PUBLIC COMMENT

Consultation on WHS incident notification

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Name or organisation

[redacted]

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General feedback

Please provide any general feedback about the issues raised in the consultation paper here.

I am a WH&S professional with around 25 years of experience in the Central Queensland area. I am currently employed as a WH&S professional by one of the worlds largest construction companies.

To help you understand my submission I would appreciate you reading the following articles and studies/abstracts as a background:

Immunological dysfunction, vaccination and Gulf War illness - PubMed (nih.gov)

Illegal vaccine link to Gulf war syndrome | Environment | The Guardian

The following study has a section towards the end which highlights issues associated with vaccine experiments being conducted during the First World War:

The Pandemic of 1918.docx (live.com)

There are also two attached documents:

Immunization is as popular as a death adder (discussing the death of children in the Bundaberg district following administration of contaminated vaccines)

Gulf war syndrome – vaccine adjuvant suspect in Gulf War Syndrome – added to influenza vaccines

Current Issues which need to be reported and tracked through the regulators databases:

On the 9 March 2023, I reported a number of serious adverse reactions to the mandated COVID vaccines to Work Health and Safety Qld which had affected coworkers and others who I know are currently working in our local community. I believed it was my duty as a WH&S professional to advise our state regulator. Just ahead of emailing WHS Qld I had forwarded a number of emails/enquiries to Safe Work Australia. I am attaching copies of these emails as part of this submission. At the time I believed the regulators would have the power to act independently and investigate what I personally believe is a major health issue affecting the workforce. I also believed that mandating and or

recommending these conditionally approved health protocols made any injuries short term or long term “notifiable injuries.”

Since forwarding this correspondence there have been more serious revelations regarding adverse reactions. SWA mention the inclusion of “long latency diseases” and “psychological/psychosocial hazards.” These types of injuries have been documented by some of Australia’s leading academics as they pertain to COVID vaccine related injuries and government lockdowns. I believe that SWA and the regulatory bodies should include these types of injuries as part of their reporting regime.

The latest ABS statistics show trends pertaining to excess deaths in Australia. These statistics should form part of an investigation into this issue.

Provisional Mortality Statistics, Jan - Apr 2023 | Australian Bureau of Statistics (abs.gov.au)

Professor Phillip Altman one of Australia’s leading Pharmacologists is warning the public about the serious adverse reactions from the COVID vaccines:

Microsoft Word - Altman Report Version 9-8-22 FINAL FINAL .docx (redunion.com.au)

AN EMERGENCY MEETING OF TGA IS NEEDED TODAY ! (substack.com)

AN EMERGENCY MEETING OF TGA IS NEEDED TODAY ! (substack.com)

Likewise Dr Peter McCullough has written a substack on the same subject and has appeared on many news clips to help inform the public.

Risk of Stroke Skyrockets with COVID-19 Infection after Vaccination (substack.com)

UK Government Disability Claims Skyrocket (substack.com)

Were 1/3 of Pfizer Shots in the EU "Placebos"? (substack.com)

The following set of testimonies are important to be aware of:

Idaho Southwest District Health Board Testimony (substack.com)

I am also attaching my emails to SWA and Qld WH&S as well as important reports which provide some evidence to support this submission.

Please duplicate the following set of questions when responding to multiple chapters of the consultation paper (note Ch 10 has a specific set of questions – refer below).

Which chapter you are referring to in your response below?

e.g. Chapter 5 – Incapacity period

Do you support the assessment of current gaps and impacts of addressing those gaps? Please provide any supporting information and evidence.

Click or tap here to enter text.

Do you support the proposed option(s)? Please explain why or why not and provide relevant evidence to support your views where possible.

Click or tap here to enter text.

What practical impact, including costs and benefits, would the option(s) have on you, your organisation or your stakeholders? Please provide any details or evidence supporting your views, including the option's likely impact on WHS outcomes or any compliance costs or concerns.

Click or tap here to enter text.

Are there any likely unintended consequences of the proposed option(s)? How could these be best mitigated?

Click or tap here to enter text.

Do you have another suggestion or preferred option for addressing the gap in WHS regulator visibility?

Click or tap here to enter text.

Additional questions **(for specific chapters)**

Chapter 7 - Capturing workplace violence

Are there particular types or circumstances of workplace violence that you think should or should not be notifiable to the WHS regulator that are not dealt with by the proposed option and descriptions? What would be the implications of including or excluding these incidents?

Click or tap here to enter text.

Chapter 10 - Long latency diseases – exposure to substances

Should exposure to hazardous substances in the workplace that cause latent diseases be recorded and reported? If so, for which substances?

Click or tap here to enter text.

How are exposures to hazardous substances currently measured in the workplace (for example, air and health monitoring)? Do you have suggestions for options to improve monitoring to provide a better understanding of exposure to hazardous substances in the workplace?

Click or tap here to enter text.

With regards to air monitoring, how are exceedances of the WES captured? Do you think recording and reporting WES exceedances is a good way to identify exposure to hazardous substances in the workplace? What other ways could exposures be recorded and reported?

Click or tap here to enter text.

Should PCBUs be required to keep records of statement of exposure documents and make them available for inspection by the regulator? Should the statement of exposure requirement be broadened from prohibited or restricted carcinogens to include other substances which are known to cause long latency diseases? If yes, how should these substances be identified?

Click or tap here to enter text.

Chapter 15 - Addressing minor gaps and ambiguities in the current incident notification provisions

Medical treatment for exposure to a substance

What health professionals should be covered by the definition of ‘medical treatment’? Please provide reasons, including examples of what treatment the health professional is likely to provide for which type of exposure.

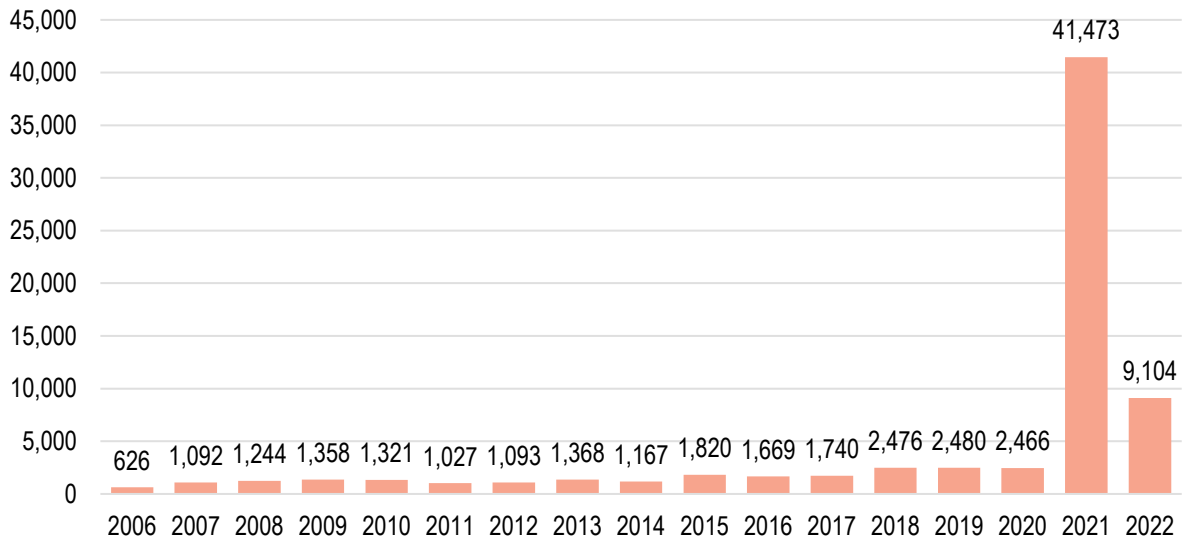
Click or tap here to enter text.

February 15, 2023

Health Alert on mRNA COVID-19 Vaccine Safety

The COVID-19 pandemic brought many challenges that the health and medical field have never encountered. Although the initial response was led by a sense of urgency and crisis management, the State Surgeon General believes it is critical that as public health professionals, responses are adapted to the present to chart a future guided by data.

The State Surgeon General is notifying the health care sector and public of a substantial increase in Vaccine Adverse Event Reporting System (VAERS) reports from Florida after the COVID-19 vaccine rollout.



Overall reports submitted to VAERS, Florida 2006–2022

In Florida alone, there was a 1,700% increase in VAERS reports after the release of the COVID-19 vaccine, compared to an increase of 400% in overall vaccine administration for the same time period *(Figure 1)*.

The reporting of life-threatening conditions increased over 4,400%. This is a novel increase and was not seen during the 2009 H1N1 vaccination campaign. There is a need for additional unbiased research to better understand the COVID-19 vaccines' short- and long-term effects.

Florida Department of Health
Office of the State Surgeon General
4052 Bald Cypress Way, Bin A-00 • Tallahassee, FL 32399-1701
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FloridaHealth.gov

The findings in Florida are consistent with various studies that continue to uncover such risks. To further evaluate this, the Surgeon General wrote a letter to the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) illustrating the risk factors associated with the mRNA COVID-19 vaccines and emphasizing the need for additional transparency.

According to a study, Fraiman J et al, *Vaccine*. 2022, mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events, including coagulation disorders, acute cardiac injuries, Bell's palsy, and encephalitis. This risk was 1 in 550 individuals, which is much higher than other vaccines.

A second study, Sun CLF et al, *Sci Rep*. 2022, found increased acute cardiac arrests and other acute cardiac events following mRNA COVID-19 vaccination.

Additionally, Dag Berild J et al, *JAMA Netw Open*. 2022, assessed the risk of thromboembolic and thrombocytopenic events related to COVID-19 vaccines and found preliminary evidence of increased risk of both coronary disease and cardiovascular disease.

While the CDC has identified safety signals for stroke among individuals 65 and older following the bivalent booster administration, there is a need for additional assessments and research regarding safety of all mRNA COVID-19 vaccines.

To support transparency, the State of Florida reminds health care providers to accurately communicate the risks and benefits of all clinical interventions to their patients, including those associated with the COVID-19 vaccine as additional risks continue to be identified and disclosed to the public.

The State of Florida remains dedicated to protecting communities from the risks of COVID-19 and other public health concerns, specifically by promoting the importance of treatment and promoting prevention through healthy habits. We encourage our health care partners and providers to do the same.

February 15, 2023

Robert M. Califf, MD, MACC
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U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Springs, MD 20993

Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
2877 Brandywine Rd, Room 2402
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Drs. Califf and Walensky,

The COVID-19 pandemic brought many challenges that the health and medical field have never encountered. Although the initial response was led by a sense of urgency and crisis management, I believe it is critical that as public health professionals, responses are adapted to the present to chart a future guided by data and common sense.

As Florida's Surgeon General, it was in the public's best interest to issue guidance for using mRNA COVID-19 vaccines in children and in young men based on the absence of a health benefit in clinical trials. This guidance followed preliminary data analyses by the Florida Department of Health. We continue to refine and expand these findings, including addressing methodological issues inherent to evaluating vaccine safety and efficacy.

In addition to Florida's analysis of mRNA COVID-19 vaccines, academic researchers throughout our country and around the globe have seen troubling safety signals of adverse events surrounding this vaccine. Their concerns are corroborated by the substantial increase in VAERS reports from Florida, including life-threatening conditions. We have never seen this type of response following previous mass vaccination efforts pushed by the federal government. Even the H1N1 vaccine did not trigger this sort of response. In Florida alone, we saw a 1,700% increase in reports after the release of the COVID-19 vaccine, compared to an increase of 400% in vaccine administration for the same period. The reporting of life-threatening conditions increased 4,400%.

This increase in adverse events, compared to the percent increase in vaccine use, further explains the significant uptick we are seeing in VAERS reports. These findings are unlikely to be related to changes in reporting given their magnitude, and more likely reflect a pattern of increased risk from mRNA COVID-19 vaccines. We need unbiased research, as many in the

academic community have performed, to better understand these vaccines' short- and long-term effects.

According to a recent study, mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events, including coagulation disorders, acute cardiac injuries, Bell's palsy, and encephalitis, to name a few. This risk was 1 in 550, much higher than other vaccines. To claim these vaccines are "safe and effective" while minimizing and disregarding the adverse events is unconscionable.

Communication between physicians and patients is a standard ethical practice that is fundamental to public health. Health care professionals should have the ability to accurately communicate the risks and benefits of a medical intervention to their patients without fear of retaliation by the federal government.

The State of Florida remains dedicated to responding to COVID-19 and other public health concerns through data-driven decisions. We will continue to shed light on the safety and efficacy of medications, including mRNA COVID-19 vaccines, that could be an imminent threat to those with preexisting conditions. We will also promote the importance of prevention by supporting good nutrition, exercise, and other healthy habits. As a father, physician, and Surgeon General for the State of Florida, I request that your agencies promote transparency in health care professionals to accurately communicate the risks these vaccines pose. I request that you work to protect the rights and liberties that we are endowed with, not restrict, and diminish them.

I look forward to your responses and appreciate your support of our collective efforts to serve the health and safety of Florida and our nation.

Sincerely,

Joseph A. Ladapo, MD, PhD
State Surgeon General

ISSN: 2475-6296

Review Article

Journal of Clinical & Experimental Immunology

COVID-19 vaccines – An Australian Review

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

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

Abstract

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

Introduction

This review is written from an Australian perspective and will concentrate on the COVID-19 mRNA vaccines. In Australia the COVID vaccination is still heavily promoted. Until April 2022 only the mRNA vaccines Comirnaty (Pfizer) and Spikevax (Moderna), as well as the vector vaccines Vaxzevria (AstraZeneca) and COVID-19 Vaccine Janssen (Janssen) were preliminarily registered for use. Every one of these vaccines forces the vaccinees body to produce the spike protein for which the genetic code is delivered into the cells as mRNA via a nanoparticle or as double stranded DNA via a viral vector. (https://www.tga.gov.au/international-covid-19-vaccines-recognised-australia).

In April 2022 yet another vaccine, Nuvaxovid (Biocelect on behalf of Novavax, based on a new concept) received preliminary approval in Australian. Nuvaxoid contains a modified spike derived from moth cells cultured after transfection using Baculovirus, which express the spike protein on their cell membrane. This spike protein is harvested and assembled onto a synthetic lipid nanoparticle, which displays 14 spike proteins each. (https://www.precisionvaccinations.com/vaccines/novavax-covid-19-vaccine). The vaccine is registered for 18 years of age and older.

The government continues to push particularly the mRNA vaccinations by encouraging a fourth vaccination and recommending the vaccine for pregnant women as well as children 5 to 11 years old. The official public message is that the mRNA vaccines are safe. However, the Therapeutic Goods Administration (TGA), the medicine and therapeutic regulatory agency of the Australian Government, states quite clearly on their website that the large-scale trials are still progressing and no full data package has been received from any company. The TGA is currently getting rolling data and safety and effectiveness are still being assessed (https://www.tga.gov.au/covid-19-vaccines-undergoing-evaluation).

Initial information

The mRNA vaccines were supposed to remain at the injection site and be taken up by the lymphatic system. This assumption proved to be wrong. During an autopsy of a vaccinated person that had died after mRNA vaccination it was found that the vaccine disperses rapidly from the injection site and can be found in nearly all parts of the body [1]. The mRNA is enveloped in liquid nano particles (LNP) containing a mixture of phospholipids, cholesterol, PEGylated lipids and cationic or ionizable lipids [2]. Research has shown that such nanoparticles can cross the blood-brain barrier [3] and the blood-placenta barrier [4], so it came as no surprise that the European Medicines Agency assessment report for the Moderna vaccine on page 47 (https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf) also noted that mRNA could be detected in the brain following intramuscular administration at about 2% of the level found in plasma. In 2021 researchers from Japan reported a disproportionately high mortality due to cerebral venous sinus thrombosis and intracranial haemorrhage. Despite not being able to prove a causal link with vaccines, as no autopsies were performed, they still believed that a link with vaccination is possible and further analysis is warranted [5].

It was furthermore stated that the mRNA will degrade quickly. Normally, mRNA breaks down within a few minutes to hours, however, the mRNA in these vaccines is nucleoside-modified to reduce potential innate immune recognition [6, 7] and it has been shown that production of the spike protein in some vaccines is kept up for an extraordinarily long time. A study by Röltgen et al. [8] found that the vaccine mRNA persists in the body up to 60 days, with 60 days being the end point of their study. It is thus unknown and impossible to define how much of the spike protein is actually produced in the vaccinated. It is a standard requirement for vaccine producers to define the amount of antigen in each injection. For a "so called "vaccine that is using the human body as the production facility there is no possible quantification of antigen. This is highly variable and dependant on the amount and stability of nanoparticles in the injection, age and fitness of the vaccinee, their immune status and the injection technique – if a blood vessel is directly injected, the nanoparticles will travel in minutes to all major organs including the brain. It is therefore impossible to assess how much spike protein any individual vaccinee produces following an inoculation. In summary, it is unknown where exactly the vaccine travels once it is injected, and how much spike protein is produced in which (and how many) cells.

Prominent cardiologist Dr Peter McCullough stated that the spike protein - a cytotoxin solely responsible for the severity of the respiratory infection - makes the use of it as immunizing agent dangerous. The spike protein in itself can produce COVID- 19 symptoms as shown in animal experiments. The S1 subunit of the SARS-CoV-2 spike protein when injected into transgenic mice overexpressing human ACE-2 caused a COVID-19 like response (a decline in body weight, dramatically increased white blood cells and protein concentrations in bronchoalveolar lavage fluid (BALF), upregulation of multiple inflammatory cytokines in BALF and serum, histological evidence of lung injury, and activation of signal transducer and activator of transcription 3 (STAT3) and nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) pathways in the lung [9].

