14-3

Therefore, with all things considered, Ed Dowd concluded, "It's the vaccine."

The sharp increase in excess death rates among UK children following COVID-19 vaccination prompts questions as to why authorities aren't calling for immediate and thorough investigations. They told us COVID measures were about "health," so why aren't they investigating what's killing children? The only plausible explanation that makes sense is that **they don't want to know the answer**.

Ed Dowd's **full interview** with **Dr. Drew** is available to watch via the **video below**:

https://rumble.com/v3dbzgg-science-journal-links-pots-and-autoimmune-disorders-to-mrna-shots-aga-wilso.html

19-1

15-1

Cleveland Clinic Peer-Reviewed Study Found that the More Vaccines You've Had, the Higher Your COVID-19 Infection Risk

Jim Hoft June 3, 2023

A groundbreaking study conducted by the renowned Cleveland Clinic, ranked as the second-best hospital in the world, has found that a higher number of COVID-19 vaccine doses received increases the risk of infection with COVID-19.

The study was published at Open Forum Infectious Diseases (OFID), wherein the studies are fully peer-reviewed.

The research, conducted with a large sample size within the healthcare system, capitalized on the early recognition of the need to maintain an effective workforce during the pandemic.

Participants in the trial were all Cleveland Clinic Health System employees working at any Cleveland Clinic facility in Ohio on September 12, 2022, the first day the bivalent vaccine was made accessible to staff.

The study, which has undergone peer review and has been published, stated, **"The risk of COVID-19 also varied by the number of COVID-19 vaccine doses previously received. The higher the number of vaccines previously received, the higher the risk of contracting COVID-19."** *(See figure below)*

Furthermore, the study found that the bivalent vaccines demonstrated an overall effectiveness of about 29% in protecting against infection with SARS-CoV-2 when the Omicron BA.4/5 lineages were the predominant circulating strains. Only 29%. However, this effectiveness decreased when the circulating strains were no longer represented in the vaccine. In the case of the XBB lineages, the study could not establish a significant protective effect.

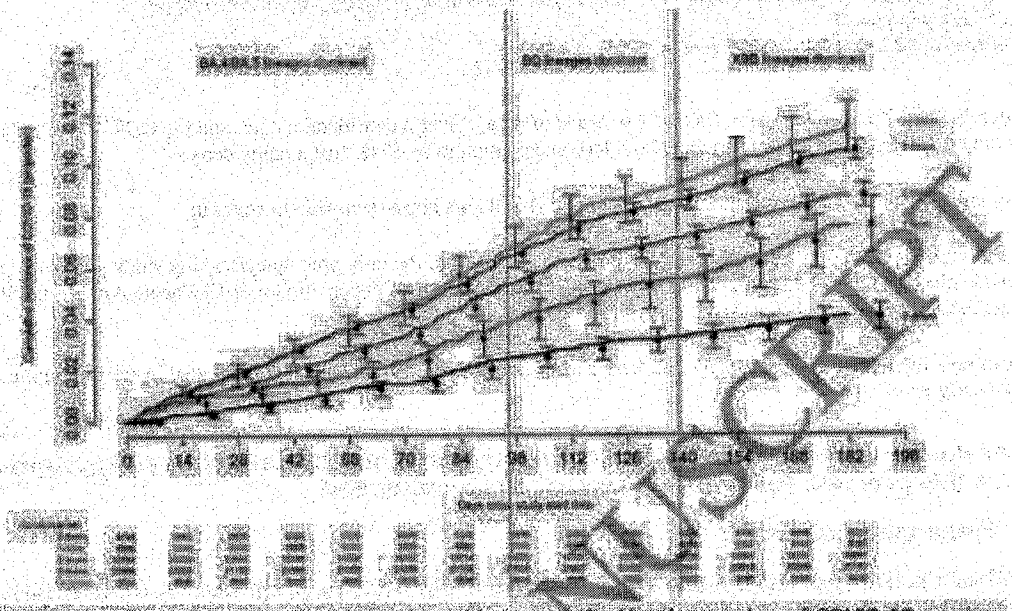


Figure 2. Cumulative Incidence of COVID-19 for subjects stratified by the number of COVID-19 vaccine doses previously received. Day zero was 12 September 2022, the day the bivalent vaccine began to be offered to employees. Point estimates and 95% confidence intervals are jittered along the x-axis to improve visibility.

15-2

"The multivariable analysis also found that the more recent the last prior COVID-19 episode was, the lower the risk of COVID-19, and the greater the number of vaccine doses previously received, the higher the risk of COVID-19," the study added.

More from the study:

The association of increased risk of COVID-19 with more prior vaccine doses was unexpected. A simplistic explanation might be that those who received more doses were more likely to be individuals at higher risk of COVID-19. A small proportion of individuals may have fit this description. However, the majority of participants in this study were young, and all were eligible to have received ≥3 doses of vaccine by the study start date, which they had every opportunity to do.

Therefore, those who received <3 doses (46% of individuals in the study) were not ineligible to receive the vaccine but rather chose not to follow the CDC's recommendations on remaining updated with COVID-19 vaccination, and one could reasonably expect these individuals to have been more likely to exhibit risk-taking behavior. Despite this, their risk of acquiring COVID-19 was lower than that that of participants those who received more prior vaccine doses.

Ours is not the only study to find a possible association with more prior vaccine doses and higher risk of COVID-19. During an Omicron wave in Iceland, individuals who had previously received ≥2 doses were found to have a higher odds of reinfection than those who had received <2 doses, in an unadjusted analysis.

A large study found, in an adjusted analysis, that those who had an Omicron variant infection after previously receiving 3 doses of vaccine had a higher risk of reinfection than those who had an Omicron variant infection after previously receiving 2 doses.

Another study found, in multivariable analysis, that receipt of 2 or 3 doses of am mRNA vaccine following prior COVID-19 was associated with a higher risk of reinfection than receipt of a single dose.

Immune imprinting from prior exposure to different antigens in a prior vaccine and class switch toward noninflammatory spike-specific immunoglobulin G4 antibodies after repeated SARS-CoV-2 mRNA vaccination have been suggested as possible mechanisms whereby prior vaccine may provide less protection than expected.
Natural News reported that another study from China stated that getting vaccinated for COVID-19 four or more results in a near-complete collapse of the immune system.

The study, conducted in a mouse model, claims that after receiving the fourth injection (including the two primary jabs and two subsequent boosters), the immune system's efficacy appears to be significantly diminished.

According to a summary of the study:

Multiple vaccine boosters after the conventional vaccination course significantly decreased RBD-specific antibody titers and serum neutralizing efficacy against the Delta and Omicron variants, and profoundly impaired CD4+ and CD8+T cell activation and increased PD-1 and LAG-3 expressions in these T cells.

Mechanistically, we confirmed that extended vaccination with RBD boosters overturned the protective immune memories by promoting adaptive immune tolerance. Our findings demonstrate potential risks with the continuous use of SARS-CoV-2 vaccine boosters, providing immediate implications for the global COVID-19 vaccination enhancement strategies.

16-1

Hohmann: Death by Injection – Top insurance researcher provides data showing staggering numbers

Jim Hoft June 3, 2023
Guest post by Leo Hohmann

Using data from the United Kingdom, a top insurance industry analyst estimates 600,000 Americans per year are dying from the Covid shots

The United States has become one of the worst countries in the world when it comes to medical transparency. But one smart analyst has found an end-run around the U.S. system that places a dark shroud of secrecy over common statistics.

The U.K. has been more transparent with its data. And that's where some are going to get stats that allow them to calculate the number of excess deaths in the U.S. since the roll out of the controversial Covid jabs two and a half years ago.

Those who trusted the system and took the Covid vaccines have a 26 percent higher mortality rate on average compared to those who declined the jab – and the death toll is even more staggering for vaccinated people under 50 years old, where mortality is 49 percent higher than for those unvaccinated.

These numbers are based on government data from the U.K. and were brought to Wisconsin Senator Ron Johnson's attention by Josh Stirling, one of the nation's top insurance analysts and formerly Senior Research Analyst for U.S. nonlife insurance at Sanford C. Bernstein & Co. Listen to the clip below from his recent testimony, which of course received zero coverage in the corporate mainstream media.

