesize that catecholamines in a "hypercatecholaminergic" state are the key trigger of SARS-CoV-2 mRNA vaccine-induced myocarditis and related outcomes and whether similar risks are also present following COVID-19 infection. A thorough, structured scoping review of the literature was performed to build the hypothesis through three pillars: detection of myocarditis risk, potential alterations and

https://pubmed.ncbi.nlm.nih.gov/35971401/

Autopsies

Case Reports > Surg Neurol Int. 2022 Mar 31;13:117. doi: 10.25259/SNI_1144_2021. eCollection 2022.

Intracranial aneurysm rupture within three days after receiving mRNA anti-COVID-19 vaccination: Three case reports

Sotaro Oshida [1], Yosuke Akamatsu [2], Yoshiyasu Matsumoto [1], Taro Suzuki [1], Takuto Sasaki [1], Yuki Kondo [1], Shunrou Fujiwara [3], Hiroshi Kashimura [2], Yoshitaka Kubo [3], Kuniaki Ogasawara [3]

Affiliations + expand

PMID: 35509565 PMCID: PMC9062907 DOI: 10.25259/SNI_1144_2021

Free PMC article

Abstract

Background: Although neurological adverse events have been reported after receiving coronavirus disease 2019 (COVID-19) vaccines, associations between COVID-19 vaccination and aneurysmal subarachnoid hemorrhage (SAH) have rarely been discussed. We report here the incidence and details of three patients who presented with intracranial aneurysm rupture shortly after receiving messenger ribonucleic acid (mRNA) COVID-19 vaccines.

https://pubmed.ncbi.nlm.nih.gov/35509565/

ARCHIVES
of Pathology & Laboratory Medicine

Volume 146, Issue 8
August 2022

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Article Contents

FEBRUARY 14 2022

Autopsy Histopathologic Cardiac Findings in 2 Adolescents Following the Second COVID-19 Vaccine Dose

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

Arch Pathol Lab Med (2022) 146 (8): 925–929.
https://doi.org/10.5858/arpa.2021-0435-SA Article history

Context.—
Myocarditis in adolescents has been diagnosed clinically following the administration of the second dose of an mRNA vaccine for coronavirus disease 2019 (COVID-19).

Objective.—
To examine the autopsy microscopic cardiac findings in adolescent deaths that occurred shortly following administration of the second Pfizer-BioNTech COVID-19 dose to determine if the myocarditis described in these instances has the typical histopathology of myocarditis.

Design.—

https://pubmed.ncbi.nlm.nih.gov/35157759/

Original Paper | Open Access | Published: 27 November 2022

Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination

Constantin Schwab, Lisa Maria Domke, Laura Hartmann, Albrecht Stenzinger, Thomas Longerich & Peter Schirmacher

Clinical Research in Cardiology **112**, 431–440 (2023) | Cite this article

A Letter to the Editors to this article was published on 25 April 2023

Abstract

Cases of myocarditis, diagnosed clinically by laboratory tests and imaging have been described in the context of mRNA-based anti-SARS-CoV-2 vaccination. Autopsy-based description of detailed histological features of vaccine-induced myocarditis is lacking. We describe the autopsy findings and common characteristics of myocarditis in untreated persons who received anti-SARS-CoV-2 vaccination. Standardized autopsies were performed on 25 persons

https://link.springer.com/article/10.1007/s00392-022-02129-5

Review

A SYSTEMATIC REVIEW OF AUTOPSY FINDINGS IN DEATHS AFTER COVID-19 VACCINATION

Nicolas Hulscher, BS [1]*, Paul E. Alexander, PhD[2], Richard Amerling, MD[3], Heather Gessling, MD[3], Roger Hodkinson, MD[3], William Makis, MD[4], Harvey A. Risch, MD, PhD[5], Mark Trozzi, MD[3], Peter A. McCullough, MD, MPH[3 6]

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Preprints with The Lancet is part of SSRN´s First Look, a place where journals identify content of interest prior to publication. Authors have opted in at submission to The Lancet family of journals to post their preprints on Preprints with The Lancet. The usual SSRN checks and a Lancet-specific check for appropriateness and transparency have been applied. Preprints available here are not Lancet publications or necessarily under review with a Lancet journal. These preprints are early stage research papers that have not been peer-reviewed. The findings should not be used for clinical or public health decision making and should not be presented to a lay audience without highlighting that they are preliminary and have not been peer-reviewed. For more information on this collaboration, see the comments published in The Lancet about the trial period, and our decision to make this a permanent offering, or visit The Lancet´s FAQ page, and for any feedback please contact preprints@lancet.com.

A Systematic Review of Autopsy Findings in Deaths after COVID-19 Vaccination

Posted: 5 Jul 2023

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4496137

July 6, 2023

Preprint Open Access

A SYSTEMATIC REVIEW OF AUTOPSY FINDINGS IN DEATHS AFTER COVID-19 VACCINATION

Nicolas Hulscher, BS; Paul E. Alexander, PhD; Richard Amerling, MD; Heather Gessling, MD; Roger Hodkinson, MD; William Makis, MD; Harvey A. Risch, MD, PhD; Mark Trozzi, MD; Peter A. McCullough, MD, MPH

ABSTRACT

Background: The rapid development and widespread deployment of COVID-19 vaccines, combined with a high number of adverse event reports, have led to concerns over possible mechanisms of injury including systemic lipid nanoparticle (LNP) and mRNA distribution, spike protein-associated tissue damage, thrombogenicity, immune system dysfunction, and carcinogenicity. The aim of this systematic review is to investigate possible causal links between COVID-19 vaccine administration and death using autopsies and post-mortem analysis.

https://zenodo.org/record/8120771

Autopsy Proven Fatal COVID-19 Vaccine-Induced Myocarditis

Nicolas Hulscher * , Roger Hodkinson , William Makis , Aseem Malhotra , Peter McCullough

Version 1 : Received: 17 July 2023 / Approved: 18 July 2023 / Online: 18 July 2023 (09:34:51 CEST)

How to cite: Hulscher, N.; Hodkinson, R.; Makis, W.; Malhotra, A.; McCullough, P. Autopsy Proven Fatal COVID-19 Vaccine-Induced Myocarditis. *Preprints.org* **2023**, 2023071198. https://doi.org/10.20944/preprints202307.1198.v1 Copy

linked to COVID-19 vaccination by independent adjudication. **Conclusions:** The temporal relationship, internal and external consistency seen among cases in this review with known COVID-19 vaccine-induced myocarditis, its pathobiological mechanisms and related excess death, complemented with autopsy confirmation, independent adjudication, and application of the Bradford Hill criteria to the overall epidemiology of vaccine myocarditis, suggests there is a high likelihood of a causal link between COVID-19 vaccines and death from suspected myocarditis in cases where sudden, unexpected death has occurred in a vaccinated person. Urgent investigation is required for the purpose of risk stratification and mitigation in order to reduce the population occurrence of fatal COVID-19 vaccine-induced myocarditis.

https://www.preprints.org/manuscript/202307.1198/v1

Blindness

vaccines

MDPI

Review

COVID-19 Vaccine-Associated Optic Neuropathy: A Systematic Review of 45 Patients

Ayman G. Elnahry [1,2,*], Mutaz Y. Al-Nawaflh [2,3], Aisha A. Gamal Eldin [4], Omar Solyman [5,6], Ahmed B. Sallam [7], Paul H. Phillips [7] and Abdelrahman M. Elhusseiny [7]