It was further shown that the spike protein S1 subunit, when added to red blood cells in vitro, could induce clotting by binding fibrinogen and ACE2 on platelets, thus triggering their aggregation [10]. The S protein also increases human cell syncytium formation, removes lipids from model membranes and interferes with the capacity of high-density lipoprotein to exchange lipids [11, 12]. Another in silico study showed that the spike protein S2 subunit specifically interacts with BRCA-1/2 and 53BP1 [13]. BRCA-1 is frequently mutated in breast cancer in women and prostate cancer in men, while 53BP1 is a well-established tumor suppressor protein.

A paper published by Liu et al. conducted single-cell mRNA sequencing of peripheral blood mononuclear cells (PBMCs) harvested from patients before and 28 days after the first injection of a COVID-19 vaccine [14]. While this vaccine was based on an attenuated virus and not a mRNA vaccine, it also is injected directly into the deltoid muscle, bypassing the mucosal and vascular barriers.

The authors found consistent alteration of gene expression following vaccination in many different immune cell types. One housekeeping gene of high importance is RNA polymerase I (POL I) which transcribes ribosomal DNA into RNA and monitors rDNA integrity in the process. Many of the downregulated genes identified by Liu et al. (2021) were linked to the cell cycle, telomere maintenance, and both promoter opening and transcription of POL I, indicative of impaired DNA repair processes [14].

Seneff et al (2022) describe another mechanism by which the mRNA vaccines could interfere with DNA repair [15]. The microRNA miR-148 has been shown to downregulate homologous recombination in the G1 phase of the cell cycle. MiR-148 is one of two microRNAs found in exosomes released by human cells following SARS-CoV-2 spike protein synthesis in the experiments by Mishra and Banerjea [16].

Natural immunity ignored

It is an amazing fact that natural immunity is completely disregarded by health authorities around the world. We know from SARS-CoV-1 that natural immunity is durable and persists for at least 12-17 years [17]. Immunologists have suggested that immunity to SARS-Cov-2 is no different. The human population has encountered and co-existed with a great number of coronaviruses throughout evolution. Most of us have cross-reacting T-cells, B cells and antibodies derived from encounters with common cold coronaviruses that can recognise SARS-CoV-2 [18-20]. A survey of more than 100 immunologists, infectious-disease researchers and virologists working on the coronavirus, who were asked whether the virus could be eradicated, showed that almost 90% of respondents believe that the coronavirus will become endemic [21]. The four human coronaviruses that cause common colds are also endemic, without there ever having been a vaccine for any of them. The existence of related viruses might explain that approximately 40% to 45% of COVID infected people are asymptomatic and about 80% of COVID cases are mild infections. In some cohorts, the asymptomatic infection figure jumps as high as 96% depending on the age and cross-immunity imparted by other viruses such as beta coronaviruses HCoV-OC43 and HCoV-HKU1, which have been proposed as a mitigating factor in the spread of SARS-CoV-2 [22-23].

The Brownstone institute has established the most updated and comprehensive library list of 150 of the highest-quality, complete, and robust scientific studies and evidence reports/position statements on natural immunity as compared to the COVID-19 vaccine-induced immunity. The consensus of these studies is that immunity induced by COVID infection is robust and long lasting (https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/).

When comparing the immune response to vaccination and natural infection, differences in the responses were detected. For example, a strong upregulation of genes associated with type I interferon production, cytotoxicity and an increase in circulating plasmablasts were only observed after natural infections [24]. In contrast, mRNA vaccines seem to suppress interferon responses [25]. A literature review by Cardozo and Veazev [26] concluded that COVID-19 vaccines could potentially worsen COVID-19 disease through antibody-dependent enhancement when natural infection occurs after vaccination, regardless of the delivery mechanism - vector or LNP containing RNA – of the nucleic acid coding for the spike protein.

A retrospective cohort study from Sweden revealed that individuals who survived and recovered from a previous infection had a lower risk of COVID-19 re-infection and hospitalisation for up to 20 months. The authors concluded that both previous infection and vaccination should be sufficient proof of immunity to COVID-19 [27, 28].

When comparing 2,653 fully vaccinated individuals with 4,361 individuals recovered from COVID-19, initial levels of antibodies were higher in the vaccinated but decreased exponentially and much faster than in individuals recovered from COVID-19 [29].

There have been discussions about risk and value of vaccination in the previously infected part of the population. Study results have shown that the second dose in people already exposed to the virus leads to a reduction of cellular immunity, inferring those individuals previously infected with COVID-19 should not get a second injection [30].

All of these facts should have led to the standard operating procedure of establishing antibody titres in patients before vaccination for SARS CoV-2, similar to other vaccinations. However, this did not happen and natural immunity is still not accepted as proof of immunity in Australia.

Protection

The vaccine was never meant to prevent the spread of the virus, but to decrease disease severity. A study at the University of California followed up on infections in the workforce after 76% had been fully vaccinated with mRNA vaccines by March 2021 and 86.7% by July 2021. In July 2021 75.2% of the fully vaccinated workforce had symptomatic COVID [31].

Paul Elias Alexander pointed out this troubling situation in an article published by the Brownstone Organisation by citing three studies where we see this emerging situation of the vaccinated increasingly being infected and transmitting the virus. The study by Chau et al. reported a seminal nosocomial outbreak occurring in fully vaccinated Hospital Care workers (HCW) in Vietnam in 2021 [32]. The second study described an outbreak in a Finnish hospital where the virus spread among HCWs and patients [33]. In this study the Delta variant of the virus was introduced by an inpatient. Both symptomatic and asymptomatic infections occurred among vaccinated HCWs. Secondary transmissions were observed from those with symptomatic infections despite the use of personal protective equipment. The third publication detailed an outbreak in an Israeli hospital, where the virus spread among vaccinated HCWs and vaccinated patients [34]. (https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/).

Acharya et al. (2021) and Riemersma et al. (2021) both showed that the vaccinated have very high viral loads similar to the unvaccinated and are therefore as infectious [35, 36]. Brown et al. (2021) and Servelitta et al (2021) suggested that vaccinated people with symptomatic infection by variants, such as Delta, are as infectious as symptomatic unvaccinated cases and will contribute to the spread of COVID even in highly vaccinated communities [37-38].

A study from the US found that increases in COVID 19 cases are unrelated to levels of COVID-19 vaccination across 68 countries and 2,947 counties in the United States. On the contrary, it seems that countries with higher vaccination rates have also higher caseloads. It was shown that the median of new COVID-19 cases per 100,000 people was largely similar to the percent of the fully vaccinated population [39].

Multiple recent studies have indicated that the vaccinated are more likely to be infected with Omicron than the unvaccinated. A study by Kirsch (2021) from Denmark suggests that people who received the mRNA vaccines are up to eight times more likely to develop Omicron than those who did not [40]. This and a later study by Kirsch (2022a) conclude that the more one vaccinates, the more one becomes susceptible to COVID-19 infection [41].

This has to be seen in context with the small risk of dying from COVID-19. A recent peer-reviewed review paper by one of the world's most cited and respected scientist, Professor John Ioannidis of Stanford University notes an infection fatality rate (IFR) for Covid of 0.00-0.57% (0.05% for under 70s), far lower than originally feared and no different to severe influenza [42]. The chances of someone under 50 years old with symptoms dying from COVID-19 is 0.05%. The chances of someone under 18 years old dying from COVID is near 0%. Those that die usually have severe underlying medical conditions. It is estimated that children are seven times more at risk to die from influenza than from COVID-19.

A worldwide Bayesian causal Impact analysis suggests that COVID-19 gene therapy (mRNA vaccine) causes more COVID-19 cases per million and more non-Covid deaths per million than are associated with COVID-19 [43]. An abundance of studies has shown that the mRNA vaccines are neither safe nor effective, but outright dangerous. Never in vaccine history have we seen 1011 case studies showing side effects of a vaccine (https://www.saveusnow.org.uk/covid-vaccine-scientific-proof-lethal).The

Covid-19 Vaccine Monitor, an interim study report for cohort event monitoring of vaccinated persons in the EU, published on June 9, 2022 concludes that across all sites 0.2-0.3% of participants reported at least one serious adverse reaction after receiving the first and/or second dose, and similar numbers are reported after the first booster. (https://zenodo.org/record/6629551)

We are now hearing that the EU issued a warning that taking the boosters may cause adverse effects to the immune system and may not be warranted [44]. A top Israeli immunologist has called on the leaders at the Israeli Ministry of Health to admit that the mass vaccination campaign has failed in Israel [45]. The vaccine is in trial phase and has been linked to not only instant side effects but also short to medium-term side effects [44]. Thorp et al. (2022) highlighted just a few of these side effects, such as miscarriage, foetal death and malformation, chronic autoimmune disease, permanent immune deficiency syndrome, chronic permanent CNS diseases and chronic cognitive disorders, seizure disorders and neonatal/infant cancers; and this only refers to foetuses and infants [46]. Not enough time has passed since administration of the first injections to know what the long-term effects might be.

Pfizer's documents show lipid nanoparticles with their mRNA cargo being distributed throughout the entire body and passing through the blood brain, placental and foetal blood brain barriers and concentrate in the ovaries. From US life insurance reports we know that the all-cause death rates were up 40% in ages 18-64 years by the end of Q3 2021, and according to life insurance companies there are 100,000 excess deaths per month in the US in all age groups, which cannot be attributed to COVID-19 alone [46].

In a recently published study by Doshi et al from August [47], the authors looked for serious adverse events (SAE) and adverse events of special interest (AESI) in the randomized phase III trials of both Pfizer and Moderna. Because both companies began unblinding study participants and offering them the vaccines only weeks after the emergency use authorization was granted by the FDA, the interim datasets from the time point of the EUA was used. By looking in depth at the total number of SAE instead of only the number of participants reporting one or more SAE, they found that the Pfizer injection was associated with a 36% higher risk of SAE in the vaccine versus the placebo group, while the Moderna vaccine was associated with a 6% increase of SAE in the vaccine group. They concluded after a simple risk-benefit analysis using the companies' own data, that for both Pfizer and Moderna excess risk of serious AESI exceeded the benefit of reduction in Covid-19 hospitalizations. They finish with a request for full transparency of the Covid-19 vaccine clinical trial data which to this day are inaccessible.

In a study by Shimabukuro et al. [48] following 3,958 pregnant participants in the v-safe pregnancy registry only 827 (20.89%) women enrolled in the study completed pregnancy. In the v-safe table the number of pregnant women registered as pregnant was 30,887 and the number registered as pregnant after vaccination with either Moderna or Pfizer vaccine was 4,804, which suggests loss of pregnancy and stillbirths in 84.45% of the pregnant women [48].

In a study concentrating on the second booster dose by Regev-Yochay et al. (2022) breakthrough infections were shown to be common, mostly very mild, but with high viral loads [49]. The vaccine efficacy against infection was as low as 30% for BNT162b2 (Pfizer) and 11% for mRNA1273 (Moderna) with local and systemic adverse reactions reported for 80% of BNT162b2 recipients and 40% of mRNA1273 [50].

Children under 18 are 51 times more likely to die from the mRNA vaccines than from COVID-19 if unvaccinated. Young adults in the age range of 18 to 29 are eight times more likely to die from vaccination than from COVID-19. Adults from 30 to 39 are 7 times more likely to die from vaccination and those aged 40 to 49 are 5 times more likely to die after vaccination. People in the group aged 50 to 59 are still twice as likely to die after vaccination than after COVID-19. Only when over 60 years of age is the chance of death equal for both causes. Even when over 80 years old the likelihood of dying from Covid inoculation is just 0.13% lower than the risk of dying from the infection. The authors concluded that the protection from COVID-19 death falls far short of the risk of dying from the vaccine for people below 50 years old [51].

According to Kostoff [52] the number of deaths attributable to each inoculation is five times higher in the most vulnerable 65+ demographic than deaths attributable to COVID–19. With decreasing age, the risk of death from COVID-19 decreases drastically. Combined with the longer-term effects of the inoculations, most of which are still unknown, this increases the risk-benefit ratio, perhaps substantially, in the lower age groups.

A study looking at the length of protection over time indicated that immunity against the delta variant of SARS-CoV-2 waned in all age groups a few months after receiving the second dose of the vaccine [53]. Another study found that antibody titres increased significantly at five weeks after the first vaccination but decreased rapidly at four months after the second injection. This significant decrease was independent of gender or age [54]. The fact that immunity after vaccinations seems to wane over time has been reported by other researchers who also found that antibody titres are decreasing by up to 40% each months [55] with no detectable antibody levels recorded in 16.1% of the subjects in one study within six months. Therefore, booster vaccinations were recommended [56]. Another study found that decrease in neutralising antibody titres to alpha, beta, gamma and delta variants was not significantly different between the different vaccines. They used modelling and predicted below 50% protection against symptomatic infection within the first year, also urgently recommending booster shots [57]. Scientists agree though, that introducing a booster too early

and too frequently carries increased risks especially for vaccines that have immune-mediated side-effects, such as myocarditis, Guillaine-Barre syndrome and thrombosis [58].

Lui et al. [59] specifically looked at protection against Omicron and concluded that the Omicron variant of COVID-19 was remarkedly resistant to neutralization by serum from individuals vaccinated with one of the four widely used COVID-19 vaccines. Serum from persons vaccinated and boosted with mRNA-based vaccine was also showing substantially diminished neutralization of Omicron.

A study investigated the neutralizing antibody titres against the reference strain WA1/2020 and omicron subvariants BA.1, BA.2, BA.2.12.1 and BA.4 or BA.5. in participants that had been double vaccinated and boosted with the Pfizer mRNA vaccine versus participants that had been vaccinated (bar one) and infected with the BA.1 or BA.2 variant of omicron on average 29 days prior. Their conclusion was that compared to the reference strain neutralising antibody titres to the Omicron variants were substantially decreased in both groups (6.4, 7.0 and 14.1 times (vaccinated) and 6.4, 5.8 and 9.6 times (infected) lower against BA.1, BA.2, BA.2.12.1 respectively and 21.0 (vaccinate) and 18.7 (infected) times lower against BA.4 or BA.5), suggesting that the later variants increasingly escape neutralizing antibodies [60].

Even a fourth shot of a Covid-19 vaccine is “not good enough” to prevent Omicron, according to a preliminary study in Israel. Sheba Hospital tested a fourth shot given to more than 270 medical workers, with 154 getting the Pfizer jab and 120 receiving Moderna. The researchers found that both groups showed a “slight” increase in antibodies - but not sufficient to prevent Omicron. Disturbingly, the vaccinated infected health care workers had relatively high viral loads, which suggests that they were infectious [49].

In a letter to the editor Yamamoto (2022) sums up the literature pointing to the fact that 8 months after being vaccinated twice the immune functions are less than those of an unvaccinated person according to a study by Nordstroem et al (2022) [61]. Booster shots can impair immunity due to a variety of factors leading to the recommendation to discontinue further booster shoots.

A paper by John Gibson from the University of Waikato looked at the excess death rate in New Zealand and found that rising excess mortality was closely related to the booster rollout. The author calculated 16 excess deaths for each 100,000 booster doses (https://repec.its.waikato.ac.nz/wai/econwp/2211.pdf).

According to the Health NSW government site the data obtained in 14 days until 16th of July 2022 continues to show the trend of worsening effects after the booster shots. Figure 1 shows the hospitalisation, the ICU admission and deaths sorted by vaccination status with a total of 806, 77 and 142 respectively. Comparing data of people infected with COVID the figures provided by the NSW Health Department (Fig 1) seem to confirm this trend.

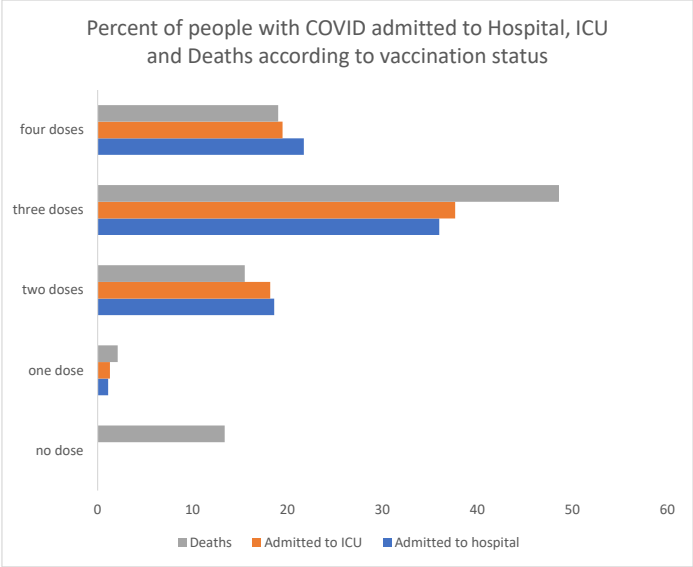

Figure 1: People diagnosed in 14 days up to the 16th of July 2022 who were submitted to hospital, ICU and died in New South Wales, Australia. Numbers represented as percentage of the total (https://www.health.nsw.gov.au/Infectious/covid-19/Documents/weekly-covid-overview-2-22-716.pdf)

Treatments

It is truly disturbing that treatments recommended by doctors in America, some of them having successfully treated COVID-19 patients, including very sick patients, have not been investigated in Australia. These treatments are mainly based on vitamins, zinc and zinc ionophores, such as ivermectin or hydroxychloroquine. The recommendation is to treat as early as possible. Scientific papers support the use of ivermectin according to Bryant et al. [62]. They found moderate to strong evidence that ivermectin can reduce COVID-19 deaths while being safe and inexpensive. The same was found for hydroxychloroquine in a review by McCullough et al, which also stated that a reduction of mortality strongly depends on an early start of the treatment. Hydroxychloroquine has been registered in the US since 1955 and has a well-characterized safety profile [63].

Yet here in Australia the recommendation is to isolate and monitor yourself. Only if you have difficulty breathing, experience loss of speech or mobility, confusion or chest pain should you contact the health care provider. Additionally, the government strongly advises not to use the following treatment for COVID-19 off label: Ivermectin, doxycycline, zinc and hydroxychloroquine (https://www.health.gov.au/health-alerts/covid-19/treatments).

