Subject: COVID-19 vaccines, Call to action.

The medical doctors, scientists and pilots who authored and undersigned this document urgently want to stress and underline the fact that the commercial airline industry, pilots, European Union Aviation Safety Agency and National Civil Aviation Authorities appear to be putting both pilots and the general public (passengers) at possible risk of serious injury or even death by operating in contravention of

Easy Access Rules for Medical Requirements[1]

- *MED.A.020 Decrease in medical fitness (A) 2&3 (B) 2*
- *GM1.MED.A.020 Decrease in medical fitness (A)(B)(C)(E)*
- *MED.B.005 General medical requirements (B)(D)*
- *ARA.MED.330 Special Medical Circumstances*
- *AMC1 ARA.MED.330 Special medical circumstances*
- *AMC1 ARA.MED.330(b)(c) Special medical circumstances*
- *GM1 ARA.MED.330 Special Medical Circumstances (B)*

EASA Guidance material for the use of medication in aviation environment[2]

- *'Main principles of medication use in aviation' statement(3)(4)*
- *'General prescribing guidance' statement(3)(4)(5)(6)*
- *'Assessment of fitness' statement(2),*
- *'Guidelines for treating physicians and AMEs' statement(1)(3)(5)(7),*
- *'Guidelines for pilots' statement(2)(5)(6)*

Which together operate to disallow medical clearance of pilots who have injected, ingested or inhaled new medication, such as recent under emergency use authorization phase 3 trial mRNA vaccines. We lead with our conclusion, and ask that EASA and Civil Aviation Authorities immediately take action to remedy this problem by:

1. Medically flagging all vaccinated pilots.

2. Discontinuing any vaccine mandate still effective today, and making sure pilots can never be mandated again to get any COVID-19 vaccines or any other new and/or unapproved medical product, in accordance with the in ARA.MED 330 'Special medical circumstances' (Easy Access Rules for Medical Requirements) referenced WMA Declaration of Helsinki.[3]

3. Prohibiting any mRNA based medical product in aviation for now and the near future, until such time as all unresolved issues of this novel technology have been remedied and these products have been prescribed to the general public for a number of years without serious issues, a favorable safety profile must have been established.

4. Putting in writing a ban on experimental medical treatments in aviation, to be included in EASA Rules for medical requirements. All non-approved and conditionally approved medical products should be prohibited.

5. Creating a database to track pilot adverse events as we fear that medical adverse events post vaccination in pilots is higher in numbers than currently assumed.

[1] https://www.easa.europa.eu/sites/default/files/dfu/Easy_Access_Rules_for_Medical_Requirements.pdf
[2] https://www.easa.europa.eu/document-library/general-publications/use-medication-aviation-environment
[3] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

6. Informing/educating pilots about the risk of COVID-19 vaccine adverse events and the immaturity of mRNA based medical products in general.

Additionally proposed safety measures to establish pilot health post vaccination

7. Without further delay and considering the by mRNA vaccine producing companies mentioned cardiovascular complications[4] [5], having vaccinated pilots undergo thorough medical re-examinations to include D-Dimer tests (to check for blood clotting problems), Troponin tests (to check for Troponin in the blood, a protein released by damaged heart muscle cells), ECG analysis, cardiac MRI and PULS test (to determine heart health). Inclusion of the cardiac MRI as a screening test for pilots is critical, as a recent study showed that using only ECG results and symptoms to screen patients resulted in a 7.4 times under-diagnosing of actual myocarditis.[6] While the PULS test is also critical as research has shown that mRNA vaccines dramatically increase Endothelial Inflammatory Markers and ACS (Acute Coronary Syndrome) risk.[7]

8. From this point forward only allowing commercial aircraft to be operated by pilots who can show D-Dimer and Troponin tests, as well as cardiac MRIs, ECGs(EASA Acceptable means of compliance and guidance material to part-MED, AMC1 MED.B.010 Cardiovascular system) [8] and PULS tests- at aeromedically acceptable levels and a clean medical examination undertaken a minimum of 11 days after each new COVID-19 injection and after each COVID-19 "booster" shot, as a review of Pharmacovigilance databases, the Pfizer test data and peer reviewed scientific and medical studies indicate that the current 48 hours waiting period as prescribed by EASA is insufficient to detect a significant number of blood clotting, myocarditis cases and neurological severe adverse events, as the median onset for blood clotting is 4 days, myocarditis 3 days (1-8 days) and neurological severe adverse events 11 days. [9] [10] [11] [12]

Put simply, any pilot flying right now in the EU, who has been vaccinated has not received an EMA (European Medicines Agency) approved vaccine, as the available vaccines are only certified under CMA.[13] Conditional Marketing Authorization (or Emergency Use Authorization EUA in the US), means a vaccine or medication is 'authorized' without comprehensive clinical data available, this opened the flood gates to deploy an unapproved and unlicensed vaccine to tens of millions of individuals before gathering proof of safety and efficacy that licensing a new vaccine or medication normally demands. This was never the intent of emergency use authorization, which was actually designed for counterterrorism measures to address chemical, biological, radiological and nuclear hazards and was never intended for use during a pandemic.[14] [15]A process called 'compassionate use' or 'expanded

[4] https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna/information-for-uk-recipients-on-covid-19-vaccine-moderna#possible-side-effects
[5] https://labeling.pfizer.com/ShowLabeling.aspx?id=14471
[6] https://jamanetwork.com/journals/jamacardiology/fullarticle/2780548
[7] https://www.ahajournals.org/doi/10.1161/circ.144.suppl_1.10712
[8] https://www.easa.europa.eu/document-library/acceptable-means-of-compliance-and-guidance-materials/amc-gm-part-med-issue-2
[9] 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021.Public Health and Medical Professionals for Transparency -https://phmpt.org
[10] https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1
[11] https://www.sciencedirect.com/science/article/pii/S027869152200206X
[12] JAMA | Original Investigation Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021
[13] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-authorised
[14] https://www.statnews.com/2020/11/09/expanded-access-not-eua-for-distributing-preapproval-covid-19-vaccines/
[15] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

access' is the use of an investigational new medication outside of clinical trials to treat patients with serious or immediately life-threatening disease or conditions when there is no comparable or satisfactory alternate treatment option. Expanded access is fundamentally different from emergency use authorization, and the distinction between the two is vitally important. Expanded access will preserve the integrity of ongoing large-scale clinical trials under the banner of experimentation while ensuring high-risk individuals have a pathway to access experimental vaccines, an emergency use authorization does not. [15] [16] [17]
Even though these new medical products are labeled 'vaccines', they should have been categorized as Gene Therapy, as evidenced by multiple official documents.
In Moderna's SEC (Security and Exchange Commission) Filling for the quarterly period ended June 30, 2020[18] the next can be read:

- In the European Union, mRNA has been characterized as a Gene Therapy Medicinal Product.
- Currently, mRNA is considered a gene therapy product by the FDA

On a website of the Dutch government 'overheid.nl', the official publication of a temporary emergency law regarding gene therapy to combat COVID-19 can be found, dated 30-03-2020. This temporary emergency law is to expedite all applications for authorization with regards to gene therapy to combat COVID-19.[19]

The Committee for Advanced Therapies is the European Medicines Agency's (EMA) committee responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMPs) and following scientific developments in the field. In their document 'Scientific recommendations on classification of advanced therapy medicinal products' they list their scientific recommendation on classification of advanced therapy medicinal products.[20] In this list a product is categorized as Gene therapy Medicinal Product which has exactly the same characteristics and mode of operation as the COVID-19 mRNA vaccines, number 97 in the list:

- **Public description of active substance**: Single messenger ribonucleic acid (mRNA) that upon translation produces two independent proteins.
- **Classification conclusion:**
  On the basis that the Product:
  (a) contains an active substance which consists of a recombinant nucleic acid administered to human beings with a view to regulating a genetic sequence;
  (b) its therapeutic effect relates directly to the product of genetic expression of this sequence;
  the EMA/CAT considers that the Product falls within the definition of a gene therapy medicinal product.

The American Society of Gene & Cell Therapy also regards both mRNA COVID-19 'vaccines' as Gene Therapy.[21]

Very little and by no means comprehensive data was available at time of CMA/EUA certification,[22] [23] as these products were and still are in phase 3 of testing. The EMA, in charge of the evaluation and

[16] https://www.fda.gov/news-events/public-health-focus/expanded-access
[17] https://www.ema.europa.eu/en/human-regulatory/research-development/compassionate-use
[18] https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm
[19] https://zoek.officielebekendmakingen.nl/stcrt-2020-18941.html
[20] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification/scientific-recommendations-classification-advanced-therapy-medicinal-products
[21] https://asgct.org/research/news/november-2020/covid-19-moderna-nih-vaccine
[22] clinicaltrials.gov/ct2/results?cond=COVID-19

supervision of medicinal products, wrote an assessment report on Pfizer's Covid-19 mRNA vaccine BNT162b2 on February 19, 2021[23] referring to study PF-07302048, a combined phase 1/2/3 study which is still ongoing (estimated study completion February 2024)[24]:

"Safety pharmacology studies

- No safety pharmacology studies were conducted with BNT162b2

Pharmacokinetics

- No traditional pharmacokinetic or biodistribution studies have been performed with the vaccine candidate BNT162b2"

Study PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001.[25]

- 8.5. Pharmacokinetics: Pharmacokinetic parameters are not evaluated in this study.
- 8.6. Pharmacodynamics: Pharmacodynamic parameters are not evaluated in this study.
- 8.7. Genetics: Genetics (specified analyses) are not evaluated in this study.
- 8.8. Biomarkers: Biomarkers are not evaluated in this study."

The purpose of phase 3 in a clinical trial is to further determine the efficacy and safety/adverse events of the drug or vaccine being developed. Approximately only 25-30% of drugs/vaccines continue to the next phase according to FDA data[26], EMA states this number to be just short of 60%. So all vaccinated individuals including pilots in fact participate in a data collecting phase on safety and efficacy, with no certainty these vaccines will even make it to authorization or be discontinued due to safety and/or efficacy issues.[27]
The 4 main vaccines used at the moment for COVID-19, Pfizer/BioNTech, Moderna, AstraZeneca and Janssen are still in phase 3, their end dates are respectively February 15 2024[24], December 29 2022[28], February 24 2023[29] and March 31 2023[30], thus authorization is not possible.
Even were the vaccinated pilots to have received a fully approved vaccine, under relevant regulations, the pilots should still not be flying for several reasons, the previously mentioned lack of safety data for one.
The reason for this cannot be overstated: history and common sense evince that significant time must elapse post EMA approval to ensure that new medical products do not end up causing adverse events. This is particularly true when the individuals who are receiving such new, experimental medical products are spending significant amounts of time at high altitude and are in control of large aircrafts carrying up to hundreds passengers who could all die or be severely injured should the pilot(s) suffer an adverse health event.

There is no substitute for time in developing vaccines or other medical products, time is necessary before a new medical product can be proven safe. Two years of Phase 2 and three years of phase 3 testing was skipped[11 31 32] in the process of developing these vaccines. The politicization of SARs-CoV-2, treatments and vaccination strategies have completely compromised long-standing safety mechanisms, one of the fundamental pillars and primary focus' in aviation.

[23] https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf
[24] https://clinicaltrials.gov/ct2/show/NCT04368728
[25] https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf
[26] https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#The_Investigational_New_Drug_Process
[27] https://investors.biontech.de/node/11931/html#ic5e06a05a31d4c4491031d3208cef8c2_2806
[28] https://clinicaltrials.gov/ct2/show/NCT04470427
[29] https://clinicaltrials.gov/ct2/show/NCT04516746
[30] https://clinicaltrials.gov/ct2/show/NCT04505722
[31] https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#Clinical_Research_Phase_Studies
[32] https://www.youtube.com/watch?v=__QUc3ZltqQ

Currently, all vaccinated pilots flying airplanes and helicopters have conditionally approved products in their systems, that is now unfortunately proving to cause all manner of neurological problems, clotting, embolic and thrombotic-related side effects (side effects which are known to occur with greater frequency and severity when at altitude). Additionally, across all populations, the inoculations have proven to result in significant increases in myocarditis and subsequent arrhythmias, heart failure, cardiac arrests and deaths. This is especially seen in the younger male cohort, to which many pilots belong.
Research also shows side effects increase in incidence with every additional shot.[10] [12] [33]

Note that in an affidavit authored in 2021 by **Theresa Long, Lieutenant Colonel in the US Army, who is a Flight Surgeon, Aerospace Medicine Specialist and an Aviation Officer Course & Mishap Training Specialist with a Master's degree in Public Health,** who collaborated with renowned cardiologist Dr. Peter McCullough and a Senior Medical Examiner-Federal Air Surgeon's Cardiology Consultant to the Federal Aviation Administration, All concluded that:

- The risk of post-vaccination myocarditis is not trivial,
- The aviation population is comprised of individuals with demographics that the CDC and FDA established (on June 25, 2021) are at greatest risk for developing post-vaccination induced myocarditis (confirmed by numerous medical research papers),
- The unpredictable and potential serious complications thereof present an unacceptable level of aeromedical risk,
- The risk stratification, screening and diagnostic testing is necessary for continued safety of flight, and
- Immunizations with COVID vaccinations should be immediately suspended until further aviation specific studies can be concluded.

During a US Senate Briefing on COVID-19 vaccine injuries, Dr. Theresa Long testifies that in one morning she had to ground three pilots, all of them shortly after their vaccination. Two of which presented with chest pain and were subsequently diagnosed with pericarditis, the third pilot felt like he was drunk and chronically fatigued within 24 hours after vaccination. He tried to 'wake himself up' by drinking a lot of coffee until he realized the problem wasn't going away.[32]

In the Affidavit in support of a motion for a preliminary injunction order, Dr. Theresa Long further testified:

'The application of risk management is critical to the safety and success in both medicine and aviation. Aerospace Medicine is a specialty devoted to safety of flight by the aeromedical dispositioning and treatment of flight crew members, as accomplished by the consistent and careful application of risk mitigation and management strategies.

Literature has demonstrated that natural immunity is durable, completed, and superior to vaccination immunity to SARs-CoV-2. mRNA vaccines produced by Pfizer and Moderna both have been linked to myocarditis, especially in young males between 16-24 years old, the majority of young new Army aviators are in their early twenties. We know there is a risk of myocarditis with each mRNA

[33]https://jamanetwork.com/journals/jamacardiology/fullarticle/2791253#:~:text=Findings%20In%20a%20cohort%20study,years%20after%20the%20second%20dose.

vaccination. We additionally now know that vaccination does not necessarily prevent infection or transmission of SARs-CoV-2.

Research shows that most individuals with myocarditis do not have any symptoms. Complications of myocarditis include dilated cardiomyopathy, arrhythmias, sudden cardiac death and carries a mortality rate of 20% at one year and 50% at 5 years. According to the National Center for Biotechnology Information, U.S. National Library of Medicine, "despite optimal medical management, overall mortality has not changed in the last 30 years."

A screening program must be established to identify those at increased risk of myocarditis, i.e. those that have, received mRNA vaccinations with Comirnaty, BioNTech or Moderna, or have any of the following symptoms chest pain, shortness of breath or palpitations They should have screening tested performed in accordance with the CDC prior to return to flight duties. Per the CDC guidelines the initial evaluation of individuals identified according to the above criteria include ECG, troponin level, inflammatory markers such as the C-reactive protein and erythrocyte sedimentation rate. It should be noted that the gold standard for diagnosis of myocarditis is end myocardial biopsy (EMB)

*The shots carry mRNA that causes the recipient to create trillions of spike proteins. This is a problem for five reasons. First, it turns out that the spike proteins are not remaining locally in the (shoulder) injection site but have been found circulating in the blood and in virtually all organs of the body. Second, the spike proteins themselves have been shown to be pathogenic (disease causing) attaching to endothelial, pulmonary and other cells, forming clots and attacking heart cells. Third, the spike proteins and their lipid nanoparticles cross the blood brain barrier, with unknown long-term effects on the brain and high concern for chronic neurodegenerative disorders. Fourth, these spike proteins interact in many signalling pathways which may trigger tumour formation, cancer, and other serious diseases. Fifth, according to Pfizer's Japanese distribution study of lipid nanoparticles accumulation, unexpected sequestering in reproductive organs and spleen raise very serious long-term concerns. As aircrew Training Program (ATP) 5-19, 1-8 states we shall: Accept No Unnecessary Risk. "An unnecessary risk is any risk that, if taken**,** will not contribute meaningfully to mission accomplishment or will needlessly endanger lives or resources. Army leaders accept only a level of risk in which the potential benefit outweighs the potential loss. From a risk management assessment perspective, with no long-term safety data regarding these five issues, this is an unacceptable risk management risk.'*

The subject matter of this Motion for a Preliminary Injunction and its devastating effects on members of the military compel me to conclude and conduct accordingly as follows:

- None of the ordered Emergency Use Covid 19 vaccines can or will provide better immunity than an infection-recovered person;
- All three of the EUA Covid 19 vaccines (Comirnaty is not available), in the age group and fitness level of my patients, are more risky, harmful and dangerous than having no vaccine at all, whether a person is Covid recovered or facing a Covid 19 infection;
- Direct evidence exists and suggests that all persons who have received a Covid 19 Vaccine are damaged in their cardiovascular system in an irreparable and irrevocable manner;
- Due to the Spike protein production that is engineered into the user's genome, each such recipient of the Covid 19 Vaccines already has micro clots in their cardiovascular system that present a danger to their health and safety;
- That such micro clots over time will become bigger clots by the very nature of the shape and composition of the Spike proteins being produced and said proteins are found throughout the user's body, including the brain;

- That at the initial stage this damage can only be discovered by a biopsy or Magnetic Resonance Image (MRI) scan;
- That due to the fact that there is no functional myocardial screening currently being conducted, it is my professional opinion that substantial foreseen risks currently exist, which require proper screening of all flight crews.
- That, by virtue of their occupations, said flight crews present extraordinary risks to themselves and others given the equipment they operate, munitions carried thereon and areas of operation in close proximity to populated areas.
- That, without any current screening procedures in place, including any Aero Message (flight surgeon notice) relating to this demonstrable and identifiable risk, I must and will therefore ground all active flight personnel who received the vaccinations until such time as the causation of these serious systemic health risks can be more fully and adequately assessed.
- That, based on the DOD's own protocols and studies, the only two valuable methodologies to adequately assess this risk are through MRI imaging or cardio biopsy which must be performed.
- That, in accordance with the foregoing, I hereby recommend to the Secretary of Defense that all pilots, crew and flight personnel in the military service who required hospitalization from injection or received any Covid 19 vaccination be grounded similarly for further dispositive assessment.
- That this Court should grant an immediate injunction to stop the further harm to all military personnel to protect the health and safety of our active duty, reservists and National Guard troops.