'The One Chart That Tells the Entire Story': Analysis Shows 26% Worse Mortality Among the Vaccinated

https://twitter.com/VigilantFox/status/1644321203295748096

And "the people who are under the age of 50 who took the vaccine now have a 49% higher mortality rate," stated top insurance analyst Josh Stirling.

"And if you were to take... **pic.twitter.com/7O4kR8Z2Xa**

— The Vigilant Fox (@VigilantFox) **April 7, 2023**

Received: 29 April 2023 | Revised: 29 July 2023 | Accepted: 15 August 2023

DOI: 10.1002/prca.202300048

Proteomics Clinical Applications

RAPID COMMUNICATION

Detection of recombinant Spike protein in the blood of individuals vaccinated against SARS-CoV-2: Possible molecular mechanisms

Carlo Brogna[1] | Simone Cristoni[2] | Giuliano Marino[3] | Luigi Montano[4] | Valentina Viduto[5] | Mark Fabrowski[6] | Gennaro Lettieri[7] | Marina Piscopo[7]

[1]Department of Research, Craniomed Group Facility Srl, Bresso, Italy

[2]ISB–Ion Source & Biotechnologies Srl, Bresso, Italy

[3]Marsanconsulting Srl. Public Health Company, Napoli, Italy

[4]Andrology Unit and Service of LifeStyle Medicine in Uro-Andrology, Local Health Authority (ASL) Salerno, Salerno, Italy

[5]Long COVID-19 Foundation, Brookfield Court, Garforth, UK

[6]Department of Emergency Medicine, Royal Sussex County Hospital, University Hospitals Sussex, Brighton, UK

[7]Department of Biology, University of Naples Federico II, Napoli, Italy

Correspondence
Marina Piscopo, Department of Biology, University of Naples Federico II, 80126 Napoli, Italy.
Email: marina.piscopo@unina.it

Carlo Brogna, Department of Research, Craniomed group facility Srl, Bresso, 20091, Italy.
Email: dir.brogna@craniomed.it

Abstract

Purpose: The SARS-CoV-2 pandemic prompted the development and use of next-generation vaccines. Among these, mRNA-based vaccines consist of injectable solutions of mRNA encoding for a recombinant Spike, which is distinguishable from the wild-type protein due to specific amino acid variations introduced to maintain the protein in a prefused state. This work presents a proteomic approach to reveal the presence of recombinant Spike protein in vaccinated subjects regardless of antibody titer.

Experimental design: Mass spectrometry examination of biological samples was used to detect the presence of specific fragments of recombinant Spike protein in subjects who received mRNA-based vaccines.

Results: The specific PP-Spike fragment was found in 50% of the biological samples analyzed, and its presence was independent of the SARS-CoV-2 IgG antibody titer. The minimum and maximum time at which PP-Spike was detected after vaccination was 69 and 187 days, respectively.

Conclusions and clinical relevance: The presented method allows to evaluate the half-life of the Spike protein molecule "PP" and to consider the risks or benefits in continuing to administer additional booster doses of the SARS-CoV-2 mRNA vaccine. This approach is of valuable support to complement antibody level monitoring and represents the first proteomic detection of recombinant Spike in vaccinated subjects.

KEYWORDS
COVID-19, mass spectrometry, SARS-CoV-2, Spike protein, vaccine mRNA

Abbreviations: m1Ψ, methyl pseudouridine; HCoV, human coronaviruses; LNPs, lipid nanoparticles; mRNA, messenger ribonucleic acid; DBS, Dry Blood Spot; SARS-CoV-2, Severe acute respiratory syndrome coronavirus 2; ACE2, Angiotensin-converting enzyme 2; S, Spike protein; PP, Double proline amino acid; wt, Wild type; IgG, Immunoglobulin G.

Carlo Brogna and Simone Cristoni contributed equally to this study.

18-1

'Spikeopathy': COVID-19 Spike Protein Is Pathogenic, from Both Virus and Vaccine mRNA

Peter I. Parry, PhD et. al August 17, 2023

Abstract

The COVID-19 pandemic caused much illness, many deaths, and profound disruption to society. The production of 'safe and effective' vaccines was a key public health target. Sadly, unprecedented high rates of adverse events have overshadowed the benefits. This two-part narrative review presents evidence for the widespread harms of novel product COVID-19 mRNA and adenovector DNA vaccines and is novel in attempting to provide a thorough overview of harms arising from the new technology in vaccines that relied on human cells producing a foreign antigen that has evidence of pathogenicity. This first paper explores peer-reviewed data counter to the 'safe and effective' narrative attached to these new technologies. Spike protein pathogenicity, termed 'spikeopathy', whether from the SARS-CoV-2 virus or produced by vaccine gene codes, akin to a 'synthetic virus', is increasingly understood in terms of molecular biology and pathophysiology. Pharmacokinetic transfection through body tissues distant from the injection site by lipid-nanoparticles or viral-vector carriers means that 'spikeopathy' can affect many organs. The inflammatory properties of the nanoparticles used to ferry mRNA; N1-methylpseudouridine employed to prolong synthetic mRNA function; the widespread biodistribution of the mRNA and DNA codes and translated spike proteins, and autoimmunity via human production of foreign proteins, contribute to harmful effects. This paper reviews autoimmune, cardiovascular, neurological, potential oncological effects, and autopsy evidence for spikeopathy. With many gene-based therapeutic technologies planned, a re-evaluation is necessary and timely.

1. Introduction

In this narrative review, we examine the solid evidence for a counter-narrative to the 'safe and effective' message that has accompanied the novel product COVID-19 vaccines, which were developed at 'warp speed' with great hope to end the pandemic. This evidence has accumulated and dampened the original optimism. The implications for the recognition of vaccine-related diagnoses and the need for therapeutics are significant for all health practitioners and many research scientists to consider.

Key problem areas appear to be (1) the toxicity of the spike protein—both from the virus and also when produced by gene codes in the novel COVID-19 mRNA and adenovectorDNA vaccines [**1**,**2**], hence the novel term 'spikeopathy'; (2) inflammatory properties of certain lipid-nanoparticles used to ferry mRNA [**3**]; (3) N1-methylpseudouridine in the synthetic mRNA that causes long-lasting action [**4**]; (4) widespread biodistribution of the mRNA [**5**] and DNA [**6**,**7**] codes via the lipid-nanoparticle and the viral-vector carrier matrices, respectively and (5) the problem of human cells producing a foreign protein in our ribosomes that can engender autoimmunity [**8**,**9**].

The emergence of SARS-CoV-2 in late 2019, and the associated disease of COVID-19, declared by March 2020 as a global pandemic by the WHO, has caused much illness, and many deaths in the elderly and the at-risk, and seriously disrupted society. An umbrella literature review of publications between December 2019 and August 2021 revealed that the greatest risk of mortality due to COVID-19 was associated with cardiovascular disease, cerebrovascular disease, and chronic renal disease [**10**]. The production of safe and effective vaccines to halt the COVID-19 pandemic was one of the most important public health interventions. Many COVID-19 vaccines have been developed across the world. In non-Western nations, most vaccines have used traditional protein-based or inactivated virus technologies.

For full 54 page document: https://www.mdpi.com/2227-9059/11/8/2287

18-2

19-1

Conflicting Evidence Of mRNA Technology Raises Serious Concerns About Rush For Use In New Vaccine Development

SEP 01, 2023 Megan Redshaw

The U.S. government and pharmaceutical companies are investing a substantial amount to develop new mRNA vaccines for infectious diseases and cancer, fueling a lucrative mRNA platform valued at $136.2 billion.
A newly established White House program announced on Aug. 23 that it is granting a total of $25 million over three years to Emory University, Yale School of Medicine, and the University of Georgia to develop personalized therapeutic vaccines against cancers and emerging infections, similar to how COVID-19 mRNA vaccines target SARS-CoV-2. They aim to use mRNA—an essential element in COVID-19 vaccines developed to prevent SARS-CoV-2 infections—to program a unique class of immune cells called dendritic cells to initiate a desired immunological response.

Pharmaceutical companies such as Moderna, BioNTech, and CureVac are conducting clinical trials using mRNA-based vaccines with advanced melanoma, ovarian, colorectal, and pancreatic cancers. The National Institutes of Health is partnering with BioNTech to develop a personalized vaccine for pancreatic cancers. In addition to COVID-19 and cancer, other mRNA-based vaccines in development target influenza, genital herpes, respiratory viruses, and shingles.