The TGA provisionally approved the first oral treatments in January 2022 for Australia, Lagevrio® (molnupiravir) and Paxlovid® (nirmatrelvir + ritonavir) and recommend that both treatments should be started as soon as possible after diagnosis of COVID-19 (https://www.health.gov.au/health-alerts/covid-19/treatments/oral). The TGA also accepted - similar to the agreement for the

provisionally approved vaccines - rolling data for COVID-19 treatments, to enable early evaluation of data as it comes to hand (https://www.tga.gov.au/apm-summary/lagevrio). In other words, both drugs have been provisionally approved on the basis of short-term efficacy and safety data and permanent approval depends on the efficacy and safety data from ongoing clinical trials and post-marketing assessment. (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01049-1)

Therefore, these treatments are still in trial phase and all patients treated with them are trial participants. Paxlovid has listed numerous potential complex and serious drug-drug interactions against its registration which could result in severe or life-threatening side effects(https://www1.racgp.org.au/newsgp/clinical/what-gps-need-to-know-about-the-new-covid-antivira).

Short Term Side Effects

Just to name a few short-term side effects: Death, Cardiac disorders such as Myocarditis, Blood and lymphatic system disorders, such as blood clots, thrombocytopenia, low platelet count, cerebral venous sinus thrombosis, capillary leakage syndrome, Congenital and genetic disorders, Eye disorders, Immune disorders, Muscular, skeletal and connective tissue disorders, Cancerous tumours, Nervous system disorders, Pregnancy and perinatal conditions, Guillain-Barre syndrome and the list goes on.

Pfizer's documents demonstrate lipid nanoparticles with their mRNA cargo being distributed to the entire body and pass through the blood brain, placental and foetal blood brain barriers and concentrate in the ovaries. The vaccine is in trial phase and has been linked to not only instant but also long-term side effects.

Thorp et al. [46] highlighted just a few of the side effects, such as miscarriage, foetal death and malformation, chronic autoimmune disease, permanent immune deficiency syndrome, chronic permanent CNS diseases and chronic cognitive disorders, seizures and neonatal/infant cancers; and this is only with regard to foetuses and infants.

The data from NSW (Figure 1) showed clearly that COVID injections were correlated with increases in hospitalization and ICU admissions and indicate a relation to death with COVID injections. The increase in hospitalisation, ICU admissions and deaths is very pronounced after the third injection although only 69% of the population took the booster shot versus 95% taking the initial series.

The Australian Bureau of statistics has just released the national death rate for March 20, 2021 up until 31 March 2022 (registered by 31 May 2022) as 44,331, which according to their own statement lies 6,609 (17.5%) above the historical average. These extra deaths cannot be explained by COVID alone (Fig 2) which is responsible for less than half of the excess deaths in the first 4 months of 2022 in Australia. Cancer, diabetes and neurodegenerative diseases are all above the baseline in this time frame (https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release?fbclid=IwAR3fpywSvxWCXTRUaZx99M6s_w_kBRdMa3b_13msQ3bNPRanFjGHi-wWTZQ).

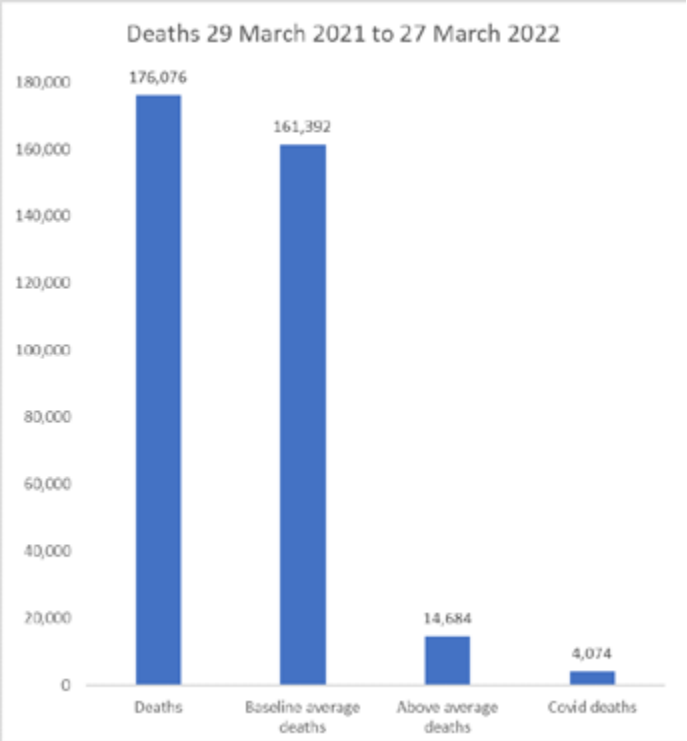

Figure 2: Death rate for Australia from 20th of March 2021 to 27 March 2022 according to the Australian Bureau of Statistics (https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release?fbclid=IwAR3fpywSvxWCXTRUaZx99M6s_w_kBRdMa3b_13msQ3bNPRanFjGHi-wWTZQ)

We get an insight into what is really going on in England where the government released COVID related death data (if the death certificate mentioned COVID) and all other death data sorted by vaccination status (Figure 3). The overall death rate for the unvaccinated was 17% while for the vaccinated it was 83%. The trend seems to be an ever increasing all causes death rate with added vaccinations without getting any protection from additional injections.

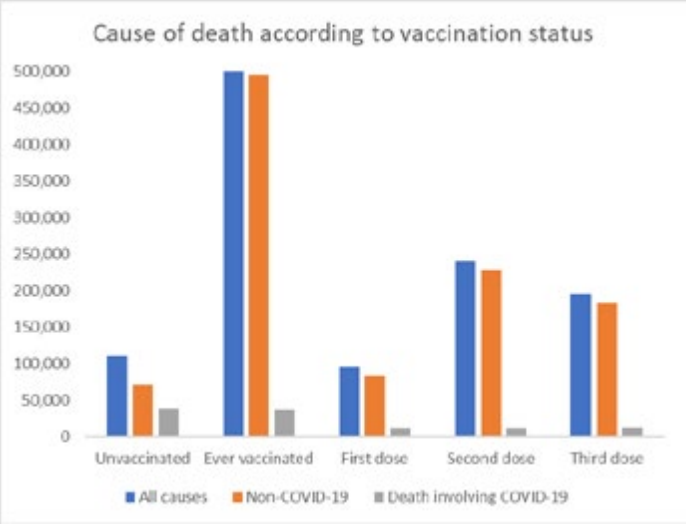

Figure 3: The cause of death according to vaccine status in the UK from the 1 January 2021 to the 31 May 2022 https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland

Unexplained deaths in Germany have been shown to be the consequence of mRNA vaccines causing an autoimmune response of CD8 T killer lymphocytes in all organ systems throughout the body. Dr Sucharit and Dr Burkhardt stated that the mRNA vaccine is killing the young and the old (https://doctors4covidethics.org/on-covid-vaccines-why-they-cannot-work-and-irrefutable-evidence-of-their-causative-role-in-deaths-after-vaccination/).

According to the VAERS database over 22,000 deaths have been associated with the COVID-19 vaccine. This is particularly alarming as according to the VAERS website adverse events including deaths are underreported by an unknown factor which could be between 10 and 100, so the actual number of deaths is likely much higher and could be over a million.

From large insurance companies in the US we know that the all-cause death rates are up 40% in ages 18-64 years and there are 100,000 excess deaths per month in the US across all age groups, which cannot be attributed to COVID-19 alone. However, caution has to be taken in interpreting these data as deaths due to suicides and delayed hospital treatment are not taken into consideration. Nevertheless, the trend seems to be the same and should raise alarm.

A study by Gat et al. on semen of male semen donors revealed a transient decrease in semen concentration and a reduction in the total motile count (TMC) after COVID-19 vaccination [64].

In January 2022 the "Save us now" organisation put together a list of 1011 case studies reporting side effects after vaccination (Table 1) (https://www.saveusnow.org.uk/covid-vaccine-scientific-proof-lethal/). Most of these side effects have not been listed in any of the vaccine brochures or on the Australian Government websites. Knowing that the mRNA vaccine can be found in nearly all organs including the brain the involvement of so many organs and tissues is not surprising. The explanation for multiple disorders and multiple affected organs post-vaccination is the toxicity of the S1 subunit of the spike protein which creates similar symptoms as the viral disease. Additionally, the lipid nanoparticles alone cause inflammation and vascular damage [65].

Table 1 A and B: All symptoms reported from the 1011 case studies listed by the "Save us now organisation" and some additional case studies by Di Mauro et al. [66]; Erro et al. [67]; Garreffa et al. [68]; Jabagi et al. [69] and Jee-Eun et al. [70] https://www.saveusnow.org.uk/covid-vaccine-scientifc-proof-lethal/

A

System organ class	Vaccine-induced SE	Pfizer/ BioNTech	Moderna	Oxford/ Astra Zeneca	Johnson & Johnson
Auditory and balance disorders	Acute vertigo [71]	x			
	Sudden sensorineural hearing loss			x	
Autoimmune disease	Autoimmune encephalitis			x	
	Autoimmune hepatitis	x	x	x	
	Graves' disease	x			
	Limbic encephalitis	x			
	Multiple sclerosis	x	x	x	
	Myasthenia gravis	x			
	Psoriasis	x		x	

	Severe autoimmune hemolytic anemia		x		
	Systemic lupus erythematosus	x			
	Vogt-Koyanagi-Harada Syndrome	x		x	
Cardiac disorders	Arrhythmia		x		
	Cardiac tamponade	x			
	Cardiomyopathy	x			
	Endocarditis		x		
	Kounis hypersensitivity-associated acute myocardial infarction	x			
	Myocardial infarction	x	x	x	
	Myocarditis *	x	x	x	x
	Myocarditis-induced Sudden Death	x			
	Myopericarditis	x	x		
	Pericarditis	x	x	x	x
	Takotsubo cardiomyopathy	x	x	x	
	Transient Cardiac Injury	x			
Death		x	x	x	x
Dermal disorders	Chilblains	x	x		
	Delayed adverse skin reactions *2	x	x	x	
	Dermal hypersensitivity (Covid arm)	x	x	x	
	Exacerbated Hailey-Hailey	x	x		
	Petechiae and peeling of fingers	x	x		
	Purpuric rash *1	x	x	x	
	Reactivation of alopecia areata	x		x	
	Reactivation of Bacille Calmette-Guérin scar	x	x		
	Sweet's syndrome	x		x	x
	Toxic epidermal necrolysis			x	
Endocrine disorders	Menstrual disorders, heavy menstrual bleeding	x	x	x	x

Gastrointestinal disorder	Appendicitis	x			
	Gastroparesis	x			
	Oral aphthous ulcers	x			
Immune and Lymphatic disorders	Allergy to PEG-ASNase	x	x		
	Anaphylaxis *4	x	x	x	
	Antibody-dependent cell cytotoxicity			x	x
	Arthritis	x			
	Complement-dependent cytotoxicity			x	x
	Hemophagocytic lymphohistiocytosis			x	
	Immune-mediated disease outbreaks	x	x	x	
	Lymphadenopathies *3	x	x	x	
	Multisystemic inflammatory syndrome	x		x	
	Rapid Progression of Angioimmunoblastic T Cell Lymphoma	x			
	Seronegative Polyarthritis	x		x	
	Splenic infarction			x	
	Thymic hyperplasia		x		
Infections	Covid-19	x	x	x	x
	Herpes Simplex	x	x	x	
	Herpes Zoster (Shingles)	x	x	x	
	Hepatitis C reactivation	x			
	Non-disseminated herpes zoster	x			
Liver and gallbladder disorders	Acute liver injury		x		
	ANCA glomerulonephritis		x		
Musculosceletal disorders	Amyotrophic neuralgia			x	
	Fasciitis		x		
	Myositis (inflammatory)	x		(x)	
	Polyarthralgia and Myalgia Syndrome			x	
	Polymyalgia rheumatica	x		x	

	Rhabdomyolysis	x	x		
	Still's disease			x	
	Synovitis	x			

*Acute Fulminant Myocarditis and Cardiogenic Shock, lymphocytic, eosinophilic, infarct-like and autoimmune myocarditis, acute haemorrhagic encephalomytitis [72].

*1 Haemorrhagic rash, Cutaneous thrombosis
*2 Eczematous, Shingles-like skin lesion, Pityriasis rosea-like reaction, Urticaria, Lichen planus-like dermatitis, Bullous drug eruption, Pruritus, Spongiotic dermatitis, Morbiliform rash, Papulovesicular reaction, Purpura annularis telangiectodes
*3 Cervical lymphadenopathy, Axillary lymphadenopathy (Garreffa et al, 2021), [68]
*4 Prolonged anaphylaxis, biphasic anaphylaxis, Anaphylactoid reaction and coronary thrombosis

B

System organ class	Vaccine-induced SE	Pfizer/ BioNTech	Moderna	Oxford/ Astra Zeneca	Johnson & Johnson
Neurological disorders	Acute inflammatory neuropathies	x	x	x	
	Abducens Nerve Palsy	x			
	Adrenomyeloneuropathy				
		x			
	Bell's palsy	x	x	x	
	Cerebral hemorrhage *8	x	x	x	x
	Cerebral venous sinus thrombosis	x	x	x	x
	Cerebral venous sinus thrombosis (CVST) with thrombocytopenia				x
	CNS demyelination	x	x	x	x
	CNS inflammation	x	x		
	Distal small fiber neuropathy			x	
	Encephalomyelitis *5	x		x	
	Encephalopathy (acute)	x	x		
	Guillain-Barré syndrome (Jee-Eun, 2022)	x	x	x	x
	Miller-Fisher syndrome	x		x	
	Myelitis *9	x	x	x	
	Neuro-ophthalmic complications with VITT			x	
	Optic neuritis	x			
	Parsonage-Turner Syndrome	x	x		
	Stroke (Jabag et al, 2021) *6	x	x	x	x
	Status epilepticus, seizures*7	x	x	x	
Olfactory disorders	Phantosmia	x			

Optical disorders	Acute corneal endothelial graft rejection	x			
	Bilateral choroiditis			x	
	Central Serous Chorioretinopathy	x			
	Diplopia			x	
	Immune mediated keratolysis			x	
	Macular Neuroretinopathy			x	
	Oculomotor palsy			x	
	Retinal necrosis due to varicella zoster reactivation	x			
	Transient visual field loss	x			
	Tolosa-Hunt syndrome	x			
	Uveitis, Panuveitis	x			
Other disorder	Pancreas allograft rejection			x	
	Pancreatitis	x			
Pregnancy outcomes	Miscarriage (Pfizer's own data)	x			
Psychiatric disorder	Depression			x	
Pulmonary disorder	Acute eosinophilic pneumonia			x	
	Squamous cell carcinoma of the lung with hemoptysis	x			
Renal and urinary disorders	Acute renal failure		x		
	Crescentic Pauci-Inmune glomerulonephritis	x	x		
	Genital necrosis with cutaneous thrombosis	x			
	IgA nephropathy	x	x		
	Lipschuetz ulcer			x	
	Nephrotic syndrome			x	x
	Macroscopic hematuria	x	x		
	Minimal change disease and acute kidney injury	x		x	
Respiratory and thoratic disorders	Asthma exacerbation	x			
	Pulmonary embolism	x	x	x	x
	Semi Occluded Vocal Tract			x	
	Vaccine-induced interstitial lung disease	x			
Tissue disorders	Hemophagocytic lymphohistiocytosis			x	

Vascular disorders	Accelerated hypertension				
	Diffuse prothrombotic syndrome			x	
	Fatal systemic capillary leak syndrome			x	
	Giant cell arteritis	x			
	Haemolysis	x		x	
	Haemorrhage *10	x	x	x	
	Inflammation and platelet activation			x	x
	Limb ischemia			x	
	Microscopic polyangiitis	x			
	Symptomatic carotid occlusion				x
	Thrombocytopenia *11	x	x	x	x
	Thromboembolic events *12	x	x	x	
	Thrombotic events *13	x	x	x	x
	Vasculitis *14	x	x	x	x

*5 Acute disseminated Encephalomyelitis, acute demyelinating Encephalomyelitis, acute haemorrhagic encephalomyelitis (Ancau et al, 2022) [72]

*6 Ischemic stroke, acute ischemic stroke and hemorrhage, haemorrhagic stroke

*7 Acute hemichorea-hemiballismus, Dyskinesia (Erro et al, 2021) [67]

*8 Intracerebral hemorrhage and thrombocytopenia, Intracerebral hemorrhage associated with vaccine-induced thrombotic thrombocytopenia

*9 Extensive longitudinal transverse myelitis, Transverse myelitis, acute transverse myelitis, partial transverse myelitis, Myelitis, Acute bilateral optic neuritis/chiasm with longitudinal extensive transverse myelitis, Neuromyelitis optica (Devic's disease)

*10 Acral hemorrhage, Pulmonary hemorrhage, Retinal haemorrhage, Lobar hemorrhage with ventricular rupture

*11 Thrombotic thrombocytopenia, Thrombocytopenia and splanchnic thrombosis, Thrombotic thrombocytopenic purpura, Immune thrombocytopenic purpura

*12 Venous thromboembolism and mild thrombocytopenia

*13 Arterial thrombosis, Cerebral venous sinus thrombosis, Both transverse sinuses thrombosis, Left sigmoid sinus thrombosis, Portal vein thrombosis, Bilateral superior ophthalmic vein thrombosis, Major artery thrombosis, Idiopathic external jugular vein thrombophlebitis, Disseminated intravascular coagulation, Ophthalmic vein thrombosis, Central retinal vein occlusion

*14 Cutaneous vasculitis, Leukocytoclastic vasculitis, Small-vessel vasculitis, Granulomatous vasculitis, Vasculitis and bursitis, ANCA-associated vasculitis, Urticarial vasculitis, Neutrophil anti-cytoplasmic antibody-associated vasculitis, Cutaneous leukocytoclastic vasculitis

Side Effects (SE) are listed by organ class in alphabetical order, not by severity. To keep these tables manageable, we sorted subclasses of specific side effects under one heading and the foot notes below explain which subclasses can be found under the listed SE. Note that not all subclasses of SE have been demonstrated for all 4 vaccines.