Dr. Theresa Long is joined by Dr. Peter Chambers, who is a lieutenant colonel, MC, FS, SF in the US Military confirming her findings and supporting her motion for a preliminary injunction order. Dr. Peter Chambers also wrote an affidavit in which he states:

'Like my colleague, LTC Long, I agree that based upon risk stratification along with treatment modalities in existence, the introduction of a substance which is still in a phase III trial is not necessary, and introduces increased risk factors for the known side effects exhibited by this phase III trial.
The mandate placed upon soldiers for a vaccine that is currently not available also poses another problem for me personally and professionally. Based upon the Centres for Disease Control (CDC) vaccine adverse effects websites known as Vaccine Adverse Events Reporting System (VAERS) data and my own experience over the last 18 months monitoring, advising and treating COVID patients, I cannot in good conscience nor under the hypocritic oath (do no harm) advise Soldiers to take an unapproved high risk "vaccine" still in a phase III trial. Just one example would be a 24 year old Soldier who presented with chest pain post "vaccine" injection and has subsequently developed myocarditis and was released from mission and currently has the heart pumping function of a normal 70 year old.
Current study of regulations, and after discussions with legal counsel has elucidated to many, to include myself, that it would make it an unlawful order to follow a mandate that does not allow for true informed consent as the current vaccine available is still in a phase three trial. The predominance of evidence exhibiting the untoward effects of this vaccine administration procedure, overwhelmingly will not allow me to allow harm to come to my soldiers, colleagues or any civilian I advise.
I have practiced medicine over 20 years and have been on the front lines of trauma, preventative, austere, and civilian based settings. My experiences during the Texas COVID response allowed me to critically assess and formulate courses of action that have been successful in mitigating COVID in the ranks during my current Border Protection operation.
I have a command that is supportive of my position and am doing all I can to develop options for every soldier individually. I do not want another 24-year-old soldier to be taken off mission with a diminished heart function as a result of the COVID injection, or another soldier to suffer long term side

effects, like myself, of this vaccine, without being informed of the possible side effects or overall effectiveness of the vaccine versus natural immunity or available therapy.'

mRNA & Spike protein

Over the last three decades, the mRNA technological platform, aimed to develop effective and safe nucleic acid therapeutic tools, is said to have overcome serious obstacles on the coded product instability, the overwhelming innate immunogenicity, and on the delivery methodologies.[34] One of the major success stories of mRNA use as a genetic vaccination tool is on the introduction of robust immunity against cancer.[35] In addition, the potential of mRNAs to restore or replace various types of proteins in cases of rare genetic metabolic disorders like Fabry disease has offered great potential therapeutic alternatives where no other medication has proved to be successful.[36] However, efforts to use mRNA as a genetic vaccine against infectious diseases, have always failed and the preliminary safety investigations regarding the COVID-19 mRNA vaccines once again seemed to be premature for a world-wide use in the general population.[37]
Due to the short development time and the novelty of the technologies adopted, these vaccines have been deployed with several unresolved issues that only the passage of time will permit to clarify[11], as Dr. Robert Malone (one of the inventors of mRNA) also states '*I do not know how to write this more strongly, this technology is immature'*.[38] This is reflected in the unprecedented amount of adverse events.

Vaccination with an mRNA vaccine initiates a set of biological events that are not only different from that induced by infection but are in several ways demonstrably counterproductive to both short- and long-term immune competence and normal cellular function. These vaccinations have now been shown to downregulate critical pathways related to cancer surveillance, infection control, and cellular homeostasis. They introduce into the body highly modified genetic material. A preprint has revealed a remarkable difference between the characteristics of the immune response to an infection with SARS-CoV-2 as compared with the immune response to an mRNA vaccine against COVID-19.[39] The biological response to mRNA vaccination as it is currently employed is demonstrably *not* similar to natural infection.

The mechanism of 'traditional' vaccines consists of inoculating viruses, which have been previously inactivated (e.g. by thermal treatments), or attenuated (e.g. by multiple passages in suboptimal growth conditions).[40] Such viruses, which lost the ability to cause acute infection, allow the immune system to recognize them as exogenous pathogens, promoting the production of specific antibodies and memory-T lymphocytes.[40] The genetic vaccines against COVID-19 which obtained the conditional authorization for use in the European Union, namely the adenoviral-based vaccines (produced by AstraZeneca and Janssen) and the mRNA vaccines (produced by Pfizer/BioNTech and Moderna), encode genetic information, which enables human cells to produce a viral antigen. More precisely, the aforementioned vaccines induce the protein synthesis machinery of human cells to

[34] Pardi et al. 2018. mRNA vaccines - a new era in vaccinology. Nat. Rev. Drug Discov. 17 (4), 261–279https://doi.org/10.1038/nrd.2017.243
[35] Van Lint et al. The ReNAissanCe of mRNA-based cancer therapy. Expert Rev. Vaccines 14 (2), 235–251. https://doi.org/10.1586/14760584.2015.957685
[36] Martini et al. 2019. A new era for rare genetic diseases: messenger RNA therapy. Hum. Gene Ther. 30 (10), 1180–1189.
[37] Doulberis et al. 2021. Does COVID-19 vaccination warrant the classical principle "ofelein i mi vlaptin. Medicina (Kaunas). 57 (3), 253.
[38] https://rwmalonemd.substack.com/p/a-health-public-policy-nightmare?utm_source=url&s=r
[39] Discrete immune response signature to SARS-CoV-2 mRNA vaccination versus infection medRxiv preprint (2021), 10.1101/2021.04.20.21255677
[40] Sell S. How vaccines work: immune effector mechanisms and designer vaccines. *Expert Rev Vaccines*. 2019; **18**: 993- 1015.

translate the genetic code of the spike protein which is located in/part of the viral capsid of SARS-CoV-2.[41] Upon its translation by the ribosomes, the spike protein gets processed by the Golgi apparatus and presented to the immune system in two forms:

i) as an entire protein, displayed on the cellular membrane, which can be recognized by B cells and T-helper cells; or

ii) ii) in the form of fragments loaded on the major histocompatibility complex I(MHCI), which presents the endogenous antigens to CD8+ T lymphocytes.

The immune system recognizes the exogenous antigen, initiates the inflammatory response and the subsequent steps leading to the production of specific antibodies by the B cells.[41] In human cells, the antigen presentation process is performed by the MHC I and II, and this mechanism is essential for the cell-mediated immunity.[42] The MHC I is a protein complex, located on the membrane of all nucleated cells, which presents to CD8+ lymphocytes fragments of endogenous antigens, generated upon the proteasomal degradation of intracellular proteins.[42] This mechanism allows the immune system to constantly screen the proteosynthetic activity of all nucleated cells of the body, in order to detect when a cell is synthesizing viral or mutant proteins. The MHC II is located on the membranes of professional antigen-presenting cells (APCs), such as macrophages, monocytes, B cells and dendritic cells, and it displays fragments of exogenous antigens ingested around the body to CD4+ lymphocytes.[42] In some cases, MHC II molecules can be found even on endothelial cells, as a consequence of inflammatory signals.[42] When a CD8+ or CD4+ lymphocyte detects a cell expressing a viral gene (e.g. due to an infection), a mutant gene (e.g. due to cancer) or a foreign gene (e.g. due to a transplant), it binds the MHC activating the immune response that leads to the destruction of the abnormal cell.[42] The aforementioned processes are essential for understanding the differences between the 'traditional' and the genetic vaccines, in terms of antigen presentation. The 'traditional' vaccines generally do not take over human cellular machinery and induce human cells to produce viral proteins, and thus, human cells do not expose viral antigens deriving from their proteosynthetic activity. On the contrary, the genetic vaccines against COVID-19 induce human cells to produce the spike protein, relying intrinsically to an autoimmune reaction, by antigen presentation on the human cell surface and flagging those cells, on any given organ since the vaccine doesn't stay in the shoulder, the injection site, as "foreign, infected, etc" causing the immune system to react with apoptosis, "cell death". Biodistribution studies are fundamental to determine in which tissues and organs an injected compound travels and accumulates.

As concerns the Pfizer/BioNTech BNT162b2 vaccine, it is injected into the deltoid muscle, which drains primarily to the axillary lymph nodes. Theoretically, the lipid nanoparticles (LNPs) in which the mRNA is encapsulated should have a very restricted biodistribution, targeting only the draining axillary lymph nodes[43] and remaining in that location. However, a pharmacokinetic study performed by Pfizer for the Japanese regulatory agency shows that the LNPs display an off-target distribution on rodents, accumulating in organs such as the spleen, liver, pituitary gland, thyroid, ovaries and in other tissues.[44] Similarly, the results of the European Medicines Agency (EMA) assessment reports

[41] Mascellino MT, Di Timoteo F, De Angelis M, et al. Overview of the main anti-SARS-CoV-2 vaccines: mechanism of action, Efficacy and Safety. *Infect Drug Resist*. 2021; **14**: 3459- 3476.

[42] Rock KL, Reits E, Neefjes J. Present yourself! By MHC Class I and MHC Class II molecules. *Trends Immunol*. 2016; **37**: 724- 737.

[43] Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med*. 2020; **383**(27): 2603- 2615.

[44] SARS-CoV-2 mRNA Vaccine (BNT162, PF-0 7302048): 2.6.5.5B. Pharmacokinetics: organ distribution continued, report number: 185350. Page 6. Accessed 23 July 2021. Available at: https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf Google Scholar

show an off-target distribution of the LNPs used by Pfizer/BioNTech and Moderna, in the liver and other organs of rodents.[45] [46]

Another harmful source of toxicity has proven to be the spike protein itself. A study measured the longitudinal plasma samples collected from recipients of the mRNA-1273 Moderna vaccine.[47] The study shows that considerable amounts of spike protein, as well as the cleaved S1 subunit, can be detected in the blood plasma several days after the inoculation. It is believed that the cellular immune responses triggered by Tcell activation, which occur days after the inoculation, lead to the death of cells presenting the spike protein, releasing it into the bloodstream.[47] The fact that the spike protein is released in the bloodstream, involves even the antigen presentation process mediated by the MHC II, due to the intake of the viral protein around the body by the APCs. Up to now, more than 1000 peer-reviewed studies evidence a multitude of adverse events in COVID-19 vaccine recipients.[48] Such studies report severe adverse reactions following vaccination, including thrombosis, thrombocytopenia, myocarditis, pericarditis, cardiac arrhythmias, nervous system disorders and other alterations. It is noteworthy that several of the aforesaid side effects had already been reported in the confidential post-authorization cumulative analysis released as part of a Freedom of Information Act (FOIA) procedure, which provides data on deaths and adverse events recorded by Pfizer between 14 December 2020 and 28 February 2021.[9] Just 11 weeks in the vaccination program these statistics were recorded:

- **Cardiovascular AESIs (Adverse event of special interest) 1403**
  Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6);
  - ✓ Relevant event onset latency (n = 1209): Range from <24 hours to21 days, median <24 hours
  - ✓ Relevant event outcome: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380);
- **Thromboembolic Events 151**
  Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism,Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2);
  - ✓ Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days;
  - ✓ Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42).
- **Stroke 275**
  Indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke,
  Cerebellar infarction and Thrombotic stroke (2 each);

[45]EMA. Assessment report Comirnaty Common name: COVID-19 mRNA vaccine (nucleosidemodified) [WWW Document]. 2020. Accessed 3.14.21. https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdfGoogle Scholar

[46] EMA. Assessment report COVID-19 vaccine moderna common name: COVID-19 mRNA vaccine (nucleoside-modified) [WWW document]. 2020. Accessed 3.14.21. https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-moderna-eparpublic-assessment-report_en.pdf Google Scholar

[47] Ogata AF, Cheng CA, Desjardins M, et al. Circulating severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine antigen detected in the plasma of mRNA-1273 vaccine recipients. *Clin Infect Dis*. 2022; **74**(4): 715- 718.

[48] ICA. *1000 Peer Reviewed Studies Questioning Covid-19 Vaccine Safety*. Informedchoice; 2022, Accessed March 7, 2022. https://www.informedchoiceaustralia.com/post/1000-peer-reviewed-studies-questioning-covid-19-vaccine-safety Google Scholar

Indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each);

- ✓ Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days;
- ✓ Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83).

- **Neurological AESIs (including demyelination)501**
  Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each);
  - ✓ Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day;
  - ✓ Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161).
- **Deaths 1223**

It is essential to underline that every human cell that intakes the LNPs and translates the viral protein (in case of the mRNA vaccines), or that gets infected by the adenovirus and expresses and translates the viral protein (in case of the adenovirus-based vaccines), is inevitably recognized as a threat by the immune system and killed. There are no exceptions to this mechanism.[49] The severity of the resulting damage and the consequences for health depend on the quantity of the cells involved, on the type of tissue and on the strength of the following autoimmune reaction. For instance, if the mRNA contained in the LNPs would get internalized by cardiac myocytes, and such cells would produce the spike protein, the resulting inflammation would likely lead to the necrosis of the myocardium, with an extent proportional to the number of involved cells. Therefore, it is fundamental to perform pharmacokinetic evaluations in humans, in order to determine the exact biodistribution of the vaccines against COVID-19, and thus to identify the possible tissues at threat.

Vaccines generally depend upon adjuvants such as aluminium and squalene to provoke immune cells to migrate to the injection site immediately after vaccination. In the history of mRNA vaccine development, it was initially hoped that the mRNA itself could serve as its own adjuvant. This is because human cells recognize viral RNA as foreign, and this leads to upregulation of type I Interferon, IFNs.[11]
Impaired type I IFN signalling is linked to many disease risks, most notably cancer, as type I IFN signalling suppresses proliferation of both viruses and cancer cells by arresting the cell cycle.

However, with time it became clear that there were problems with this approach, both because the intense reaction could cause flu-like symptoms and because IFN-α could launch a cascade response that would lead to the breakdown of the mRNA before it could produce adequate amounts of SARS-CoV-2 spike glycoprotein to induce an immune response.[50] A breakthrough came when it was discovered experimentally that the mRNA coding for the spike protein could be modified in specific ways that would essentially fool the human cells into recognizing it as harmless human RNA. A

[49] Role of the antigen presentation process in the immunization mechanism of the genetic vaccines against COVID-19 and the need for biodistribution evaluations P. Polykretis
[50] De Beukelaer et al 2012-2020 Type I interferons interfere with the capacity of mRNA lipoplex vaccines to elicit cytolytic T cell responses.

seminal paper[51] demonstrated through a series of *in vitro* experiments that a simple modification to the mRNA such that all uridines were replaced with pseudouridine could dramatically reduce innate immune activation against exogenous mRNA.[52] Later it was discovered that 1-methylpseudouridine as a replacement for uridine was even more effective than pseudouridine and could essentially abolish the TLR response to the mRNA, preventing the activation of blood-derived dendritic cells. This modification is applied in both the mRNA vaccines on the market[53].

Prolonged detection of vaccine mRNA in lymph node germinal centers and spike antigen in lymph node germinal centers and blood following SARSCoV-2 mRNA vaccination was seen in a study earlier this year.[54] The biodistribution, quantity, and persistence of vaccine mRNA and spike antigen after vaccination and viral antigens after SARS-CoV-2 infection are incompletely understood but are likely to be major determinants of immune responses. Researchers performed in situ hybridization with control and SARS-CoV-2 vaccine mRNA-specific RNA Scope probes in the core needle biopsies of the ipsilateral axillary lymph node that were collected 7–60 days after the second dose of mRNA-1273 or BNT162b2 vaccination and detected vaccine mRNA collected in the germinal centers of lymph nodes on days 7, 16, and 37 postvaccination, with lower but still appreciable specific signal at day 60. [54] Immunohistochemical staining for spike antigen in mRNA-vaccinated patient lymph nodes varied between individuals but showed abundant spike protein in germinal centers 16 days post-second dose, with spike antigen still present as late as 60 days post-second dose. This is most likely due to the modification of the mRNA, replacing the uridine for a pseudouridine, resulting in the body no longer identifying the mRNA as foreign.[54]
In another study Pathologists Prof. Arne Burkhardt and Prof. Walter Lang and their team[55] succeeded in reliably detecting the vaccine spike protein in the vascular system of a person who died 4 months after the vaccination and who had vascular lesions and vaccine-induced myocarditis. Detection was successful using an antibody specific for the spike protein using conventional immunohistochemistry on the tissue section. The suspicion that the spike protein formed in the body as a result of the vaccination against COVID-19 could be responsible for the pathologically determined inflammation and lesions in vessels has thereby been confirmed immune histologically for the first time. This team of scientist led by Prof. Burkhardt and Lang in a letter asked 10 questions to BioNTech[55], unfortunately they did not answer the question on the duration of spike protein formation and nor were they wiling to answer the question regarding the number of lipid nanoparticles in a Comirnaty dose. The question as to which cells and tissues spike proteins are formed was neither answered, however when answering another question, BioNTech made a reference to vaccine particle distribution studies in mice and rats, which showed that these were detectable throughout the entire body, the particles did not remain at the injection site.

