

Covid-19 Vaccination: A Travesty of Medical Ethics

Following emergency use authorization of Covid-19 vaccines, peer-reviewed publications confirm an increasing toll of *severe adverse events and fatalities*. The aim of this report and website, is to raise awareness of the break-down of medical ethics in relation to Covid-19 vaccinations. Particular attention has been afforded to mRNA and adenovirus vector vaccine induced thrombotic thrombocytopenia (VITT), myocarditis and Guillain Barre' syndrome (GBS), in this introductory report.

Brief Background

The first reported cases of unusual thrombotic events in combination with thrombocytopenia were observed just 1 to 2 weeks following vaccination against SARS-CoV-2 with ChAdOx1 nCov-19 (Astra Zeneca). The clinical characteristics of the first 11 patients with this syndrome (for whom clinical data were available), were described by Greinacher et al. in the New England Journal of Medicine (published 9 April 2021). Thrombotic events included cerebral venous thrombosis (in 9 patients), splanchnic vein thrombosis (in 3 patients), pulmonary embolism (in 3 patients), and other types of thrombi (in 4 patients); 5 of 10 patients had more than one thrombotic event. The outcome was fatal in 6 out of these 11 index patients (1). Of note, no thrombotic signal was detected in clinical trials leading to the approval of the ChAdOx1 nCoV-19 vaccine (2).

Shortly thereafter (16 April 2021, New England Journal of Medicine), Scully et al reported findings in 23 patients, who presented with thrombosis and thrombocytopenia 6 to 24 days after receiving the first dose of the Astra Zeneca vaccine. On the basis of their clinical and laboratory features, they were able to identify a novel underlying mechanism involving the formation of anti-platelet factor (PF4) antibodies. Seven fatalities were reported at the time of publication of this case series (3).

Concurrently, similar cases of the newly described "Vaccine Induced Thrombotic Thrombocytopenia (VITT)" (or thrombotic thrombocytopenic syndrome (TTS)), were described with the Ad26.COV2.S (Johnson & Johnson) vaccine (4). The development of blood clots in 6 vaccine recipients, including the death of a 45-year-old woman in Virginia, led the US Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) to call for a 2 week pause on administering the Johnson & Johnson vaccine, on 13 April 2021 (5).

By May 2021, the CDC reported 28 cases of cerebral venous sinus thrombosis (of which three resulted in death). As of 4 April 2021, 169 cases of cerebral venous sinus thrombosis (CVST) and 53 cases of splanchnic vein thrombosis (SVT) had been reported to the European drug safety database EudraVigilance (6).

In July 2021, the FDA and European Medicine Agency (EMA) recommended updates to the product information of Johnson & Johnson and AstraZeneca Covid-19 vaccines, respectively, to include warnings of increased risk for Guillain-Barre syndrome following

vaccination. At the time, there were 100 preliminary reports of GBS (of which 95 were serious and 1 death reported) shortly following vaccination with Johnson & Johnson Covid-19 vaccination. By comparison to the Pfizer vaccine, this translated to an 8-fold greater risk of GBS following Johnson & Johnson vaccination (7,8).

In relation to the Pfizer–BioNTech (BNT162b2) vaccine, the earliest associated fatality reported by media was in January 2021, following the death of an obstetrician in Miami Beach, Florida, secondary to intracranial haemorrhage. He had received the Pfizer vaccine 16 days prior to his death, and eventually succumbed to a complication of severe immune thrombocytopenia. At the time, investigators including the CDC concluded his death as natural (9).

In May 2021, an expert review commissioned by the Norwegian Medicines Agency concluded that a causal link between the Pfizer-BioNTech vaccine and death was “likely” in 10 of 100 cases and “possible” in 26, of elderly individuals in nursing homes in Norway (10). Since then, multiple reports of immune thrombocytopenia, VITT, myocarditis and pericarditis closely associated with the Pfizer vaccine have emerged. In June 2021, FDA added a warning about the risk of myocarditis and pericarditis to fact sheets for Moderna and Pfizer-BioNTech Covid-19 vaccines (11). Four potential ‘adverse events of interest’ (AEI) in persons aged 65 Years and older were also documented a month later -namely, pulmonary embolism, acute myocardial infarction, immune thrombocytopenia, and disseminated intravascular coagulation (12).

Vaccine Induced Thrombotic Thrombocytopenia

Case reports and series of severe vaccine associated adverse events, such as VITT, have been published almost weekly in a host of medical journals throughout the course of the year. In an almost rehearsed manner, most reports, including those documenting vaccine-associated *fatalities* are concluded by authors and/or journal editors highlighting the “rarity” of the event and the premise that “benefits of Covid-19 vaccination outweigh the potential risks”.