COVID-19 vaccines cause more side effects than any other vaccine, a fact that is attributed to its interactions with the immune system. Not only does spike protein produces unwanted side effects, but mRNA and nanoparticles do as well. Seneff et al [15] enumerated Covid-19 vaccine effects on the innate immune system, importantly a decrease of type I interferon signalling, as well as disturbances in the regulation of protein synthesis affecting the formation of immune cells and the apoptosis of tumor cells. These are major disturbances that in turn can lead to a multitude of disorders such as those listed in Table 1. The suppression of the interferon response by the mRNA vaccines alone can lead to a wide variety of disorders, such as reactivation of viral infections and reduce the immune system's ability to not only fight disease but to keep tumors and autoimmune reactions suppressed [73]. A case report by Glas et al from [74] illustrates the effects of a disseminated viral infection on an immune-suppressed patient: In this instance fatal multiorgan failure associated with disseminated Herpes simplex virus-1 infection. Considering that reactivation and spread of dormant viral infections including Herpes simplex and Herpes zoster are listed as side effects from both mRNA injections as well as the Astra Zeneca vaccine, it is maybe not surprising that pathology reports by Dr Sucharit and Dr Burkhardt (2021) show multiorgan failure as cause of death in several cases of post-vaccine deaths.

Spike proteins enter the circulation when the cell they were attached to is destroyed by the immune system. The freely circulating spike proteins attach to any cell that expresses ACE2 receptors, explaining the multitude of sites where disorders occur [75]. Another method of viral spread that escapes the immune system is the formation of syncytia which can be induced by the spike protein itself. Heterotypic cell-in-cell structures with lymphocytes inside multinucleate syncytia are prevalent in the lung tissues of coronavirus disease 2019 (COVID-19) patients. This membrane fusion is dictated by a bi-arginine motif within the polybasic S1/S2 cleavage site leading to the formation of multinucleate syncytia. Host metalloproteases (ADAM-17 and ADAM-10) promote such spike protein-mediated lung cell fusion [76, 77]. Pepe et al (2022) [77] showed furthermore that the formation of tunneling nanotubes can be induced by Covid-19 in a so far undisclosed way and used to transport viral particles or indeed viral components like S and N proteins from infected to ordinarily non-permissive cells, e.g. neuronal cells. There are multiple ways in which the virus and the spike protein can spread throughout the body and from cell to cell without attracting too much attention from the immune system. Further weakening of the immune system through rashly promoted genetic intervention can only lead to more severe disease.

What needs to be further emphasised is that the majority of deaths with and from COVID- 19 occur in the elderly with multiple co-morbidities and generally weaker immune systems. Yet they are vaccinated with an injection that amplifies underlying disorders (Fig 4) and is dependent on a strong immune response. Ironically, the survival of many of those patients is probably due to their immune system not being able to mount a significant response to the induced spike protein production.

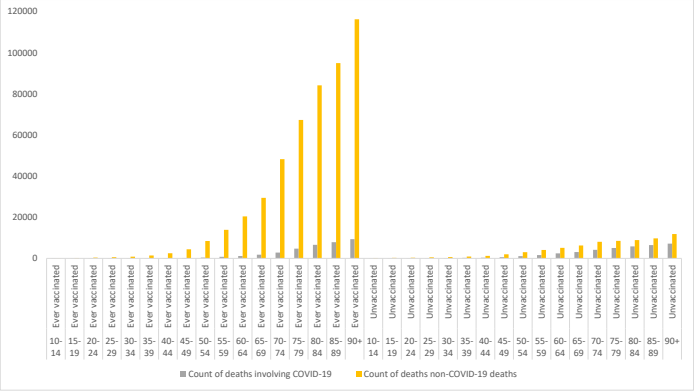

Figure 4: Death rate due to COVID and other causes comparing the vaccinated (at least one vaccination) and unvaccinated in each age group. The data of deaths occurring was for the period of the 1st of January 2021 to 31st of May 2022 in England (https://www.ons.gov.uk/)

Long Term Side Effects

Long-term risks of vaccination as predicted by scientists, many already validated by scientists and doctors:

Vaccine-induced autoimmunity, pathogenic priming, multisystem inflammatory disease and autoimmunity, antibody dependent enhancement (ADE), activation of latent viral infections, neurodegeneration and prion disease, increased thrombosis, cardiomyopathy and other vascular events following vaccination, babies suffering enduring adverse consequences, mRNA reverse transcribing intracellularly into the DNA and death due to autoimmune disease long after vaccination [78-84].

Some More Details

Autoimmune Disease

A study by Lyons-Weiler [79] revealed that over 1/3 of SARS CoV-2 proteins, including the spike protein show problematic homology to key proteins in the human adaptive immune system which might lead to autoimmune reactions against these proteins. Kelleni [78] reports on the potential risk of the vaccine to induce auto-immune diseases such as thrombocytopenia, myocarditis and immune induced thrombosis and thromboembolism which can have fatal outcomes and might be behind some of the post vaccination reports on sudden deaths.

Antibody Dependent Enhancement (ADE)

Hasan et al. [80] analysed data from the National Health Service published by Public Health England and showed that the death rate due to the Delta variant infection was eight times higher in fully vaccinated than in unvaccinated infected people. The authors suggest that in a subset of individuals the pre-existing anti-S-IgG titre induced by vaccination may be sub-neutralizing and leading to accelerated infectivity via ADE, which is displayed as higher death rates.

Prion Disease

The potential risk factors of the mRNA or vector DNA vaccine are protein sequences that can induce TDP-43 and FUS to aggregate into prion configuration, which might lead to neurodegenerative diseases, such as Alzheimers [85]. The spike protein encoded by the mRNA binds to the ACE2 receptor which releases zinc molecules. Zinc also causes TDP-43 to transform into a pathological prion [81]. The link with neurodegenerative disease is the ability of the spike protein to interact with the heparin binding amyloid forming proteins. A study indicated that the S1 protein forms a stable bond with the aggregation-prone proteins, which might initiate aggregation of brain proteins and thereby accelerate neurodegeneration [82]. Finisterer and Scorza [86] further stated that SARS-CoV-2 vaccines trigger neurological adverse reactions and both mild and severe neurological side effects have been occasionally reported. Studies support the theory that the onset and progression of neurodegenerative diseases such as Alzheimer and Parkinson disease, including TDP-43 proteinopathy, are associated with propagation of protein aggregates between neuronal cells. These speculations are supported by a case report of prion disease due to vaccination from Turkey [87, 88].

Thrombosis, Capillary Leakage Syndrome and Myocarditis

Scientific studies have raised serious concerns about the safety of AstraZeneca after reports of cerebral venous sinus thrombosis and a variety of other thrombotic events the AstraZeneca vaccination with studies reporting such events in medical journals. Kircheis [22] reported that other serious conditions have been reported for COVID vaccines such as capillary leakage syndrome

(AstraZeneca) and coronary myocarditis (Pfizer).

Pregnancy and Vaccination

Some concerns about vaccinating pregnant women were voiced by Anand and Stahel [83]. Walsh et al. [89]. reported that the results of the Pfizer vaccine demonstrate a broad immune response to vaccination with stimulation of neutralizing antibody responses, stimulation of CD4+ cells and growth of effector memory CD8+T cells in men and women. Anand and Stahel [83] hypothesised that one could assume this would also happen in pregnant women. This would not be favourable for a perinatal outcome and might lead to preterm birth and fetal loss, as a good outcome relies on amplifcation of helper T cell type 2 and regulatory T cell activity coupled with decreased Th1 response [90]. Evidence has suggested that mothers with variant CD4+ T cell responses give birth to babies that may suffer enduring adverse consequences [91].

Side Effects Acknowledged but Played Down as Extremely Small Risk

The TGA report in Australia on a weekly basis and the report of the 2nd of September 2021 mentioned nine more blood clots and low platelet counts, confirmed as probably Thrombocytopenia syndrome linked to the AstraZeneca vaccine with two connected deaths during that week, one from Queensland and one from NSW. An assessment of the 125 cases of thrombosis with thrombocytopenia syndrome (TTS) showed that women in the younger age groups were slightly more likely to develop TTS in more unusual places such as brain and abdomen with more serious outcomes projected (TGA).

Another rare side effect is Guillian-Barre syndrome (GBS), which affects the nerves. Up to the 29 August 99 reports of GBS after vaccination have been received. Further 61 reports of immune thrombocytopenia were lodged after AstraZeneca vaccination. For the Pfzer vaccine the TGA reports 293 instances of suspected myocarditis and/or pericarditis following vaccination to the 29 August 2021. Nine of these reports were from children 16 to 17 years of age. A study concluded that observations of increased thrombosis, cardiomyopathy and other vascular events following vaccination might be caused by the mRNA vaccines dramatically increasing inflammation of the endothelium and T cell infiltration of cardiac muscle [92].

Whistleblowers

At a parliament enquiry by US senator Ron Johnson lawyer Thomas Renz presented three US military doctors, Drs. Samuel Sigoloff, Peter Chambers, and Theresa Long, whose declarations he planned to use in federal court under penalty of perjury. These doctors revealed a 300% increase in miscarriages in the military above the five-year average in 2021 with the five-year average being 1,499 miscarriages per year while in the first 10 months of 2021 the registered miscarriages were 4,182. Other diseases went up in a similar fashion such as an almost 300% increase in cancer diagnoses (from a five-year average of 38,700 per year to 114,645 in the first 11 months of 2021). Neurological issues increased by 1000% from a baseline average of 82,000 to 863,000 in 2021. Some other increased conditions were:

- 269% increase of myocardial infarction
- 291% increase of Bell's palsy
- 156% increase of children's congenital malformations of military personnel
- 471% increase of female infertility
- 467% increase of pulmonary embolisms

https://newlifenarrabri.wordpress.com/2022/02/01/jo-nova-huge-spike-in-us-military-injuries-from-covid-vaccinations/ and https://www.ronjohnson.senate.gov/2022/2/sen-johnson-to-secretary-austin-has-dod-seen-an-increase-in-medical-diagnoses-among-military-personnel

According to an interview in February 2022 with Julian Gillespie, who is currently fighting in court against the vaccine mandates, an evaluation of the TGA reports revealed that Australia's average of adverse events after vaccination since 1971 up to 2020 is recorded as 2.4 death per year and up to 3,500 adverse events per annum. Since the rollout of the COVID vaccines there have been 755 deaths and 105,000 adverse events in a year with these figures likely to be underreported. https://rumble.com/vtv5pe-julian-gillespie-update-on-avn-judicial-review-to-stop-vaccines-in-australi.html?fbclid=IwAR34RTAAYX_nf9eTe1LOJSxuZ0-TbUFasXPQ37qhPEqrQI9wNe8Yig4ZwQ8

The question is how many deaths and side effects are we accepting as normal for vaccines and where do we draw the line to say more investigations need to be done before any further vaccines are distributed?

Conclusion

Never in Vaccine history have 57 leading scientists and policy experts released a report questioning the safety and efficacy of a vaccine [93]. They not only questioned the safety of the current Covid-19 injections, but were calling for an immediate end to all vaccination. Many doctors and scientists around the world have voiced similar misgivings and warned of consequences due to long-term side effects. Yet there is no discussion or even mention of studies that do not follow the narrative on safety and efficacy of Covid-19 vaccination.

In the USA, as Blaylock [94] states it very nicely, federal bureaucrats have forced the acceptance of special forms of care and prevention, which includes experimental mRNA vaccines [93]. Medical experts that have questioned the safety of these vaccines have been attacked and demonised, called conspiracy theorists and have been threatened to be de-registered if they go against the narrative. Alternative treatments were prohibited and people who never practised medicine are telling experienced doctors how to do their job. AHPRA is doing the same here in Australia to the detriment and in ignorance of science. When Adjunct Professor John Skerritt, who is currently the Deputy Secretary and directly responsibility for both the Therapeutic Goods Administration and the Office of Drug Control, was asked why the registration process for vaccines was shortened he wrote: "It is nonsense to assert that vaccines typically take 10 years to licence. The standard regulatory process for vaccines is about 10-12 calendar

months and in the case of COVID-19 vaccines this period was shortened by accepting data on a rolling basis, teams reviewing different parts of the dossier in parallel, working collaboratively with international regulators, and by many members of the teams working long hours" (personal e-mail communication). One has to wonder how they propose to assess long-term side effects. Can we really trust any pharmaceutical drug approval by the TGA after this statement?

Pfizer never planned to reveal its clinical trial data and had to be ordered by a judge in the USA to release the data to the public. Even then they and the CDC tried to limit the number of pages published per month which would have made the full study data public knowledge sometime in the 2070ies. The reason given was that some proprietary information had to be blacked out before release to the public. Again, it is inconceivable why it would be impossible to go through the study data in a few months, when it took the CDC less than 4 weeks to give the injections emergency use authorization - unless you want to entertain the idea that the study data were never actually read and scrutinised, a frightening perspective.

As scientists we put up hypotheses and test them using experiments. If a hypothesis is proven to be true according to current knowledge it might still change over time when new evidence comes to light. Hence, sharing and accumulating knowledge is the most important part of science. The question arises when and why this process of science has been changed. No discussion of new knowledge disputing the safety of the COVID-19 vaccines is allowed. Who gave bureaucrats the means to destroy the fundaments of science and tell scientists not to argue the science?

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From: [redacted]
Date: Sat, 11 Mar 2023, 10:23 am
Subject: Re: Webform submission from: Contact us
To: [redacted]
Cc: [redacted]

Good morning and thanks for providing this avenue to submit my documentation.

By way of explanation I have forwarded four emails to Safe Work Australia over the last few weeks outlining concerns in regard to COVID vaccine injuries which have affected coworkers and others in our local community. As I explain in my emails I have worked as a WH&S advisor since the 1990's in the Central Qld area.

I have attached copies of my emails and several attachments I believe are important documents which show that there is evidence supporting this claim.

Why I believe this issue falls within the jurisdiction of the state WH&S regulator is as follows:

- COVID vaccines were mandated by many state based employers/organisations
- COVID vaccines were promoted by many state based employers/organisations
- COVID vaccines were provisionally approved by the TGA
- There was little to no disclosure of potential serious side effects in regards to the general workforce to alert them of the potential adverse reactions. People who I have spoken to have told me they were told the injection site may get a bit sore. The more serious side effects were downplayed.

I wish to further explain that it is not my role or my right to provide the names of any workers who have communicated their health concerns to me in connection with COVID vaccine injuries. I have where relevant advised them to notify the relevant organisations. Most of the people I have spoken to are reluctant to do so.

I will give you a very brief idea of the types of issues that have been communicated to me:

- 1 individual had blood clotting on the spine after COVID boosters - now requiring expensive medication - doctors have advised of a direct link with the COVID vaccines
- 1 individual 11 months off work with heart complications (myocarditis) - doctors have advised of a direct link with the COVID vaccines
- 1 individual 6 weeks off work and advised by doctors that they could have died - doctors have advised of a direct link with the COVID vaccines
- 1 individual 1 week unable to work or move around much out of bed after first Pflzer vaccine injection

As I have explained to SWA it is difficult as a professional to walk away and ignore these issues.

I am hoping that our regulators show leadership and investigate why workers are suffering from these health protocols.

I also have concerns that individuals may have adverse reactions that affect their own safety and the safety of coworkers during work activities. This is especially the case where high risk work is being undertaken. I hope I have explained my concerns concisely but also thoroughly.

Kind regards
[redacted]

On Fri, Mar 10, 2023 at 11:34 AM [redacted] wrote:

Hello again [redacted] – I believe you can, but if you email the documents through to this address, we will pass them on to the assessment centre for allocation to the correct area of WHSQ, along with your contact details.

From: [redacted]
Sent: Friday, 10 March 2023 4:39 AM
To: [redacted]
Subject: Re: FW: Webform submission from: Contact us

Hi

I wish to attach documents. Is that possible through your online service?

[redacted]

On Thu, Mar 9, 2023 at 6:34 PM [redacted] wrote:

Hello [redacted] – the best way to report your concerns is through our online form https://www.worksafe.qld.gov.au/services/raise-a-workplace-safety-concern or by calling 1300 362 128.

Kind regards, WHSQ

From: [redacted]
Sent: Thursday, 9 March 2023 7:15 AM
To: [redacted]>
Cc: [redacted]
Subject: Webform submission from: Contact us

Submitted on Wed, 2023-03-08 21:14 Submitted by: Anonymous Submitted values are: [redacted] [1] *Your enquiry* I would appreciate an email contact for a concern I wish to raise with the Queensland WH&S Regulator in relation to the health effects of COVID vaccines on the general workforce. I am a WH&S professional, practicing in that vocation since the 1990's. I have contacted Safe Work Australia and they have referred me to my local regulator. I am specifically chasing the name and contact details of an officer working for the regulator who I can forward information to. [redacted]

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To whom it may concern

I have been employed in the private sector (in Queensland) for many years as a work health and safety advisor/coordinator. Since the 1990's.

I wish to bring your attention to an alarming number of health alerts in connection with the COVID vaccine rollout. I have attached documents recently published by Florida Health which show a 4,400% increase in life-threatening adverse reactions from COVID vaccines. These documents are freely available on their website.

A medical professional based in the Whitsundays Dr Melissa McCann has highlighted potential issues with TGA reporting associated with deaths from vaccines.