Research shows the antibodies induced by the vaccines fade in as little as 3–10 weeks after the second dose,[56] such that people are being advised to seek booster shots at regular intervals. It has also become apparent that rapidly emerging variants such as the Delta and now the Omicron strain are showing resistance to the antibodies induced by the vaccines, through mutations in the spike protein.[57] Furthermore, it has become clear that the vaccines do not prevent transmission of the disease, but can only be claimed to reduce symptom severity.[58] A study comparing vaccination rates

[51] Karikó et al 2005 Suppression of RNA recognition by toll-like receptors: the impact of nucleoside modification and the evolutionary origin of RNA
[52] Andries et al 2015 N1-methylpseudouridine-incorperated mRNA outperforms pseudouridine-incorperated mRNA by providing enhanced protein expression and reduced immunogenicity in mammalian cell lines and mice
[53] Park et al 2021 mRNA vaccines for COVID-19: what, why and how.
[54] https://www.cell.com/cell/pdf/S0092-8674(22)00076-9.pdf
[55] https://www.pathologie-konferenz.de/
[56] Shrotri et al. 2021 Spike-antibdy warning after second dose of BNT162b2 or ChAdOx1. Lancet 398 (10298), 385-387
[57] Yahi et al 2021. Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? J. Infect. 83 (5), 607–635. https://doi.org/10.1016/j.jinf.2021.08.010.
[58] Kampf et al 2021 The epidemiological relevance of the COVID-19-vaccinated population is increasing. Lancet. Reg. Health – Europ. 11, 100272 https://doi.org/10.1016/j.lanepe.2021.100272

with COVID-19 infection rates across 68 countries and 2947 counties in the United States in early September 2021, found no correlation between the two, suggesting that these vaccines do not protect from spread of the disease.[59] Regarding symptom severity, even this aspect is beginning to be in doubt, as demonstrated by an outbreak in an Israeli hospital that led to the death of five fully vaccinated hospital patients.[60] Similarly, Brosh-Nissimov et al. (2021)[61] reported that 34/152 (22%) of fully vaccinated patients among 17 Israeli hospitals died of COVID-19.
Even more worrisome, shocking and confirming statistics were updated on April 17th 2022 on the Public Health of Canada website, the COVID-19 daily epidemiology update.[62] Between February 6th and May 1st of this year, 72% of the COVID deaths was on account of people who were vaccinated.

In short:

- mRNA vaccines promote sustained synthesis of the SARS-CoV-2 spike protein, without any knowledge of or control over the duration.
- Prolonged spike protein expression results in a maintained risk of adverse events long after the inoculation. (research shows at least up to 4 months)
- The lipid nanoparticles in which the mRNA is encapsulated, doesn't have the theoretical very restricted biodistribution, but an off-target distribution likely to accumulate in organs.
- Suppression of type I interferon responses results in impaired innate immunity.
- The mRNA vaccines potentially cause increased risk to infectious diseases and cancer.
- Mechanisms and processes involving mRNA are neither fully identified and mapped nor fully understood, resulting in still unresolved issues.

Considering all, mRNA in general is an immature, novel technology, very complex and not fully developed, this alone is reason enough to ban the mRNA technology for now and the near future from aviation. We cannot allow pilots to be injected repeatedly with a medical product with unresolved issues, which need time and research to be resolved. As pharmaceutical companies are starting with developing new mRNA vaccines for other infectious diseases as influenza we need to stop this from further increasing safety risks in aviation. The rules and guidelines in aviation have been broken with these COVID vaccines and this needs to be stopped without further delay, for all mRNA vaccines and mRNA based medical products.
The recent newly developed booster shots to protect against Omicron subvariants BA.1 and BA.4-5 have received Conditional Marketing Authorization. This CMA is based on a study where only 300 people were given Comirnaty BA.1 and based on the conclusions of this study Comirnaty BA.4-5 also received CMA, without any human study.[63] *'Comirnaty Original/Omicron BA.4-5 is **expected** to trigger immunity against both the original strain of SARS-CoV-2 and the subvariants BA.4 and BA.5, and its safety profile is **expected** to be comparable to that of Comirnaty and Comirnaty Original/Omicron BA.1.* This is absolutely unacceptable, in general, but especially regarding aviation safety.'[63] How can a medical product which has been conditionally approved, based on assumptions made on results from a study of a different booster, with a cohort of only 300 people, ever be allowed in aviation?

Although the main focus here is on the mRNA vaccines, other vaccines, like AstraZeneca and Janssen have shown to be harmful as well. These vector vaccines contain an inactivated cold virus (that

[59] Subramanian et al. Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States. Eur. J. Epidemiol. 2021, 1-4. doi: 10.1007/s10654-021-00808-7.
[60] Shitrit, et al 2021. Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021. Euro Surveill. 26 (39), 2100822 https://doi.org/10.2807/1560-7917.ES.2021.26.39.2100822.
[61] Brosh-Nissimov,et al., 2021. BNT162b2 vaccine breakthrough: clinical characteristics of 152 fully vaccinated hospitalized COVID-19 patients in Israel. Clin. Microbiol. Infect. 27 (11), 1652–1657. https://doi.org/10.1016/j.cmi.2021.06.036.
[62] https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html
[63] https://www.ema.europa.eu/en/documents/overview/comirnaty-epar-medicine-overview_en.pdf

cannot replicate) with an instruction (code) that tells your cells to make spike proteins. The immune system reacts by producing antibodies, just as it does in response to the RNA vaccines.[64] These vaccines should also be banned from aviation as they are new, rapidly developed and as a consequence there is little data on safety, efficacy but many adverse events. Most countries paused or stopped using these vaccines early on in their vaccination programs, as a result of many reported cases of people who developed widespread blood clots, low platelet counts, and internal bleeding; *"It's a very special picture" of symptoms, says Steinar Madsen, medical director of the Norwegian Medicines Agency. "Our leading haematologist said he had never seen anything quite like it."*[65]

Adverse Events

VigiAccess[66] is a web-based tool for searching VigiBase to retrieve summarised statistical representation of the data available on potential side effects that have been reported to the World Health Organization Programme for International Drug Monitoring (WHO PIDM). VigiAccess was designed to deliver greater transparency to the medical safety system by providing a basic overview of the potential side effects reported in association with any particular medicinal product.

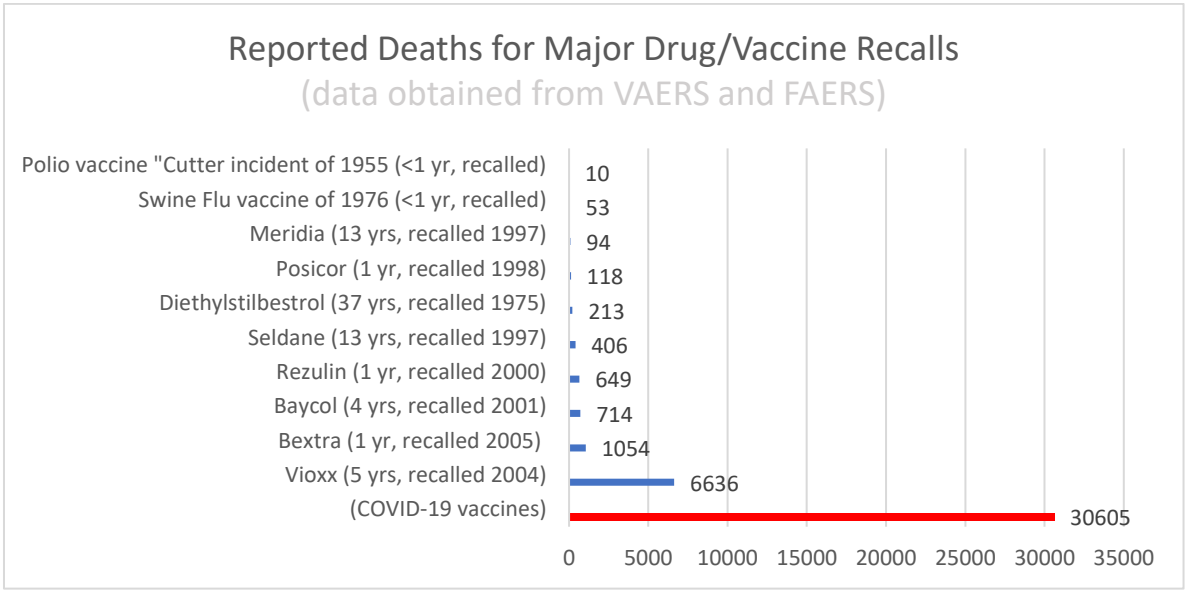
Vaccine	Years	ADRs (Adverse Drug Reaction)
Mumps vaccine	1972-2022	728
Rubella vaccine	1971-2022	2.649
Measles vaccine	1968-2022	6.261
Smallpox vaccine	1968-2022	7.440
Tetanus vaccine	1968-2022	15.527
Hepatitis A vaccine	1989-2022	48.802
Rotavirus vaccine	2000-2022	75.056
Hepatitis B vaccine	1984-2022	107.738
Polio vaccine	1968-2022	126.704
Meningococcal vaccine	1976-2022	141.150
Pneumococcal vaccine	1980-2022	251.579
Influenza vaccine	1968-2022	287.338
Covid-19 vaccine	**2020-2022**	**4.259.683**

Dataset 11-09-2022

While these statistics are already worrisome, bear in mind that under reporting of adverse events in Pharmacovigilance systems is a well-known fact. A meta-analysis done in 2006[67] and more recent studies[68] show a staggering 82 to 98 percent under reporting, with a median under reporting rate of 94 percent. This figure is also confirmed by FDA, where the under reporting rate for VAERS is between 87-99 percent. A study by Harvard Pilgrim Health care, Inc. shows only 1-13% of serious events are reported to the FDA and fewer than 1% of vaccine adverse events are reported.[68]
So the actual adverse event figure for the COVID-19 vaccines is more likely to be at least somewhere around 70.000.000.
Over the 31 years history of VAERS up to February 3 2022, there were a total of 10.321 deaths reported as a "symptom" in association with any vaccine and 8.241 (80%) of those deaths were

[64] https://www.rivm.nl/en/covid-19-vaccination/questions-and-background-information/vaccines#:~:text=The%20vaccines%20made%20by%20AstraZeneca,response%20to%20the%20RNA%20vaccines.
[65] https://www.science.org/doi/10.1126/science.371.6536.1294
[66] Vigiaccess.org
[67] Under-reporting of adverse drug reactions: A systemic review https://pubmed.ncbi.nlm.nih.gov/16689555/
[68] https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

linked to COVID-19 vaccines. Importantly, only 14% of COVID-19 VAERS-reported deaths as of June 2021 could have vaccination ruled out as a cause.[11] [69] The most up to date VAERS data reports more than 30.000 deaths related to COVID-19 vaccines and less than 10.000 for all other vaccines combined since 1990.[70]This strongly suggests that these unprecedented vaccines exhibit unusual mechanisms of toxicity that go well beyond what is seen with more traditional vaccines.
The data in the Pfizer post authorization adverse event report shows 1223 deaths in just the first 12 weeks of vaccination. Looking back in history these statistics are already well above any number of deaths for which a medical product has been taken off market. In 1976, the swine flu mass vaccination campaign was halted after a series of adverse event reports including 53 deaths. The polio vaccine was recalled in less than one year after 10 reported deaths.[71] The number and severity of adverse event reports including deaths related to COVID-19 vaccines is unprecedented and more than sufficient for an immediate recall of all COVID-19 vaccines. The Pfizer post authorization data alone showed already more than enough harmful data to halt these vaccines, however they are still on the market and even worse, still available and recommended to pilots.



Data updated through: August 8th 2022[72]

We have confined our focus, among many known adverse events to the vaccines, to only those that could result in immediate incapacitation of a pilot:

- Cardiac: including, but not limited to pericarditis and myocarditis.

  Pericarditis is an inflammation that affects the pericardium, a thin membrane that surrounds the heart. This can lead to debilitating symptoms that can impact daily life, similar to symptoms of a heart attack, the most common sign of pericarditis is sharp chest pains. There are many types of pericarditis ranging from acute to chronic, and the signs may differ for each patient.[73] If you neglect to seek treatment for pericarditis, your symptoms can

[69]McLachlan, S et al , 2021. Analysis of COVID-19 vaccine death reports from the vaccine adverse events reporting system (VAERS) database. Preprint. https://doi.org/10.13140/RG.2.2.26987.26402.
[70] https://vaersanalysis.info/2022/09/02/vaers-summary-for-covid-19-vaccines-through-8-26-2022/
[71] https://worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report/
[72] https://vaersanalysis.info/2022/05/14/vaers-summary-for-covid-19-vaccines-through-5-6-2022/
[73] https://www.myocarditisfoundation.org/pericarditis/

transform into long-term health issues with severe implications. Some of the most common complications of pericarditis include:

- Cardiac Tamponade
- Pericardial effusion
- Infection
- Myocarditis

Myocarditis is an inflammation of the heart muscle. This inflammation enlarges and weakens the heart, creates scar tissue and forces it to work harder to circulate blood and oxygen throughout the body.[74]

Myocarditis is a particularly insidious disease with multiple reported manifestations, sometimes even without symptoms which makes it an even more dangerous condition regarding flight safety. As exposure to high altitude triggers a series of physiological responses intended to maintain adequate tissue oxygenation. These adaptive mechanisms may cause major problems in people with pre-existing cardiovascular disease who are not able to compensate for such physiological changes.[75] There is vast literature that highlights asymptomatic cases of myocarditis, which are often underdiagnosed, as well as cases in which myocarditis can possibly be misdiagnosed as acute coronary syndrome (ACS). Moreover, several comprehensive studies demonstrate that myocarditis is a major cause of sudden, unexpected deaths in adults less than 40 years of age, and assess that it is responsible for 12–20% of these deaths[76] [77] [78], hence a very serious threat to health and safety in aviation.

Mortality rates for myocarditis have been reported by the The Myocarditis Treatment Trial[79], 20% and 56% at 1 year and 4.3 years, respectively. Survival with giant cell myocarditis is substantially lower, with <20% of patients surviving 5 years.[80] These outcomes are similar to the Mayo Clinic's observational data of 5-year survival rates that approximate 50%.[81]

Number of symptoms reported in VAERS, restricted to the US population, for the year 2021, for various disorders of the heart, showing total counts for COVID-19 vaccines and for all vaccines.

Symptom	Covid-19 Vaccines	All Vaccines	Percent COVID-19
Myocarditis	2,322	2,361	98.3
Arrest	1,319	1,371	96.2
Arrhythmia	1,069	1,087	98.3
Myocardial infarction	2,224	2,272	97.9
Cardiac failure	1,156	1,190	97.1
TOTAL	8,090	8,281	97.7

11

[74] https://www.myocarditisfoundation.org/about-myocarditis/

[75] https://cardiovascmed.ch/article/doi/cvm.2017.00478

[76] Feldman, A. M. & McNamara, D. Myocarditis. *N. Engl. J. Med.* **343**, 1388–1398 (2000).

[77] Ali-Ahmed, F., Dalgaard, F. & Al-Khatib, S. M. Sudden cardiac death in patients with myocarditis: Evaluation, risk stratification, and management. *Am. Heart J.* **220**, 29–40. https:// doi. org/ 10. 1016/j. ahj. 2019. 08. 007 (2020).

[78] Drory, Y. *et al.* Sudden unexpected death in persons less than 40 years of age. *Am. J. Cardiol.* **68**, 1388–1392. https:// doi. org/ 10. 1016/ 0002- 9149(91) 90251-f (1991).

[79] Mason et al, for the Myocarditis Treatment Trial Investigators. A clinical trial of immunosuppressive therapy for myocarditis. *N Engl J Med.* 1995; *333*: 269–275. Crossref. PubMed.

[80] Cooper LT, et al, for the Multicenter Giant Cell Myocarditis Study Group Investigators. Idiopathic giant-cell myocarditis: natural history and treatment. *N Engl J Med.* 1997; *336*: 1860–1866. Crossref. PubMed.

[81] Grogan M, Redfield MM, Bailey KR, Reeder GS, Gersh RJ, Edwards WD, Rodeheffer RJ. Long-term outcome of patients with biopsy-proved myocarditis: comparison with idiopathic dilated cardiomyopathy. *J Am Coll Cardiol.* 1995; *26*: 80–84. Crossref. PubMed.