COURAGEOUS DISCOURSE

check for updates

Citation: Elnahry, A.G.; Al-Nawaflh, M.Y.; Gamal Eldin, A.A.; Solyman, O.; Sallam, A.B.; Phillips, P.H.; Elhusseiny, A.M. COVID-19 Vaccine-Associated Optic Neuropathy: A Systematic Review of 45 Patients. *Vaccines* **2022**, *10*, 1758. https://doi.org/10.3390/vaccines10101758

Academic Editor: Rohan Bir Singh

Received: 25 September 2022
Accepted: 19 October 2022
Published: 20 October 2022

4. Discussion

In this systematic review of published cases of optic neuropathy following COVID-19 vaccination, we found that COVID-19 vaccination was associated with several forms of optic neuropathy, most commonly AION and optic neuritis. All subtypes of COVID-19 vaccines, including mRNA, viral vector, and inactivated viral vaccines were associated with optic neuropathy. However, protein subunit vaccines, such as the Novavax vaccine, were not reported as a cause of optic neuropathy in the current review. The temporal association between vaccine administration and the development of optic neuropathies in these cases makes a causal link plausible, with a mean time from vaccination to the development of ocular symptoms of 9.6 ± 8.7 days. Cases with a late onset of optic neuropathy, however, are less likely to be related to vaccination and could be coincidental. Vaccines and their adjuvants are meant to robustly activate the innate immune system, and adaptive immunity then follows. Overactivation of this response, however, may occur in some patients and lead to rare immune-mediated complications.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9609672/

Risk assessment of retinal vascular occlusion after COVID-19 vaccination

Jing-Xing Li [1 2 3], Yu-Hsun Wang [4], Henry Bair [5 6], Shu-Bai Hsu [7 8], Connie Chen [9 10], James Cheng-Chung Wei [11 12 13 14], Chun-Ju Lin [15 16 17]

Affiliations + expand

PMID: 37130882 PMCID: PMC10153772 DOI: 10.1038/s41541-023-00661-7

matching between the vaccinated and unvaccinated cohorts. Individuals with COVID-19 vaccination had a higher risk of all forms of retinal vascular occlusion in 2 years after vaccination, with an overall hazard ratio of 2.19 (95% confidence interval 2.00-2.39). The cumulative incidence of retinal vascular occlusion was significantly higher in the vaccinated cohort compared to the unvaccinated cohort, 2 years and 12 weeks after vaccination. The risk of retinal vascular occlusion significantly increased during the first 2 weeks after vaccination and persisted for 12 weeks. Additionally, individuals with first and second dose of BNT162b2 and mRNA-1273 had significantly increased risk of retinal vascular occlusion 2 years following vaccination, while no disparity was detected between brand and dose of vaccines. This large multicenter study strengthens the findings of previous cases. Retinal vascular occlusion may not be a coincidental finding after COVID-19 vaccination.

https://pubmed.ncbi.nlm.nih.gov/37130882/

Immune regulation

Res Sq preprint, version 2, posted 2021 June 16
doi: 10.21203/rs.3.rs-612103/v2

PPRID: PPR357777
EMSID: EMS127858

Pathogenic antibodies induced by spike proteins of COVID-19 and SARS-CoV viruses

Huiru Wang [1], Qiuchi Chen [2], Yue Hu [3], Xiancong Wu [2], Lin Dai [2], Yuekai Zhang [3], Fang Li [2], Jinfeng Lu [3], Yuxing Chen [2], and Xiaoling Liu [2]

Abstract

This study, using a virus-free mouse model, explores the pathogenic roles of certain antibodies specific to the spike proteins of highly pathogenic coronaviruses such as the COVID-19 and the SARS-CoV viruses. Our data showed that these pathogenic antibodies, through a mechanism of Antibody Dependent Auto-Attack (ADAA), target and bind to host vulnerable cells or tissues such as damaged lung epithelium cells, initiate a self-attack immune response, and lead to serious conditions including ARDS, cytokine release, and death. Moreover, the pathogenic antibodies also induced inflammation and hemorrhage of the kidneys, brain, and heart. Furthermore, the pathogenic antibodies can bind to unmatured fetal tissues and cause abortions, postpartum labors, still births, and neonatal deaths of pregnant mice. Novel clinical interventions, through disrupting the host-binding of these pathogenic antibodies, can be developed to fight the COVID-19 pandemic. In addition, the new concept of ADAA explored by this study may be applicable to other infectious diseases, such as the highly pathogenic influenza infections. It should be noted that the majority of anti-spike antibodies are non-pathogenic, as only 2 of 7 monoclonal antibodies tested showed significant pathogenic effects.

https://www.researchgate.net/publication/352467843_Pathogenic_antibodies_induced_by_spike_proteins_of_COVID-19_and_SARS-CoV_viruses

Class switch towards non-inflammatory IgG isotypes after repeated SARS-CoV-2 mRNA vaccination

Pascal Irrgang, Juliane Gerling, Katharina Kocher, Dennis Lapuente, Philipp Steininger, Monika Wytopil, Simon Schäfer, Katharina Habenicht, Jahn Zhong, George Ssebyatika, Thomas Krey, Valeria Falcone, Christine Schülein, Antonia Sophia Peter, Krystelle Nganou-Makamdop, Hartmut Hengel, Jürgen Held, Christian Bogdan, Klaus Überla, Kilian Schober, Thomas H. Winkler, Matthias Tenbusch

doi: https://doi.org/10.1101/2022.07.05.22277189

Now published in *Science Immunology* doi: 10.1126/sciimmunol.ade2798

infections. While IgG antibodies were affinity matured and of high neutralization capacity, the switch in constant domains caused changes in fragment crystallizable (Fc)-receptor mediated effector functions, including a decreased capacity to facilitate phagocytosis. IgG4 induction was neither induced by Th2 cells nor observed after homologous or heterologous SARS-CoV-2 vaccination with adenoviral vectors. In addition, IgG2- and IgG4-producing memory B cells were phenotypically indistinguishable from IgG1- or IgG3-producing cells. Since Fc-mediated effector functions are critical for antiviral immunity, the described class switch towards non-inflammatory IgG isotypes, which otherwise rarely occurs after vaccination or viral infection, may have consequences for the choice and timing of vaccination regimens using mRNA vaccines.

https://www.medrxiv.org/content/10.1101/2022.07.05.22277189v1

Class switch toward noninflammatory, spike-specific IgG4 antibodies after repeated SARS-CoV-2 mRNA vaccination

PASCAL IRRGANG, JULIANE GERLING, KATHARINA KOCHER, DENNIS LAPUENTE, PHILIPP STEININGER, KATHARINA HABENICHT, MONIKA WYTOPIL, STEPHANIE BEILEKE, SIMON SCHÄFER, [...], AND MATTHIAS TENBUSCH +13 authors Authors Info & Affiliations

SCIENCE IMMUNOLOGY • 22 Dec 2022 • Vol 8, Issue 79 • DOI: 10.1126/sciimmunol.ade2798

nizations. This class switch was associated with a reduced capacity of the spike-specific antibodies to mediate antibody-dependent cellular phagocytosis and complement deposition. Because Fc-mediated effector functions are critical for antiviral immunity, these findings may have consequences for the choice and timing of vaccination regimens using mRNA vaccines, including future booster immunizations against SARS-CoV-2.

https://www.science.org/doi/10.1126/sciimmunol.ade2798

IgG4 Antibodies Induced by Repeated Vaccination May Generate Immune Tolerance to the SARS-CoV-2 Spike Protein

by Vladimir N. Uversky [1,*], Elrashdy M. Redwan [2,3], William Makis [4] and Alberto Rubio-Casillas [5,6]

reported to induce higher-than-normal IgG4 synthesis. Overall, there are three critical factors determining the class switch to IgG4 antibodies: excessive antigen concentration, repeated vaccination, and the type of vaccine used. It has been suggested that an increase in IgG4 levels could have a protecting role by preventing immune over-activation, similar to that occurring during successful allergen-specific immunotherapy by inhibiting IgE-induced effects. However, emerging evidence suggests that the reported increase in IgG4 levels detected after repeated vaccination with the mRNA vaccines may not be a protective mechanism; rather, it constitutes an immune tolerance mechanism to the spike protein that could promote unopposed SARS-CoV2 infection and replication by suppressing natural antiviral responses. Increased IgG4 synthesis due to repeated mRNA vaccination with high antigen concentrations may also cause autoimmune diseases, and promote cancer growth and autoimmune myocarditis in susceptible individuals.