Although mRNA platforms are appealing because they reduce costs and shorten the vaccine development timeline, **evidence and experience suggest the mRNA technology used for novel COVID-19 vaccines is associated with various harms and neither prevents COVID-19 nor its transmission.**

Evidence Challenging Vaccine 'Safe and Effective' Narrative

The unprecedented rates of adverse events following COVID-19 vaccination overshadow the benefits, according to researchers from Australia who say the SARS-CoV-2 spike protein, whether from the virus or created from genetic code in mRNA and adenovector DNA vaccines, is toxic and causes a wide array of diseases.

In their recently published paper published in Biomedicines titled, "'Spikeopathy': COVID-19 Spike Protein Is Pathogenic, from Both Virus and Vaccine mRNA," **the researchers explored peer-reviewed data countering the "safe and effective" narrative attached to new technologies used to develop mRNA and adenovector DNA vaccines at "warp speed" to end the pandemic.**

Spike protein pathogenicity, termed "spikeopathy," describes the ability of the spike protein to cause disease, and the researchers say it can affect many organ systems.

Researchers noted the following key problem areas:

Spike protein toxicity (spikeopathy) from both the virus and when produced by gene codes in people vaccinated with COVID-19 vaccines.

Inflammatory properties in specific lipid nanoparticles (LNPs) used to transport mRNA.

Long-lasting action caused by N1-methyl pseudouridine in the synthetic mRNA—also referred to as modRNA.
Widespread distribution of mRNA and DNA codes via the LNP and viral vector carrier matrices, respectively.
Human cells produce a foreign protein that can cause autoimmunity.

Now that vaccines utilizing mRNA technology have been available and widely distributed for several years, data show these vaccines produce foreign antigens in human tissues and increase the risk of autoimmune, neurological, cardiovascular, inflammatory disorders, and cancers, especially when the vaccine ingredients do not remain localized at the injection site. An antigen is any substance that stimulates an immune response. If the immune system encounters an antigen that is not found on the body's own cells, it will launch an attack against that antigen.

Pharmacokinetic and pharmacodynamic data show the design of the mRNA and adenovector DNA COVID-19 vaccines allow uncontrolled biodistribution, durability, and persistent bioavailability of the spike protein inside the body after vaccination. Pharmacokinetics is the study of how the body interacts with administered substances for the entire duration of exposure. Pharmacodynamics assesses the drug's effect on the body more closely.

12-3

19-2

This may explain the unprecedented number of adverse events that appear to be associated with the spike protein produced by the gene-based technologies employed by Pfizer, Moderna, AstraZeneca, and Johnson & Johnson, as well as the viral vector DNA technology used by other countries, researchers said.

mRNA Vaccines Are Gene Therapy and May Cause Harm

Gene-based COVID-19 vaccines are therapeutic products that actually fit within the FDA's definition of gene therapy because they cause the cells of the vaccinated person to produce antigens for transmembrane expression that invokes an immune response. By design, these novel vaccine platforms risk tissue damage secondary to autoimmune responses raised against cells expressing foreign spike antigens, researchers said.

The FDA was aware of the pathogenicity of spike proteins before releasing COVID-19 vaccines to the public. **In an October 2022 meeting with its vaccine advisors, the FDA presented a highly accurate list of potential adverse events associated with COVID-19 vaccines, including neurological, cardiovascular, and autoimmune "possible adverse events."**

React19, an organization that provides financial, emotional, and physical support to those experiencing long-term injuries from COVID-19 vaccines, provided a list of over 3,400 published papers and case reports of injuries affecting more than 20 organ systems. More than 432 peer-reviewed papers relate to papers and case reports of myocarditis, cardiomyopathy, myocardial infarction, hypertension, aortic dissection, postural orthostatic tachycardia syndrome (POTS), tachycardia, and conduction disturbance—a problem with the electrical system that controls the heart's rate and rhythm.

The most common group of adverse events reported following COVID-19 vaccination to both pharmacovigilance databases and Pfizer involve neurological disorders. According to the paper, neurological symptoms and cognitive decline with accelerated neurodegenerative disease are features of acute COVID-19 vaccine injuries and, to some extent, long COVID syndrome. Research suggests (pdf) LNPs transporting the mRNA to make spike proteins can cross the blood-brain barrier and cause neurotoxic effects.

Lipid Nanoparticles Are Toxic and Pro-Inflammatory

It's not just the spike protein that can cause disease. LNPs that serve as the delivery method are also toxic and pro-inflammatory.

Research from 2018 showed even small amounts of nanoparticles taken up by the lungs can lead to cytotoxic effects. Ingested nanoparticles have been shown to affect lymph nodes, the liver, and the spleen, while when injected as a drug carrier, they can pass any barrier and translocate to the brain, ovaries, and testes, mainly after phagocytosis by macrophages, which help distribute them across the body. The effects on the reproductive system suggest lipid nanoparticles can be cytotoxic and damage DNA.

According to the authors, two components in the mRNA lipid nanoparticle complexes, ALC-0315 and ALC-0159, are concerning, as they have never been used in a medicinal product and are not registered in either the European Pharmacopoeia or in the European C&L Inventory database. A question posed to the European Parliament in December 2021 pointed out that the manufacturer of the nanoparticles specifies the nanoparticles are for research only and not for human use. The European Commission responded that the excipient in Pfizer's Comirnaty vaccine "has been demonstrated to be appropriate ... in compliance with the relevant EMA scientific guidelines and standards."

Still, this could explain the root cause of numerous post-vaccination adverse events, researchers said.
*Read more **here...***

18-A

20-1

Science Mag: 'Rare Link Between Coronavirus Vaccines and Long Covid-Like Illness Starts to Gain Acceptance'

Chris Menahan | Information Liberation July 6th 2023

So-called "Long Covid" in "rare" cases may actually be "Long Vax," Science Magazine reports.
From **Science.org**:

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

COVID-19 vaccines have saved millions of lives, and the world is gearing up for a new round of boosters. **But like all vaccines, those targeting the coronavirus can cause side effects in some people, including rare cases of abnormal blood clotting and heart inflammation. Another apparent complication, a debilitating suite of symptoms that resembles Long Covid, has been more elusive, its link to vaccination unclear and its diagnostic features ill-defined. But in recent months, what some call Long Vax has gained wider acceptance among doctors and scientists, and some are now working to better understand and treat its symptoms.**

"You see one or two patients and you wonder if it's a coincidence," says Anne Louise Oaklander, a neurologist and researcher at Harvard Medical School. "But by the time you've seen 10, 20," she continues, trailing off. "Where there's smoke, there's fire."

Cases seem very rare—far less common than Long Covid after infection. **Symptoms can include persistent headaches, severe fatigue, and abnormal heart rate and blood pressure. They appear hours, days, or weeks after vaccination and are difficult to study. But researchers and clinicians are increasingly finding some alignment with known medical conditions. One is small fiber neuropathy, a condition Oaklander studies, in which nerve damage can cause tingling or electric shock–like sensations, burning pain, and blood circulation problems. The second is a more nebulous syndrome, with symptoms sometimes triggered by small fiber neuropathy, called postural orthostatic tachycardia syndrome (POTS). It can involve muscle weakness, swings in heart rate and blood pressure, fatigue, and brain fog.**

Patients with postvaccination symptoms may have features of one or both conditions, even if they don't meet the criteria for a diagnosis. Both are also common in patients with Long Covid, where they're often attributed to an immune overreaction.

Although more researchers are now taking Long Vax seriously, regulators in the United States and Europe say they have looked for, but have not found, a connection between COVID-19 vaccines and small fiber neuropathy or POTS. **"We can't rule out rare cases," says Peter Marks, director of the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research, which oversees vaccines. "If a provider has somebody in front of them, they may want to take seriously the concept [of] a vaccine side effect," he says. But Marks also worries about "the sensational headline" that could mislead the public, and he emphasizes that vaccine benefits far outweigh any risks.**

Despite the uncertainties, **German Minister of Health Karl Lauterbach acknowledged in March that though rare, Long Covid–like symptoms after vaccination are a real phenomenon. He said his ministry was working to organize funding for studies, although none has been announced so far.**
We can't study the side effects of these vaccines (or any others) lest anything negative we learn lead to bad headlines.