➢ Clotting, Embolism and Thrombosis

Thrombosis is the formation of a blood clot, known as thrombus, within a blood vessel. It prevents blood from flowing normally through the circulatory system. Complications of thrombosis can be life-threatening, such as a stroke or heart attack.[82] There are two main types of thrombosis:

- Arterial thrombosis refers to a blood clot that blocks an artery. Arteries carry blood away from the heart to the organs. Arterial blood clots can block blood flow to the heart and brain, often resulting in a heart attack or stroke.
- Venous thrombosis also known as venous thromboembolism or VTE, refers to a blood clot in a vein. Veins carry blood from the organs to the heart. VTE is a condition that includes deep vein thrombosis DVT and pulmonary embolism.

An embolism is the lodging of an embolus, a blockage-causing piece of material, inside a blood vessel. In the case of the vaccine side effects the embolus is a blood clot (thrombus). An embolism can cause partial or total blockage of blood flow in the affected vessel. Such a blockage (a vascular occlusion) may affect a part of the body distant from the origin of the embolus.

The onset interval, time after inoculation, for thrombosis, DVT and pulmonary thrombosis in the table below all have a sharp peak in the 15-30 days range. This coincides with pulmonary embolism (blood clot in the lung), a life-threatening condition, also 15-30 day interval.[11]

Number of symptoms reported in VAERS, restricted to the US population, for the year 2021, for various specific types of thrombosis, showing total counts for COVID-19 vaccines and for all vaccines. Pulmonary embolism, a highly related symptom, is also shown.

Symptom	Covid-19 Vaccines	All Vaccines	Percent COVID-19
Thrombosis	3,899	3,951	98.7
Deep vein thrombosis	2,275	2,297	99.0
Pulmonary thrombosis	631	646	97.7
Cerebral thrombosis	211	215	98.1
Portal vein thrombosis	89	90	98.9
Superficial vein thrombosis	81	81	100
Peripheral artery thrombosis	74	74	100
Mesenteric vein thrombosis	55	56	98.2
Venous thrombosis	41	41	100
TOTAL	7,356	7,451	98.7
Pulmonary embolism	3,100	3,137	98.8

11

These statistics once more show the numbers reported in VAERS regarding COVID-19 vaccines are absurd compared to all other vaccines combined.

➢ Neurologic

A Europe based case study tracking neurological symptoms following COVID-19 vaccination identified debilitating neurological conditions.[83] The divers diagnosis included cerebral

[82] https://thrombosis.org/patients/what-is-thrombosis/

[83] Khayat-Khoei, M., Bhattacharyya, S., Katz, J., Harrison, D., Tauhid, S., Bruso, P., Houtchens, M.K., Edwards, K.R., Bakshi, R., 2021 Sep 4. COVID-19 mRNA vaccination leading to CNS inflammation: a case series. J. Neurol. 1–14. https://doi. org/10.1007/s00415-021-10780-7

venous sinus thrombosis (occurs when a blood clot forms in the brain's venous sinuses. This prevents blood from draining out of the brain. As a result, blood cells may break and leak blood into the brain tissues, forming a haemorrhage). Nervous system demyelinating diseases, a demyelinating disease is any condition that results in damage to the protective covering (myelin sheath) of nerves throughout the nervous system. When the myelin sheath is damaged, nerve impulse transmission is impaired, causing neurological problems.[84] Inflammatory neuropathies are acquired disorders of peripheral nerves and occasionally of the central nervous system that can affect individuals at any age. The course can be monophasic, relapsing, or progressive.[85] And optic neuropathy. Optic neuropathy is a generic term indicating various medical condition of the optic nerve, causing impaired vision or blindness.[86]

Due to the known under reporting of vaccine adverse events, enriching current vaccine safety surveillance systems with additional data sources may improve the understanding of COVID-19 vaccine safety.

To do this a unique dataset from Israel National Emergency Medical Services (EMS) from 2019 to 2021 was used to evaluate the association between the volume of cardiac arrest (CA) and acute coronary syndrome (ACS) EMS calls in the 16–39-year-old population with potential factors including COVID-19 infection and vaccination rates.[87] An increase of over 25% was detected in both call types during January–May 2021, compared with the years 2019–2020. Using Negative Binomial regression models, the weekly emergency call counts were significantly associated with the rates of 1st and 2nd vaccine doses administered to this age group but were not with COVID-19 infection rates. While not establishing causal relationships, the findings raise concerns regarding vaccine-induced undetected severe cardiovascular side-effects and underscore the already established causal relationship between vaccines and myocarditis, a frequent cause of unexpected cardiac arrest in young individuals.

Data from regulatory surveillance and self-reporting systems, including the Vaccine Adverse events Reporting System (VAERS) in the United States[88], the Yellow Card System in the United Kingdom[89] and the EudraVigilance system in Europe[90], associate similar cardiovascular side-effects with a number of COVID-19 vaccines currently in use. More recently, several studies established probable causal relationship between the mRNA vaccines of BNT162b2 and mRNA-1273[91 92 93 94]as well as adenovirus (ChAdOx1) vaccines[95] with myocarditis, primarily in children, young and middle-age adults. The study by the Ministry of Health in Israel, a country with one of the highest vaccination rates in the world, assesses the risk of myocarditis after receiving the 2nd vaccine dose to be

[84] https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/expert-answers/demyelinating-disease/faq-20058521#:~:text=A%20demyelinating%20disease%20is%20any,even%20stop%2C%20causing%20neurological%20problems.

[85]https://pubmed.ncbi.nlm.nih.gov/20941668/#:~:text=Inflammatory%20neuropathies%20are%20acquired%20disorders,classified%20as%20acute%20or%20chronic.

[86] https://kraffeye.com/blog/optic-neuropathy-symptoms-causes-treatment#:~:text=Optic%20neuropathy%20is%20a%20catch,over%20time%2C%20when%20not%20treated.

[87] https://www.nature.com/articles/s41598-022-10928-z

[88] *Vaccine Adverse Event Reporting System (VAERS)*. https:// vaers. hhs. gov/

[89] https://yellowcard.mhra.gov.uk/

[90] *EudraVigilance - European database of suspected adverse drug reaction reports: How to report a side effect*. https:// www. adrre ports. eu/ en/ report_ side_ effect. html

[91] *Surveillance of Myocarditis (Inflammation of the Heart Muscle) Cases Between December 2020 and May 2021 (Including)*. https://www. gov. il/ en/ depar tments/ news/ 01062 021- 03

[92] Bozkurt, B., Kamat, I. & Hotez, P. J. Myocarditis with COVID-19 mRNA vaccines. *Circulation* **144**, 471–484 (2021).

[93] Larson, K. F. *et al.* Myocarditis after BNT162b2 and mRNA-1273 vaccination. *Circulation* https:// doi. org/ 10. 1161/ CIRCU LATIO NAHA. 121. 055913 (2021).

[94] Verma, A. K., Lavine, K. J. & Lin, C.-Y. Myocarditis after Covid-19 mRNA vaccination. *N. Engl. J. Med.* https:// doi. org/ 10. 1056/ NEJMc 21099 75 (2021).

[95] Patone, M. *et al.* Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection. *Nat. Med.* **66**, 1–13 (2021).

between 1 in 3000 to 1 in 6000 in men of age 16–24 and 1 in 120,000 in men under 30.[96] [97] A follow up study by the US Centers for Disease Control (CDC) based on the VAERS and V-Safe self-reporting systems further confirms these findings.[98]

Moreover, because the IEMS is a national organization the data provide a more comprehensive access to the respective incidence of the conditions being studied. This stands in contrast to the known very partial and biased access provided by adverse event self-reporting surveillance systems, and highlights the importance of incorporating additional data sources into these systems[99].

However, it is important to highlight several significant differences between the CA and ACS EMS calls. For CA events, it is reasonable to assume that the IEMS data includes almost all of the relevant events, since CA events almost always involve calling EMS services. Moreover, the diagnosis of CA is relatively more straightforward. In contrast, for ACS events, while EMS calls capture a significant fraction of the respective incidents, direct hospital walk-in will not be accounted for in the EMS data. In Israel this is estimated to be 50% of all events. Additionally, the diagnosis of ACS events is more involved, and while EMS protocols during the study period did not change, it is reasonable to assume a higher rate of diagnosis error.

The main finding of this study concerns with increases of over 25% in both the number of CA calls and ACS calls of people in the 16–39 age group during the COVID-19 vaccination. There is a robust and statistically significant association between the weekly CA and ACS call counts, and the rates of 1st and 2nd vaccine doses administered to this age group. At the same time there is no observed statistically significant association between COVID-19 infection rates and the CA and ACS call counts(see the graphs on the next pages). This result is aligned with previous findings which show increases in overall CA incidence were not always associated with higher COVID-19 infections rates at a population level[100] [101] [102], as well as the stability of hospitalization rates related to myocardial infarction throughout the initial COVID-19 wave compared to pre-pandemic baselines in Israel[103]. These results also are mirrored by a report of increased emergency department visits with cardiovascular complaints during the vaccination rollout in Germany[104] as well as increased EMS calls for cardiac incidents in Scotland[105].

[96] Vogel, G. & Couzin-Frankel, J. *Israel reports link between rare cases of heart inflammation and COVID-19 vaccination in young men*

[97] Wise, J. Covid-19: Should we be worried about reports of myocarditis and pericarditis after mRNA vaccines?. *BMJ* **373**, n1635.

[98] *COVID-19 Vaccine safety updates Advisory Committee on Immunization Practices (ACIP) June 23, 2021*. https:// www. cdc. gov/ vacci nes/ acip/ meeti ngs/ downl oads/ slides- 2021- 06/ 03- COVID- Shima bukuro- 508. pdf

[99] Lee et al, Postapproval vaccine safety surveillance for COVID-19 vaccines in the US. *JAMA* **324**, 1937–1938 (2020).

[100] Sun, et al 2021 Worse cardiac arrest outcomes during the COVID-19 pandemic in Boston can be attributed to patient reluctance to seek care: Study examines cardiac arrest outcomes among Boston patients during the COVID-19 pandemic. *Health Aff* https:// doi. org/ 10. 1377/ hltha ff. 2021. 00250

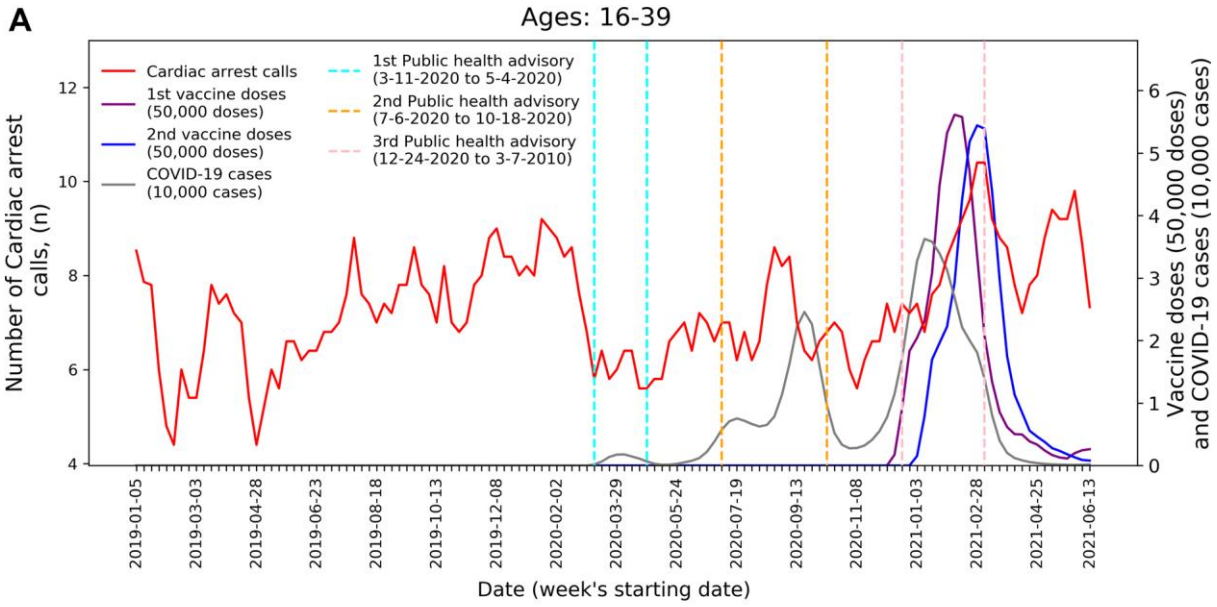
[101] Chan, P. S. *et al.* Outcomes for out-of-hospital cardiac arrest in the United States during the coronavirus disease 2019 pandemic. *JAMA Cardio.* 6, 296–303 (2021).

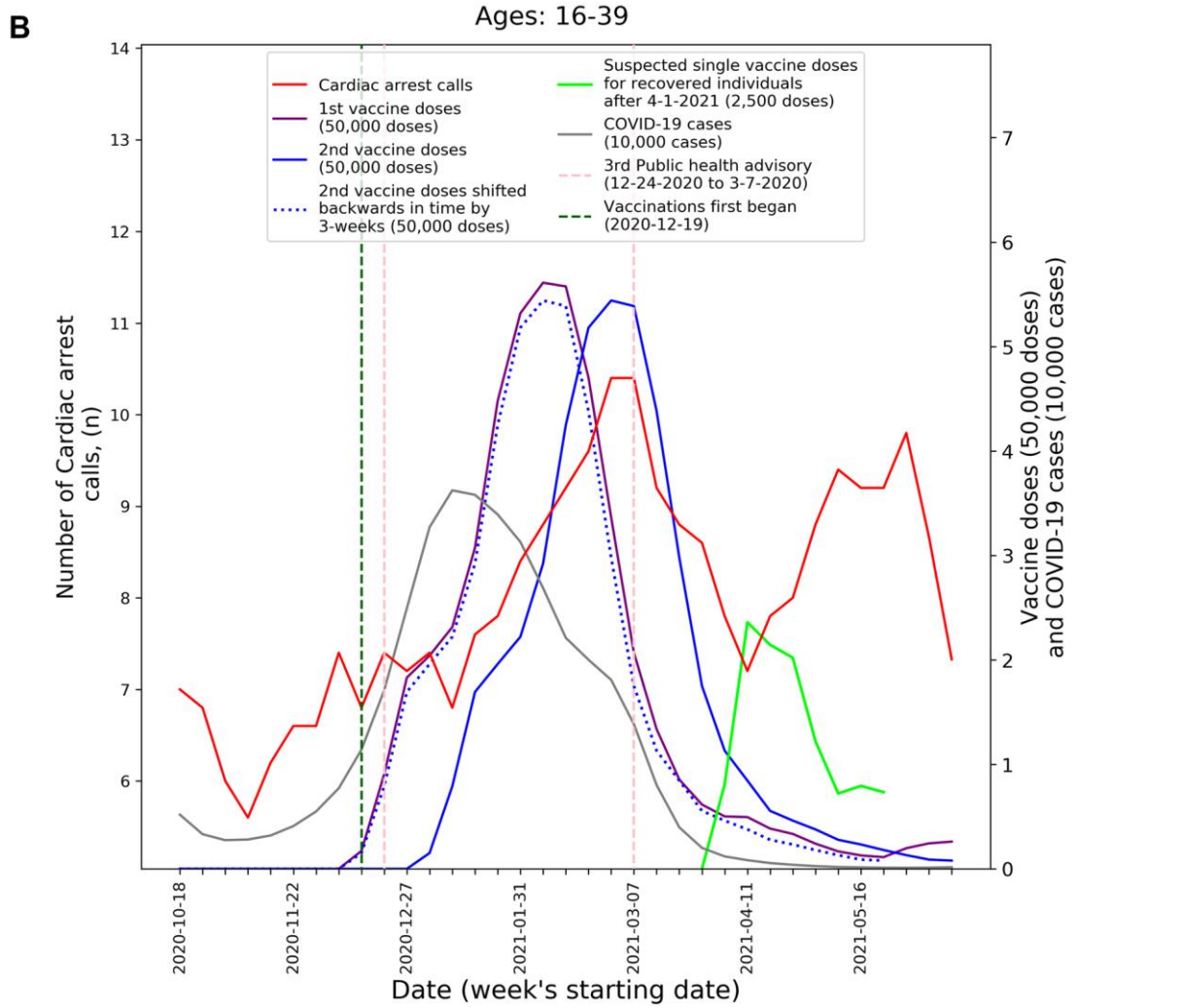
[102] Uy-Evanado, A. *et al.* Out-of-hospital cardiac arrest response and outcomes during the COVID-19 pandemic. *Clin. Electrophysiol.* 7, 6–11

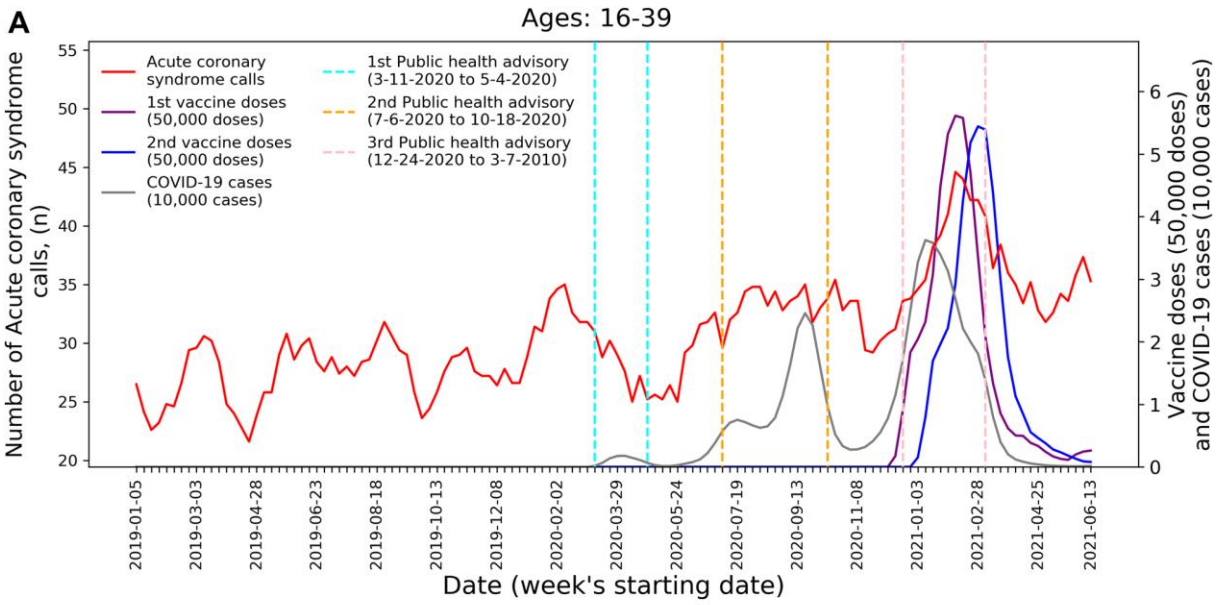
[103] Fardman, A. *et al.* Acute myocardial infarction in the Covid-19 era: Incidence, clinical characteristics and in-hospital outcomes—A multicenter registry. *PLoS ONE* **16**, e0253524 (2021).