Keywords: IgG4 antibodies; mRNA vaccines; immuno-tolerance; auto-immunity; SARS-CoV-2; COVID-19

https://www.mdpi.com/2076-393X/11/5/991

> Sci Rep. 2023 Jan 14;13(1):763. doi: 10.1038/s41598-023-28101-5.

Hybrid and herd immunity 6 months after SARS-CoV-2 exposure among individuals from a community treatment program

Parawee Chevaisrakul [1], Putthapoom Lumjiaktase [2], Pongtorn Kietdumrongwong [3], Ittiporn Chuatrisorn [4], Pongsan Chatsangjaroen [2], Nittaya Phanuphak [5]

close contacts. The levels of immunity were not different between patients and close contacts. Anti-RBD IgG against SARS-CoV-2 increased in a dose-dependent manner with the number of vaccine doses. Interestingly, the T-cell response decreased soon after a booster dose of vaccine. Asymptomatic SARS-CoV-2 infection could not enhance immunity against SARS-CoV-2 among vaccinated close contacts. Full vaccination was crucial to provide hybrid immunity. However, when designing vaccine strategies, T-cell exhaustion after multiple vaccinations should be considered.

https://pubmed.ncbi.nlm.nih.gov/36641523/

Front Oncol. 2023; 13: 1158124.
Published online 2023 May 1. doi: 10.3389/fonc.2023.1158124
PMCID: PMC10183601
PMID: 37197431

B-cell lymphoblastic lymphoma following intravenous BNT162b2 mRNA booster in a BALB/c mouse: A case report

Sander Eens,[1,2,*] Manon Van Hecke,[3] Kasper Favere,[1,2,4,5] Thomas Tousseyn,[3] Pieter-Jan Guns,[1] Tania Roskams,[3] and Hein Heidbuchel[2,4]

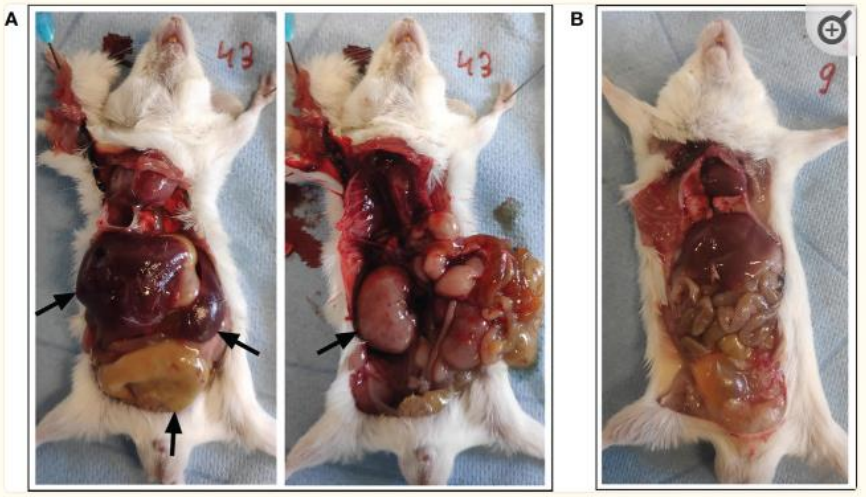

Figure 2

Necropsy examination of organs following spontaneous death. **(A)** A disproportional enlargement of several of the animal's major organs was observed at necropsy, including the liver, kidneys, spleen, and intestines (*black arrows*). **(B)** Animal with normal phenotype for reference.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10183601/

Fertility

JOURNAL ARTICLE

Marked variability in institutional deliveries and neonatal outcomes during the COVID-19 lockdown in Nigeria

Get access >

Beatrice N Ezenwa ✉, Iretiola B Fajolu, Simon Pius, Obumneme B Ezeanosike, Kenechukwu Iloh, Dominic Umoru, Olukemi Tongo, Isa Abdulkadir, Angela A Okolo, Helen M Nabwera ... Show more

Transactions of The Royal Society of Tropical Medicine and Hygiene, trad030,
https://doi.org/10.1093/trstmh/trad030
Published: 02 June 2023 **Article history** ▾

Conclusions

The COVID-19 lockdown had markedly deleterious effects on healthcare seeking for deliveries and neonatal care that varied between zones with no consistent pattern.

https://academic.oup.com/trstmh/advance-article-abstract/doi/10.1093/trstmh/trad030/7188764?redirectedFrom=fulltext&login=false

The SARS-CoV-2 spike protein binds and modulates estrogen receptors

OSCAR SOLIS, ANDREA R. BECCARI, DANIELA IACONIS, CARMINE TALARICO, CAMILO A. RUIZ-BEDOYA, JEROME C. NWACHUKWU, ANNAMARIA CIMINI, VANESSA CASTELLI, RICCARDO BERTINI, [...], AND MICHAEL MICHAELIDES +21 authors Authors Info & Affiliations

lung levels. Postmortem lung experiments from infected hamsters and humans confirmed an increase in cytoplasmic ERα and its colocalization with S in alveolar macrophages. These findings describe the discovery of a S-ERα interaction, imply a role for S as an NRC, and advance knowledge of SARS-CoV-2 biology and coronavirus disease 2019 pathology.

https://www.science.org/doi/10.1126/sciadv.add4150

COVID-19 Vaccines: The Impact on Pregnancy Outcomes and Menstrual Function

James A. Thorp, M.D.
Claire Rogers, M.S.P.A.S., P.A.-C
Michael P. Deskevich, Ph.D.
Stewart Tankersley, M.D.
Albert Benavides, B.S.
Megan D. Redshaw, J.D.
Peter A. McCullough, M.D., M.P.H.

The proportional reporting ratio comparing AEs reported after COVID-19 vaccines with those reported after influenza vaccines is significantly increased (≥ 2.0) for COVID-19 vaccine for menstrual abnormality, miscarriage, fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal cardiac arrest, fetal arrhythmias, fetal vascular malperfusion, fetal growth abnormalities, fetal abnormal surveillance, placental thrombosis, fetal death/stillbirth, low amniotic fluid, preeclampsia, premature delivery, preterm premature rupture of membrane, and premature baby death.

When normalized by time-available, doses-given, or number of persons vaccinated, all COVID-19 vaccine AEs far exceed the safety signal on all recognized thresholds.