By way of example, one of the largest multi-centre cohort studies in the UK, documenting 95 cases of cerebral venous sinus thrombosis (with and without thrombocytopenia) with 37 fatalities over 7 weeks, concluded, “*However, VITT appears to be a very rare side-effect of vaccination with the ChAdOx1 (Oxford–AstraZeneca) vaccine, the risk of which is likely to be greatly outweighed by the benefit of vaccination against COVID-19 for most people.*” (13)

Remarkably, this particular adverse event (VITT) is repeatedly described as a “new syndrome”; giving rise to the development of multiple consensus guidelines to aid diagnosis and management (14–18). As described by the most recent consensus statement by the National Institute for Health and Care Excellence (NICE), “*Because VITT is a new condition, there is limited evidence available to inform clinical management. Identification and management of the condition is evolving quickly as the case definition becomes clearer.*” (18)

Furthermore, the diagnosis and management of this adverse event necessitates tertiary level care, that generally includes CT venography, CT pulmonary angiography, a multi-disciplinary team of intensivists, clinical haematologists, radiologists, neurologists and neurosurgeons. Management is fraught with challenges in the setting of severe thrombocytopenia (that predisposes to massive haemorrhage) concurrent to widespread venous and arterial thrombo-embolism. Therapeutic modalities are also costly, and may comprise of the use of non-heparin drugs for anticoagulation, high dose steroids, platelet transfusion, plasma exchange, monoclonal antibodies, intravenous immunoglobulin, hemicraniectomy and long-term rehabilitation for survivors (18,19)

Indeed, initial concerns raised by senior medical consultants have been largely overlooked, e.g. Professor of Haematology at Oslo University hospital and author of an early Norwegian study of 5 patients with VITT, Pål Holme (20), commented in April 2021, *"Historically, I cannot imagine any vaccine with such severe side effects that hasn't been withdrawn. I understand that we are in a very unusual crisis situation with COVID, but we have other vaccines that have not been shown to have this side effect."* (21)

Subsequently, further studies have linked VITT and venous thromboembolism, including cerebral venous thrombosis (CVST) to the Pfizer (22–26) and Moderna (27–29) Covid-19 vaccines, albeit at a seemingly lower incidence.

Myocarditis

Of similar concern are the scores of published reports of myocarditis and pericarditis, temporally associated with both mRNA and adenovirus vector vaccines. Oft-repeated, are the phrases "rare" and "mild", in the context of vaccine-associated myocarditis. However, analysis of case reports of afflicted individuals, reveal occurrences of fulminant myocarditis (30–33), fatalities (32–34) as well as worrisome cardiac magnetic resonance imaging (MRI) findings in survivors.

A case series of 7 patients hospitalised for myocarditis following either Pfizer/ Moderna/ Johnson & Johnson covid-19 vaccination, revealed left ventricular ejection fraction ranging from 35% to 62%, with 5 of 7 having some degree of hypokinesis. Cardiac magnetic resonance imaging (MRI) demonstrated multifocal subepicardial late gadolinium enhancement (LGE) in all patients (35).

To note, LGE is widely used for detecting regional fibrosis or other forms of irreversible injury (36). It has a specificity of 100% and accuracy of 92% in acute 'infarct-like' myocarditis (37). A study evaluating the prognostic value of cardiac MRI tissue characterization in patients with suspected myocarditis, revealed that the presence of LGE was associated with a more than doubling risk of major adverse cardiac events (MACE) (hazard ratio [HR]: 2.22; 95% confidence interval [CI]: 1.47 to 3.35; $p < 0.001$). Annualized MACE rates were 4.8% and 2.1% corresponding to LGE presence and absence, respectively ($p < 0.001$). In the multivariable model, LGE presence maintained significant association with MACE (HR: 1.72; 95% CI: 1.08 to 2.76; $p = 0.023$) (38).

Concerningly, similar cardiac MRI findings have been reported in the majority of published cases of vaccine-associated myocarditis, corresponding to significantly elevated cardiac troponin levels (10-to-400-fold the upper limits of their respective reference ranges) in many cases (32,39–45).

Attention is called to the following points, in relation to acute myocarditis -

1. It is a medical fallacy to consider inflammation of the myocardium as “mild”, moreso, in the presence of overt biochemical and radiological evidence of severity.