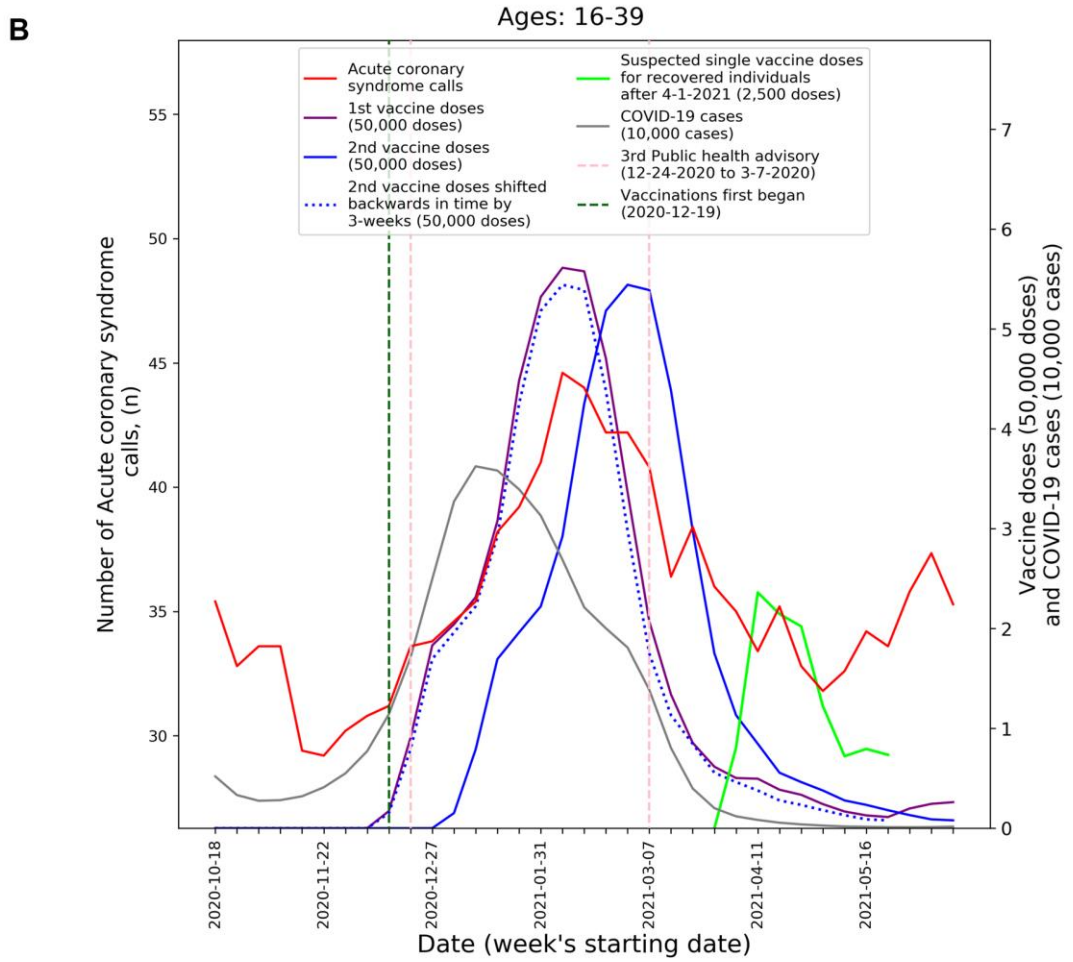
[104] Team, S (Robert Koch-Institut, 2021).

[105] *Public Health Scotland - COVID-19 wider impacts on the health care system*. https:// scotl and. shiny apps. io/ phs- covid- wider- impact/


A
Ages: 16-39
Cardiac arrest calls
1st vaccine doses (50,000 doses)
2nd vaccine doses (50,000 doses)
COVID-19 cases (10,000 cases)
1st Public health advisory (3-11-2020 to 5-4-2020)
2nd Public health advisory (7-6-2020 to 10-18-2020)
3rd Public health advisory (12-24-2020 to 3-7-2010)
Number of Cardiac arrest calls, (n)
Vaccine doses (50,000 doses) and COVID-19 cases (10,000 cases)
Date (week's starting date)


B
Ages: 16-39
Cardiac arrest calls
1st vaccine doses (50,000 doses)
2nd vaccine doses (50,000 doses)
2nd vaccine doses shifted backwards in time by 3-weeks (50,000 doses)
Suspected single vaccine doses for recovered individuals after 4-1-2021 (2,500 doses)
COVID-19 cases (10,000 cases)
3rd Public health advisory (12-24-2020 to 3-7-2020)
Vaccinations first began (2020-12-19)
Number of Cardiac arrest calls, (n)
Vaccine doses (50,000 doses) and COVID-19 cases (10,000 cases)
Date (week's starting date)


A
Ages: 16-39
Acute coronary syndrome calls
1st vaccine doses (50,000 doses)
2nd vaccine doses (50,000 doses)
COVID-19 cases (10,000 cases)
1st Public health advisory (3-11-2020 to 5-4-2020)
2nd Public health advisory (7-6-2020 to 10-18-2020)
3rd Public health advisory (12-24-2020 to 3-7-2010)
Number of Acute coronary syndrome calls, (n)
Vaccine doses (50,000 doses) and COVID-19 cases (10,000 cases)
Date (week's starting date)


B
Ages: 16-39
Acute coronary syndrome calls
1st vaccine doses (50,000 doses)
2nd vaccine doses (50,000 doses)
2nd vaccine doses shifted backwards in time by 3-weeks (50,000 doses)
Suspected single vaccine doses for recovered individuals after 4-1-2021 (2,500 doses)
COVID-19 cases (10,000 cases)
3rd Public health advisory (12-24-2020 to 3-7-2020)
Vaccinations first began (2020-12-19)
Number of Acute coronary syndrome calls, (n)
Vaccine doses (50,000 doses) and COVID-19 cases (10,000 cases)
Date (week's starting date)

Although we have confined our focus to the severe adverse events that pose a direct risk during flight, there are several adverse events which at first sight might not be perceived as severe, but are equally incapacitating during flight and are mentioned in EASA Rules for Medical Requirements[1] as reason to assess pilots as unfit. These adverse events represent an even bigger part of all adverse events reported(bear in mind the underreporting in pharmacovigilance systems), than the severe ones we have focused on and thus make these vaccines utterly dangerous and unsuitable for use in aviation. *'Any therapeutic agent that is likely to significantly interfere with mentation, alertness, vision, coordination, judgement, etc., should be prohibited for all safety-critical personnel.'* ICAO doc 8984 Manual of Civil Aviation Medicine[106]

- **Migraine**
  Applicants with an established diagnosis of migraine or other severe periodic headaches likely to cause a hazard to flight safety should be assessed as unfit. AMC1 MED.B.065 Neurology
- **Haemorrhagic/ischaemic events of the neurological system**
  Applicants with a disorder of the nervous system due to vascular deficiencies including haemorrhagic and ischaemic events should be assessed as unfit. AMC1 MED.B.065 Neurology
- **Syncope**
  Applicants who experienced loss of consciousness without significant warning should be assessed as unfit. AMC1 MED.B.010 Cardiovascular system
- **Impaired consciousness**
  Episode of disturbance of consciousness, In the case of a single episode of disturbance of consciousness, which can be satisfactorily explained, a fit assessment may be considered, but applicants experiencing a recurrence should be assessed as unfit. AMC1 MED.B.065 Neurology
- **Seizure/Epilepsy**
  Applicants with a diagnosis of epilepsy should be assessed as unfit unless there is unequivocal evidence of a syndrome of benign childhood epilepsy associated with a very low risk of recurrence, and unless the applicant has been free of recurrence and off treatment for more than 10 years. One or more convulsive episode after the age of 5 should lead to unfitness. AMC1 MED.B.065 Neurology

Severe Adverse Events	**Reported in VigiAccess**
Myocarditis	25.686
Pericarditis	21.006
Cardiac Arrest	4.996
Arrhythmia	28.825
Thrombosis	18.323
Deep vein Thrombosis	18.332
Pulmonary Embolism	27.044
Less severe but 'unfit' by EASA	
Migraine	45.629
Haemorrhagic/ischaemic events	17.379
Syncope	64.852
Impaired Consciousness	65.979
Seizure/Epilepsy	26.117

Dataset 11-09-2022 [66]

[106] https://www.icao.int/publications/pages/publication.aspx?docnum=8984

The increased risk for flight safety regarding these adverse events stems from the fact that the prolonged production of spike protein in the body makes it impossible to predict when or if one will endure such adverse event. And with the underreporting rate in mind, these number are really serious. It cannot simply be mitigated by a 'no fly' period of 48 hours as prescribed by EASA (SIB 2021-06), as mentioned earlier the spike protein expression was seen at least up to 4 months after inoculation and the median onset for most severe adverse events exceeds 48 hours.

Attached to this letter is a list of pilots in VAERS who have suffered adverse event post-vaccination. It is by no means an exhaustive list. Rather, it represents a sampling of ten individuals, aged 30 to 70, fairly even split between Moderna and Pfizer inoculations (with one Janssen), who were otherwise healthy, many were athletic. But within a short period of time after their vaccination, these pilots suffered vaccine-related adverse events that were very serious:

- Myocardial Infarction (heart attack)
- Atrial Fibrillation
- Pericarditis
- Brain Swelling
- Elevated Intra-Cranial Pressure affecting Spinal Cord and Brain Stem
- Sub-Arachnoid Haemorrhages (Brain Bleed)
- Blindness

Half had cardiac issues, the other half had brain issues, and in a majority of the nine cases, VAERS listed their injury as 'life threatening', permanently disabling' or both. Not only were the large majority of these individuals suffering life-ruining injuries and career-ending injuries, they were not the specimens of pilot health required by aviation industry regulators in order to ensure passenger safety.
That said we urge EASA national CAA's and AMEs to create a database to track pilot adverse events as we fear that medical adverse events post-vaccination in pilots is higher in numbers than currently assumed.

Safety Information Bulletin EASA

We are aware of the Safety Information Bulletin published on 25th of march by EASA, SIB 2021-06[107], which states that pilots should simply not fly for 48 hours post-vaccination, based on the fact that EASA assumes the vaccines to be safe.
Long-term pre-clinical and Phase I safety trials were combined with Phase II trials[108], then phase II and III trials were combined[109] and even those were terminated early and placebo arms given the injections[110], resulting in the inadequacy of these combined phase I, II, and III trials to evaluate mid-term and long-term side effects from mRNA vaccines. Thus, given that multiple years of phase 2 and phase 3 clinical trials were skipped[11 32 110], and that no significant human testing was done in connection with these vaccines and conditional authorization was based on safety data generated

[107] https://www.easa.europa.eu/sib-2021-06
[108] Folegatti PM, Ewer KJ, Aley PK, et al. Safety and immunogenicity of the ChAdOx1 nCoV287 19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, singleblind, randomised controlled trial. Lancet (2020) 396:467–783. doi:10.1016/S0140- 6736(20)31604-23
[109] Ramasamy MN, Minassian AM, Ewer KJ, et al. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. Lancet (2021) 396:1979–93. doi: 10.1016/S0140-6736(20)32466-
[110] https://www.ijbs.com/v17p1461.htm

during trials that lasted only 2 to 3.5 months[108] [109] [111] [112], the undersigned authors of this document would like to know on exactly what comprehensive scientific studies or other basis the designation of 'safe' was predicted? Put simply, how did EASA determine safety, given the wholesale absence of any significant studies on humans, including the absence of any studies on pilots, who often undertake long-haul flights which put their cardiac and vascular system under significant stress and can thus magnify the cardiac and vascular side effects from experimental medical products? It appears to the undersigned that the determination of 'safe' was not issued in good faith nor after actual due diligence, and the only relevant clinical trial of note is the one being conducted on the pilots as we speak.

SIB 2021-06: *'…Although the vast majority of side effects reported so far are mild and do not put into question in any way the safety of the approved vaccines, they may be further enhanced by in-flight conditions while at cruise level, such as lower air pressure and mild hypoxic environment. At this time, no evidence is available regarding the impact of in-flight conditions on the severity of the side effects, nor on the resulting impact on the performance of the crew members during their safety related tasks'.*

The lack of evidence on the impact of in-flight conditions is due to the fact, no studies were performed regarding in-flight conditions, hence no evidence available, so how is it perceived to be safe? However, a lot of studies were already done or ongoing at this time regarding adverse events following inoculation with one of the COVID-19 vaccines, multiple severe adverse events are documented in large numbers which clearly indicate a safety risk, and thus do put into question the safety of these vaccines, especially for pilots. This is contradictory to everything in aviation, every aspect of aviation has one simple fundamental endpoint, is it safe? ' If there is doubt, there is no doubt' as the old aviation saying goes. This safety mentality and the cautiousness towards new medical products is reflected in ICAO doc 8984 Manual of Civil Aviation Medicine: *'The medical examiner should avoid recommending medicines that are new to market; it is better to wait until a medicine is well established and any side effects recognized.'* [106]

The safety mindedness for which aviation is well-known must be preserved, the politicization of these vaccines and their rollout must not be allowed to completely undermine this safety culture. Vaccinated pilots don't even comply anymore to the medical requirements, which is unheard of in aviation and unacceptable.

SIB 2021-06: *'EASA is closely monitoring developments related to the SARS-CoV-2 outbreak and the development and roll-out of vaccines'*

If EASA is closely monitoring developments related to the SARS-CoV-2 outbreak and the development and roll-out of vaccines, why is there no new SIB or any other way of alerting pilots about the increase in adverse events following the inoculations? Or better yet why are the vaccines still perceived safe for pilots, when data collected from studies all around the world and pharmacovigilance systems show it's abundantly clear they are a big threat to flight safety. Pfizer and Moderna even had to include myocarditis and pericarditis as adverse events in their package leaflet.[113] [114] In the Guidelines for Aero-Medical Centres and Aeromedical Examiners regarding the examination and assessment of applicants[115] the statement is made that pilots themselves should observe warnings by manufacturers, *'In regard to the SARS-CoV-2 vaccination, as with any other drug, in the context of MED.A.020, ATCO.MED.A.020 and corresponding GM, the recipients are*

[111] 7. Polack FP, Thomas SJ, Kitchin N. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Engl J Med (2020) 383:2603–2615. doi:10.1056/NEJMoa203457

[112] Chu L, McPhee R, Huang W, et al. mRNA-1273 Study Group. A preliminary report of a randomized controlled phase 2 trial of the safety and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine. Vaccine (2021) S0264-410X(21)00153-5. doi:10.1016/j.vaccine.2021.02.00

[113] https://labeling.pfizer.com/ShowLabeling.aspx?id=14471

[114] https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna/information-for-healthcare-professionals-on-covid-19-vaccine-moderna#marketing-authorisation-numbers

[115] https://www.easa.europa.eu/en/document-library/general-publications/guidelines-aero-medical-centres-and-aeromedical-examiners

required to observe the precautions stipulated by its manufacturer.' When dealing with a new and conditionally approved medical product, without years of safety data available, which is this widely distributed, shouldn't this be the job of the Aviation Authorities and Safety Agencies? Especially when these same bodies state these vaccines can be perceived as safe and promise to closely monitor the role out of the vaccines.