Australian Govt Concealed Vaccine Myocarditis Deaths. Cited Concern over "Vaccine Hesitancy' - YouTube

I personally have witnessed coercion and bullying by employers to mandate these protocols. Because I am close to retirement I was willing to resign or be made redundant rather than be pushed into something I wasn't comfortable with. I have also been privy to many issues relating to serious adverse reactions amongst my colleagues and friends. I have friends and colleagues who have reported up to 11 months off work due to heart inflammation with medical advice that the condition was related to the COVID vaccines. All I hear from the mainstream is the vaccines are "safe and effective"?

I noted the NSW shadow minister for WH&S speaking out about WorkSafe NSW on the recent 60 Minutes "silicosis" expose. The shadow minister for WH&S spoke out strongly about issues they observed with NSW WorkSafe. The shadow minister used the word "inept" to describe their lack of action in this area. On a personal level I was inspired by this story. *In my opinion it is a carbon copy of what we are seeing with this health protocol.*

We are relying on organizations such as yours to fully investigate what is potentially a major health and safety issue. Please find attached a health alert from Florida Health.

There are many other issues coming to light that need to be investigated to ensure the health and safety of workers and others in the community.

I have also attached a copy of the Altman Report which clearly shows that some of Australia's leading minds in the health profession are sounding alarm bells.

I fully realize that you are not a health department but I would expect that Safe Work Australia is cognizant of the harm and potential fallout for the Australian workforce. I would also expect your department to investigate this issue with an open mind realizing that the major players may be corrupt and acting out of self-interest. This issue was made evident while investigating the silicosis issues affecting our workforce.

I refer your organization to your protocol for incident reporting:

Incident reporting | Safe Work Australia

I believe vaccine related illnesses are notifiable due to the fact that they were mandated.

Only work-related incidents are notifiable

To be notifiable, an incident must arise out of the conduct of the business or undertaking. An incident is not notifiable just because it happens at or near a workplace.

Who is responsible for notifying?

Any person conducting a business or undertaking (PCBU) from which the 'notifiable incident' arises must ensure the regulator is notified immediately after becoming aware it has happened.

Procedures should be put into place to ensure work health and safety incidents are promptly notified to the people responsible for responding to them, for example a manager and then notified to the regulator, if required.

Qld health professionals have been sounding the alarm for a long time:

An open letter to Australian politicians on COVID-19 vaccine mandates for healthcare workers (substack.com)

- *We all have an inherent duty of care*
- *Seeing a hazard/issue we own it and have a responsibility to do something about it*

Some journalists have attempted to highlight issues over the years:
The other drug war - the politics of big business (smh.com.au)

How big pharma could be influencing your healthcare - The University of Sydney
Are pharma payments to nurses impacting your healthcare? - The University of Sydney
Pharmaceutical industry donates millions to both Australian political parties | Pharmaceuticals industry | The Guardian

I will pass this email on to my local member as a record of reporting it.

Kind regards

[redacted]

[redacted]

[redacted]

Gmail [redacted]

More Questions Requiring Answers

[redacted] Sun, Feb 26, 2023 at 9:07 AM

To: [redacted]

To whom it may concern

Every Australian citizen should watch the following clip:

The TGA's Actions Are Truly Inexcusable - YouTube

Skerritt caught lying gain and Labor covers for him - Senate Estimates 16.02.23 - YouTube

Chris Martenson, (a qualified pathologist) dissects the facts available in this latest TGA controversy. As I explained previously as a work health and safety professional I have been asked on many occasions by colleagues why they have become ill after taking one or more of the COVID vaccines. I am reliably informed by these colleagues that medical professionals have diagnosed their illnesses as vaccine adverse reactions.

The limited research I have been able to do points to the fact that the science behind the vaccine rollout is flawed (or corrupt).

You don't have to dig deep to find damning evidence in connection with corporate profits from the COVID treatments:

Pandemic riches: COVID-19 vaccine profits mint nine new billionaires (9news.com.au)

Billionaires' wealth rises to $10.2 trillion amid Covid crisis | The super-rich | The Guardian

As work health and safety professionals we must remind ourselves that our professional aim is to determine the real root cause and its associated causal factors. This is something I have had to do on many occasions while completing TapRoot incident investigations.

[redacted]

Journal of American Physicians and Surgeons
Mission Statement
The *Journal of American Physicians and Surgeons*, the official peer-reviewed journal of the Association of American Physicians and Surgeons (AAPS), is committed to publishing scholarly articles related to the practice of medicine and to promoting open debate and scientific integrity.

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Typesetting and Printing
Skyline Printing Co., Inc.
Tucson, AZ

Website
www.jpands.org

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Journal of American Physicians and Surgeons (ISSN 1543-4826)
is published quarterly.

Correspondence

Appreciation for Winter Issue

The Journal's winter 2017 issue was a masterpiece of information, and copies should be handed out at every medical office and hospital to all families. Thank you AAPS for standing for Hippocratic medicine.

The article on low-dose radiation by Dr. Bobby R. Scott[1] fascinated me as a former nuclear missile submarine service physician. I concluded years ago that the low levels of radiation in which we lived for months and years would do exactly what this article describes—promote longevity. The Navy Bureau of Medicine and Surgery may have data concerning this issue.

Dr. Orient's review of *The Kingdom of Speech* by Tom Wolfe,[2] which describes his criticisms of evolution, is welcomed by those few of us who have doubted Darwin. Wolfe describes[3] "a web node" entitled "The Mystery of Language Evolution," in which it is stated that "eight heavyweight Evolutionists—linguists, biologists, anthropologists, and computer scientists—were… giving up when it came to the question of where speech—language—comes from and how it works." The conclusion must be that although "speech defines man," speech is inexplicable by man. Evolution fails.

In my books *Happy Ending* and *Everybody* For *Everybody*, I propose a hierarchy of words. They enable the conscious-of-consciousness nature of being human. They should be used with dignity, class, and sophistication; they enable more than we can imagine and more than science can study.

Samuel A. Nigro, M.D.
Cleveland Heights, Ohio

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Vaccine Adjuvant, Suspect in Gulf War Syndrome, Added to Influenza Vaccine

Government manipulation of vaccine-related data, as discussed by Brian Hooker in the last issue,[1] is not unprecedented or restricted to studies of measles-mumps-rubella vaccine.

After serving in the U.S. Navy during Desert Shield, I was a member of the Naval Research Advisory Committee. At that time, around 1993, I had the opportunity to meet with a former colleague who was the lead researcher assigned to figuring out the truth of Gulf War Syndrome (GWS).

Initially, it was concluded that the disorder was most likely due to stress, because of the protean manifestations of the disease and the fact that both victims and non-victims appeared to have the same environmental and vaccine exposures. Most GWS victims were reservists, while most in-theater personnel were on active duty. Thus, it was reasoned that the stress of being unexpectedly jerked out of private life into a combat zone played a causative role in GWS.

Later, it was determined that GWS victims had received vaccine from different production lots than had the non-victims. Much sleuthing was required because the military purposely did not record all anthrax vaccines in service records, and when they did, often it was as "Vac A" or "Vac B."

Some of the lots had squalene adjuvant MF59, and some did not. Subject testing revealed—even in reservists who did not actually deploy to the Gulf—that anti-squalene antibodies were present in nearly all GWS victims and in none of the non-victims.[2,3] Other large studies confirmed the statistically significant positive association between certain vaccines and GWS, but at least

two papers dispute this. Unlike in the randomized controlled study of the reservists, authors of the latter two papers used self-reported symptoms as their diagnostic criteria. This would be expected to artificially inflate the GWS population, and thus obscure any real association. As anthrax expert Dr. Meryl Nass wrote, after noting numerous other confirmatory studies, "…citing research that lacked the power to discern a relationship, and ignoring all studies that did show a relationship, does not enhance confidence in the vaccine. It also calls into question the independence of this CDC vaccine review."[4]

Squalene fell into disrepute for a number of years and was taken out of U.S. vaccines. In 2009, Patricia El Hinnawy, a spokesperson for the U.S. Food and Drug Administration (FDA) said, "There is no squalene in any FDA-approved vaccine in the U.S. There is no squalene in any kind of seasonal flu vaccine or in the H1N1 vaccine." She was quoted in *Wired* magazine to "shatter the myths" spread by irrational fearmongers.[5]

But this year's influenza vaccine Fluad® was fast tracked by Novartis and does contain squalene. In an attempt to block the fast tracking of this vaccine, Barbara Loe Fisher, co-founder and president of the non-profit nongovernmental organization (NGO) National Vaccine Information Center (NVIC), challenged the FDA by saying that Novartis failed to demonstrate that Fluad® with squalene was more effective or safer than an equivalent non-squalene vaccine in the small clinical trial being used to justify accelerated licensure.

In fact, Fluad® was far more reactive. "Compared to Agriflu [a vaccine that does not contain squalene], Fluad produced a much higher number of pain, tenderness, redness and swelling reports; a higher number of systemic adverse event reports and more deaths and cases of new onset chronic disease." Fisher asked, "Why does Fluad need to be fast tracked to licensure for the elderly without additional evidence? There is public concern that fast tracking Fluad is really about fast tracking MF59 to licensure so it can be added to lots of new vaccines targeting infants, pregnant women and every American without adequate evidence for safety or effectiveness."[6]

Even for the most die-hard vaccine advocates, those who put their full faith in FDA honesty, this story should give food for thought and I hope concern. The evidence for squalene as the causative agent for GWS has been accepted into mainstream literature, and along with other known adjuvant-induced diseases, now falls under the rubric of ASIA or autoimmune syndrome induced by adjuvants.[7]

There is no perfectly safe existence, and scientific understanding changes over time. So, the use of squalene years ago, when anthrax on the battlefield was a real potential threat and time was limited, may not constitute criminal negligence. But today, adding squalene while ignoring the growing body of scientific literature, dismissing the irredeemable damage done to veterans, and impugning the reputation of honest doubting physicians who take their Oath of Hippocrates seriously, is totally reprehensible.

Consider also how Novartis introduced squalene clandestinely, after assuring the American public years ago that it had removed all squalene from its drugs, by using a code name (MF-59), and by fast tracking its release, thus giving less time for public and scientific response.

Today, civilians—not just military personnel—have lost their right to avoid taking the vaccine if they want to keep their jobs. That should induce more, not less caution during vaccine development. But it appears that to Big Pharma and its handmaiden FDA, the prime directive is profit, not safety.

Lee Merritt, M.D.
Logan, Iowa

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No Increased Risk of Cancer after Long-term Low-dose-rate Radiation Exposure in Taiwan

In the Journal's winter issue, Bobby Scott discussed natural cancer-facilitating oxidative damage and barriers to cancer and their enhancement by low radiation doses, leading to a reduction in natural cancer.[1] Evidence of this radiobiology was studied in the "serendipitous experiment" that started 35 years ago with the inadvertent exposure of those who occupied more than 180 buildings in Taiwan that were constructed using steel contaminated with radioactive cobalt-60.[2] These buildings were constructed in the early to mid-1980s and occupied, starting in 1983, by more than 8,000 people over differing time intervals. It was not until mid-1992 that the people who resided or studied in these buildings began to be identified and informed about this hazard.[2,3] In 1996, residents began to be evacuated from apartments with high radiation levels; half of them were moved as of 2003.[3]

The early analysis by Chen et al. published in this journal in 2004[3] suggested a remarkable decrease in cancer rates in the exposed population. However, a recent article by Hsieh et al.[4] states that risks of leukemia, breast cancers, and all cancers were significantly increased for occupants of the contaminated buildings. The Hsieh et al. study is an update of the cancer risks that were reported by Hwang et al. in 2006[5] and updated in 2008.[6]

In a letter to the editor, Mohan Doss[7] states that Hsieh et al. used Cox proportional risk models to determine the hazard ratios for cancer incidence and claim that dose-dependent risks were statistically significant. These conclusions are similar to those of the 2008 update by Hwang et al. However, the 2006 article by Hwang et al. showed (in Table III) that 95 "all cancers" cases were observed up to the end of 2002, while 114.9 were expected. This is a significant reduction of all cancers following years of exposure to low-dose radiation. Doss pointed out that Hsieh et al. failed to discuss the significant reduction in total cancers in the irradiated cohort. Doss also recommended that additional data with better statistics be obtained before concluding that there is increased risk for

specific cancer types. Use of proportional hazard models for estimating hazard ratios is not justified because the results from such analysis can mask the observation of a reduction of all cancers.[7]

It is not appropriate to simply link a low dose of ionizing radiation, using a mathematical model, to an increased risk of cancer. Because of the high natural incidence of cancers and the many factors that affect cancer risk, it is impossible to establish a statistical relationship between low doses or low levels of radiation and an elevated risk of cancer. It is well known that a high dose or a high dose rate is harmful. Such exposures inhibit or damage the adaptive protection systems and shorten longevity. They may also increase the risk of cancer. However, there is evidence that low doses or a low dose rate of radiation stimulates the protection systems, and this can reduce both radiogenic and non-radiogenic cancer incidence.[8,9]

For the long-term exposures experienced in Taiwan, "cumulative dose" is not a useful statistic. The adaptive protection systems produce more antioxidants to neutralize the radiation-induced reactive oxygen species (ROS) that damage biomolecules, including DNA. The systems that repair the damage caused by ROS and direct radiation "hits" are up-regulated. The systems that remove unrepaired cells are also stimulated, as is the immune system for enhanced destruction of cancer cells, resulting in a lower risk of cancer.[9]

Dose rate is the proper variable for assessing the Taiwan exposures, and longevity (not cancer) is the more appropriate measure of the health effect. Studies on animals and humans generally reveal that there is an increase of lifespan when the ambient dose rate is above the normal background level, but not higher than the threshold for the onset of harmful effects.[9]

The 2004 study by Chen et al. determined, very roughly, the radiation exposures received by the occupants, and calculated the expected cancer mortality using the linear no-threshold (LNT) model.[3] For three cohorts (high, medium and low), it evaluated the mean annual dose in the first year (1983), the 20-year cumulative dose, and the 20-year "collective dose." In 1983, the 1,100 people in the high cohort received doses whose average was about 525 mSv; their 20-year doses averaged 4,000 mSv. In 1983, the 900 people in the medium cohort received doses whose average was about 60 mSv; their 20-year doses averaged 420 mSv.[3] [The equivalent dose, sieverts (Sv), equals absorbed dose, gray (Gy), for gamma radiation. 1 gray equals 1 joule/kg.]

Chen et al. estimated the collective dose of the exposed population to be 4,000 person-Sv, and calculated the expected number of radiogenic excess leukemia and cancer deaths to be about 70, from 1983 to 2002. However, only two leukemia and five cancer deaths were reported during this period among the occupants. Chen et al. could not obtain their registration data and could not correct for the risk factors, such as age at initial exposure. The calculated number of non-radiogenic cancer deaths was 232, assuming the demographics of the occupants to be the same as the population of Taiwan.[3] In fact, the average age of the occupants was younger than that of the comparison population.

The 2006 study by Hwang et al.[5] had the proper registration data for 7,271 subjects and much more accurate information about their individual radiation exposures. Cancer risks were determined and compared with those populations with the same temporal and geographic characteristics in Taiwan by standardized incidence ratios (SIR), adjusted for age and gender. The association of cancer risks with excess cumulative exposure was further evaluated for their relative risks by the Poisson multiple regression analysis. As shown in the first line of Table III in Hwang et al. (2006), for the period 1983-2002, the total number of observed cancers was 95; the expected number was 114.9, and the SIR for all cancers was 0.83 (95% CI: 0.66-0.99). This indicated a significant reduction of "all cancers" after low-dose irradiation.

As mentioned above, dose rate is the proper variable, and longevity is the most appropriate measure of radiogenic health effects. The analysis by Cuttler et al. of a study on groups of dogs exposed to different dose rates of cobalt-60 irradiation revealed a threshold dose rate for the onset of reduced lifespan of 700 mGy per year (see Figure 1 below).[9] Assuming that dogs model humans, a lifespan increase of up to about 15 percent could be expected for a dose rate between the normal background level and the 700 mGy per year threshold for harmful effects. The average 1983 exposure in the high-dose Taiwan cohort was 535 mSv (the equivalent of 525 mGy for gamma radiation), as calculated by Chen et al.[3]

The proper comparison of dose rate vs. longevity has not been reported for the Taiwan experience.

Jerry M. Cuttler, D.Sc.
Ontario, Canada

1. Scott BR. Small Radiation doses enhance natural barriers to cancer. *J Am Phys Surg* 2017;22:105-110.
2. Chang WP, Chan C-C, Wang J-D. 60Co contamination in recycled steel resulting in elevated civilian radiation doses: causes and challenges. *Health Phys* 1999;73:465-472.
3. Chen WL, Luan YC, Shieh MC, et al. Is chronic radiation an effective prophylaxis against cancer? *J Am Phys Surg* 2004;9:6-10. Available at: http://jpands.org/vol9no1/chen.pdf. Accessed Feb 23, 2018.
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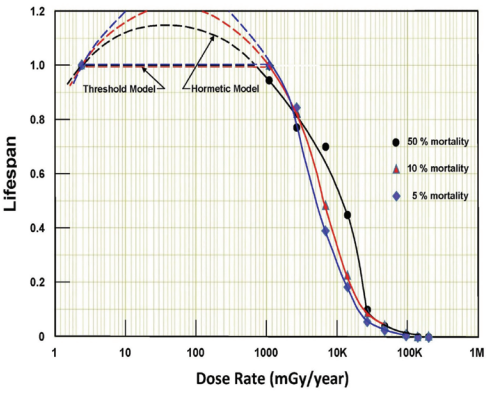

Figure 1. Lifespans of Groups of Dogs at Different Cobalt-60 γ-Radiation Dose Rates. The black dot is the normalized lifespan of the 50% mortality dog in each group. The red triangle and the blue diamond are the normalized lifespans of 10% and 5% mortality (more radiation-sensitive) dogs.[9]

Gmail [redacted]

RE: Impact of the COVID vaccination program on the Australian workforce [SEC=OFFICIAL]

[redacted] Wed, Mar 8, 2023 at 3:23 PM
To: [redacted]

Hi [redacted]

Thanks for replying.