These results necessitate a worldwide moratorium on the use of COVID-19 vaccines in pregnancy.

https://www.jpands.org/vol28no1/thorp.pdf

Post injection Therapy

> Molecules. 2022 Aug 24;27(17):5405. doi: 10.3390/molecules27175405.

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

Takashi Tanikawa [1], Yuka Kiba [2], James Yu [3], Kate Hsu [3], Shinder Chen [3], Ayako Ishii [4], Takami Yokogawa [2], Ryuichiro Suzuki [5], Yutaka Inoue [1], Masashi Kitamura [2]

Affiliations + expand

PMID: 36080170 PMCID: PMC9458005 DOI: 10.3390/molecules27175405

Free PMC article

spike protein (S protein), and cleavage of the S protein is essential for viral entry. Nattokinase is produced by *Bacillus subtilis* var. *natto* and is beneficial to human health. In this study, we examined the effect of nattokinase on the S protein of SARS-CoV-2. When cell lysates transfected with S protein were incubated with nattokinase, the S protein was degraded in a dose- and time-dependent manner. Immunofluorescence analysis showed that S protein on the cell surface was degraded when nattokinase was added to the culture medium. Thus, our findings suggest that nattokinase exhibits potential for the inhibition of SARS-CoV-2 infection via S protein degradation.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9458005/

Viruses. 2021 Mar; 13(3): 425.
Published online 2021 Mar 6. doi: 10.3390/v13030425
PMCID: PMC7999995
PMID: 33800932

The Combination of Bromelain and Acetylcysteine (BromAc) Synergistically Inactivates SARS-CoV-2

Javed Akhter,[1,2,†] Grégory Quéromès,[3,†] Krishna Pillai,[2,†] Vahan Kepenekian,[1,4,†] Samina Badar,[1,5] Ahmed H. Mekkawy,[1,2,5] Emilie Frobert,[3,6,‡] Sarah J. Valle,[1,2,5,‡] and David L. Morris[1,2,5,*‡]

Abstract

Severe acute respiratory syndrome coronavirus (SARS-CoV-2) infection is the cause of a worldwide pandemic, currently with limited therapeutic options. The spike glycoprotein and envelope protein of SARS-CoV-2, containing disulfide bridges for stabilization, represent an attractive target as they are essential for binding to the ACE2 receptor in host cells present in the nasal mucosa. Bromelain and Acetylcysteine (BromAc) has synergistic action against glycoproteins by breakage of glycosidic linkages and disulfide bonds. We sought to determine the effect of BromAc on the spike and envelope proteins and its potential to reduce infectivity in host cells. Recombinant spike and envelope SARS-CoV-2 proteins were disrupted by BromAc. Spike and envelope protein disulfide bonds were reduced by Acetylcysteine. In in vitro whole virus culture of both wild-type and spike mutants, SARS-CoV-2 demonstrated a concentration-dependent inactivation from BromAc treatment but not from single agents. Clinical testing through nasal administration in patients with early SARS-CoV-2 infection is imminent.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7999995/

ELSEVIER
Volume 90, January 2021, 107172

Short communication

Chicken Egg Yolk Antibodies (IgYs) block the binding of multiple SARS-CoV-2 spike protein variants to human ACE2

Shuangshi Wei [a 1], Shengbao Duan [a b 1], Xiaomei Liu [a], Hongmei Wang [a], Shaohua Ding [a], Yezhou Chen [a], Jinsong Xie [a], Jingjing Tian [a], Nong Yu [c], pingju Ge [d], xinglin Zhang [d], Xiaohong chen [d], Yong Li [a], Qinglin Meng [a]

effectively prevent and control this pandemic. This study evaluated the potential efficacy of Egg Yolk Antibodies (IgY) as a neutralizing agent against the SARS-CoV-2. We investigated the neutralizing effect of anti-spike-S1 IgYs on the SARS-CoV-2 pseudovirus, as well as its inhibitory effect on the binding of the coronavirus spike protein mutants to human ACE2. Our results show that the anti-Spike-S1 IgYs showed significant neutralizing potency against SARS-CoV-2 pseudovirus, various spike protein mutants, and even SARS-CoV *in vitro*. It might be a feasible tool for the prevention and control of ongoing COVID-19.

https://www.sciencedirect.com/science/article/pii/S156757692033639O

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Free Radical Biology and Medicine

Volume 206, September 2023, Pages 106-110

Toxicity of the spike protein of COVID-19 is a redox shift phenomenon: A novel therapeutic approach

Laurent Schwartz [a], Manuel Aparicio-Alonso [b], Marc Henry [c], Miroslav Radman [d], Romain Attal [e], Ashraf Bakkar [f]

Highlights

- COVID-19 protein toxicity is a redox shift phenomenon.
- Redox shift is due to Warburg effect and mitochondrial impairment.
- The cytokine storm is a consequence of mitochondrial dysfunction.
- Lipoic acid, Methylene Blue and Chlorine dioxide relieve COVID-19 spike protein toxicity.

https://pubmed.ncbi.nlm.nih.gov/37392949
/

Strategies for the Management of Spike Protein-Related Pathology

by Matthew T. J. Halma [1], Christof Plothe [2], Paul Marik [3] and Theresa A. Lawrie [1,*]

[1] EbMCsquared CIC, 11 Laura Place, Bath BA2 4BL, UK
[2] Center for Biophysical Osteopathy, Am Wegweiser 27, 55232 Alzey, Germany
[3] Front Line COVID-19 Critical Care Alliance (FLCCC), 2001 L St. NW Suite 500, Washington, DC 20036, USA
* Author to whom correspondence should be addressed.

Microorganisms **2023**, *11*(5), 1308; **https://doi.org/10.3390/microorganisms11051308**

Received: 16 March 2023 / Revised: 4 May 2023 / Accepted: 10 May 2023 / Published: 17 May 2023

(1) Establishing a healthy microbiome
(2) Inhibiting spike protein cleavage and binding (stopping ongoing damage)
(3) Clearing the spike protein from the body (clearing the damaging agents)
(4) Healing the damage caused by the spike protein (restoring homeostasis and boosting the immune system)

https://www.mdpi.com/2076-2607/11/5/1308

Removal of prescribing restrictions on ivermectin

Published: 3 May 2023

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From 1 June 2023, prescribing of oral ivermectin for 'off-label' uses will no longer be limited to specialists such as dermatologists, gastroenterologists and infectious diseases specialists.

In its final decision published today, the Therapeutic Goods Administration (TGA) has removed the restriction through its scheduling in the Poisons Standard because there is sufficient evidence that the safety risks to individuals and public health is low when prescribed by a general practitioner in the current health climate.

This considers the evidence and awareness of medical practitioners about the risks and benefits of ivermectin, and the low potential for any shortages of ivermectin for its approved uses. Also, given the high rates of vaccination and hybrid immunity against COVID-19 in Australia, use of ivermectin by some individuals is unlikely to now compromise public health.