Every year EASA publishes the EPAS, European Plan for Aviation Safety, a rolling 5-year plan in which a wide array of safety and non-safety related topics is addressed.
Edition 2022-2026[116]: *'Addressing the safety issues emerging from COVID-19, this edition supports the further modernisation of the aviation system, in the areas of safety, efficiency, level playing field and environmental protection.'*

Chapter 18: COVID-19

- Shortage of operational and technical staff (SI-5018)
- Increase of cybersecurity issues related to the pandemic situation (SI-5017)
- Reduced available financial resources (SI-5019)
- Increased presence of wildlife on aerodromes (SI-5010)
- The scale of aircraft storage and subsequent destorage may lead to technical failures (SI-5011)
- Aviation personnel fatigue (SI-5002)
- Decreased well-being of aviation professionals during shutdown (SI-5006/5007)
- Skills and knowledge degradation due to lack of recent practice (SI-5003)
- Prevention and treatment of unruly passengers in the context of COVID-19 (SI-5021)
- Shutdown, restart and gradual recovery of a complex system is unpredictable (SI-5005)
- Risk assessments based on previous normal operations are no longer valid (SI-5008)
- Reduced focus on, or prioritisation of safety (SI-5009)
- Reduced oversight by competent authorities (SI-5001)
- Extent and duration of COVID-19 exemptions and temporary rules (SI-5012)
- Documentation and database updates may not have been applied (SI-5004)
- Crew fatigue due to unavailability of rest facilities at destination or extended duty period (SI-5013)
- Missing suppliers and difficulty liaising with suppliers (SI-5020)
- Transfer of pilots from one fleet to another resulting in low hours on type (SI-5015)

A lot of subjects/issues, however, no mention whatsoever concerning COVID-19 vaccines and their impact on safety.

In the supporting information: how EPAS is developed[117], the next quote can be read:
'Safety: — The actions in this category are driven by the need to increase or maintain the current level of safety in the aviation sector.'
This is contradictory to the double standard employed regarding the vaccines and their related adverse events. As these are a huge risk to aviation, the level of safety is therefore not maintained and efforts should be made without delay to restore flight safety.

[116] https://www.easa.europa.eu/document-library/general-publications/european-plan-aviation-safety-2022-2026
[117] https://www.easa.europa.eu/downloads/134923/en

In April 2021 EASA published an updated version of 'Review of Aviation Safety Issues Arising from the COVID-19 Pandemic, version 2[118] that in addition to the safety issues, listed the existing and available mitigations, where applicable.

List of identified safety issues:

- Infrastructure and Equipment;
- Training, Checking and Recency;
- Management Systems;
- **Human Performance;**
- Financial Impacts on Safety.
- Outdated Information;
- Unusual approach profiles in the pandemic circumstances (Unstable approaches),
- Increase of cyber-security issues related to the pandemic situation,
- Transfer of pilots from one fleet to another resulting in low hours on type,
- Maintenance of electrical systems and visual aids at aerodromes,
- Decreased funding of aviation regulatory authorities,
- Reduction in training effectiveness due to COVID-19 restrictions,
- Rapid growth of cargo operations during the pandemic,
- Reduction in Contracted Fees to Ground Handling Service Providers,
- Knowledge transfer missed for new generation aviation personnel,
- ANSPs returning to operations after being closed for several months,
- Carriage of hand sanitiser in the cabin.

The identified safety issues listed in the **Human Performance** section:

- Reduced adherence to procedures in the new working environment
- Decreased wellbeing of aviation professionals during shutdown and on return to work
- Flight crew fatigue due to unavailability of rest facilities at destination or extended duty period
- Personnel no longer working collaboratively
- Aviation personnel fatigue
- Unusual approach profiles in the circumstances of the pandemic (unstable approaches)
- Roster adaptations to reduce transmission of illness may create different team behaviours
- Impact of the pandemic on the ground handling industry – human factors

Again no mention whatsoever concerning COVID-19 vaccines and their impact on safety.

Merely the lack of safety data and the use of this never before utilised technology (mRNA) should suffice for a ban on COVID-19 vaccines and all mRNA based medical products now and in the near future. No one knows what the next dose will bring in terms of adverse events, short term or long term, yet a rising amount of data is showing an increase in adverse events after every dose. Myocarditis, pericarditis, neurological problems, clotting, and embolic and thrombosis-related side effects are really serious and dangerous conditions, most likely career-ending for a pilot. But far more important, potentially disastrous if these were to come to expression during flight. An additional

[118] https://www.easa.europa.eu/newsroom-and-events/news/easa-updates-review-aviation-safety-issues-arising-covid-19-pandemic

problem caused by career-ending conditions, is the hesitancy to report these adverse events, as this would cause a pilot to lose his medical and hence his license.

The vaccine efficacy has dropped with every new variant of the corona virus, with Omicron there isn't even a significant difference anymore whether you are unvaccinated or if you've had one or two shots. Data from the Netherlands[119], Canada[120], Belgium[121] and the United Kingdom[122], show the fast majority of confirmed corona cases are amongst the population who have been vaccinated 3 or 4 times. A recent study shows how and why vaccinated people are more susceptible to being infected, than people with natural immunity.[123]
The Dutch Institute for Public Health(RIVM) state the vaccine efficacy against hospitalization, from March 15th to June 28th, to be -52% in the 50-69 age group and against an ICU admission -20% for all age groups combined.[124] In 2020, prior to COVID-19 vaccine rollout, the Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. Peter Doshi et al. adapted the Brighton Collaboration list to evaluate serious adverse events of special interest observed in mRNA COVID-19 vaccine trials through secondary analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines (NCT04368728 and NCT04470427). Combined, the mRNA vaccines were associated with an absolute risk increase of serious adverse events of special interest of 12.5 per 10,000. The excess risk of serious adverse events of special interest surpassed the risk reduction for COVID-19 hospitalization relative to the placebo group in both Pfizer and Moderna trials (2.3 and 6.4 per 10,000 participants, respectively).[125]
Dr. Aseem Malhotra came to the same conclusion in his recent study: 'In the non-elderly population the "number needed to treat" to prevent a single death runs into the thousands. Re-analysis of randomised controlled trials using the messenger ribonucleic acid (mRNA) technology suggests a greater risk of serious adverse events from the vaccines than being hospitalised from COVID-19. Pharmacovigilance systems and real-world safety data, coupled with plausible mechanisms of harm, are deeply concerning, especially in relation to cardiovascular safety.'[126] [127]
If pilots are still allowed to be vaccinated, while the efficacy of the vaccines has dropped to almost nothing, the adverse events keep rising in numbers and evidence shows the vaccines are a big threat to safety, then '*…the need to increase or maintain the current level of safety in the aviation sector'* described by EASA is not lived up to.

EASA Rules for Medical Requirements & Guidelines

These are the rules and guidelines laid down in EASA part MED and the guideline leaflet regarding use of medication in aviation, which are either violated or disregarded. These solely and/or together operate to disallow medical clearance of pilots who have injected any of the COVID-19 vaccines.
Due to these violations regarding pilot health (and thereby flight safety) and possibly even vaccine mandates still in force in some countries, we were interested in doctors opinions involved in aviation, the Aeromedical experts (AMEs). In '*bold Italic'* in the text below are the reactions of Dutch AME's

[119] https://www.rivm.nl/coronavirus-covid-19/actueel/wekelijkse-update-epidemiologische-situatie-covid-19-in-nederland
[120] https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html
[121] https://covid-19.sciensano.be/nl/covid-19-epidemiologische-situatie
[122] https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports
[123] https://www.medrxiv.org/content/10.1101/2022.04.18.22271936v1.full.pdf
[124] https://www.rivm.nl/sites/default/files/2022-07/VE_rapport_20220705_definitief.pdf?fbclid=IwAR1apeGA_6LnESv4Vii6sfN5HQ75abaTaSWMOzonDRdmcHYwlVuZWbUMiKY
[125] https://www.sciencedirect.com/science/article/pii/S0264410X22010283
[126] https://insulinresistance.org/index.php/jir/article/view/71
[127] https://insulinresistance.org/index.php/jir/article/view/72

(who prefer to remain anonymous) to the question: 'Are pilots allowed to participate in a phase 3 clinical trial? And what are the relevant EU regulations?'

- MED.A.020 Decrease in medical fitness

  (a) Licence holders shall not exercise the privileges of their licence and related ratings or certificates, and student pilots shall not fly solo, at any time when they:

  (2) take or use any prescribed or non-prescribed medication which is likely to interfere with the safe exercise of the privileges of the applicable licence;

  (3) receive any medical, surgical or other treatment that is likely to interfere with the safe exercise of the privileges of the applicable licence.

With the current data on adverse events post inoculation and every week more data and research papers becoming available, it's clear that the risk of severe adverse events is much higher than propagated. The German Federal Ministry of Health (BMG) on Wednesday admitted 1 of every 5,000 COVID-19 injections cause "serious side effects." [128] [129] Peter Doshi et al, established in their recent study the increased risk of severe adverse event at 12.5 per 10.000 (Pfizer and Moderna combined)[125]. These statistics result in a violation of MED.A.20 (a)(2)(3) by pilots who are vaccinated or will be vaccinated, as it indicates that the vaccines are likely to interfere with the safe exercise of the privileges of a pilot's license.

- GM1.MED.A.020 Decrease in medical fitness

  MEDICATION – GUIDANCE FOR PILOTS AND CABIN CREW MEMBERS
  (a) Any medication can cause side effects, some of which may impair the safe performance of flying duties. Equally, symptoms of colds, sore throats, diarrhoea and other abdominal upsets may cause little or no problem whilst on the ground but may distract the pilot or cabin crew member and degrade their performance whilst on duty. The in-flight environment may also increase the severity of symptoms which may only be minor whilst on the ground. Therefore, one issue with medication and flying is the underlying condition and, in addition, the symptoms may be compounded by the side effects of the medication prescribed or bought over the counter for treatment. This guidance material provides some help to pilots and cabin crew in deciding whether expert aero-medical advice by an AME, AeMC, GMP, OHMP or medical assessor is needed.

  (b) Before taking any medication and acting as a pilot or cabin crew member, the following three basic questions should be satisfactorily answered:
  (1) Do I feel fit to fly?
  (2) Do I really need to take medication at all?
  (3) Have I given this particular medication a personal trial on the ground to ensure that it will not have any adverse effects on my ability to fly?

  (e) Many preparations on the market nowadays contain a combination of medicines. It is, therefore, essential that if there is any new medication or dosage, however slight, the effect should be observed by the pilot or the cabin crew member on the ground prior to flying. It should be noted that medication which would not normally affect pilot or cabin crew

[128] https://childrenshealthdefense.org/defender/germany-covid-vaccine-side-effects/
[129] https://alexberenson.substack.com/p/the-german-government-admits-hundreds

performance may do so in individuals who are 'oversensitive' to a particular preparation. Individuals are, therefore, advised not to take any medicines before or during flight unless they are completely familiar with their effects on their own bodies. In cases of doubt, pilots and cabin crew members should consult an AME, AeMC, GMP, OHMP or medical assessor, as applicable.

- MED.B.005 General medical requirements

  Applicants for a medical certificate shall be assessed in accordance with the detailed medical requirements set out in Sections 2 and 3.
  They shall, in addition, be assessed as unfit where they have any of the following medical conditions which entails a degree of functional incapacity which is likely to interfere with the safe exercise of the privileges of the licence applied for or could render the applicant likely to become suddenly unable to exercise those privileges:
  (b) active, latent, acute or chronic disease or disability;

  (d) effect or side effect of any prescribed or non-prescribed therapeutic, diagnostic or preventive medication taken.

- Main principles of medication use in aviation

  - Use of medication: Take into consideration the side effects and the importance of them in the aviation domain.

  - Balance benefit and risk ratio: AMEs should assess the illness itself, the impact of the medication and the risk and benefits for the patient in his/her working environment.

- General prescribing guidance
  - Examine the side effects of drugs.
  - Decide on a period of grounding if needed depending on the type of disease, the kind of drug and the familiarisation with any possible side effects.

  - Helpful questions to ask yourself:
    - ✓ Are the potential side effects more of a risk than the medical condition?
    - ✓ Efficacy of the medication? Individual sensitivity?
    - ✓ Does the medical condition itself preclude the safe operation of the flying activity?
    - ✓ Which is the right medication for this disease?

- Assessment of fitness
  A pilot should not fly or operate if:

  - The medication could have side effects that could affect the performance or increase the risk of incapacitation.

- Guidelines for treating physicians and AMEs
  - Accept that all medication can have potential side effects.
  - Consider the impact of side effects in the aviation related working environment
  - Always consider a period of grounding when beginning new treatment.

- Guidelines for pilots

    - Be aware that medications can have side effects which could affect flight safety and work performance.
    - Be prepared to be grounded or prevented from working when taking medication for the first time.

All the above mentioned rules and guidelines relate to potential side effects or the need for a 'No-fly' period for pilots taking medical products, in order to maintain the highest level of flight safety. A 'No-fly'/waiting period is obviously to assess whether a person has an allergic reaction or any other adverse event from the medical product taken. The 48 hours advised waiting period by EASA (which is the standard for vaccines) isn't adequate, as median onset for multiple severe adverse events surpasses 48 hours. EASA SIB 2021-06 indicates that NCA (National Competent Authorities) could implement different waiting periods when justified by medical publications, this has however not been done, not by NCA's nor by EASA itself, even though medical publication clearly indicate the necessity for a longer waiting period. Reviewing documents obtained through a Freedom of Information Act it becomes clear that (at least) the Dutch NCA (ILenT) tried to avoid making any decision regarding the vaccines. A verbatim internal e-mail response by an ILenT employee to a colleague, regarding a question on possible restrictions following AstraZeneca vaccination:'…the general policy regarding vaccines applies, the advised 48 hours waiting period. We don't get involved, we stay out of it.'

The known adverse events and their high rate of occurrence make the COVID-19 vaccines a flight safety risk, the highest level of safety cannot be guaranteed anymore.
'A pilot should not fly or operate if: The medication could have side effects that could affect the performance or increase the risk of incapacitation.' On its own this guideline to pilots in fact disallows the injection of the COVID-19 vaccines.

> ***"A pilot is not allowed to exercise the privileges of their license when taking medication that potentially could have a negative impact on flight safety, this applies to all classes of medical certificates".***
>
> ***"First and foremost, we don't take any risks in aviation. A new medicine/vaccine poses a risk and is therefore never allowed. Once the product is fully approved, used and prescribed by medical doctors for a substantial amount of time and proven safe, it might be allowed and prescribed in aviation. A great example is the new generation anticoagulants: DOACs. Fully EMA approved, but not allowed to be prescribed to pilots, it took 2 years for these products to be perceived as proven safe and to be cleared for use in aviation".***

This is a very clear and concise explanation of how the rules, guidelines and aviation mentality normally operate together to maintain the highest level of safety. Similar to the previously referenced paragraph found in ICAO doc 8984: *'The medical examiner should avoid recommending medicines that are new to market; it is better to wait until a medicine is well established and any side effects recognized.'*[106] With all the data available on adverse events, safety and efficacy, the Conditional Marketing Authorization might actually no longer be justified, as this is subject to specific safety and efficacy conditions and criteria.[130]

The simple basic question 'Do I feel fit to fly?' (GM1.MED.A.020 Decrease in medical fitness) is a crucial one for a pilot regarding flight safety and cannot be answered with any certainty regarding new medical products.

[130] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation#criteria-and-conditions-section

"Medicine/vaccine still being tested, in this case phase 3, should be categorized as 'other treatment' under GM1 MED.A.020.(f). There is no way of knowing if one would experience adverse events, nor can ones fitness be assessed when taking a new and unknown medical product".

- MED.A.020 Decrease in medical fitness

  (b) In addition, holders of a medical certificate shall, without undue delay and before exercising the privileges of their licence, seek aero-medical advice from the AeMC, AME or GMP, as applicable, when they:

  (2) have commenced the regular use of any medication;

- GM1.MED.A.020 Decrease in medical fitness

  (c) Confirming the absence of adverse effects may well need expert aero-medical advice.

- Guidelines for pilots
  - Inform the AME when taking medication.

- Guidelines for treating physicians and AMEs
  - For AMEs: Understand the regulatory principles, guidelines and regulations.

Informing and/or seeking aero-medical advice from AME's has not been done by most pilots and seems it also wasn't deemed necessary by regulatory bodies, which is risky when dealing with new and conditionally approved medical products, without even knowing the impact of the working conditions on possible adverse events.
Even during the annual medical checkup, no questions are asked. Have you been vaccinated? How many times? Have you experienced any side effects? With the concerning amount of severe adverse events reported, these questions should at least be documented for every pilot. When it comes to COVID-19 vaccines the double standard is remarkable, normally medicine use in aviation is quite restrictive and rightfully so. Informing and consulting an AME or AeMC is usually necessary when taking any kind of medicine. On the website of KLM Healthservices a Dutch AeMC[131], it is stressed to inform an AME on the use of any medicine, the indication for which it is taken, dosage and duration[131], so how can this not be deemed necessary for unprecedented conditionally approved vaccines.

The answers provided by the AME's to the question 'Are pilots allowed to participate in a phase 3 clinical trial? And what are the relevant EU regulations?', go beyond the scope of clinical trials and imply new medical products should be steered clear of in aviation.

"First and foremost, we don't take any risks in aviation. A new medicine/vaccine poses a risk and is therefore never allowed. Once the product is fully approved, used and prescribed by medical doctors for a substantial amount of time and proven safe, it might be allowed and prescribed in aviation. A great example is the new generation anticoagulants: DOACs. Fully EMA approved, but not allowed to be prescribed to pilots, it took 2 years for these products to be perceived as proven safe and to be cleared for use in aviation".