When you say that SWA is not a regulator that is not to say that they cannot investigate matters that impact the health of the Australian workforce. Hence the recent correspondence (call for public comment) on silicosis and engineered benchtops. After reading SWA's new 10 year strategy I was of the belief that they were aiming at greater involvement from all stakeholders. As a veteran WH&S specialist I was hoping for some consultation. Consultation is one of the greatest tools at our disposal. If I was to ignore a health related issue in my workplace I would find myself liable for negligence under the law. This is another reason I am not ignoring the issue of COVID vaccine injury as it pertains to the workforce.

I forwarded my last email to SWA to [redacted] who heads our Qld Industrial Relations and therefore is responsible for Qld WH&S. That is certainly a position that is related to our state regulator.

As for the TGA I have issues with the way the COVID pandemic was handled by all levels of government. Hence why I included clips and articles covering the coverup of deaths of minors. Long COVID and COVID vaccine injuries are real and pose a real threat to workers and others in the community. Heart conditions and fatigue do not mix with heavy machinery and other high risk tasks. This issue cannot be evaded for ever.

With so many health alerts and publications written by highly respected academics in Australia and elsewhere one would expect SWA to begin to follow up and investigate. Surely you are independent of other government bodies where you see cause?

What I am looking for is real leadership and investigation.

I will now contact Qld WH&S as you recommend and attempt to gain some help and involvement.

Kind Regards

[redacted]

[redacted]

[redacted]

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Sex-specific differences in myocardial injury incidence after COVID-19 mRNA-1273 Booster Vaccination

Brief Title: Myocardial Injury after COVID-19 mRNA-1273 Booster Vaccination

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Word count: 3321 (max. allowed 3500)

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This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1002/ejhf.2978

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Abstract (246, maximum 250 words)

Aims: To explore the incidence and potential mechanisms of oligosymptomatic myocardial injury following COVID-19 mRNA booster vaccination.

Methods and Results: Hospital employees scheduled to undergo mRNA-1273 booster vaccination were assessed for mRNA-1273 vaccination-associated myocardial injury, defined as acute dynamic increase in high-sensitivity cardiac troponin T (hs-cTnT) concentration above the sex-specific upper-limit of normal on day 3 (48-96h) after vaccination without evidence of an alternative cause. To explore possible mechanisms, antibodies against IL-1RA, the SARS-CoV2-Nucleoprotein(NP) and -Spike(S1) proteins and an array of 14 inflammatory cytokines were quantified. Among 777 participants, median age 37 years, 69.5% women, 40 participants (5.1% [95%CI, 3.7-7.0%]) had elevated hs-cTnT concentration on day 3 and mRNA-1273 vaccine-associated myocardial injury was adjudicated in 22 participants (2.8% [95%CI, 1.7-4.3%]). Twenty cases occurred in women (3.7% [95%CI, 2.3-5.7%]), two in men (0.8% [95%CI, 0.1-3.0%]). Hs-cTnT-elevations were mild and only temporary. No patient had ECG-changes, and none developed major adverse cardiac events within 30 days (0% [95%CI, 0-0.4%]). In the overall booster cohort, hs-cTnT concentrations (day 3; median 5 [IQR, 4-6] ng/L) were significantly higher compared to matched controls (n=777, median 3 [IQR, 3-5] ng/L, $p<0.001$). Cases had comparable systemic reactogenicity, concentrations of anti-IL-1RA, anti-NP, anti-S1, and markers quantifying systemic inflammation, but lower concentrations of IFN-λ1(IL-29) and GM-CSF versus persons without vaccine-associated myocardial injury.

Conclusion: mRNA-1273 vaccine-associated myocardial injury was more common than previously thought, being mild and transient, and more frequent in women versus men. The possible protective role of IFN-λ1(IL-29) and GM-CSF warrant further studies.

Key Words

COVID-19

mRNA vaccine

Myocardial injury

Myocarditis

COVID-19 booster vaccination

Cardiac Troponin

Introduction

Myocardial injury, manifesting clinically as myocarditis, has recently emerged as a possible severe adverse event following the administration of COVID-19 mRNA-vaccines occurring mainly in young men a few days after vaccination. Using passive surveillance following vaccination with BNT162b2-mRNA (Pfizer-BioNTech) or mRNA-1273 (Moderna), COVID-19 mRNA-vaccination associated myocarditis is currently considered rare[1]. However, passive surveillance detects mostly severe cases requiring hospitalization.[2,3]

We hypothesized that COVID-19 mRNA-vaccine-associated myocardial injury following booster vaccination may be much more common, as symptoms may be unspecific, mild or even absent, escaping passive surveillance. Due to waning immunity months after mRNA COVID-19 vaccinations there is an apparent need for (repeated) booster vaccinations for billions of people worldwide.[4,5] Thus knowing the true incidence of mRNA vaccine-associated myocardial injury is of major importance for informed decision-making by patients, physicians and public health authorities.

We therefore conducted a prospective active surveillance study to address this major unmet need. Secondary aims were to provide a "safety net" for persons identified with COVID-19 mRNA-vaccine-associated myocardial injury to allow early detection and preventive measures to avoid possible aggravation, and to evaluate potential mechanisms underlying COVID-19 mRNA-vaccine-associated myocardial injury.

Methods

Study design and study population

This prospective investigator-initiated industry-independent active surveillance study was approved by the local ethics committee. Employees of the University Hospital Basel, Switzerland, scheduled to receive mRNA-1273 first booster vaccination, and who provided written informed consent, were offered active-surveillance. Exclusion criteria were cardiac events or cardiac surgery within 30 days prior to vaccination or patients missing the study visit, therefore missing hs-cTnT measurement on Day 3.

Active surveillance and laboratory methods

Medical history was assessed on the day of the booster vaccination (day 1). On day 3 (48-96 hours) after vaccination, participants were assessed for possible myocarditis-related symptoms and a venous blood sample for the measurement of high-sensitivity cardiac troponin T (hs-cTnT, Elecsys, sex-specific 99th-perentile of healthy individuals and upper-limit of normal (ULN) 8.9 ng/L in women and 15.5 ng/L in men, limit of detection 3 ng/L) was obtained.[6,7] If the hs-cTnT concentration was elevated on day 3, participants were informed, asked to avoid strenuous exercise in order to minimize additional strain of the myocardium and associated cardiomyocyte injury, and offered follow-up including clinical evaluation, a second hs-cTnT measurement, and a 12-lead electrocardiogram (ECG). The follow up visit was scheduled, if feasible, the next working day. After extensive discussion with the local ethics committee and the COVID-19 task force of the University Hospital Basel, it was prioritized that this study should interfere as little as possible with the motivation of the hospital staff to obtain the mRNA-1273 first booster vaccination and the logistics of booster vaccination itself. Accordingly, blood draws were performed only after the vaccination.

Potential mechanisms underlying vaccine-associated myocardial injury

We evaluated three potential mechanisms of COVID-19 mRNA-vaccination-associated myocardial injury: anti-IL-1RA-autoantibodies,[8] pre-existing vaccine/infection-induced immunity against SARS-CoV2 (i.e. anti-SARS-CoV2-Nucleoprotein(NP) and -Spike(S1) IgG), and systemic reactogenicity/inflammation. Anti-IL-1RA-, -NP-, and S1-IgG were quantified using the Luminex platform (Luminex Corporation, Austin, Texas)[9] (**Supplementary Methods).** Systemic inflammation was assessed by measuring 14 biomarkers using the LEGENDplex™ Human Anti-Virus Response Panel (IL-1β, IL-6, IL-8, IL-10, IL-12p70, IFN-α, IFN-β, IFN-λ1(IL-29), IFN-λ2/3(IL-28), IFN-γ, TNF-α, IP-10, GM-CSF), the IL-1RA assay (both Biolegend, San Diego, CA, USA), and C-reactive protein (CRP; Elecsys; ULN 5.0 mg/L).

Adjudication of COVID-19 mRNA vaccine associated myocardial injury

Given the in general superior sensitivity of hs-cTnT-elevations versus the ECG or cardiac imaging for acute myocardial injury,[10,11] COVID-19 mRNA vaccine-associated myocardial injury was defined as acute dynamic hs-cTnT-elevation above the sex-specific 99th-perentile ULN (8.9 ng/L in women and 15.5 ng/L in men) on day 3, without evidence of an alternative cause, irrespective of symptoms, ECG, or cardiac imaging abnormalities. In the absence of a baseline hs-cTnT concentration immediately prior to the vaccination, strict criteria were applied in the adjudication of COVID-19 mRNA vaccine associated myocardial injury. For the differentiation of acute COVID-19 mRNA vaccine-associated myocardial injury versus possible chronic preexisting myocardial injury, four criteria were used: first, the extent of the hs-cTnT elevation (the higher the elevation, the more likely acute), second, the extent in the change of hs-cTnT from day 3 to day 4 (the larger the change the more likely acute), third, previous hs-cTnT measurements if available in the medical history of the participants, and fourth, the likelihood for hs-cTnT elevation according to known causes of chronic myocardial injury, including age and preexisting cardiovascular diseases. To emphasize how physicians could miss COVID-19 mRNA vaccine-associated myocardial injury in women, a sensitivity analysis, using a uniform ULN cutoff (14 ng/L) was used for adjudication. To further verify

that COVID-19 mRNA booster vaccination may increase hs-cTnT concentration, hs-cTnT concentration on day 3 in the overall cohort receiving COVID-19 mRNA booster vaccination was compared to matched controls.

Follow-up

Major adverse cardiac events (MACE) including acute heart failure, cardiac death, life-threatening arrhythmia and acute myocardial infarction (AMI) were assessed at 30-day follow-up. A flowchart of the active surveillance program is depicted in **Figure 1A and the Graphical Abstract.**

Matching

To assess cardiomyocyte injury also as a continuous variable, hs-cTnT concentrations on day 3 after vaccination were compared to age-, sex-, history of coronary artery disease/AMI-matched patients (controls) that had presented with acute chest discomfort to the emergency department in a multicenter study (NCT00470587) and were centrally adjudicated as having a non-cardiac cause. Seven hundred seventy-seven booster-vaccinated subjects and 3716 eligible controls (fulfilling inclusion criteria) were identified. Matching was conducted using a nearest neighbor propensity score matching method, without replacement of controls and with a case-to-control-ratio of 1:1.[12] For details see **Supplementary Methods**.

Statistical Analysis

Continuous variables were reported as median and interquartile range (IQR), categorical variables as counts and percentages. Difference in characteristics between subjects with and without SARS-CoV-2 mRNA vaccine-associated myocardial injury were assessed using the Mann Whitney U test for continuous variables, and the Pearson chi2 test or Fisher exact test for categorical variables, when appropriate. All hypothesis testing was 2-tailed with a significance level of $p<0.05$. Statistical analyses were performed using R version 4.1.3 (R Foundation for Statistical Computing). Reporting is in accordance with the Strengthening the Reporting of

Observational studies in Epidemiology (STROBE) statement (**Supplemental Table 1**). We did not adjust for multiple testing for the evaluation of different potential mechanisms underlying COVID-19 mRNA-vaccine-associated myocardial injury due to the exploratory nature of the analysis.

Results

From December 10th, 2021, to February 10th, 2022, 1871 employees of the University Hospital Basel were screened (1294 females [69.2%] and 577 males [30.8%]), of which 835 provided written informed consent to participate in the study, and of these, 777 (93%, 540 females [69.5%] and 237 males [30.5%]) were eligible for analysis (**Table 1, Figure 1 and Figure 2A**). The median age was 37 years (IQR 30-50), and 69.5% were women. Age-, sex-, and history of coronary artery disease/AMI-matched controls had comparable baseline characteristics (**Supplemental Table 2 and Supplemental Figure 1-3**).

COVID-19 mRNA-1273 vaccine-associated myocardial injury

Hs-cTnT concentrations (**Supplemental Figure 4**) above the sex-specific ULN were detected in 40 participants (5.1% [95%CI, 3.7-7.0%]). In 18 of them (17 women, median age 59 years [IQR 57-60], median hs-cTnT concentration 10ng/L [IQR 9-11], **Supplemental Table 3**), an alternative cause was considered most likely (**Supplemental Table 4**). mRNA-1273 vaccine-associated myocardial injury was adjudicated in 22 patients (2.8% [95% confidence interval [CI], 1.8-4.3 %]), with 20 cases occurring in women (3.7% [95%CI, 2.3-5.7%]) and 2 in men (0.8% [95%CI, 0.1-3.0%]), with a median age of 46 years (IQR 33-54). This sex difference was statistically significant (p=0.03). On day 3, median hs-cTnT concentration of the 20 women and 2 men with mRNA-1273 vaccine-associated myocardial injury was 13.5 ng/l (IQR 9.0-18.8; **Figure 2B**). It decreased in all but one patient on the follow up visit to a median value of 6.0 ng/l (IQR 4.0-14.0), being again in the normal range in half of the participants.

In the overall cohort receiving the mRNA-1273 booster, hs-cTnT concentrations (day 3) were significantly higher compared to matched controls (median 5 [IQR 4-6] ng/L vs 3 [IQR 3-5] ng/L, p<0.001). **Figure 3** illustrates this difference, indicating an overall shift towards higher hs-cTnT concentrations in the booster cohort versus matched controls, for both female

(median 4 [3-6] ng/L vs 2.99 [2.99-4] ng/L) and male (median 6 [5-8] ng/L vs 4 [2.99-6] ng/L) participants.

None of the participants with elevated markers of myocardial injury related to mRNA vaccination had a history of cardiac disease (**Supplemental Table 5**). Eleven participants (50%) had unspecific symptoms including fever and chills, two had chest pain, and none had ST-segment depression or T-wave inversion (**Supplemental Table 5**). Predefined and prospectively recorded symptoms occurred with comparable frequency in participants developing mRNA-1273 vaccine-associated myocardial injury versus those that did not.

No definitive case of myocarditis was found. However, the two participants (both women) with vaccine-associated myocardial injury and chest pain met the Brighton Collaboration case definition Level 2, indicating probable myocarditis in those patients (0.3% [95% confidence interval [CI], 0.1-0.9 %]).[13]

Sensitivity analysis

When using a uniform ULN of 14 ng/L, mRNA-1273 vaccine-associated myocardial injury was adjudicated in 14 patients (1.8% [95% CI, 1.0-3.0 %]), with 9 cases occurring in women (1.7% [95%CI, 0.8-3.2%]) and 5 in men (2.1% [95%CI, 0.7-4.9%]), with a median age of 53 years (IQR 38-56). On day 3, median hs-cTnT concentration of the 9 women and 5 men with mRNA-1273 vaccine-associated myocardial injury was 17.5 ng/l (IQR 15.5-20.5). It decreased in all but one patient on the follow up visit to a median value of 14.0 ng/l (IQR 10.0-19.0), being again below the uniform ULN in half of the participants (**Supplemental Figure 5**).

MACE

Thirty-day follow-up was completed in 775 participants (99.7%) and no participant developed MACE (0% [95%CI 0-0.4%]).

Possible mechanisms of mRNA-1273 vaccine-associated myocardial injury

Antibodies against IL-1RA were detected with comparable and low frequency in participants with mRNA-1273 vaccine-associated myocardial injury versus those without (1 in 22 [4.5%] vs 23/742 [3.1%]; Fisher exact test P-value=0.51). The plasma levels of IL-1RA were also comparable between the two groups. There was no difference in the magnitude of the anti-S1-IgG and the frequency of subjects positive for anti-NP-IgG (i.e. serological evidence for prior infection with SARS-CoV2) in participants with mRNA-1273 vaccine-associated myocardial injury versus those without (**Table 2**). Also, most tested markers of systemic inflammation had comparable concentrations in participants with mRNA-1273 vaccine-associated myocardial injury versus those without. In contrast, levels of IFN-λ1 and GM-CSF were lower in cases with mRNA-1273 vaccine-associated myocardial injury versus those without **(Supplemental Figures 6 and 7**).

Discussion

This prospective investigator-initiated, industry-independent study was performed to test the hypothesis that mRNA-1273 booster vaccination-associated myocardial injury may be more common than currently thought as symptoms may be unspecific, mild or even absent, escaping passive surveillance detecting only hospitalized cases. We report four main findings.