However, the TGA does not endorse off-label prescribing of ivermectin for the treatment or prevention of COVID-19.

https://www.tga.gov.au/news/media-releases/removal-prescribing-restrictions-ivermectin

Longcovid

Ongoing symptoms and functional impairment 12 weeks after testing positive to SARS-CoV-2 or influenza in Australia: an observational cohort study

Matthew Brown, John Gerrard, Lynne McKinlay, John Marquess, Teneika Sparrow, Ross Andrews

doi: https://doi.org/10.1101/2023.04.16.23288205

Conclusions In a highly vaccinated population exposed to the SARS-CoV-2 omicron variant, long COVID may manifest as a post-viral syndrome of no greater severity than seasonal influenza but differing in terms of the volume of people affected and the potential impact on health systems. This study underscores the importance of long COVID research featuring an appropriate comparator group.

https://www.medrxiv.org/content/10.1101/2023.04.16.23288205v1

Rare link between coronavirus vaccines and Long Covid–like illness starts to gain acceptance

Studies probe unusual cases of neurologic complications, blood pressure swings, and other side effects

3 JUL 2023 • 4:30 PM • BY GRETCHEN VOGEL, JENNIFER COUZIN-FRANKEL

https://www.science.org/content/article/rare-link-between-coronavirus-vaccines-and-long-covid-illness-starts-gain-acceptance

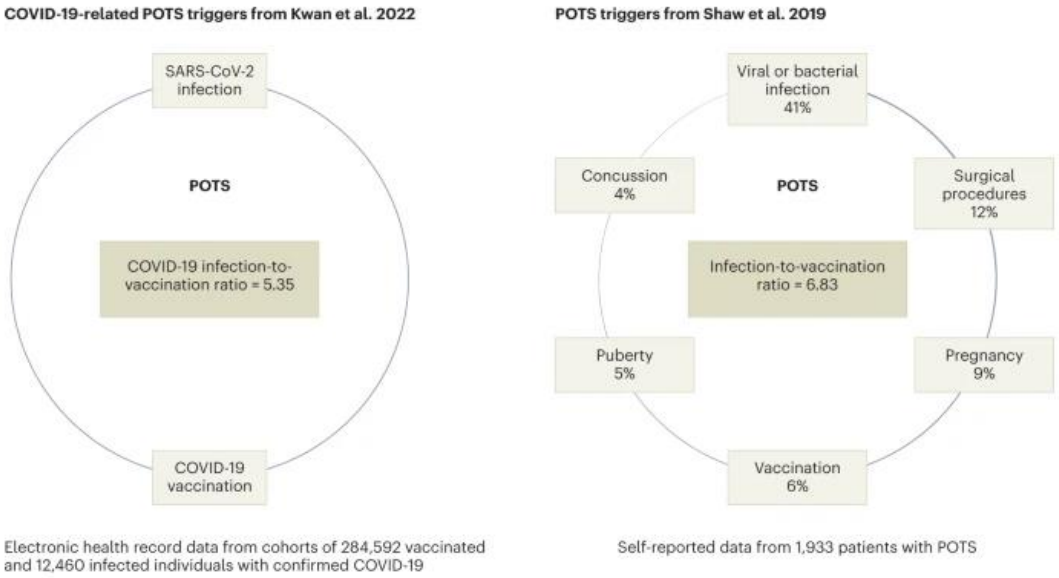
News & Views | Published: 12 December 2022

Cardiology

The risks of POTS after COVID-19 vaccination and SARS-CoV-2 infection: it's worth a shot

Svetlana Blitshteyn & Artur Fedorowski

Fig. 1: Known triggers of POTS and infection-to-vaccination ratios.



Data taken from Kwan et al.[12] and Shaw et al.[6].

https://www.nature.com/articles/s44161-022-00180-z

JAMA Network Open

Original Investigation | Infectious Diseases

Prevalence and Characteristics Associated With Post–COVID-19 Condition Among Nonhospitalized Adolescents and Young Adults

Joel Selvakumar, MD; Lise Beier Havdal, MD; Martin Drevvatne, MD; Elias Myrstad Brodwall, MD; Lise Lund Berven, PhD; Tonje Stiansen-Sonerud, MSc; Gunnar Einvik, MD, PhD; Truls Michael Leegaard, MD, PhD; Trygve Tjade, MD; Annika E. Michelsen, PhD; Tom Eirik Mollnes, MD, PhD; Fridtjof Lund-Johansen, MD, PhD; Trygve Holmøy, MD, PhD; Henrik Zetterberg, MD, PhD; Kaj Blennow, MD, PhD; Carolina X. Sandler, PhD; Erin Cvejic, PhD; Andrew R. Lloyd, MD, PhD; Vegard Bruun Bratholm Wyller, MD, PhD

Abstract (continued)

CONCLUSIONS AND RELEVANCE The persistent symptoms and disability that characterize PCC are associated with factors other than SARS-CoV-2 infection, including psychosocial factors. This finding raises questions about the utility of the World Health Organization case definition and has implications for the planning of health care services as well as for further research on PCC.

JAMA Network Open. 2023;6(3):e235763. doi:10.1001/jamanetworkopen.2023.5763

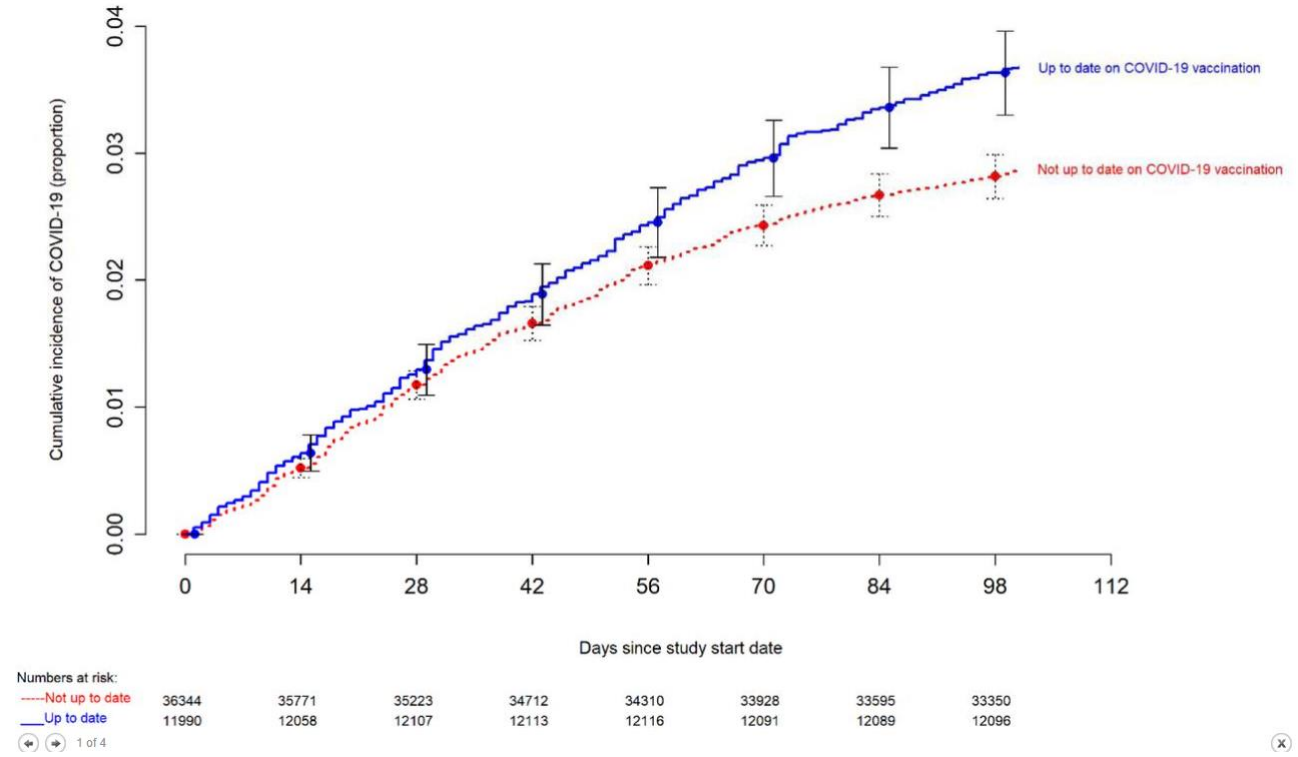
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2802893