20-2

RFK Jr. debates both a doctor and the moderator of this NewsNation town hall on his stance on vaccine safety. Legacy media is going to have a tough time with this. **pic.twitter.com/0ff3ZeUeN6**

— Dire Report (@DireReport) **June 29, 2023**

Avoiding negative headlines to keep from panicking the plebs is what Science™ is all about.

Researchers led by cardiologists Alan Kwan and Susan Cheng at Cedars-Sinai Medical Center analyzed a health database of almost 285,000 people in the Los Angeles area; all had received at least one COVID-19 shot. **They found that within 90 days after a shot, the rate of POTS-related symptoms was about 33% higher than in the 3 months before; 2581 people were diagnosed with POTS-related symptoms after vaccination, compared with 1945 beforehand.** However, the study found a bigger effect from COVID-19 itself: The rate of POTS symptoms in about 12,000 unvaccinated people after infection was 52% higher than beforehand. **Although Kwan cautions against extrapolating these numbers to a wider population, he says the pattern is intriguing. "Our data show a relatively clear signal that there probably is an increase in POTS after vaccination and after infection," he says.**

Others find the study compelling. **"Even last year I was a little bit cautious" about the link between POTS and vaccination, says Tae Chung, a neuromuscular physiatrist who runs the POTS clinic at Johns Hopkins University. "I didn't have quantitative data to back it up, but now I feel like I do."** Still, Chung stresses that this paper and other data also suggest COVID-19 vaccines protect against POTS and other Long Covid symptoms, and he remains a strong advocate for vaccination.

AN IMMUNE OVERREACTION to SARS-CoV-2 spike protein, which COVID-19 vaccines use to induce protective antibodies, is one possible cause of these symptoms. One theory is that after vaccination some people generate another round of antibodies targeting the first. Those antibodies could function somewhat like spike itself: Spike targets a cell surface protein called the angiotensin-converting enzyme 2 (ACE2) receptor, enabling the virus to enter cells. The rogue antibodies might also bind to ACE2, which helps regulate blood pressure and heart rate, says Bernhard Schieffer, a cardiologist at the University of Marburg. If those antibodies disrupt ACE2 signaling, that could cause the racing heart rates and blood pressure swings seen in POTS.

[...] **Postvaccination illness is "a long, relentless disease,"** says Lawrence Purpura, an infectious disease specialist at Columbia University [...] who treats both Long Covid patients and those with chronic symptoms after vaccination.

A DIAGNOSIS OF POTS or small fiber neuropathy post-vaccination can guide treatment. In POTS, doctors focus on increasing salt and fluid intake to boost blood volume and maintain blood pressure. Beta blockers, which slow racing hearts, may also help.

Small fiber neuropathy is treated with various medications to manage symptoms, and for severe cases sometimes intravenous immunoglobulin (IVIG), an expensive and hard-to-access antibody mixture that can tamp down immune overreactions. Some case studies report that IVIG helped people with postvaccine small fiber neuropathy, at least temporarily.

A more radical approach is plasma exchange, which is sometimes used for autoimmune disorders. Here the patient's plasma—the liquid part of the blood containing antibodies and proteins—is separated from the blood cells and discarded. The blood cells are then returned to the patient along with a replacement liquid.

Plasma exchange helped a man who developed small fiber neuropathy following his second dose of a COVID-19 vaccine, Schelke and colleagues reported in October 2022 in Muscle & Nerve. "He responded

20-3

very well," with months of improvement, Schelke says, but recently returned with worsening symptoms.

Incidentally, the quadruple-vaxxed 30-year-old German bodybuilder Jo "Joesthetics" Lindner — who died suddenly from an aneurysm last week — told an interviewer a few weeks ago that he got plasma treatment twice after suffering from post-vax issues.

HOLY MOLY!!

Listen to this interview from Joesthetics just a couple of weeks ago.

He took 4 jabs and found heavy metals in his blood.
Then died of aneurysm today! **pic.twitter.com/qFLMVK5xAi**
— aussie17 (@_aussie17) **July 1, 2023**

Lindner also **suffered from rippling muscle disease** and was clearly taking all sorts of steroids, so who knows if it was actually linked (or what quality of treatment he received in Thailand).

Regardless, Long Vax is clearly a major issue but our authorities are ignoring it almost entirely to, in their own words, avoid negative headlines. Tens of millions of Americans took these shots due to fear of losing their jobs and being locked in their homes forever and those who experienced horrible side effects were told to shut their mouths and were censored on social media.

Despite including endless caveats and shilling the vax themselves, I'm sure Science Mag will get harassed for even publishing this.

20-1

222 ivermectin COVID-19 studies, 172 peer reviewed, 99 comparing treatment and control groups

September 2023 Liu, Lifschitz, Lespine, Saha, Redação MPV, Chamie, Ma

https://c19ivm.org/

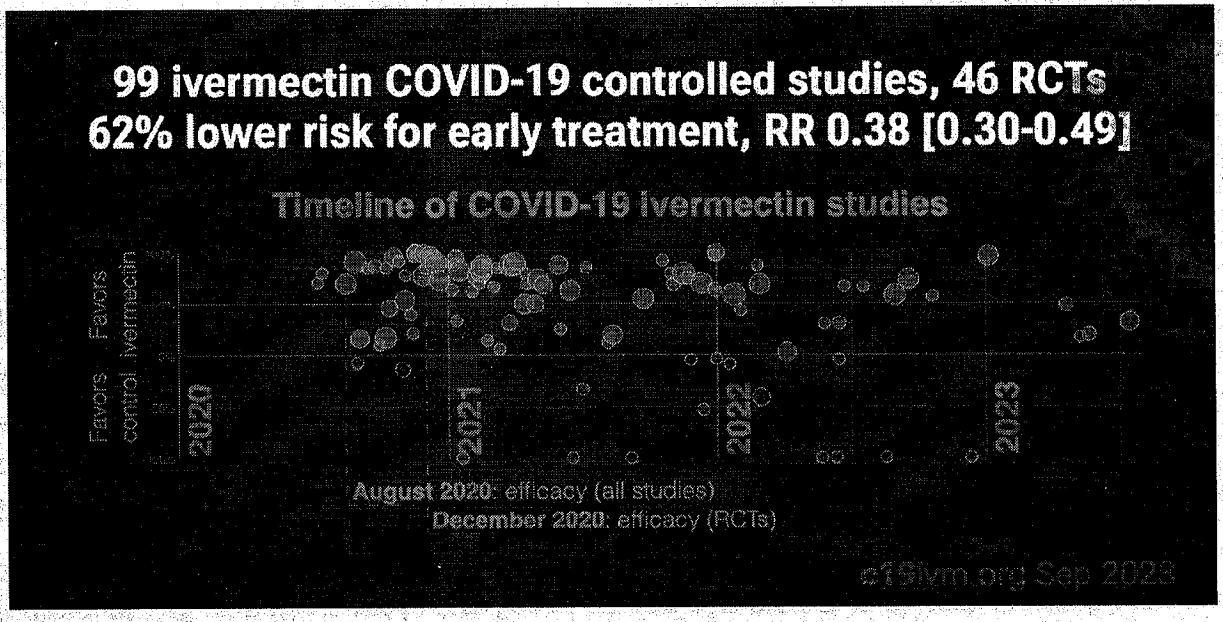
22-1

COVID-19 treatment studies for Ivermectin

FULL 80 plus page DOCUMENT: https://c19ivm.org/

Ivermectin for COVID-19
99 studies from **1,089** scientists
137,255 patients in **28** countries
Statistically significant lower risk
for **mortality, ventilation, ICU, hospitalization, recovery, c**
ases, and viral clearance.
85%, 62%, 41% lower risk for prophylaxis, early, and late
treatment CI 77-90%, 51-70%, 27-52%
55% lower risk in **46 RCTs** CI 40-66%
49% lower **mortality** from **51** studies CI 35-60%
COVID-19 IVERMECTIN STUDIES. SEP 2023. C19IVM.ORG

00.511.5+All studies62%With exclusions66%Mortality49%Hospitalization34%Recovery43%Cases81%Viral clearance42%RCTs55%Prophylaxis85%Early62%Late41%FavorsivermectinFavors control



221 ivermectin COVID-19 studies, 171 peer reviewed, 99 comparing treatment and control groups. Recent:
Lifschitz
Lespine
Saha
Redação MPV
Chamie

22-2

Ma
Abd-Elmawla. ACTIV-6 TOGETHER PRINCIPLE COVID-OUT. Ivermectin was adopted in all or part of 22 countries (39 including non-government medical organizations). Submit updates/corrections.