First, our findings confirmed the study hypothesis. mRNA-1273 booster vaccination-associated elevation of markers of myocardial injury occurred in about one out of 35 persons (2.8%), a greater incidence than estimated in meta-analyses of hospitalized cases with myocarditis (estimated incidence 0.0035%) after the second vaccination.[14,15] Elevated hs-cTnT was independent of previous COVID infection or the interval since the last vaccine dose. Among the overall group of participants, hs-cTnT concentration on day 3 after mRNA-1273 booster vaccination as a continuous variable, was significantly higher compared to a well-matched control cohort. Second, all cases were mild with only a transient and short period of myocardial injury (maximum hs-cTnT concentration 35ng/L). No patient showed ECG changes and, no patient developed MACE within 30 days. Potentially, such outcomes were averted by the safety net provided by early detection and early implementation of preventive measures for deterioration including avoidance of strenuous exercise. Notably, systemic reactogenicity (fever, chills, body aches), and chest pain occurred with comparable frequency in participants with versus without mRNA-1273 booster vaccine-associated cTnT elevations. Third, when using sex-specifc ULN cutoffs for myocardial injury adjudication, mRNA-1273 booster vaccine-associated myocardial injury occurred significantly more often in women versus men (3.7% versus 0.8%). This is in striking discrepancy to the sex-distribution of vaccine-associated myocardial injury in the setting of clinical myocarditis following the first and second vaccinations detected by passive surveillance, which occurred predominately in young men.[2,3,16] Median age of participants developing mRNA-1273 vaccine-associated myocardial injury was 46 years. Thereby, also the age-distribution is different to that of most reported

vaccine-associated clinical myocarditis cases.[2,3] When using a uniform (and thereby higher in women and lower in men compared to the sex-specific) ULN cutoff for adjudication, the incidence rate of vaccine-associated myocardial injury declined in women and increased in men. Fourth, the predominate mechanisms underlying mRNA-1273 booster vaccination-associated myocardial injury did not seem to include antibodies neutralizing IL-1RA, which were suggested to be involved in the pathophysiology of severe COVID-19 mRNA vaccine-associated myocarditis in young male patients, [8] pre-existing vaccine/infection-induced immunity against SARS-CoV2, nor systemic inflammation. In contrast, levels of IFN-λ1 and GM-CSF, both modulators of the immune responses to acute viral infection, vaccination, and tissue inflammation, were lower in cases with mRNA-1273 vaccine-associated myocardial injury versus those without.[17-19] However, we did not adjust for multiple testing nor for potential confounders for the evaluation of different potential immunological mechanisms underlying COVID-19 mRNA-vaccine-associated myocardial injury due to the exploratory nature of the analysis and should thus be considered as a hypothesis-generating analysis. IFN-λ limits inflammation induced tissue damage in viral infections[20] and in models of ischemic myocardial injury.[21] Whether IFN-λ1 deficiency may reduce myocardial protection and thereby promote vaccine-associated myocardial injury needs to be further investigated. In a phase 3 trial, pegIFN- λ reduced hospitalisations and emergency visits in patients with COVID-19[22] and in a phase 2 study, pegIFN- λ accelerated viral decline in outpatients with COVID-19,[17,18] thereby further strengthening the rational of the hypothesis that IFN-λ1 deficiency may be involved in vaccine-associated myocardial injury. GM-CSF exerts pro-inflammatory effects, and both administration and inhibition of GM-CSF are tested as potential therapeutics in COVID-19.[19] Whether low GM-CSF blood levels are a risk factor for immune-mediated cTnT elevations remains to be further elucidated. The significantly higher rate of mRNA-1273 booster vaccination-associated myocardial injury in women versus men may at least partly be related to the higher vaccine dose per body weight or myocardial mass in women and therefore dose-

dependent toxic effects. Clinically overt severe vaccination-associated myocarditis may then occur following a second hit, possibly mediated by neutralizing autoantibodies targeting IL-1RA, microvascular thrombosis, or direct cardiac myocyte injury unrelated to inflammation.[8,23]

Our findings following mRNA-1273 booster vaccination extend and corroborate observations in two recent active surveillance studies after BNT162b2 vaccination.[24,25] Among 324 health care workers, mean age 51 years, 59.2% women, who received a fourth dose of BNT162b2 in Israel, two participants (one woman and one man) developed vaccine-related myocardial injury on day 3 (incidence 0.6%, maximum hs-cTnI concentration 22.1ng/L). One had mild symptoms including fever and chest pain, one was asymptomatic. Both had a normal ECG and echocardiography.[24] Among 301 adolescents in Thailand, mean age 15 years, receiving the second dose of BNT162b2, five participants (incidence 1.7%), all boys, developed vaccine-related myocardial injury on either day 2 or day 3.[25] One of them had very high hs-cTnT concentrations (593ng/L) and late-gadolinium enhancement indicating myocarditis in cardiac magnetic resonance (CMR) imaging. When comparing these studies, it is important to highlight major differences in study population and study methodology.

Therefore, the main finding of this study, that subclinical mRNA vaccine-associated myocardial injury is much more common than estimated based on passive surveillance, has been confirmed and generalized in these complimentary cohorts of slightly older health care workers in Israel and adolescents in Thailand. Additional active surveillance studies are needed to externally validate two specific findings of this study: the even higher rate of mRNA-1273 booster vaccination associated myocardial injury overall, and particularly in women. At least in part, these findings seem explained by the use of sex-specific ULN for hs-cTnT in this versus a uniform ULN in the two other studies, as well as using mRNA-1273, which also had resulted in a higher rate of hospitalizations due to clinical myocarditis versus BNT162b2 in prior passive surveillance studies.[2,3,26,27] Of note, mRNA-1273 had also resulted in higher immunogenicity and protection from COVID-19 versus BNT162b2 in large observational studies.[28,29]

Vaccine-related myocarditis has previously been reported following smallpox vaccination with an observed incidence of 16.11/100,000, which was nearly 7.5-fold higher than the expected background incidence.[30] In contrast, myocarditis following other vaccines is rare.[31] Similar to our finding with mRNA vaccination, there is evidence that the frequency of subclinical myocardial injury may also be higher after smallpox vaccination. A study on US military personnel found subclinical cTnT elevations in 2.87% of 1081 smallpox vaccinated subjects, or a 60-times higher rate than overt clinical cases.[32] The same study found no cTnT elevation in 189 subjects vaccinated with the inactivated influenza vaccine. This suggest that vaccine characteristics are relevant for the observed cTnT increase.

The long-term consequences of vaccine-related myocardial injury detected by transient and mostly mild hs-cTnT/I elevations on day 2 or 3 are unknown. Given the small extent of acute cardiomyocyte injury in our study, i.e. cTnT levels of about one-fourth of those observed in patients with spontaneous myopericarditis,[10] and its transient nature, good long-term outcomes can be expected. COVID-19 associates with a substantially higher risk for myocarditis that mRNA vaccination[33], and myocarditis related to COVID-19 infection has shown a higher mortality than myocarditis related to mRNA-vaccination.[34,35] Thus, for the majority of individuals, the overall very favorable risk-benefit ratio of booster immunizations persists.[14,15,36-39] However, further studies are needed to assess the impact of mRNA vaccine-associated myocardial injury on the long-term risk of cardiac arrhythmias and heart failure. Also, evidence generated in the perioperative setting should help avoid the over-simplistic assumption that the absence of typical chest pain on day 3 after vaccination in most cases would per se indicate a favorable prognosis: perioperative myocardial injury not associated with chest discomfort had comparable unfavorable long-term outcome versus perioperative myocardial injury with chest discomfort.[40]

By providing novel insights regarding the incidence, extent, duration, patient characteristics, possible mechanisms, and outcome of mRNA-1273 booster vaccination-

associated myocardial injury, this study aims to help patients, physicians, and public health authorities make informed decisions regarding future booster vaccinations.[4] Importantly, this study also may help manufacturers fine-tune the dose and composition of future vaccines.

It is mandatory to put our findings into perspective with the incidence and extent of myocardial injury associated with COVID-19 infection. Before the COVID-19 vaccine were available, the incidence and extent of myocardial injury associated with COVID-19 infection was much higher than observed in this active surveillance study after booster vaccination.[37,41,42] Data on the incidence of COVID-19 associated myocardial injury in populations with high immunity against SARS-CoV2 are not yet available.

Alternative, yet unlikely, contributors to the elevated cTnT in our study include cardiomyocyte injury associated with strenuous exercise, or in the context of a high inflammatory response to the vaccination or a non-cardiac source. While exercise was not restricted between vaccination and first hs-cTnT measurement, none of the detected cases reported strenuous exercise preceding the blood draw on day 3. Importantly, prior exercise was also not restricted among the matched control group, and even strong exercise typically only leads to an increase in hs-cTnT concentration of on average 1 ng/l.[43] Moreover, neither the clinical symptoms (i.e. fever, chills, muscle sore), nor the measured markers of systemic inflammation indicated an overshooting inflammatory response in subjects with hs-cTnT elevation. In contrast to some rather rare chronic active skeletal muscle diseases such as muscle dystrophies, acute skeletal muscle injury, even when as extensive as in patients with rhabdomyolysis, has been found not to be a non-cardiac source of elevated hs-cTnT concentrations.[44-46] Also, interference has been reported as a possible confounding factor for cTn elevations. However, this issue seems to predominantly affect the current hs-cTnI and not the current hs-cTnT assay.[47] Therefore, the acute dynamic increase in hs-cTnT-concentration following mRNA COVID-19 vaccination has to be considered indicating myocardial injury and not secondary to the intramuscular injection and local skeletal muscle injury. Lastly, unknown

prior cardiac disease may have been contributing to some of the extent of myocardial injury observed. Therefore, conservative criteria were used for the adjudication of mRNA-1273 booster vaccination-associated myocardial injury and 18 additional patients with hs-cTnT elevation on day 3 were classified as more likely having chronic myocardial injury.

The following limitations should be considered when interpreting our findings. First, to interfere as little as possible with the motivation of the hospital staff to obtain the mRNA-1273 booster vaccination and its logistics, we restricted the study to blood draws after vaccination. Thus, baseline hs-cTnT values were not available. The lack of a baseline hs-cTnT concentration was therefore addressed threefold: a) by requiring a relevant change in hs-cTnT concentration from day 3 to the follow up visit as additional criteria to adjudicate mRNA vaccine-associated myocardial injury; b) by conservative adjudication in that 18 participants with mild hs-cTnT-elevations on day 3 (17 women, one man), and either no available hs-cTnT concentration at follow up visit or one with no relevant change, were considered to reflect pre-existing known or assumed cardiac disease rather than mRNA-1273 booster vaccine-associated myocardial injury (although the differential diagnosis in these 18 patients includes persistent vaccine associated myocardial injury); Thereby, among the 40 participants (5.1%) detected to have increased hs-cTnT concentration on day 3 after mRNA-1273 booster vaccination, only 22 participants (2.8%) were adjudicated to have mRNA-1273 vaccine-associated myocardial injury. For comparison, using the sex-specific 99th-percentile as the ULN, among presumably healthy individuals only 1% of persons are expected to have increased levels. c) by adding an age-, sex-, and history of coronary artery disease/AMI matched control group. Despite our efforts to address the lack of baseline hs-cTnT concentration, we may have still misclassified a small number of participants. Future studies using baseline values for adjudicating acute dynamic hs-cTn-elevation above the sex-specific ULN are warranted to confirm our findings. Second, the time-course of mRNA-1273 vaccine-associated myocardial injury is incompletely understood. Accordingly, by measuring hs-cTnT on day 3 after mRNA-1273 booster

vaccination, which was in line with other studies,[24] we might have missed cases that peaked earlier and had already returned to normal on day 3. Third, the 4th universal definition of myocardial infarction states that "elevated cTn levels may be indicative of acute myocardial injury if the pattern of values is rising and/or falling". No specific percentage change was proposed, thus in some patients the distinction between acute and chronic was challenging. In those cases, we adjudicated those patients as chronic injury, thus choosing the more conservative approach. Fourth, this study recruited unselected healthcare workers of a university hospital. Thereby, the study population was relatively young and 70% women. Further studies are warranted to extend the findings regarding incidence of mRNA-1273 booster vaccination-associated myocardial injury and 30-day MACE to other populations. Both may differ particularly in older persons with a higher preexisting burden of cardiovascular disease. Fifth, no CMR imaging was performed, as the amount of vaccine-induced cardiomyocyte injury in this study was below the expected limit of detection of CMR for late gadolinium enhancing myocardial lesions indicative of myocarditis (usually a hs-cTnT concentration of about 50-100ng/L).[10,11] These thresholds were predefined in collaboration with imaging experts, but are based on expert opinion rather than large prospective studies. Sixth, it is unknown whether and to what extent early detection and management, such as asking cases to avoid strenuous exercise, contributed to the excellent outcomes at 30-days. Seventh, given the absence of another in-vivo technique with comparable sensitivity to hs-cTnT/I regarding acute cardiomyocyte injury, it remains unknown whether mRNA-1273-vaccine-induced myocardial injury resulted in cardiomyocyte cell death and thereby irreversible loss of cardiomyocytes, or sublethal injury.

In conclusion, using active surveillance, mRNA-1273 vaccine-associated mild transient myocardial injury was found to be much more common than previously thought. It occurred in one out of 35 persons, was mild and transient, and more frequent in women versus men. Neither anti-IL-1RA, nor pre-existing vaccine/infection-induced immunity or systemic inflammation

seemed to be dominant mechanisms of myocardial injury. No participant developed MACE within 30-days.

Funding

This work was supported by research grants from the University of Basel and the University Hospital Basel, Switzerland.

Conflict of interest

Dr. Koechlin received a research grant from the Swiss Heart Foundation, the University of Basel, the Swiss Academy of Medical Sciences and the Gottfried and Julia Bangerter-Rhyner Foundation, as well as the "Freiwillige Akademische Gesellschaft Basel" and speaker honoraria from Roche Diagnostics and Siemens outside the submitted work. Prof. Mueller has received research support from the Swiss National Science Foundation, the Swiss Heart Foundation, the University of Basel, the University Hospital Basel, the KTI, Abbott, Beckman Coulter, BRAHMS, Idorsia, Ortho Diagnostics, Novartis, Roche, Siemens, and Singulex, as well as speaker/consulting honoraria from Amgen, Astra Zeneca, Bayer, BMS, Boehringer Ingelheim, Daiichi Sankyo, Idorsia, Novartis, Osler, Roche, and Sanofi, all outside the submitted work. C.T.B. has received research support from the Swiss National Science Foundation, the Uniscientia Foundation, the FSRMM, and ROCHE, all outside of this work, and participated in a study that received independent funding from Moderna. M.B. has received research support from the Swiss National Science Foundation. P.L.A has received research grants from the Swiss Heart Foundation (FF20079 and FF21103) and speaker's honoraria from Quidel, paid to the institution, outside the submitted work. The remaining authors have nothing to disclose.

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Figure legends

Graphical Abstract

Figure 1: Patient Flow chart. Hs-cTnT = high-sensitivity cardiac troponin T

Figure 2: Panel A: Flowchart of the active surveillance program and incidence of mRNA-1273 vaccination-associated myocardial injury. Panel B: High-sensitivity cardiac troponin T (hs-cTnT) concentrations in patients with mRNA-1273 vaccination-associated myocardial injury. The triangles represent the median, points represent the individual patients, the dashed lines labeled ULN represent the sex-specific upper limit of normal. (Both men with vaccination-associated myocardial injury had identical concentrations on day 3 (17 ng/L), therefore only one point is shown. One male patient did not have a follow up visit, hence only one line is shown).

Figure 3: Cumulative distribution curve of cardiomyocyte injury as quantified by high-sensitivity cardiac troponin T (hs-cTnT) concentrations stratified by sex. The dashed lines indicate the sex-specific upper reference limits. Hs-cTnT = high sensitivity cardiac troponin T.

Tables

Variable	Overall	No vaccine-associated myocardial injury	Vaccine-associated myocardial injury	p
n	777	755	22	
Age, median [IQR]	37 [30, 50]	37 [29, 50]	46 [33, 54]	0.12
Sex				0.03
Male, n (%)	237 (30.5)	235 (31.1)	2 (9.1)	
Female, n (%)	540 (69.5)	520 (68.9)	20 (90.9)	
History of COVID-19 infection	82 (10.6)	80 (10.6)	2 (9.5)	1
Number of previous COVID-19 vaccinations, n(%)				0.20
One vaccination	1 (0.1)	1 (0.1)	0 (0.0)	
One vaccination after COVID-19	37 (4.8)	37 (4.9)	0 (0.0)	
Two vaccinations	714 (92.0)	694 (92.0)	20 (90.9)	
Two vaccinations after COVID-19	24 (3.1)	22 (2.9)	2 (9.1)	
Days since last vaccination, median [IQR]	206.0 [188.0, 230.0]	205.0 [188.0, 229.0]	222.0 [187.2, 253.2]	0.14
History of CAD, n (%)	3 (0.4)	3 (0.4)	0 (0.0)	1
History of AMI, n (%)	1 (0.1)	1 (0.1)	0 (0.0)	1
History of heart surgery, n (%)	3 (0.4)	3 (0.4)	0 (0.0)	1

Variable	Overall	No vaccine-associated myocardial injury	Vaccine-associated myocardial injury	p
History of myocarditis, n (%)	3 (0.4)	3 (0.4)	0 (0.0)	1
History of heart failure	2 (0.3)	2 (0.3)	0 (0.0)	1
Symptoms following vaccination n (%)				
Chest pain	63 (8.1)	61 (8.1)	2 (9.1)	0.70
Palpitations	70 (9.0)	69 (9.1)	1 (4.5)	0.71
Dyspnea	23 (3.0)	23 (3.0)	0 (0.0)	1
Fever and/or chills	270 (34.7)	263 (34.8)	7 (31.8)	0.95
Body aches	356 (45.8)	347 (46.0)	9 (40.9)	0.80
Biomarkers				
Hs-cTnT (day 3), median [IQR]	5 [4-6]	5 [4-6]	13.5 [9-18.8]	<0.001

Table 1. Baseline characteristics and vaccine-associated symptoms stratified by adjudicated vaccine-associated myocardial injury.