Efficacy

Risk of Coronavirus Disease 2019 (COVID-19) among Those Up-to-Date and Not Up-to-Date on COVID-19 Vaccination

Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Steven M. Gordon

doi: https://doi.org/10.1101/2023.06.09.23290893



https://www.medrxiv.org/content/10.1101/2023.06.09.23290893v1

JOURNAL ARTICLE ACCEPTED MANUSCRIPT

Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine

Nabin K Shrestha, Patrick C Burke, Amy S Nowacki, James F Simon, Amanda Hagen, Steven M Gordon

Open Forum Infectious Diseases, ofad209, https://doi.org/10.1093/ofid/ofad209

Published: 19 April 2023 **Article history** ▾

Conclusions

The bivalent COVID-19 vaccine given to working-aged adults afforded modest protection overall against COVID-19 while the BA.4/5 lineages were the dominant circulating strains, afforded less protection when the BQ lineages were dominant, and effectiveness was not demonstrated when the XBB lineages were dominant.

https://academic.oup.com/ofid/advance-article/doi/10.1093/ofid/ofad209/7131292?login=false

Severity

ELSEVIER

Volume 216, Part 3, 1 January 2023, 114655

Age-stratified infection fatality rate of COVID-19 in the non-elderly population

Angelo Maria Pezzullo [a b], Cathrine Axfors [a], Despina G. Contopoulos-Ioannidis [a c], Alexandre Apostolatos [a d], John P.A. Ioannidis [a e]

Highlights

- Across 31 systematically identified national seroprevalence studies in the pre-vaccination era, the median infection fatality rate of COVID-19 was estimated to be 0.034% for people aged 0–59 years people and 0.095% for those aged 0–69 years.
- The median IFR was 0.0003% at 0–19 years, 0.002% at 20–29 years, 0.011% at 30–39 years, 0.035% at 40–49 years, 0.123% at 50–59 years, and 0.506% at 60–69 years.
- At a global level, pre-vaccination IFR may have been as low as 0.03% and 0.07% for 0–59 and 0–69 year old people, respectively.
- These IFR estimates in non-elderly populations are lower than previous calculations had suggested.

https://www.sciencedirect.com/science/article/pii/S001393512201982X?via%3Dihub

Regulation-fraud

FDA oversight of clinical trials is "grossly inadequate," say experts

BMJ 2022 ; 379 doi: https://doi.org/10.1136/bmj.o2628 (Published 16 November 2022)
Cite this as: *BMJ* 2022;379:o2628

Maryanne Demasi, investigative journalist

This lack of oversight was not an isolated case, *The BMJ* has learnt. Regulatory documents show that only nine out of 153 Pfizer trial sites[1] were subject to FDA inspection before licensing the mRNA vaccine. Similarly, only 10 out of 99 Moderna trial sites[2] and five of 73 remdesivir trial sites[3] were inspected.

Now, facing a backlog of site inspections, experts have criticised the FDA's oversight of clinical trials, describing it as "grossly inadequate." They say the problem, which predated covid-19, is not limited to a lack of inspections but also includes failing to notify the public or scientific journals when violations are identified—effectively keeping scientific misconduct from the medical establishment.

The FDA is "endangering public health" by not being candid about violations that are uncovered during clinical trial site inspections, says David Gortler, a pharmacist and pharmacologist who worked as an FDA medical reviewer between 2007 and 2011 and was then appointed as a senior adviser to the FDA commissioner in 2019-21.

https://www.bmj.com/content/379/bmj.o2628

Surg Neurol Int. 2022; 13: 475.
Published online 2022 Oct 21. doi: 10.25259/SNI_377_2022
PMCID: PMC9610448
PMID: 36324959

The pharmaceutical industry is dangerous to health. Further proof with COVID-19

Fabien Deruelle

Conclusion:

By supporting and selecting only the one side of science information while suppressing alternative viewpoints, and with obvious conflicts of interest revealed by this study, governments and the media constantly disinform the public. Consequently, the unscientifically validated vaccination laws, originating from industry-controlled medical science, led to the adoption of social measures for the supposed protection of the public but which became serious threats to the health and freedoms of the population.

Keywords: Behavior modification, Conflicts of interest, COVID-19, Scientific censorship, Side effects, Vaccination

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9610448/?utm_source=substack&utm_medium=email

Int J Risk Saf Med. 2023 Jan 23. doi: 10.3233/JRS-220043. Online ahead of print.

The coverage of medical injuries in company trial informed consent forms

David Healy [1], Augusto Germán Roux [2], Brianne Dressen [3]

Affiliations + expand

PMID: 36710689 DOI: 10.3233/JRS-220043

Abstract

Best practice consent forms in company clinical trials detail the financial coverage for medical treatment of injuries. In trials undertaken for licensing purposes these arrangements can raise concerns. We detail three cases in which elements of the consent forms appear misleading and designed to elicit a consent to participation that might not be forthcoming if volunteers for these clinical trials were aware that what is outlined in principle is not likely to happen in practice. Beyond clinical trial participants, these consent forms have wider implications. Medical coverage of injuries sustained in a clinical trial is a nexus where business, scientific and ethical considerations meet. It is not clear that anyone to date has grappled with the issues posed. This paper uses three clinical trials to illustrate the problems to be addressed.

https://pubmed.ncbi.nlm.nih.gov/36710689/

Preprint | PDF Available

FDA knew as of February 2021 that the mRNA vaccine crosses the placenta, passes into milk, and causes adverse events in breastfed infants

April 2023

Authors:

Helene Banoun
French Institute of Health and Medical R...

FDA Report: spontaneously collected adverse events for Pfizer BNT162b2 vaccine between December 11, 2020, and February 28, 2021 This is the report of adverse event reports from Pfizer's safety database until February 28, 2021: this database includes cases reported spontaneously by health authorities, in the medical literature, collected by Pfizer-funded programs, by non-interventional studies. This collection therefore concerns only a little more than two and a half months of vaccine administration (between December 11, 2020, the date of authorization, and February 28, 2021). This document therefore confirms that the vaccine (or its product spike) can cross the placental barrier. It was already known from 4 publications that the vaccine mRNA could pass into the milk during the first week after the injection. The adverse events reported here all concern this first week and therefore confirm these publications. The pathologies described for premature babies could be due to the toxic effect of the spike protein which could have passed from the mother to the fetus or even be produced directly by the fetus after transfection of the cells. In fact, it seems to be thrombosis and heart problems which are the effects most often described in people who have directly received the vaccine. Can we continue to recommend mRNA vaccines to pregnant and breastfeeding women?

https://www.researchgate.net/publication/370107164_FDA_knew_as_of_February_2021_that_the_mRNA_vaccine_crosses_the_placenta_passes_into_milk_and_causes_adverse_events_in_breastfed_infants

The UK government's attempt to frighten people into covid protective behaviours was at odds with its scientific advice

BMJ 2023 ; 380 doi: https://doi.org/10.1136/bmj.p652 (Published 21 March 2023)
Cite this as: *BMJ* 2023;380:p652

Stephen Reicher, professor [1], John Drury, professor of social psychology [2], Susan Michie, professor of health psychology and director [3], Robert West, professor [4]

When Hancock and Case advocated scare tactics they were going against the scientific advice they had been given. They were not, as some have suggested,[10] [11] in lockstep with their scientific advisors.