IvermectinAll

Aug 17	Redação MPV	Greg Tucker-Kellogg publishes fraudulent study to attack ivermectin

Discussion of errors in [medrxiv.org]. This paper is highly flawed. For example, authors claim that there were "499 reported deaths - a citywide post-hospi the study period", whi..

Aug 10	Covid Analysis	Ivermectin for COVID-19: real-time meta analysis of 99 studies (ivmmeta)

Statistically significant lower risk is seen for mortality, ventilation, ICU admission, hospitalization, recovery, cases, and viral clearance. All remain significan 54 independent teams in 24..

Aug 8	Chamie et al., Cureus, doi:10.7759/cureus.43168	COVID-19 Excess Deaths in Peru's 25 States in 2020: Nationwide Trends, Confounding Factors Ivermectin Treatment by State

Ecological analysis showing that ivermectin distribution correlated significantly ($p<0.002$) with the reduction in excess deaths across 25 states in Peru. Iver treatment in Peru in May 2020 and distributed..

Jul 16	Osati et al., medRxiv, doi:10.1101/2023.07.13.23292643	Clinical manifestations and mortality among hospitalized COVID-19 patients in Tanzania, 2021

32% lower mortality ($p=0.02$). Retrospective 1,387 hospitalized PCR confirmed COVID-19 patients in Tanzania, showing lower mortality with ivermectin tre multivariable analysis.

Jul 14	Vottero et al., Molecular Sciences, doi:10.3390/ijms241411449	Computational Prediction of the Interaction of Ivermectin with Fibrinogen

In Silico study showing that ivermectin may bind with high affinity to multiple sites on fibrinogen and may interfere with SARS-CoV-2 spike protein – fibrin formation of fibrin clots resistant to de..

Jul 8	Breitinger et al., Virology Journal, doi:10.1186/s12985-023-02095-y	Patch-clamp studies and cell viability assays suggest a distinct site for viroporin inhibitors on t

In Vitro analysis of inhibitors against the SARS-CoV-2 E ion channel. - The E protein of SARS-CoV-2 is a viroporin that forms ion channels important for viral and SARS-CoV-2 are highly similar. - ..

Jul 1	Abd-Elmawla et al., Journal of Zhejiang University-SCIENCE B, doi:10.1631/jzus.B2200385	Suppression of NLRP3 inflammasome by ivermectin ameliorates bleomycin-induced pulmonai

Animal study showing that ivermectin alleviated pulmonary inflammation and fibrosis induced by bleomycin in a rat model. Authors note this may add to patients with pulmonary fibrosis from COVID-19..

Jun 12	Choi et al., Journal of Korean Medical Science, doi:10.3346/jkms.2023.38.e195	Two Years of Experience and Methodology of Korean COVID-19 Living Clinical Practice Guideli

Review of the development of COVID-19 treatment guidelines in Korea. Authors claim "continuous evidence updates" and "living recommendations", how been updated si..

Jun	Wade et al., Value in Health,	Variation in Demographic Characteristics, Socioeconomic Status, Clinical Presentation and Sel

S1-5

22-3

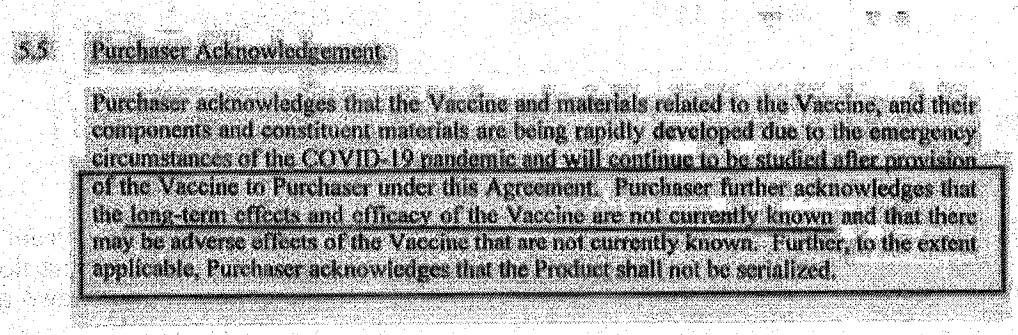
Leaked Pfizer Contract Admits There May Be Adverse Effects

And Efficacy Was Not Known

NE - NAKEDEMPEROR.SUBSTACK.COM SEP 7, 2023

At least three months after Pfizer signed contacts with the UK, US and the EU, Pfizer signed its Covid vaccine contract with the National Department of Health of South Africa. Dated 30 March 2021, this contract was signed a whole month after the Cumulative Analysis of Post-Authorization Event Reports. This report had identified a plethora of adverse events over the first few months of vaccine rollout.

The recently leaked South African document contains clauses similar to those seen in other disclosed Pfizer contracts.



5.5 Purchaser Acknowledgement.

Purchaser acknowledges that the Vaccine and materials related to the Vaccine, and their components and constituent materials are being rapidly developed due to the emergency circumstances of the COVID-19 pandemic and will continue to be studied after provision of the Vaccine to Purchaser under this Agreement. Purchaser further acknowledges that the long-term effects and efficacy of the Vaccine are not currently known and that there may be adverse effects of the Vaccine that are not currently known. Further, to the extent applicable, Purchaser acknowledges that the Product shall not be serialized.

Page 21 of 46

555
21

It is not a surprise that the long-term effects and efficacy of the vaccine were not known. This was one massive experiment called 'warp speed', of course they didn't know what would happen.

Furthermore, it is not a surprise that Pfizer wanted purchasers to acknowledge that there may be adverse effects of the Vaccine that are not currently known. mRNA did not have a good record with side effects and until the pandemic was only being used on the seriously ill.

What is shocking is that this information was hidden from the general public and instead replaced with the brainwashing mantra of 'Safe and Effective'.

Pfizer themselves had no idea if it was safe or effective but people lost their jobs, friends and families because they realised that this mantra was obviously a lie. How many more people would have chosen not to get vaccinated if this acknowledgment clause had been made public? And if fewer people had been vaccinated, they would not have been able to bring in vaccine mandates.

What is also concerning is that in the same paragraph Pfizer asks the purchaser to acknowledge that the vaccine would not be serialised.

Serialisation is the process where every individual vial of a vaccine gets a unique serial number. Think of it as a fingerprint for each vaccine. Why is it important? Three reasons: safety, traceability, and legal coverage.
Bad batches can be traced and like DNA at a crime scene, if someone claims that the vaccine caused an adverse event, then the serial number is a crucial piece of evidence.

22-4

1-1

Perhaps this was done for cost or speed reasons but it is also likely that this was done to reduce liability and make it difficult to provide direct evidence of bad batches or direct links with adverse events.

Many of the released Pfizer contracts to date have redacted this information and you can see why.

23-1

New Study finds all Covid Variants have been made in a BioLab

RHODA WILSON AUGUST 31, 2023

In the USA, covid hospitalisations are up because of variant EG.5.1 and there's a scary new variant dubbed BA.X from Denmark and Israel, we're told. Because of the BA.X variant "scientists" are demanding rules from lockdown be reimposed on Britain.

Mark Steyn pointed out a recent Japanese study showing that all previous SARS-CoV-2 variants were not naturally occurring and were made in a laboratory. Based on this we can make the presumption that the new EG.5.1 and BA.X variants have been as well, irrespective of which country is claiming the variant as its own.

For their study, Atsuki Tanaka and Takayuki Miyazawa, of Osaka Medical University and Kyoto University, wanted to trace the historical evolution of the omicron variant of SARS-CoV2 by studying viral sequences found "in the wild" and deposited in public databases.

In doing this they found around **100 separate omicron subvariants that could not conceivably have arisen through natural processes**. The existence of these variants seems to provide definitive proof of large-scale lab creation and release of covid viruses.

Moreover, the variants appear to form comprehensive panels of mutations typical of those used in "reverse genetics" experiments to systematically test the properties of different parts of viruses, Substacker PSMI wrote.

Who's Making the Variants?