IQR: interquartile range. The patient with only one previous vaccination had received Johnson & Johnson's Janssen COVID-19 Vaccine which is a full primary immunization. According to Swiss authorities, past COVID-19 infection and one vaccination were regarded equivalent to having had two vaccinations (without previous COVID-19 infection) for primary immunization in Switzerland. History of heart surgery: one bypass surgery, one atrial septal aneurysm and one atrial septal defect. CAD=coronary artery disease; AMI=acute myocardial infarction

Variable	Overall	No vaccine-associated myocardial injury	Vaccine-associated myocardial injury	p
n	764	742	22	
Antibodies				
anti NP (MFI)	138.2 [65.0, 322.6]	139.0 [66.0, 325.0]	103.5 [33.6, 192.8]	0.052
anti S1(MFI)	1641.0 [870.8, 3254.0]	1641.0 [877.8, 3281.0]	1686.5 [757.5, 2614.8]	0.76
anti IL-1RA (MFI)	30.8 [23.0, 48.1]	31.0 [23.0, 48.0]	25.5 [19.5, 46.9]	0.31
Systemic inflammation				
IL-1RA (pg/ml)	621.3 [438.0, 832.0]	621.3 [440.5, 829.1]	605.3 [426.5, 895.2]	0.968
IL-1β (pg/ml)	6.8 [3.4, 13.2]	6.8 [3.4, 13.2]	7.0 [3.6, 9.4]	0.57
IL-6 (pg/ml)	1.7 [0.5, 3.4]	1.7 [0.5, 3.4]	1.5 [0.5, 2.7]	0.62
IL-8 (pg/ml)	4.2 [3.1, 5.9]	4.3 [3.1, 6.0]	3.9 [3.3, 5.7]	0.65
IL-10 (pg/ml)	9.8 [3.9, 25.8]	9.8 [3.9, 25.6]	10.4 [3.2, 31.5]	0.91
IL-12p70 (pg/ml)	10.0 [4.8, 18.1]	10.1 [4.9, 18.2]	8.0 [2.7, 14.3]	0.289
CRP (mg/l)	5.5 [2.8, 10.2]	5.4 [2.8, 10.1]	6.9 [4.3, 10.1]	0.28
TNF-α (pg/ml)	5.6 [1.7, 17.6]	5.7 [1.7, 17.7]	4.1 [1.7, 11.9]	0.43
IFN-β (pg/ml)	3.9 [0.8, 8.9]	3.9 [0.8, 9.1]	3.0 [0.8, 6.4]	0.13
IFN-γ (pg/ml)	16.9 [6.4, 37.5]	16.9 [6.6, 38.0]	15.5 [4.0, 30.4]	0.42

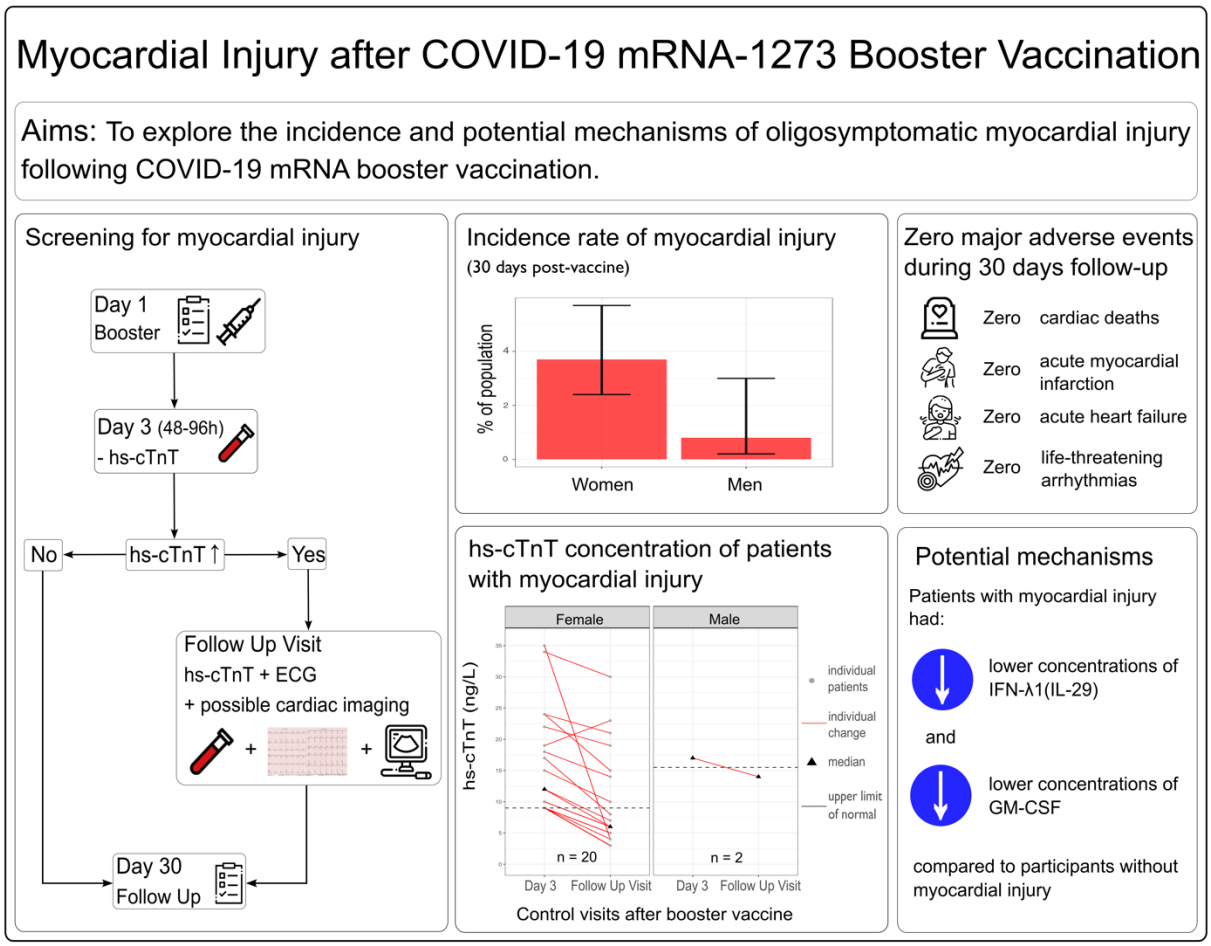
IFN-α2 (pg/ml)	2.5 [0.7, 5.4]	2.5 [0.7, 5.4]	2.0 [1.3, 3.8]	0.70
IFN-λ1 (pg/ml)	11.4 [3.8, 21.8]	11.8 [3.9, 22.3]	5.3 [2.9, 10.8]	0.015
IFN-λ2-3 (pg/ml)	7.8 [4.1, 12.9]	7.9 [4.2, 12.9]	5.5 [3.1, 8.6]	0.052
GM-CSF (pg/ml)	2.0 [0.6, 4.4]	2.0 [0.6, 4.5]	0.6 [0.6, 2.9]	0.039
IP-10 (pg/ml)	49.8 [25.8, 120.2]	49.8 [25.4, 120.8]	49.5 [31.2, 78.9]	0.984

Table 2. Inflammatory biomarkers stratified by adjudicated vaccine-associated myocardial injury.

In 13 patients (without vaccine-associated myocardial injury) the volume provided to the immunology laboratory was insufficient to measure the inflammatory biomarkers.

anti-NP = anti-nucleoprotein antibody; anti-S1 = anti-spike antibody; anti IL-1RA = anti-interleukin 1 receptor antagonist antibody; IL = interleukin; CRP = C-reactive protein; GM-CSF = granulocyte-macrophage colony stimulating factor TNF = tumor-necrosis factor; IFN = interferon, IP= interferon gamma-induced protein 10; MFI= median fluorescence intensity

Figures



Graphical Abstract

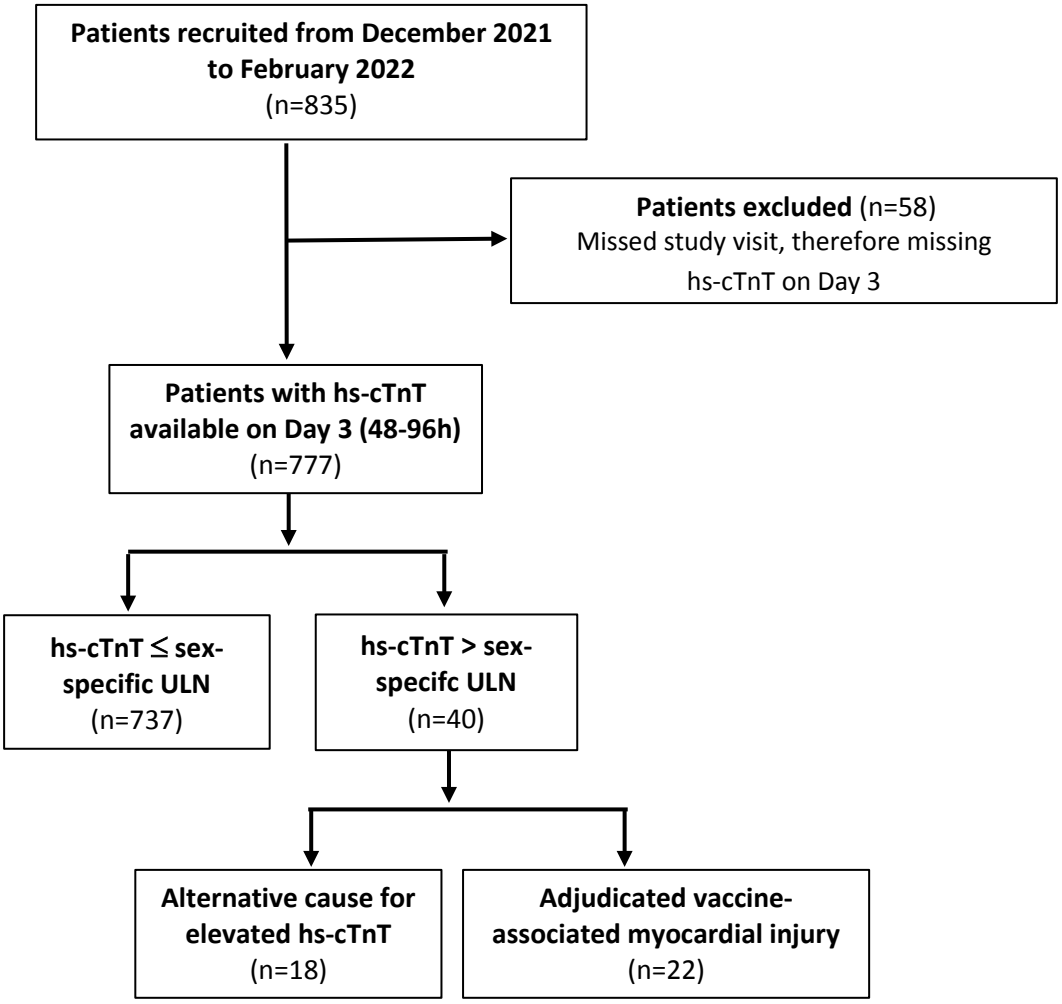


Figure 1. Patient flow chart

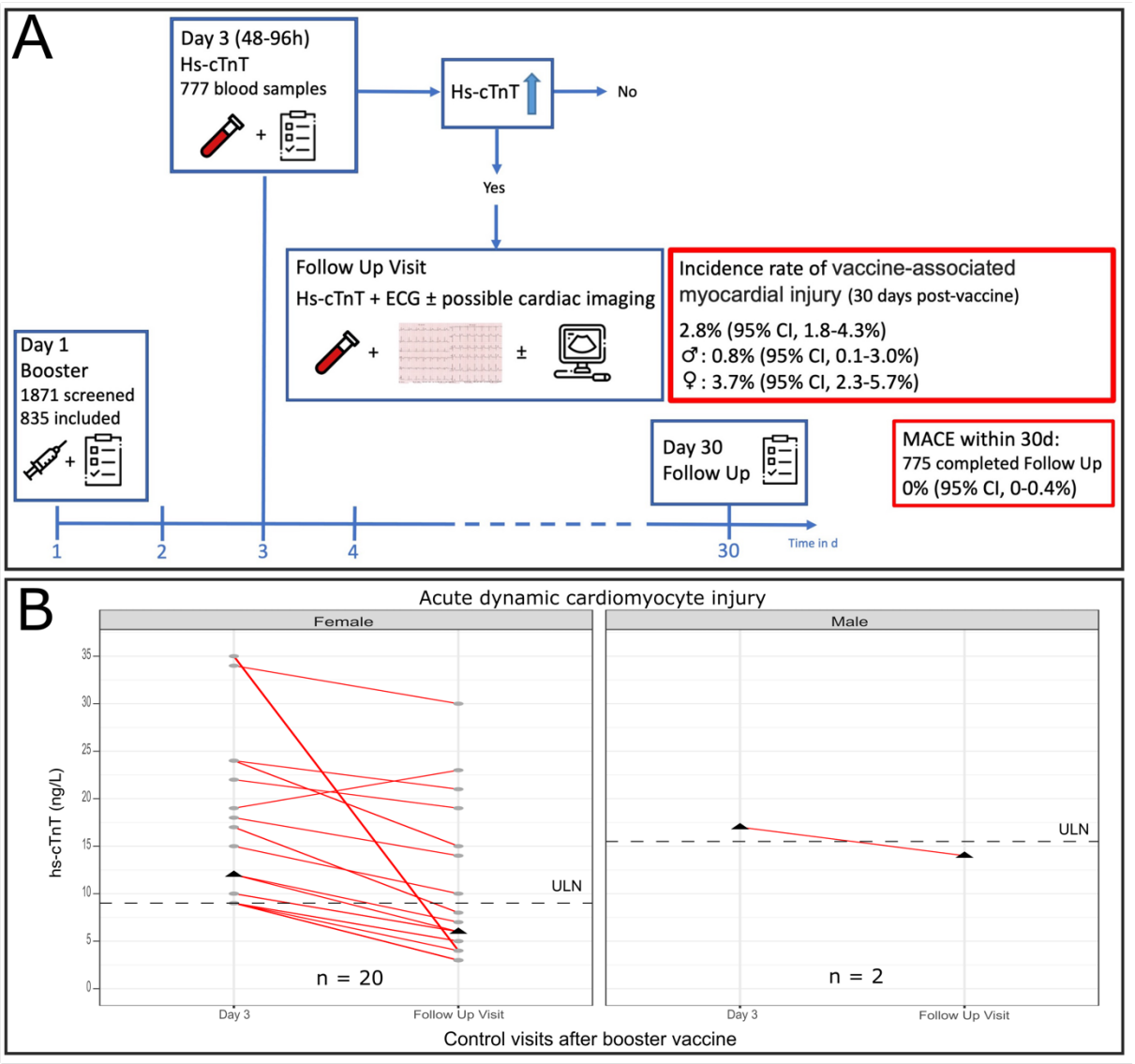


Figure 2.

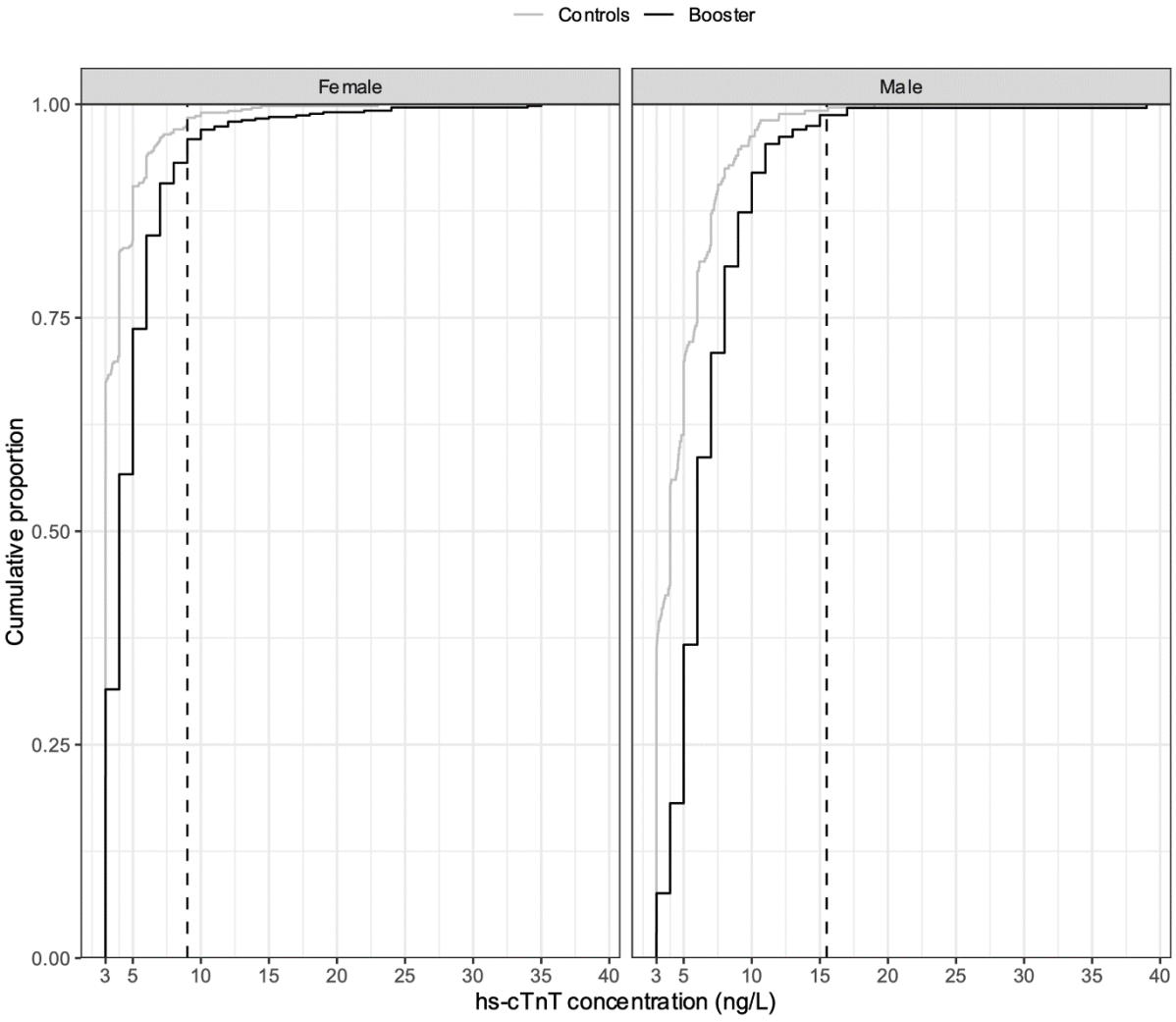


Figure 3.