In March 2020, before vaccines and effective treatments were available, the behavioural science advisory group to the UK Government, SPI-B, was asked to report on "Options for increasing adherence to social distancing measures."[12] The group evaluated 10 possible options. One of these was persuasion. Here, SPI-B concluded that: "*the perceived level of personal threat needs to be increased among those who are complacent, using hard-hitting emotional messaging. To be effective this must also empower people by making clear the actions they can take to reduce the threat.*"

https://www.bmj.com/content/380/bmj.p652

COVID-19 vaccine boosters for young adults: a risk benefit assessment and ethical analysis of mandate policies at universities

Kevin Bardosh [1, 2], Allison Krug [3], Euzebiusz Jamrozik [4], Trudo Lemmens [5], Salmaan Keshavjee [6], Vinay Prasad [7], Marty A Makary [8], Stefan Baral [9], Tracy Beth Høeg [10, 11]

Correspondence to Dr Euzebiusz Jamrozik, University of Oxford Wellcome Centre for Ethics and Humanities, Oxford, OX3 7LF, UK; euzebiusz.jamrozik@ethox.ox.ac.uk

unethical because they: (1) are not based on an updated (Omicron era) stratified risk-benefit assessment for this age group; (2) may result in a net harm to healthy young adults; (3) are not proportionate: expected harms are not outweighed by public health benefits given modest and transient effectiveness of vaccines against transmission; (4) violate the reciprocity principle because serious vaccine-related harms are not reliably compensated due to gaps in vaccine injury schemes; and (5) may result in wider social harms. We consider counterarguments including efforts to increase safety on campus but find these are fraught with limitations and little scientific support. Finally, we discuss the policy relevance of our analysis for primary series COVID-19 vaccine mandates.

https://jme.bmj.com/content/early/2022/12/05/jme-2022-108449

PERSPECTIVE | VOLUME 31, ISSUE 1, P146-157, JANUARY 11, 2023 Download Full Issue

Rethinking next-generation vaccines for coronaviruses, influenzaviruses, and other respiratory viruses

David M. Morens • Jeffery K. Taubenberger • Anthony S. Fauci

DOI: https://doi.org/10.1016/j.chom.2022.11.016 • Check for updates

design more challenging, these factors by themselves cannot fully explain the lack of elicitation of long-term protective immunity against other respiratory mucosal viruses like the more phenotypically stable RSV.

Taking all of these factors into account, it is not surprising that none of the predominantly mucosal respiratory viruses have ever been effectively controlled by vaccines. This observation raises a question of fundamental importance: if natural mucosal respiratory virus infections do not elicit complete and long-term protective immunity against reinfection, how can we expect vaccines, especially systemically administered non-replicating vaccines, to do so? This is a major challenge for future vaccine development, and overcoming it is critical as we work to develop "next-generation" vaccines.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9832587/

mRNA: Vaccine or Gene Therapy? The Safety Regulatory Issues

by Helene Banoun

Independent Researcher, 13001 Marseille, France

Int. J. Mol. Sci. **2023**, *24*(13), 10514; **https://doi.org/10.3390/ijms241310514**

Received: 9 June 2023 / Revised: 19 June 2023 / Accepted: 21 June 2023 / Published: 22 June 2023

with this rapid approval. The mode of action of COVID-19 mRNA vaccines should classify them as gene therapy products (GTPs), but they have been excluded by regulatory agencies. Some of the tests they have undergone as vaccines have produced non-compliant results in terms of purity, quality and batch homogeneity. The wide and persistent biodistribution of mRNAs and their protein products, incompletely studied due to their classification as vaccines, raises safety issues. Post-marketing studies have shown that mRNA passes into breast milk and could have adverse effects on breast-fed babies. Long-term expression, integration into the genome, transmission to the germline, passage into sperm, embryo/fetal and perinatal toxicity, genotoxicity and tumorigenicity should be studied in light of the adverse events reported in pharmacovigilance databases. The potential horizontal transmission (i.e., shedding) should also have been assessed. In-depth vaccinovigilance should be carried out. We would expect these

https://www.mdpi.com/1422-0067/24/13/10514

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Vaccine

Available online 13 July 2023

In Press, Corrected Proof ⓘ What's this?

COVID-19 mRNA vaccines as hypothetical epigenetic players: Results from an *in silico* analysis, considerations and perspectives

Rossella Talotta

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https://doi.org/10.1016/j.vaccine.2023.07.007

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RT-PCR

Peer Review Process at Eurosurveillance

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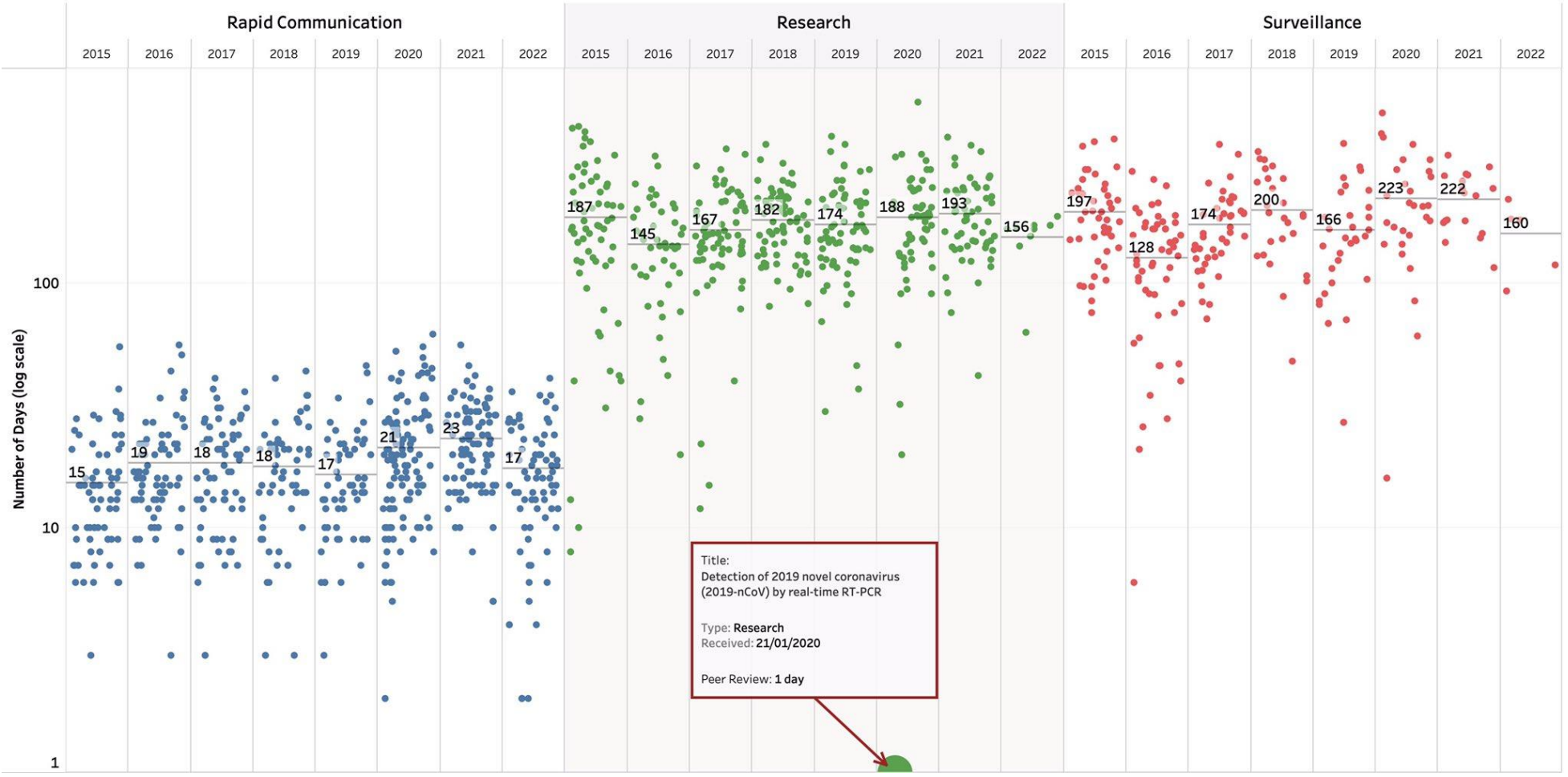