By Mark Steyn

On the one hand, mask mandates are back. On the other hand, the *Associated Press* ("AP") says that's all a conspiracy theory. On the other other hand, covid hospitalisations are up – and there's a scary new variant from... (hurls dart at map of the world) Denmark and... (hurls second dart, backward over shoulder) Israel. On the other hand, that eighth shot is sure to work:

I take it most of the above is just prepping the battlefield for next year's presidential election. But, as you know, I am more interested in the news that doesn't make the news. Which is why this Norman Fenton tweet caught my eye. Many of you will have seen Professor Fenton on *The Mark Steyn Show*. So, I followed the links through to a research paper by two Japanese fellows – Atsushi Tanaka of Osaka Medical and Pharmaceutical University and Takayuki Miyazawa of Kyoto University.

I don't know these guys. Could be they're just another wing of that big conspiracy theory the AP is banging on about. Professor Tanaka has published peer-reviewed papers on the 'Significance of N-Sulfation of Heparan Sulfate as a Host Cell Factor for Chikungunya Virus Infection', and Professor Miyazawa has done likewise in prestigious journals on the 'Emergence of Infectious Malignant Thrombocytopenia in Japanese Macaques (Macaca fuscata) by SRV-4'. So, if they are mere conspiracy theorists, they've constructed a pretty elaborate cover.

Professors Tanaka and Miyazawa's new paper is called: '*Unnaturalness in the evolution process of the SARS-CoV-2 variants and the possibility of deliberate natural selection*'.

What does that mean? Well, everyone except the brain-dead and the more aggressive interns of Ofcom's fact-checkers now accepts that the covid came from a lab leak. How long is it since you've heard anyone even on *MSNBC* or Facebook say the word "pangolin" with a straight face? But Messrs Tanaka and Miyazawa have taken it to the next level:

In this study, we aimed to clarify the evolutionary processes leading to the formation of SARS-CoV-2 Omicron variants, focusing on Omicron variants with many amino acid mutations in the spike protein among SARS-CoV-2 isolates. To determine the order in which the mutations leading to the formation of the SARS-CoV-2 Omicron variants, we compared the sequences of 129 Omicron BA.1-related isolates, 141 BA.1.1-related isolates, and 122 BA.2-related isolates, and tried to dissolve the evolutionary processes of the SARS-CoV-2 Omicron variants, including the order of mutations leading to the formation of the SARS-CoV-2 Omicron variants and the occurrence of homologous recombination. As a result, we concluded that the formations of a part of Omicron isolates BA.1, BA.1.1, and BA.2 were ***not the products of genome evolution as is commonly observed in nature****... [Emphasis added.]*

The analysis we have shown here is that the Omicron variants are formed by an entirely new mechanism that cannot be explained by previous biology.

In the genetic variation in the S protein in these variants, most of the mutations were non-synonymous (Fig. 1). ***There were no synonymous mutations in the Alpha, Beta, Gamma, Delta, or Mu variants, but only one each in the Lambda and Omicron variants.*** *Among these variants, the Omicron variant (BA.1 lineage), which shows the greatest accumulation of mutations in the S protein, is primarily non-synonymous in the S protein and has only one synonymous mutation at c25000u.* ***The synonymous/non-synonymous ratio is abnormal, given how human coronaviruses have mutated.*** *[Emphasis added.]*

What "synonymous" means in this context is that normally, when something mutates naturally, it does so mostly in ways that don't change the nature of the original: hence, such mutations are merely synonymous. When you have a "synonymous/non-synonymous ratio" as "abnormal" as that of the covid variants, that means they are not occurring naturally:

The fact that most of these mutations occurred without synonymous mutations (Fig. 2) suggests that none of these mutations arose as a result of trial-and-error random mutations in nature.

In other words, not only did the covid come from a lab, but *so did the variants*:

Suppose the SARS-CoV-2 Omicron variant and its one amino acid reversion mutants were artificially and systematically generated. In that case, we should suspect that the other variants (Alpha to Delta) may also be artificially generated viruses.

Oh, really? But why would anyone do such a thing?

One idea, the hypothesis that these viruses were artificially generated, is more reasonable than proposing a novel mutation acquisition mechanism. However, **is there any reason to artificially create these mutants**, which are unlikely to have occurred naturally, given the current SARS-CoV-2 epidemic? [Emphasis added.]

Well, that's the question, isn't it? It's just about possible to believe that the original strain escaped from the lab accidentally. But is it possible to believe that every artificially created variant from Alpha to Omicron also escaped from the lab accidentally whenever the Covid showed signs of flagging? (Including presumably the incoming referenced at the top.) You'll recall Boris Johnson as late as December 2021 insisting that the impending Omicron made it more urgent than ever that you get your booster, or he might have to cancel Christmas.

Norman Fenton links to a Substack article by a bloke called 'PSMI' that concludes: "Someone, somewhere, really is doing all this deliberately."

In fairness, the Japanese chappies aren't yet willing to go there:

It is inimical to virus research to consider that artificially synthesised viruses were deliberately spread throughout the world... Furthermore, we do not conclude that these viruses were artificially synthesised and distributed based on malicious intent.

If you say so. Nevertheless:

The analysis we have shown here concludes that the Omicron variants are formed by a completely new mechanism that cannot be explained by previous biology.

That's pretty interesting, isn't it? Particularly if you're one of these politico-media zombies droning "Follow the science... Must follow the science" thirty times a day. Well, for eleven years I've been stuck in the dank toilet of the DC Superior Court for being a soi-disant "science denier". Yet I managed to "follow the science" all the way to Osaka and Kyoto and I was discombobulated by what I found there. Why is it only PSMI and a couple of others and not the science and health correspondents of the *BBC* and *The New York Times* that are interested in the ostensibly startling revelation that all the major covid "variants" are also lab creations?

As I mentioned the other day, when this thing got going, my initial assumption was that, as with SARS, the Chinese were lying to the world. It then became plain that, in fact, the Americans – Fauci and the public-health bureaucracy – were lying to the world, about taxpayer-funded "gain-of-function" research offshored via a CIA front to Wuhan. Among the more curious details in the new Japanese paper is this:

23-3

The following results presented in this study may support the hypothesis that the Omicron variants may have been artificially synthesised rather than naturally occurring:

1) the presence of Omicron variant-associated isolates with one mutation site being Wuhan-type;

2) the almost complete absence of synonymous mutations in the S protein in these isolates;

3) ***the Omicron variant, which should have been first reported to WHO from South Africa on November 24, 2021, was already endemic in Puerto Rico in 2020****, and that there were isolates that were recombinants between Omicron strains BA1 and BA2. [Emphasis added.]*

How about that? Puerto Rico is a territory not of Japan but of the United States. Yet it takes a couple of guys in Osaka and Kyoto to reveal that the Omicron was endemic on American turf over a year before its official release date? Is it really credible that Fauci & Co didn't know that? And, if not, do they know where it came from? And, if so, why aren't they telling us?

24-1

PREGNANCY AND LACTATION CUMULATIVE REVIEW

1. INTRODUCTION

As part of the Biological Licensing Application (BLA) submission, the U.S. Food and Drug Administration (FDA) has requested a cumulative review and summary of relevant cases reported in Pfizer's pharmacovigilance (Safety) database from the time of drug product development to 28-FEB-2021.

2. METHODOLOGY

Pfizer's safety database contains cases of adverse events (AEs) reported spontaneously to Pfizer, cases reported by the health authorities (HAs), cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events (SAEs) reported from clinical studies regardless of causality. The safety database was searched for all BNT162b2 vaccine cases reporting any exposure to vaccine during pregnancy (mother and/or baby) or exposure to baby via lactation from all time through 28 February 2021. A search of the Pfizer safety database identified 673 case reports.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

3. RESULTS

Of the 673 case reports identified in the search, 458 involved BNT162b2 exposure during pregnancy (mother/fetus) and 215 involved exposure during breast-feeding.

- In 210 out of the 458 cases, maternal exposure (PTs Maternal exposure timing unspecified, Maternal exposure during pregnancy, Maternal exposure before pregnancy,

Exposure during pregnancy) was reported either with no associated AEs or with AE off-label use/product use issue for either the mother or the baby.

- Among the remaining 248 cases, the most commonly reported AEs were product use issue (83), off-label use (81), pain (including but not limited to vaccination site pain/pain/pain in extremity)(101), headache (57), abortion spontaneous (51), fatigue (43), pyrexia (26), chills (24), myalgia (23), nausea (22), arthralgia (16), dizziness (15), malaise (12), lymphadenopathy (11) and asthenia (11).