[131] https://klmhealthservices.com/veelgestelde-vragen-vliegmedisch/

"A pilot is not allowed to exercise the privileges of their license when taking medication that potentially could have a negative impact on flight safety, this applies to all classes of medical certificates".

"Medicine/vaccine still being tested, in this case phase 3, should be categorized as 'other treatment' under GM1 MED.A.020.(f). There is no way of knowing if one would experience adverse events, nor can ones fitness be assessed when taking a new and unknown medical product".

"Participating in a clinical trial, unless for eczema cream for instants, will heavily conflict with the class 1 medical requirements, as these are very restrictive."

"There is only one option for pilots, never ever participate".

After we received the answers to this question, we've asked another question: What is your professional opinion on the COVID-19 vaccines being available to pilots? None of them replied.

- General prescribing guidance

    - Consider the working conditions (such as altitude, cabin pressure, stress…) in relation with the disease and treatment.

EASA SIB 2021-06 showed there is no data available on the working conditions with regard to the vaccines and their related adverse events. Do the working conditions such as lower air pressure and mild hypoxic environment, have any impact on adverse events rate and/or severity? Do they further enhance the adverse events? These are key questions and should have been addressed before any pilot could have been allowed to be vaccinated, as the onset or aggravation of adverse events mid-air, should be avoided at all cost. Gathering this data should have been a priority and should still be a priority. ARA.MED.330 Special medical circumstances provides the guide to establish a safe environment to research working conditions, their impact on adverse events and the overall influence of the vaccines to pilot performance without compromising flight safety.

- ARA.MED.330 Special medical circumstances

    (a) When new medical technology, medication or procedures are identified that may justify a fit assessment of applicants otherwise not in compliance with the requirements, research may be carried out to gather evidence on the safe exercise of the privileges of the licence.

    (b) In order to undertake research, a competent authority, in cooperation with at least one other competent authority, may develop and evaluate a medical assessment protocol based on which these competent authorities may issue a defined number of pilot medical certificates with appropriate limitations.

    (c) AeMCs and AMEs may only issue medical certificates on the basis of a research protocol if instructed to do so by the competent authority.

    (d) The protocol shall be agreed between the competent authorities concerned and shall include as a minimum:

        (1) a risk assessment;

        (2) a literature review and evaluation to provide evidence that issuing a medical certificate based on the research protocol would not jeopardise the safe exercise of the privileges of the licence;

(3) detailed selection criteria for pilots to be admitted to the protocol;
(4) the limitations that will be endorsed on the medical certificate;
(5) the monitoring procedures to be implemented by the competent authorities concerned;
(6) the determination of end points for terminating the protocol.

(e) The protocol shall be compliant with relevant ethical principles.

(f) The exercise of licence privileges by licence holders with a medical certificate issued on the basis of the protocol shall be restricted to flights in aircraft registered in the Member States involved in the research protocol. This restriction shall be indicated on the medical certificate.

(g) The participating competent authorities shall:
(1) provide the Agency with:
(i) the research protocol before implementation;
(ii) the details and qualifications of the nominated focal point of each participating competent authority;
(iii) documented reports of regular evaluations of its effectiveness;
(2) provide the AeMCs and AMEs within their jurisdiction with details of the protocol before implementation for their information.

- AMC1 ARA.MED.330 Special medical circumstances

GENERAL
The protocol should:
(a) assess the incapacitation risk;
(b) assess the risk of subtle impairment of performance;
(c) undertake a risk-benefit analysis;
(d) include a review of the regulations in use in other major aviation States and ICAO;
(e) determine which class of medical certificate is included in the scope;
(f) estimate the number of pilots likely to be included;
(g) list all anticipated risks to the protocol and provide a risk management strategy including appropriate limitations for every anticipated risk; where the risk of subtle impairment of performance is identified, the protocol should include requirements for minimum simulator testing or minimum line-flying under supervision or both;
(h) nominate medical research experts, if necessary, to provide advice on research methods.

- AMC1 ARA.MED.330(b)(c) Special medical circumstances

GENERAL
Initial medical certificates issued on the basis of a protocol should only be issued by the competent authority. Thereafter, the competent authority should decide whether the AeMC or AME may issue the medical certificate

- GM1 ARA.MED.330 Special Medical Circumstances

(b) The protocol is to enable experience to be gained in special medical circumstances in a controlled manner. This is to facilitate a better understanding of the treatment or condition, so that an evidence-based decision concerning its implementation may be considered.

(c) The protocol and its implementation should comply with the principles described in the following publication of the World Medical Association (WMA): "WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects", as last amended. [3]

ARA.MED.330 'Special medical circumstances' describes how new medical technology, medication or procedures need to be handled with regards to flight safety. Although this chapter is aimed at, using new medical technology, medication or procedures to justify a fit assessment of applicants otherwise not in compliance with the requirements, it doesn't change in any way how EASA requires new medical technology, medication or procedures are to be approached.
The COVID-19 vaccines are new and unprecedented in more than one way, so definitely fall in this category and ARA.MED.330 should therefor have been followed. In this way data could have been collected on in-flight conditions further enhancing adverse events and the resulting impact on the performance of crew members during safety related tasks, in a controlled environment without compromising flight safety.

Concluding

It's time to rethink the vaccines, it's time for the aviation industry to take the responsibility it has always taken when needed. Even though pharmaceutical companies persuasively state that a certain drug or vaccine is safe, in aviation there have always been higher safety standards and never before were these set aside. These vaccines have been developed and manufactured in more or less one year, where normally the clinical trials alone take at least up to 6-7 years, but even up to 10-15 years is not uncommon.[26] [132] [133]Aviation as a collective needs to take responsibility once again and protect our pilots and with them our passengers, if we don't protect them who will?
The vaccines are unprecedented in more than one way and not proven safe, rather proven harmful. In a meeting of the FDA with Vaccine and Related Biological Products Advisory Committee on September 17 of 2021, 16 of 19 members even voted against the authorization of any Covid booster vaccines in the age group 16 years and older having noted that the vaccine program has breached the defining test under the EUA statute as to whether the experimental treatment benefits outweigh the risks; in fact, they found the shots are far more dangerous than helpful in this age group and some voiced concerns that this would apply generally to all age groups.[134]

Mandating COVID-19 vaccines or any other medical product as new as these vaccines should never be accepted by aviation authorities, neither implemented by governments nor by commercial companies/airlines. It is unconscionable to mandate injections/medical treatments without exemption, especially when the medical product is new and still undergoing its first years of study. Safety needs to be restored and the vaccines banned from aviation, if not, this is an accident waiting to happen.
The references used in this letter are just a fraction of medical and scientific research papers available confirming the problems arising from the (novel mRNA based) COVID-19 vaccines and the unprecedented numbers of adverse events linked to it. Considering all data used in this letter, this at the very least establishes an increasing doubt regarding the safety of these vaccines and again whenever there is any doubt, there is no doubt. Normally in aviation, an industry which doesn't take

[132] https://www.bioclever.com/duration-of-clinical-trials-and-observational-studies-n-46-en
[133] https://massivebio.com/how-long-do-clinical-trial-phases-take/
[134] https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement#event-information

any chances when it comes to safety, the very presence of doubt means an immediate halt to any operation. For instance, when a certain type of aircraft is involved in an accident and the cause can't be determined, but suspicion rises it might have been a technical issue or failure of some sort, or the cause is known and needs immediate modification on all aircrafts of this type, then all these aircrafts are grounded worldwide until further notice. We face a similar situation, all be it not technical but health related, yet not less perilous and thus the solution should be the same, halt these vaccines. The evidence is piling up and cannot and should not be ignored anymore. Even though governments might push the vaccines, it doesn't relief us from our duty to keep safety our top priority.

In light of the concerns for flight safety by the undersigned, we would like to ask EASA and the Dutch National Aviation Authority (Inspectie Leefomgeving en Transport, IlenT) to answer the following questions:

1. Please explain how EASA/ ILenT assesses Covid-19 vaccines' suitability for use by Class 1-3 medical certificate holders since their roll out.

2. Does EASA/ ILenT collect reports of Covid-19 vaccine effects, side-effects and severe adverse events (including suspected or proven resultant death) occurring in any Class 1-3 medical holder? And if so, please explain how this data is collected.

3. Is EASA/ ILenT aware of any Covid-19 vaccine-induced adverse events in any NL Class 1-3 medical certificate holder? If so, of how many such events is EASA/ ILenT aware and how does EASA/ ILenT categorise their severity?

4. Does EASA/ ILenT keep data relating to the numbers of Class 1-3 medical certificates that:
   - are held;
   - temporarily suspended;
   - permanently suspended;

   in any given year? If so, how many years of such data does EASA/ ILenT hold?

5. Holders of Class 1-3 medical certificates are expected to self-report medical issues to the AMEs or AeMCs, except where issues are actually detected during a medical examination. How and when does EASA/ ILenT, via its medical system, become aware of certificate holders' medical issues if they do not self-report those issues to the Civil Aviation Authority?

6. On an average, per yearly basis, approximately what proportion of all flights within NL airspace is conducted by multi-pilot crews and what proportion is conducted single pilot?

7. Does EASA/ ILenT hold data documenting (on a yearly basis) passenger and crew medical:
   - incidents;
   - accidents; and
   - diversions due to medical emergency of any aircraft inside NL airspace and/or on PH-registered aircraft globally?

8. How many Class 1-3 medical certificate holders has EASA/ ILenT authorised to engage in:
   - any phase 1, 2 or 3 clinical trial for any Covid-19 drug, treatment, therapy, protocol or vaccine; and/or
   - any form of trial, protocol or evaluation of "mix-and-match" Covid-19 boosters use e.g. Pfizer vaccination followed by another manufacturer's vaccine?

This document is in no way an attempt to assert blame to anyone, no one person, agency or authority. It is however a call to action addressed to our aviation authorities, safety agencies and airlines to act and fulfill their obligations, without interference from politics, by once again committing to the highest safety standards set by these very same bodies.

Actions to regain flight safety:

1. Medically flagging all vaccinated pilots.

2. Discontinuing any vaccine mandate still effective today, and making sure pilots can never be mandated again to get any COVID-19 vaccines or any other new and/or unapproved medical product, in accordance with the in ARA.MED 330 'Special medical circumstances' (Easy Access Rules for Medical Requirements) referenced WMA Declaration of Helsinki.[3]

3. Prohibiting any mRNA based medical product in aviation for now and the near future, until such time as all unresolved issues of this novel technology have been remedied and these products have been prescribed to the general public for a number of years without serious issues, a favorable safety profile must have been established.

4. Putting in writing a ban on experimental medical treatments in aviation, to be included in EASA Rules for medical requirements. All non-approved and conditionally approved medical products should be prohibited.

5. Creating a database to track pilot adverse events as we fear that medical adverse events post vaccination in pilots is higher in numbers than currently assumed.

6. Informing/educating pilots about the risk of COVID-19 vaccine adverse events and the immaturity of mRNA based medical products in general.

Additionally proposed safety measures to establish pilot health post vaccination

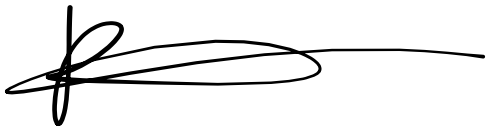
7. Without further delay and considering the by mRNA vaccine producing companies mentioned cardiovascular complications[4] [5], having vaccinated pilots undergo thorough medical re-examinations to include D-Dimer tests (to check for blood clotting problems), Troponin tests (to check for Troponin in the blood, a protein released by damaged heart muscle cells), ECG analysis, cardiac MRI and PULS test (to determine heart health). Inclusion of the cardiac MRI as a screening test for pilots is critical, as a recent study showed that using only ECG results and symptoms to screen patients resulted in a 7.4 times under-diagnosing of actual myocarditis.[6] While the PULS test is also critical as research has shown that mRNA vaccines dramatically increase Endothelial Inflammatory Markers and ACS (Acute Coronary Syndrome) risk.[7]

8. From this point forward only allowing commercial aircraft to be operated by pilots who can show D-Dimer and Troponin tests, as well as cardiac MRIs, ECGs(EASA Acceptable means of compliance and guidance material to part-MED, AMC1 MED.B.010 Cardiovascular system)[8] and PULS tests- at aeromedically acceptable levels and a clean medical examination undertaken a minimum of 11 days after each new COVID-19 injection and after each COVID-19 "booster" shot, as a review of Pharmacovigilance databases, the Pfizer test data and peer

reviewed scientific and medical studies indicate that the current 48 hours waiting period as prescribed by EASA is insufficient to detect a significant number of blood clotting, myocarditis cases and neurological severe adverse events, as the median onset for blood clotting is 4 days, myocarditis 3 days (1-8 days) and neurological severe adverse events 11 days.[9] [10] [11] [12]

We thank you for your anticipated efforts in providing your insight into the above mentioned questions and look forward to receiving your reply by email in due course.

Sincerely,



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Aussie Freedom Flyers
Australia

Greg Hill, Director
Free to Fly
Canada

Dr. Tess Lawrie, MBBCH, PhD
Director Evidence-based Medicine Consultancy
Co-founder World Council for Health

Wijbe van der Meulen
Offshore Medic

Arjen Ypma
Pharmacist,
Private Pilot

Marc Bikker
Commander B787

VAERS Event Details

Details for VAERS ID: 1026783-1

Event Information			
Patient Age	33.00	**Sex**	Male
State / Territory	Mississippi	**Date Report Completed**	2021-02-12
Date Vaccinated	2021-02-01	**Date Report Received**	2021-02-12
Date of Onset	2021-02-01	**Date Died**	
Days to onset	0		
Vaccine Administered By	Private	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	Yes
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	UNK	SYR	LA

Symptom
ACOUSTIC STIMULATION TESTS
BALANCE TEST
BURNING SENSATION
COMPUTERISED TOMOGRAM
CONFUSIONAL STATE
CSF PRESSURE INCREASED
DISORIENTATION
DIZZINESS
HEAD DISCOMFORT
HEADACHE
HYPERSENSITIVITY
INNER EAR DISORDER
MAGNETIC RESONANCE IMAGING
NAUSEA
PARAESTHESIA
PRESYNCOPE
TREMOR
VERTIGO
VISION BLURRED
VISUAL FIELD TESTS

Adverse Event Description

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Over a dozen test including balance, vision, hearing, spinal cord pressure, ct scan, and mri. All performed on 02/10/2021 and 02/11/2021.	None	

Medications At Time Of Vaccination	History/Allergies
None	None,None

I noticed a headache in the very top of my head within an hour of getting the vaccine. I thought it was normal because everyone I know said they got a headache from it. Over the next few hours, the pain moved down the back of my neck and became a burning sensation at the bottom of my skull. The pain was not excruciating but was constant. I thought it would eventually go away. I'm a pilot and fly for a living. Two days after receiving the vaccine I flew my plane and immediately noticed something was wrong with me. I was having a very hard time focusing. Approximately 2 hours into my flying I felt sudden and extreme pressure in my head and nearly blacked out. I immediately landed and stopped flying. Two days later I tried flying again and the exact same thing happened again after 20 minutes. The burning in my neck intensified and was now accompanied by dizziness, nausea, disorientation, confusion, uncontrollable shaking, and tinkling in my toes and fingers. I immediately went to my hometown doctor and he diagnosed me with vertigo. He prescribed me meclizine on Friday 02/05/2021. I took the medicine as prescribed all weekend with no relief. Monday 02/08/2021 I made an appointment for that Wednesday at the Institute. During Wednesday 02/10/2021-02/11/2021 I had roughly 1015 test performed on me including balance, eye and hearing test, CT scan, MRI, and measured my spinal fluid pressure. The physician determined on 02/11/2021 that I had an allergic reaction to the Pfizer COVID vaccine the severely increased the pressure in my spinal cord and brain stem. That pressure causes my vision problems and ultimately ruptured my left inner ear breaking off several crystals in the process. I cannot fly with this condition. I'm currently taking Diamox to reduce the pressure in my spinal cord and brain stem.

VAERS Event Details

Details for VAERS ID: 1651301-1

Event Information			
Patient Age	69.00	**Sex**	Male
State / Territory	New Hampshire	**Date Report Completed**	2021-08-28
Date Vaccinated	2021-01-12	**Date Report Received**	2021-08-28
Date of Onset	2021-03-15	**Date Died**	
Days to onset	62		
Vaccine Administered By	Private	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODERNA	011L20A	1	IM	LA
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODERNA	012M20A	2	IM	LA

Symptom
BLINDNESS UNILATERAL
MACULAR OEDEMA
RETINAL VEIN OCCLUSION

Adverse Event Description
On the morning of March 15, 2021 I got up and noted that I had no vision in my right eye. As a commercial pilot I considered this an emergency and sought specialist care from a retina specialist near our winter home in. That specialist diagnosed an episode of macular edema, caused by an occlusion of a vein behind my right eye. I was treated with injections of Avastin, an off label drug that has been effective in patients with this problem. I received one injection on March 15, 2021 and a second by the same doctor on April 12, 2021, before returning to my home. My course of treatment has continued at Medical Center also with injections of Avastin. My vision is now 20/50 in my right eye. After

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	None.	

Medications At Time Of Vaccination	History/Allergies
"1. An ""over 50"" multi vitamin 2. A pro-biotic"	None.,None.