The epidemiological impact of digital and manual contact tracing on the SARS-CoV-2 epidemic in the Netherlands: empirical evidence

Wianne Ter Haar, Jizzo Bodriesz, Roderick P. Venekamp, Ewout Schuit, Susan van den Hof, Wolfgang Ebbers, Mirjam Kretzschmar, Jan Kluytmans, Carl Moons, Maarten Schim van der Loeff, Amy Matser, Janneke H. H. M. van de Wijgert

doi: https://doi.org/10.1101/2023.04.27.23289149

Conclusions Our data suggest that the impact of DCT and MCT on the SARS-CoV-2 epidemic in the Netherlands was limited. However, DCT impact might be enlarged if app use coverage is improved, contact-tracers are eliminated from the digital notification process to minimise delays, and DCT is combined with self-testing.

https://www.medrxiv.org/content/10.1101/2023.04.27.23289149v1

Low SARS-CoV-2 Cq values in healthcare workers with symptomatic COVID-19 infections, regardless of symptom severity, The Netherlands, January to August 2022

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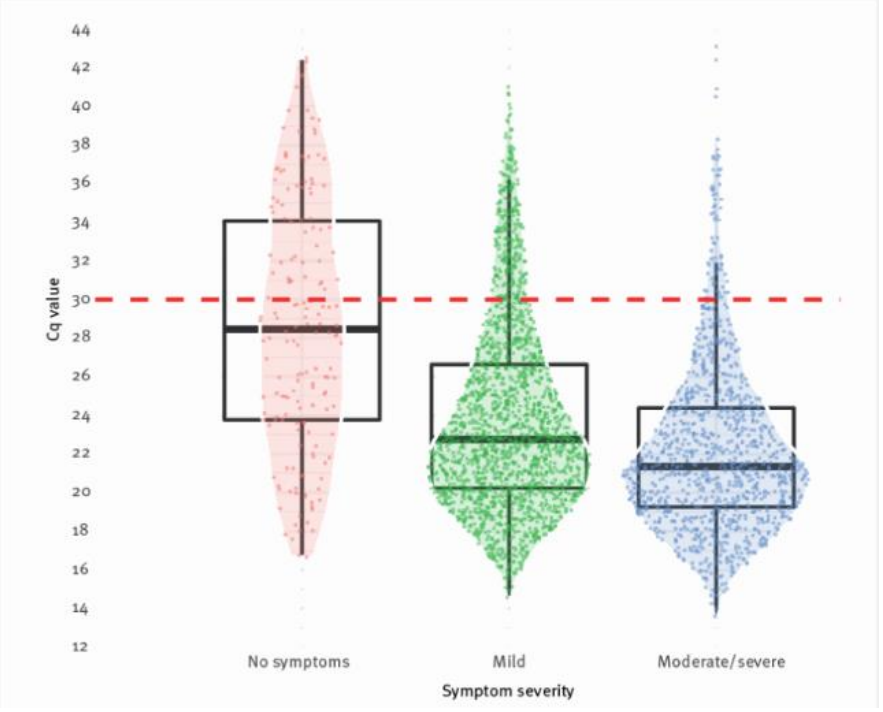
Carsten van Rossum[1], Corianne Meijer[1], Ingrid JM van Weerdenburg[1], Edmée C Bowles[1], Chantal P Rovers[2], Jaap ten Oever[2] Nannet DJ van der Geest[4], Matthew B McCall[1], Alma Tostmann[1]

Figure 1. Distribution of Cq values of SARS-CoV-2 PCR in healthcare workers without and with mild or moderate/severe symptoms, January–August 2022 (n = 2,990)



https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2023.28.4.2300007

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Major Shortcomings of the First Who-Recommended RT-QPCR to "Detect" SARS-CoV-2 and to "Diagnose".; COVID-19: NGS Provides Evidence that Successive Waves of SARS-CoV-2 Variants Lack Genomic Relationship

Ulrike Kämmerer, Sona Pekova, Rainer Johannes Klement, Rogier Louwen, Pieter Borger, Klaus Steger

Medical Microbiology & Infectious Diseases

https://pure.eur.nl/en/publications/major-shortcomings-of-the-first-who-recommended-rt-qpcr-to-detect

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4248632

face-masks

Overview of tight fit and infection prevention benefits of respirators (filtering face pieces, FFP)

Johannes K. Knobloch • Gefion Franke • Muriel J. Knobloch • Birte Knobling • Günter Kampf

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and coffee filter shaped respirators (30.9% of 3392 fit tests passed). Respirators with ear loops showed very poor tight fit (3.6% of 222 fit tests passed). In four randomized controlled trials, single use respirators were not shown to be superior to surgical masks for the prevention of laboratory-confirmed viral respiratory infections, even when adjusted with a fit test. Therefore, we consider the mandatory use of respirators to be disproportionate and not supported by evidence. Further evidence should be generated, in which scenarios respirators might provide an effective benefit as part of occupational health and safety. For situations with confirmed benefits only high quality disposable respirators with head straps or respiratory protective equipment of higher protective levels should be used.

https://www.journalofhospitalinfection.com/article/S0195-6701(23)00030-0/fulltext

Physical interventions to interrupt or reduce the spread of respiratory viruses

Tom Jefferson, Liz Dooley, Eliana Ferroni, Lubna A Al-Ansary, Mieke L van Driel, Ghada A Bawazeer, Mark A Jones, Tammy C Hoffmann, Justin Clark, Elaine M Beller, Paul P Glasziou, John M Conly Authors' declarations of interest

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https://doi.org/10.1002/14651858.CD006207.pub6

Medical/surgical masks compared to no masks

We included 12 trials (10 cluster-RCTs) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness (two trials with healthcare workers and 10 in the community). Wearing masks in the community probably makes little or no difference to the outcome of influenza-like illness (ILI)/COVID-19 like illness compared to not wearing masks (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; 9 trials, 276,917 participants; moderate-certainty evidence. Wearing masks in the community probably makes little or no difference to the outcome of laboratory-confirmed influenza/SARS-CoV-2 compared to not wearing masks (RR 1.01, 95% CI 0.72 to 1.42; 6 trials, 13,919 participants; moderate-certainty evidence). Harms were rarely measured and poorly reported (very low-certainty evidence).

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006207.pub6/full