2. Paradoxically, patients with milder presentations of acute myocarditis have shown a more progressive course, with higher risk for death or the need for cardiac transplantation in some studies, in contrast to fulminant myocarditis (46). The one-year mortality rate among patients with acute (non-fulminant) myocarditis has ranged between 10-15% in previous longitudinal studies (46–48)

To best highlight this point, reference is made to a case study of a 15-year-old male, who presented clinically with myocarditis (of undetermined aetiology). At follow-up, echocardiography was reported to show at least mildly impaired left ventricular function, while cardiac MRI demonstrated an ejection fraction of 42% and a pattern of late gadolinium enhancement. The patient remained asymptomatic, yet demised suddenly 2 years later. The post mortem distribution of scarring was concordant with the in vivo cardiac MRI LGE findings (49).

Hence, a declaration of non-severity, based only on the acute presentation of vaccine-associated myocarditis and clinical findings (duration of hospitalization, echocardiogram results and resolution of symptoms) is unsupported and misleading to the public.

3. Acute myocarditis has a wide range of presentations, including asymptomatic or mild flu-like symptoms. These cases are most often missed clinically. Sudden cardiac death may also be the only presenting sign, related to inflammation involving the conduction system, and giving rise to fatal arrhythmias. Myocarditis has been shown to contribute to sudden death in up to 20% of cases in autopsy studies of young adults (50,51).

In relation to covid-19 vaccinations, this phenomenon is illustrated by the sudden death of a 22 year old previously healthy man who developed chest pain 5 days after the first dose of the BNT162b2 mRNA vaccine and died 7 hours later. Histological examination of the heart on autopsy revealed isolated atrial myocarditis, with neutrophil and histiocyte predominance. Extensive contraction band necrosis was observed in the atria and ventricles. The primary cause of death was determined to be myocarditis, causally-associated with the Pfizer vaccine (34).

4. The long-term risks of cardiomyopathy and heart failure from vaccine-associated myocarditis is currently unknown, but remains a reasonable concern in an otherwise young, healthy population.

Guillain Barre Syndrome

A systematic review of published cases and an analysis of electronic medical records data from Taiwan's largest multi-institutional healthcare system was recently published, determining clinical features of GBS associated with COVID-19 vaccination (52). Thirty nine cases of GBS associated with Covid-19 vaccinations were found in the following distribution - ChAdOx1-S (25/39), followed by BNT162b2 (12/39), Ad26.COV2.S (1/39) and CoronaVac (1/39).

The classic form of GBS was the most common presentation. However, bilateral facial palsy with paresthesia was also frequently found in GBS after COVID-19 vaccination. There was one fatality and nine patients required mechanical ventilation during hospitalization. Twelve (out of thirty) patients scored >4 on the GBS-disability scale (i.e. indicating bedridden or chair-bound status) during follow-up or after discharge.

Conclusions

The purpose of this website (<https://covvaxse.com/>) is to track and collate peer-reviewed case reports, case series, review articles and guidelines on Covid-19 vaccine-associated severe side effects and fatalities.

At the time of this write-up, at least 150 publications related to serious adverse events and 195 deaths (of previously healthy individuals) had been traced. The true figure of casualties and survivors enduring life-long complications from VITT, myocarditis, Guillaine barre' syndrome and other side effects is indeterminate and will likely remain so. No doubt, this represents just the tip of the ice-berg, beneath which lies a buried tale of coerced, mass experimentation upon a desperate society.

As we approach the one year anniversary of Covid-19 vaccination roll-outs, perhaps it is time (or past time) to consider the following points of reflection -

1. How many collateral deaths and severe adverse events from a *prophylactic drug* with rapidly diminishing returns, are acceptable, before being withdrawn from the market?
2. Is it ethical to compare risks of a disease to that of its short-lived prophylaxis, thereby justifying and legitimising deaths and injury to healthy people?
3. Are coercive and mandatory regulations morally acceptable in the mass deployment of prophylactic means, that are associated with *any* risk of death or severe harm to healthy individuals?
4. Can adverse events truly be considered 'rare' when -
 - Clinical manifestations include asymptomatic/ non-specific symptoms and sudden death?
 - Diagnosis requires specialized personnel and equipment that are often scarce in resource-poor settings?

5. Can innovative prophylactic measures be described as 'safe' in light of confirmed deaths, severe, debilitating side effects and uncertainty of long-term consequences?
6. Can a vaccine be considered "effective" if it requires multiple 'boosters' per year, while still demonstrating poor efficacy in the prevention of transmission, herd immunity and rapidly waning benefits for severe disease?
7. What is the case to support mandatory vaccinations in light of the above, and with prospects of achieving herd immunity being "likely impossible", as acknowledged by the CDC's Covid-19 Epidemiology Task Force? (53)
8. Are we witnessing, in real-time, gross violation of the Nuremberg code (54), as billions are subjected to a novel drug following intimidation and loss of civil liberties, behind a smoke-screen of 'informed consent' (that is not genuinely informed)?

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16/12/2021

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