- There were 6 cases reporting AE(s) related to premature deliveries.

    - AER 2021166927 Baby report of fetal tachycardia noted 1 week after the neonate's mother received the second dose of the vaccine. The baby was delivered at 35 weeks and 3 days of gestation due to non-reassuring status during monitoring post vaccination. The baby was hospitalized for 5 days. The clinical outcome of fetal tachycardia was unknown.

    - AER 2021015910 Maternal report of a 29-year old female who was pregnant when receiving BNT162B2. She had spontaneous rupture of membranes at 36 weeks of gestation, one day after her 2nd dose of vaccine. Unspecified therapeutic measures were taken as a result of premature rupture of membranes and the mother was recovering.

    - AER 2021191405 Baby case of a fetus of unspecified gender who received BNT162B2 transplacentally. The patient's mother received vaccination during the second trimester (13-28 weeks) and experienced premature labor. A live infant was delivered but passed away a day later. Cause of death was cited as extreme prematurity with severe respiratory distress and pneumothorax.

    - AER 2021182609 Maternal report (AER 2021193635 associated Baby report) of a 32-year-old female patient received BNT162B2 during the second-trimester (13-28 weeks) and experienced preterm premature rupture of membranes, premature baby/Premature delivery. Outcome of preterm premature rupture of membranes and premature delivery was recovered with sequelae. Concomitant medications included acetylsalicylic acid and dalteparin sodium.

    - AER 2021155967 Baby report: A neonate patient's mother (mother was reported as 37-year-old) received BNT162B2 during 13-28 weeks of gestation and experienced foetal exposure during pregnancy, premature baby less than 26 weeks, respiratory distress and pneumothorax. Cause of death for the neonate was premature baby less than 26 weeks and severe respiratory distress and pneumothorax.

    - AER 2021203938 Baby report: Patient's 33-year old mother had preterm delivery at 24 weeks and 2 days via emergency caesarean section. The fetus experienced maternal exposure during pregnancy via transplacental route on an unspecified date.

- There were 53 reports of spontaneous abortion (51)/ abortion (1)/ abortion missed (1) following BNT162b2 vaccination. Of these reports, 4 cases were COVID-19 positive (including suspected), and 13 cases had relevant medical history of endometriosis (1), abortion spontaneous (10), polycystic ovaries (1), menstruation irregular (1). These cases were therefore excluded from the review. One patient had a medical history of COVID-19 (unknown if ongoing) and was excluded from the review. The remaining 39 cases are summarized in Table 1.

Table 1. Summary of Patients with Outcome of Pregnancy – Abortion spontaneous

Age	Medical History	Outcome of Pregnancy
40 years	Not provided	The patient was unaware of her pregnancy at the time of vaccination. Suspected abortion occurred at 6 weeks of pregnancy.
37 years	Not provided	Patient received vaccine during first trimester (1-12 weeks) on 19 Jan 2021 and suffered spontaneous abortion on 3 Feb 2021.
33 years	Not provided	Patient received first dose of vaccine during first trimester (1-12 weeks). Abortion occurred at 3 weeks of pregnancy.
32 years	Not provided	Patient was vaccinated during first trimester (1-12 weeks) on 23 Dec 2020 and suffered a spontaneous abortion on 06 Jan 2021.
39 years	Asthma / Eosinophilic oesophagitis	Patient received vaccination at gestation of 6 weeks and spontaneous abortion occurred 11 days post vaccination.
31 years	Not provided	Patient experienced spontaneous abortion 8 days after receiving 2nd vaccine at 6 weeks pregnant.
35 years	Asthma / Gastrooesophageal reflux disease	Patient experienced missed abortion in the 7th week of pregnancy on an unspecified date with outcome of unknown.
33 years	Pregnancy	The patient was unaware of her pregnancy at the time of vaccination, which occurred at gestational age of approximately 3 weeks. Spontaneous abortion occurred at gestational age of 6 weeks.
34 years	Pregnancy	Patient was 3 weeks pregnant at the time of the first vaccination, without knowing she was pregnant. She found out she was pregnant one week after the vaccination. She then had a spontaneous abortion in week 6 of pregnancy.
Unknown	Not provided	Patient received vaccine at an unspecified time during pregnancy Spontaneous abortion, gestational age unknown.
34 years	Continuous positive airway pressure / Overweight / Sleep apnoea syndrome	Patient reported that she was unknowingly pregnant upon receiving COVID-19 vaccine dose 1. Spontaneous abortion occurred at 4 weeks of pregnancy.
Unknown	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 5 weeks of gestation.
37 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 6 weeks of pregnancy.
31 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 5 weeks of gestation.
32 years	Not provided	Patient received her first vaccine dose at 3 weeks of pregnancy and experienced spontaneous abortion about 5-6 days before her second dose.

Table 1. Summary of Patients with Outcome of Pregnancy – Abortion spontaneous

Age	Medical History	Outcome of Pregnancy
23 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 1 month of pregnancy.
29 years	Pregnancy	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 4-5 weeks of gestation.
34 years	Not provided	The patient experienced spontaneous abortion at a routine OBGYN visit, gestational age unknown.
38 years	Not provided	Patient had spontaneous abortion at 12 weeks after receiving the second dose of vaccine.
29 years	Anxiety/Seasonal allergy	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 6 weeks of gestation.
41 years	Pregnancy	Patient was vaccinated during first trimester (6 weeks, also reported 1-12 weeks). Spontaneous abortion was diagnosed on 09 Jan 2021 (17 days after vaccination administration).
32 years	Pregnancy	The patient had spontaneous abortion at 5.5 weeks, which was conceived 3 days after receiving the vaccine.
36 years	Allergy to animal/Food allergy/Seasonal allergy	The patient was unaware of her pregnancy at the time of vaccination. Spontaneous abortion occurred during 5th week of pregnancy.
30 years	Clinical trial participant	Patient was vaccinated during first trimester (1-12 weeks). Spontaneous abortion occurred 1 week after first dose.
26 years	Not provided	Patient was vaccinated during first trimester (1-12 weeks). Spontaneous abortion occurred 1 day after vaccination.
28 years	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
Unknown	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
25 years	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
Unknown	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
34 years	Not provided	Patient received vaccine at 4 weeks 5 days of pregnancy. Spontaneous abortion occurred during Week 8 of gestation.
29 years	Pregnancy	Patient experienced spontaneous abortion 10 days after first dose of vaccine during first trimester of pregnancy.
21 years	Not provided	Patient was vaccinated during first-trimester (1-12 weeks) and experienced spontaneous abortion after 12 days.
30 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 11 weeks of pregnancy.
36 years	Coronavirus test negative/Deep vein thrombosis	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion occurred at 4 weeks of pregnancy.
39 years	Drug hypersensitivity	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred during Week 8 of gestation
26 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred after 5 weeks of pregnancy.
Unknown	Not provided	Spontaneous abortion occurred 3 days post first dose of BNT162b2.
Unknown	Not provided	Miscarriage after receiving both doses of COVID-19 vaccine

- The remaining 215 cases reported exposure via lactation. In 174 of the 215 reports, there was no AE reported other than 'Exposure via breast milk/maternal exposure during breast feeding'. In the remaining 41 cases, AEs were reported in the infants following BNT162b2 exposure via lactation (see Table 2).

Table 2. Number of Adverse Events Reported in Infants with 'Exposure via Lactation'

Preferred Term	Number of Events
Pyrexia	9
Off label use	8
Product use issue	7
Infant irritability	5
Headache	5
Rash	5
Diarrhoea	3
Illness	3
Insomnia	3
Suppressed lactation	3
Breast milk discolouration	2
Infantile vomiting	2
Lethargy	2
Pain	2
Peripheral coldness	2
Urticaria	2
Vomiting	2
Abdominal discomfort	1
Agitation	1
Allergy to vaccine	1
Angioedema	1
Anxiety	1
Axillary pain	1
Breast pain	1
Breast swelling	1
Chills	1
Cough	1
Crying	1
Dysgeusia	1
Dysphonia	1
Eructation	1
Epistaxis	1
Eyelid ptosis	1
Facial paralysis	1
Fatigue	1
Increased appetite	1
Lymphadenopathy	1
Myalgia	1
Nausea	1
Paresis	1
Poor feeding infant	1
Poor quality sleep	1
Pruritis	1
Restlessness	1

Table 2. Number of Adverse Events Reported in Infants with 'Exposure via Lactation'

Preferred Term	Number of Events
Rhinorrhoea	1
Roseola	1
Skin exfoliation	1
Vision blurred	1

There were 10 SAEs reporting with the PT Exposure via lactation. Six of these SAEs were reported in infants.