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

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VAERS Event Details

Details for VAERS ID: 1743012-1

Event Information			
Patient Age	30.00	**Sex**	Male
State / Territory	Arizona	**Date Report Completed**	2021-09-29
Date Vaccinated	2021-06-18	**Date Report Received**	2021-09-29
Date of Onset	2021-06-22	**Date Died**	
Days to onset	4		
Vaccine Administered By	Military	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	3
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	UNK		

Symptom
AORTITIS
ASTHENIA
BLOOD TEST
CHEST PAIN
COMPUTERISED TOMOGRAM
DIZZINESS
DYSPNOEA
ELECTROCARDIOGRAM ABNORMAL
ELECTROENCEPHALOGRAM
GASTROOESOPHAGEAL REFLUX DISEASE
PAIN
PERICARDITIS
PULMONARY VASCULITIS

Adverse Event Description
Symptoms began almost immediately as constant dizziness, body aches, overall weakness. Two months later I woke up with severe chest pain and difficulty breathing. As a military pilot, my flight doctor took an EKG (abnormal results) and instructed me to visit the ER. I was diagnosed with inflammation of the heart cavity and pulmonary arteries. Upon being admitted to a local Medical Center, I was later diagnosed with vasculitis, specifically aortitis. During this timeframe I was also diagnosed with gastroesophageal reflux disease. I was completely healthy prior to the vaccination and there is not a single member of my family with any of the listed conditions. Presently, I am on a high dosage of prednisone and methotrexate to deal with the inflammation. I am also awaiting a medical evaluation board with the military group to determine if I'm allowed to remain on flying status and in the military.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Blood tests, CT Scans, EKGs, aEEG, etc.	None	

Medications At Time Of Vaccination	History/Allergies
None	None,None

VAERS Event Details

Details for VAERS ID: 1245452-1

Event Information			
Patient Age	37.00	**Sex**	Male
State / Territory	California	**Date Report Completed**	2021-04-21
Date Vaccinated	2021-03-19	**Date Report Received**	2021-04-23
Date of Onset	2021-03-21	**Date Died**	
Days to onset	2		
Vaccine Administered By	Unknown	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	USMODERNATX, INC.MOD20210	**Report Form Version**	2
Recovered	Unknown	**Serious**	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODERNA	045A21A	1	OT	

Symptom
ATRIAL FIBRILLATION
BLOOD THYROID STIMULATING HORMONE
ELECTROCARDIOGRAM
STRESS ECHOCARDIOGRAM
THYROID HORMONES DECREASED

Adverse Event Description

Atrial fibrillation; Thyroid hormone (TSH) goes down; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ATRIAL FIBRILLATION (Atrial fibrillation) in a 37-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 045A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 19-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Mar-2021, the patient experienced ATRIAL FIBRILLATION (Atrial fibrillation) (seriousness criterion medically significant) and THYROID HORMONES DECREASED (Thyroid hormone (TSH) goes down). At the time of the report, ATRIAL FIBRILLATION (Atrial fibrillation) and THYROID HORMONES DECREASED (Thyroid hormone (TSH) goes down) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Mar-2021, Blood thyroid stimulating hormone: low (Low) Low. On 21-Mar-2021, Electrocardiogram: atrial fibrillation (abnormal) Atrial fibrillation. On 21-Mar-2021, Stress echocardiogram: atrial fibrillation (abnormal) Atrial fibrillation. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not provided. The patient was in emergency room for few hours and was given 3 doses of apixaban (Eliquis) for treatment for the events. The patient was on holter monitor for 3 days. The patient reported, his thyroid level comes near normal after one and half weeks. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. He is pilot and kept off the duty for Atrial fibrillation.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Lab Data	Current Illness	Adverse Events After Prior

VAERS Event Details

Details for VAERS ID: 1702509-1

Event Information			
Patient Age		**Sex**	Male
State / Territory	Foreign	**Date Report Completed**	2021-09-13
Date Vaccinated	2021-06-14	**Date Report Received**	2021-09-16
Date of Onset	2021-06-22	**Date Died**	
Days to onset	8		
Vaccine Administered By	Other	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NLPFIZER INC202101120866	**Report Form Version**	2
Recovered	Yes	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	Unknown
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FC3143	1		

Symptom
ALANINE AMINOTRANSFERASE
ANGIOGRAM
ASPARTATE AMINOTRANSFERASE
BLOOD CHOLESTEROL
BLOOD CREATINE PHOSPHOKINASE
BLOOD CREATININE
BLOOD GLUCOSE
BLOOD LACTATE DEHYDROGENASE
BLOOD POTASSIUM
BLOOD PRESSURE MEASUREMENT
BLOOD SODIUM
BLOOD TRIGLYCERIDES
C-REACTIVE PROTEIN
CARDIAC FUNCTION TEST
COMPUTERISED TOMOGRAM
ECHOCARDIOGRAM
ELECTROCARDIOGRAM
GLOMERULAR FILTRATION RATE
HAEMATOCRIT
HAEMOGLOBIN
HIGH DENSITY LIPOPROTEIN
LDL/HDL RATIO
LIPOPROTEIN (A)
LOW DENSITY LIPOPROTEIN
MEAN CELL HAEMOGLOBIN
MEAN CELL VOLUME
PERICARDITIS
PHYSICAL EXAMINATION

PLATELET COUNT
RED BLOOD CELL COUNT
TOTAL CHOLESTEROL/HDL RATIO
TROPONIN
WHITE BLOOD CELL COUNT

Adverse Event Description

Pericarditis/chest pressure and irregular heartbeat; This is a spontaneous report from a contactable consumer downloaded from the regulatory authority, regulatory authority number NL-LRB-00665454. A 38-year-old male patient received bnt162b2 (COMIRNATY), via an unspecified route of administration on 14Jun2021 (Lot Number: FC3143) as DOSE, 1 SINGLE for COVID-19 immunization. Medical history included not smoking, alcohol and drugs, hypertension, hypercholesterolaemia, diabetes and vascular disease from an unknown date. Family history of cardiovascular disease (father had a myocardial infarction at age 36). The patient's concomitant medications were not reported. The patient experienced pericarditis on 22Jun2021and recovered from pericarditis two weeks after onset on 14Jul2021. The patient experienced pericarditis following administration of COMIRNATY treated with in ambulance: nitrospray, ascal; rest and 3 days ibuprofen 3dd400mg. The patient is a pilot and an athlete (triathlons). During a training week, patient after the patient woke up, he experienced chest pain with radiating pain to his neck and jaw. Ambulance came and gave him nitrospray and Ascal, which reduced his pain. The patient underwent tests: CTa: no coronary stenosis, ECG: showed diffuse ST elevation compared to his ECG in 2020. Echo cor showed observations fitting with an athlete's heart. The patient had no previous COVID-19 infection. The event occurred on the sixth day after a hard week of training (cycling). Woke up with chest pressure and irregular heartbeat. Finally picked up by ambulance and presented to cardiologist. The patient had diagnostic procedures: EKGs, CT, blood. The patient was admitted on 22Jun2021 to - in the Cardiology department in connection with thoracic pain. As conclusion: VG familial burden for cardiovascular disease: Observation of thoracic pain, coronary artery disease was excluded by CTa coronaries; Slightly dilated heart with slight eccentric left ventricular hypertrophy consistent with sports heart in tall athlete; and Diffuse ST elevation increase compared to EKG 2020. Diagnosis: pericarditis based on sports heart. The patient takes ibuprofen 3dd400mg for 3 days and Poli for 3 weeks + EKG. The patient was instructed to return earlier in case of fever, dyspnea, dizziness, increase in pain. The patient had referral to sports cardiologist. Check-up appointment: 3 weeks, outpatient clinic after admission. The patient woke up around 5:30 this morning to go to the toilet. No trouble getting up yet. When lying back in bed, a feeling of pressure in the chest. Couldn't walk anymore, vas 6/7. Radiated to jaw and neck. Is a pilot and has never noticed any heart problems during major inspections. No palpitation complaints, dyspnea or dyspnea of effort. No edema or nocturia. No vegetative phenomena. In the ambulance nitro spray and charged with ascal. After the spray complaints dropped to VAS 1. Per physical examination: BP: 121/76 mmHg, HR 55/min, cor: s1 s2 grade 1/6 ejection promptle, no pericardial rub, pulm: VAG; EKG: 22Jun2021: Sinus bradycardia 44/min, intermediate cardiac axis PQ 0.17 QRS 0.10 QT 0.45, diffuse ST elevation in all leads. Echo sound. Per quality and rhythm: the image quality of the examination is good. Sinus bradycardia around 46 bpm. LV: The left ventricle is slightly dilated. Eccentric LVH, RWT 0.37 at a mass of 130 gr/m2. Left ventricular systolic function is good. The left ventricular EF measured 65%. Combination of findings is consistent with normal LV diastolic function. RV: The right ventricle is moderately dilated. The systolic function of the RV is normal. Atria: The left atrium is slightly dilated (15-41 ml/m2). The right atrium is severely dilated. Floppy atrial septum. AoV: The aortic valve is tricuspid and opens well. Edges of the aortic valve thickened. Track ADI. MV: The mitral valve is normal. MINOR mitral insufficiency, TV: The tricuspid valve is normal. Minor tricuspid valve insufficiency. PV: The pulmonary valve is normal. Physiological pulmonary valve insufficiency. Great vessels: undilated ascending aorta. VCI is dilated, collapses 29% on sniff. CTA Coronaries 22Jun2021, 12:16, Calcium score 0,

heart rate 52/min. Prospective scan protocol. No coronary stenoses. No mass or lymphadenopathy in the mediastinum. Depicted lung fields clear. No indication of current pathology in the scanned trajectory. Conclusion: no coronary stenoses. Lab Collection date: 22Jun2021. Hemoglobin 8.9 mmol/L Hematocrit 0.42 L/L Erythrocytes: 4.7 x10^12/L Leukocytes: 4.0x10^9/L MCV 90 fL MCH: 1.88 fmol Thrombytes 212 x10^9/L Sodium : 138 mmol/l Potassium: 3.5 mmol/l Creatinine 84 u¦mol/L eGFR CKD epi >90 ml/min AST: 41 U/L (H) ALT 36 U/L LD: 327 U/l (H) CK : 712 U/l (H) Cholesterol 4.1 mmol/l HDL cholesterol 1.4 mmol/l Cholesterol-HDL ratio: 3.0 LDL cholesterol: 2.4 mmol/l Triglycerides 0.7 mmol/l (L) Glucose 6.6 mmol/l HS troponin I: <10 mg/l Lipoprotein a follows CRP <5 mg/l.
The patient was seen on 15Jul2021 at the Cardiology Outpatient Clinic for check-up after a recent visit to first heart aid. As conclusion, VG familial burden for cardiovascular disease. On 1. 22Jun2021, the patient visit emergency room for pericarditis. Now completely complaint-free; Slightly dilated heart with slight eccentric left ventricular hypertrophy consistent with sports heart in endurance athlete. No further outpatient monitoring indicated. The patient is referred back to the general practitioner. Anamnesis, Had no more complaints. Per her physical examination; BP 142/75 mmHg, cor: s1s2 no prompt; ECG: SR 44/min, intermediate heart axis, PQ 0.17 QRS 0.10 QTc 0.41, decrease ST elevation compared to 22-6-21 0.5 mm ST elevation I, aVL, V5, V6 and 2 mm ST elevation V3-V4. The patient had no medication in use. The outcome of pericarditis was recovered on 14Jul2021. No follow-up attempts are possible. No further information is expected.

Lab Data	**Current Illness**	**Adverse Events After Prior Vaccinations**

VAERS Event Details

Details for VAERS ID: 1768479-1

Event Information			
Patient Age	32.00	**Sex**	Male
State / Territory	California	**Date Report Completed**	2021-10-07
Date Vaccinated	2021-06-01	**Date Report Received**	2021-10-07
Date of Onset	2021-06-01	**Date Died**	
Days to onset	0		
Vaccine Administered By	Private	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

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"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (JANSSEN))	JANSSEN	201A21A	1	SYR	LA

Symptom
AMNESIA
ARRHYTHMIA
COGNITIVE LINGUISTIC DEFICIT
DIZZINESS
FATIGUE
FEELING ABNORMAL
GAIT DISTURBANCE
HEAD DISCOMFORT
IMPAIRED WORK ABILITY
MENTAL IMPAIRMENT
MOTION SICKNESS
MUSCLE TWITCHING
STRESS
VERTIGO

Adverse Event Description
Morning following injection, I experienced extreme dizziness and brain discomfort. Dizziness was bad enough to make walking difficult and even created motion sickness. 5 months later the dizziness has eased but still present, flying, driving, elevators, anything seems to trigger some form of dizziness. Hights of about 10 feet give bad vertigo, I am a pilot and aircraft mechanic and this creates an issue working on jets and I do not want to possibly loose my pilots medical. Brain fog is also long lasting still and makes mental clarity difficult which was never an issue until the day after the shot. My heart has created irregular heart rhythms, I have physical stress and tire easily and my muscles will shake and twitch after minimal effort. Biggest concern is dizziness and clarity and loss of short term memory, talking in front of large audiences for work has become difficult since my cognitive skills seem to have diminished from the lasting brain fog.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
None yet	None	

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VAERS Event Details

Details for VAERS ID: 1376453-1

Event Information			
Patient Age	45.00	**Sex**	Male
State / Territory	Colorado	**Date Report Completed**	2021-06-06
Date Vaccinated	2021-06-03	**Date Report Received**	2021-06-06
Date of Onset	2021-06-04	**Date Died**	
Days to onset	1		
Vaccine Administered By	Pharmacy *	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	No

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Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only
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"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EW0178	2	SYR	RA

Symptom
VERTIGO

Adverse Event Description
Severe vertigo experienced for four days and counting. Early morning symptoms are the worst, but symptoms continue throughout the day and evening. As a professional helicopter pilot, I cannot perform my job with these symptoms.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
No tests performed yet	None	

Medications At Time Of Vaccination	History/Allergies
None	None,Penicilin

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats:

Data contains VAERS reports processed as of 05/13/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. (/wonder/help/vaers.html#Reporting)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: May 25, 2022 2:04:22 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 05/13/2022, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on May 25, 2022 2:04:22 PM

VAERS event Details

Details for VAERS ID: 1388581-1

Event Information			
Patient Age	47.00	Sex	Mele
State / Territory	Ohio	Date Report Completed	2021-06-10
Date Vaccinated	2021-04-27	Date Report Received	2021-06A0
Date of Onset	2021-04-28	Date Died	
Days to onset	1		
Vaccine Administered	Pharmacy *	Vaccine Purchased	Not Applicable *
Mfr/ Imm Project Number	NONE	Report Form Version	2
Recovered	Yes	Serious	Yes

Event Categories	
Death	No
Life Threatening	Yes
Permanent Disability	[90
Congenital Anoma'y / Birth Defect	No
Hospitalized	Yes
Days in Hospital	10
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	
Emergency Room *	Yes
Office Visit *	Yes

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Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODE-RNA	046B21A	1		AR

Symptom
ANGIOGRAM CEREBRAL NORMAL
ARACHNOID CYST
COMPUTERISED TOMOGRAM HEAD ABNORMAL
HEADACHE
IMPAIRED WORK ABILITY
NAUSEA
PHOTOPHOBIA
SUBARACHNOID HAEMORRHAGE
ULTRASOUND DOPPLER
VOMITING

Adverse Event Description
Vaccine information (brand name, dosage, lot number) Date, time, and location administered: Date: 4/27/2021; Time: ? m; Location: Pharmacy Date and time when adverse event(s) started: Date: 4/28/2021; Time: afternoon Description of the adverse event, including medical treatment and diagnosis: Description: Symptoms include: Worst headache of life Exam Findings include: No focal neurologic findings but given history, CT head ordered.

Lab Data	Current Illness	Adverse Events After prior Vaccinations

VAERS Event Details

Details for VAERS 1358033-1

Event Information			
Patient Age	70.00	Sex	Mate
State / Territory	Utah	Date Report Completed	2021-05-28
Date Vaccinated	2021-04-22	Date Report Received	202/-05-28
Date of Onset	2021-04-24	Date Died	
Days to onset	2		
Vaccine Administered By	Pharmacy *	Vaccine Purchased	Not Applicable
Mfr/ Imm Project Number		Report Form Version	2
Recovered	Unknown	Serious	Yes

Event Categories	
Death	
Life Threatening	Yes
Permanent Disability	No
Congenital Anomaly / Birth Defect *	
Hospitalized	Yes
Days in Hospital	2
Existing Hospitalization Prolonged	
Emergency Room / Office Visit **	
Emergency Room *	Yes
Office Visit *	Yes

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"N/A" will appear when information is not available: on this report form version.

Vaccine-Type	Vacclne	Manufacturer	Lot	Dose	Route	Site.
COVID19 VACCINE	cov1D19 (COVID19 (MODERNA))	MODERNA	007C21A	2	SYR	LA

Symptom
JOINT RANGE OF MOTION DECREASED
MYOCARDIAL INFARCTION
THROMBOSIS

Adverse Event Description
2 days after second shot blood clot in left arm. Hit while walking in my home. Could not lift my arm. 5 days later heart attack. Pilot with EKG yearly. Last EKG less than one month from my heart attack on April 29, 2021

Lab Data	Current Illness	Adverse Fvents After Prior Vaccinations
On going	None	

Medications At Time Of Vaccination	History/Allergies
None	None,None