- A 15-month old infant with medical history of vomiting experienced skin exfoliation and infant irritability while being breastfed (latency <7 days). The outcome of the event 'skin exfoliation' was not recovered and outcome of event 'infant irritability' was unknown. No causality was reported by the physician.

- A 9-month old infant with a medical history of meningococcal vaccine and no history of allergies, asthma, eczema or anaphylaxis experienced rash and urticaria a day after exposure via lactation. The outcome of the events was 'resolved' and event did not happen after the second day. No causality assessment was provided.

- A day after the mother received vaccination, a baby developed a rash after breastfeeding. At the time of the report, the event was 'not recovered. A causality assessment was not provided.

- An 8-month old infant experienced angioedema one day after his mother received vaccination. The event was considered non-serious by health authority and the outcome at the time of the report was unknown. No causality was provided.

- There were 2 cases reporting 'illness' after exposure via breast milk'. In the first case, a 6-month old infant developed an unspecified sickness 2 days post mother's vaccination. The outcome of the event sickness was recovered, and no causality assessment was provided. The second case, a 3-month old infant developed an unspecified illness and required hospitalization for 6 days post exposure via breast milk (>7 days latency). The event outcome was reported as 'recovering' and no causality assessment was provided.

4. SUMMARY AND CONCLUSION

The cases reviewed above are indicative of what is in the Pfizer safety database as of 28 February 2021. The sponsor (Pfizer/BioNTech) will continue to monitor and report on all pregnancy exposure and lactation cases. It is important to note that the spontaneous safety database is intended for hypothesis generation and not hypothesis testing.

24-8

Document Approval Record

Document Name:	COVID-19 Vaccine - Safety Review for PLLR Label Update
Document Title:	COVID-19 Vaccine - Safety Review for PLLR Label Update

Signed By:	Date(GMT)	Signing Capacity
Maroko, Robert T	20-Apr-2021 16:11:58	Business Line Approver

25-1

Scientific Publications Directory

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. Primarily, the information is incredibly challenging to find. Here, we share an ever growing list of peer-reviewed studies specific to Covid vaccine adverse events. This list is curated and maintained by our dedicated staff of injured PhDs and medical professionals.

Before diving in, please take a look at our Research Primer: **How to Read and Understand Research** for tools to how best approach the massive amount of information found in the document below. As always, this is for informational purposes only. Please discuss with your trusted medical team.

Are we missing a few? Please **email us** and let us know.

Showing 1 to 25 of total 3,541 entries

Search:

Show 25 entries

Title Link	Author	
"Bilateral Sequential Acute Macular Neuroretinopathy in an Asian Indian Female with β Thalassemia Trait following (Corona Virus Disease) COVID-19 Vaccination and Probable Recent COVID Infection- Multimodal Imaging Study." https://pubmed.ncbi.nlm.nih.gov/35050826/	Sanjay et al (1)	Ophthalmology
"COVID arm" detected by MR neurography" https://pubmed.ncbi.nlm.nih.gov/34746453/	Komiya et al	Dermatology
"Covid arm": Abnormal side effect after Moderna COVID-19 vaccine" https://pubmed.ncbi.nlm.nih.gov/34750923/	Picone et al (1)	Dermatology
"COVID Arm": Very delayed large injection site reactions to mRNA COVID-19 vaccines" https://pubmed.ncbi.nlm.nih.gov/33864927/	Ramos & Kelso	Dermatology
"COVID Toes" After mRNA COVID-19 Vaccines" https://pubmed.ncbi.nlm.nih.gov/34162525/	Kelso et al	Dermatology

18-P

25-2

Title Link	Author	
"COVID-19/SARS-CoV-2 virus spike protein-related delayed inflammatory reaction to hyaluronic acid dermal fillers: a challenging clinical conundrum in diagnosis and treatment" https://pubmed.ncbi.nlm.nih.gov/33559733/	Munavalli et al (1)	Dermatology
"Marginal keratitis following COVID 19 vaccination" https://pubmed.ncbi.nlm.nih.gov/35756698/	Farrell et al	Ophthalmology
"Reversible cytotoxic lesion of the corpus callosum following SARS-CoV-2 mRNA vaccine administration: a finding to be aware of" https://pubmed.ncbi.nlm.nih.gov/35488375/	Procaccini et al	Neuro
"Smoldering" Rejection of Keratolimbal Allograft" https://pubmed.ncbi.nlm.nih.gov/35383621/	Gouvea et al	Rheum-Endo-Ortho
"Vitreous Hemorrhage and Long-Lasting Priapism After COVID-19 m-RNA Based Vaccine: A Case Report" https://pubmed.ncbi.nlm.nih.gov/35505605/	Casarini et al	Rheum-Endo-Ortho
'Blue toes' following vaccination with the BNT162b2 mRNA COVID-19 vaccine https://pubmed.ncbi.nlm.nih.gov/33620081/	Davido et al	Dermatology
'COVID arm' - histological features of a delayed-type hypersensitivity reaction to Moderna mRNA-1273 SARS-CoV2 vaccine https://pubmed.ncbi.nlm.nih.gov/34242422/	Kempf et al	Dermatology
'COVID vaccine arm' may present after both mRNA vaccines vaccination https://pubmed.ncbi.nlm.nih.gov/34416053/	Gregoriou et al	Dermatology
(Autol) A flare of Still's disease following COVID-19 vaccination in a 34-year-old patient https://pubmed.ncbi.nlm.nih.gov/34797392/	Jeon et al	Rheum-Endo-Ortho
(Female genital ulcers) Post COVID-19 Vaccination Vulvar Aphthous Ulcers: An Unpopular Case Series https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8929996/	Lawson et al	OB-GYN
10 Cases of Immune Thrombocytopenia (ITP): Relapse Versus de novo After COVID-19 Vaccination	Al-Ahmad et al (1)	Rheum-Endo-Ortho

19-1

25-3

Title Link	Author	
https://pubmed.ncbi.nlm.nih.gov/35108113/		
10 cases Reactivation of Herpes Zoster Virus After COVID-19 Vaccination: Is There Any Association? https://pubmed.ncbi.nlm.nih.gov/35746994/	Agrawal et al	ID
11 cases of SARS-CoV-2 vaccine-associated subacute thyroiditis https://pubmed.ncbi.nlm.nih.gov/35182366/	Yorulmaz & Tekin	Endocrine
11 patients with Delayed skin reaction after mRNA-1273 vaccine against SARS-CoV-2: a rare clinical reaction https://pubmed.ncbi.nlm.nih.gov/34433495/	Hoff et al	Dermatology
111In-Pentetreotide Uptake Due to COVID-19 Vaccination https://pubmed.ncbi.nlm.nih.gov/34619700/	Koyasu & Nakamoto	Immune System
12 cases of GBS Acute-onset polyradiculoneuropathy after SARS-CoV2 vaccine in the West and North Midlands, United Kingdom https://pubmed.ncbi.nlm.nih.gov/34786740/	Loo et al	Neuro
12 yoMEosinophilic cellulitis in response to BNT162b2 COVID-19 vaccination https://pubmed.ncbi.nlm.nih.gov/35522122/	Ikediobi et al	Dermatology
12% of chronic ITP patients have exacerbation of ITP in 2-5 days following vaccination https://pubmed.ncbi.nlm.nih.gov/34075578/	Kuter	Rheum-Endo-Ortho
12yoM A Case of Multisystem Inflammatory Syndrome in a 12-Year-old Male After COVID-19 mRNA Vaccine https://pubmed.ncbi.nlm.nih.gov/34978781/	Yalçinkaya et al	MIS-V
12yoM Multisystem Inflammatory-like Syndrome in a Child Following COVID-19 mRNA Vaccination https://pubmed.ncbi.nlm.nih.gov/35062704/	Poussaint et al	MIS-V

50-1