

Inadvertent Exposure to Pharmacologically Designed Lipid Nanoparticles Via Bodily Fluids: Biologic Plausibility and Potential Consequences

Matthew Halma^{1*}, Jessica Rose², Peter A. McCullough³

Abstract

Exposure to lipid nanoparticles, modified mRNA, adenoviral DNA, and/or spike protein from a Covid-19 injectable product or through secondary exposure via blood transfusion, is a potential source of human physiological harm. Blood reactions are an acknowledged side-effect of Covid-19 product injection; not limited to haemolysis, paroxysmal nocturnal hemoglobinuria, chronic cold agglutinin disease, immune thrombocytopenia, haemophagocytosis, hemophagocytic lymphohistiocytosis, and many other blood-related conditions. Adverse event occurrence in these contexts has motivated investigation into the cardiovascular mechanisms of harm by Covid-19 injectable products, and their biodistribution properties and pharmacokinetics. Biodistribution may not be limited to the body of the product recipient, as a growing body of evidence demonstrates the possibility of secondary exposure to injection by-products. These can be via bodily fluids and include the following routes of exposure: blood transfusion, organ transplantation, breastfeeding, and possibly other means. As Covid-19 injectable products are associated with an increased risk of stroke, the persistence of product artifacts in the blood presents a possible threat to a recipient of a blood donation from an injected donor who suffered from Vaccine Induced Thrombosis or Thrombocytopenia (VITT). We assess the feasibility and significance of these risks with an overview of the case report literature of blood disorders in injected individuals, pharmacovigilance reports from the US Vaccine Adverse Events Reporting System (VAERS), and a meta-analysis of the available literature on organ transplants from injected organ donors. Our analysis establishes biological mechanistic plausibility, a coherent safety signal in pharmacovigilance databases for secondary product content exposure (for the cases of blood transfusion and breastfeeding), and also an elevated level of adverse events in organ transplants from VITT-deceased donors, echoing increases in organ transplantation-related complications seen in national statistics for some countries. Secondary exposure to product artifacts is a potential explanation for some of the cases put forth, and requires a deeper investigation.

*Correspondence: matt@worldcouncilforhealth.org

1. EbmC Squared CIC, 11 Laura Place, Bath BA2 4BL, UK

2. Independent Researcher

3. Truth for Health Foundation, Tucson, AZ, USA

Keywords

blood transfusion, breastfeeding exposure, COVID-19, lipid nanoparticles, mRNA injectable product, pharmacovigilance, VAERS

Introduction

Since the introduction of Covid-19 injectable products, much attention has been given to the safety signal for myocarditis, as well as to the development of blood clots and hemolysis. SARS-CoV-2 exerts its pernicious impacts via the cardiovascular system [1-4], and most of the fatalities from Covid-19 were associated with cardiovascular inflammation and clotting [5-9]. Covid-19 injectable products developed during 2020 initially and superficially showed promising levels of protection in the clinical trials leading to their approval in many nations [10,11]. However, a strong cardiovascular safety signal emerged associated with the AstraZeneca product [12-14], leading to its suspension in several nations [15]. A thrombotic safety signal was also found in the Johnson and Johnson adenovirus-vectored product [16-18], also leading to its suspension in the USA [19].

Soon thereafter, a similar safety signal was observed for the Moderna and Pfizer modified mRNA injectable products [20], both modified messenger RNA (mRNA)-based products encapsulated in lipid nanoparticles (LNPs). Currently, several countries no longer promote the use of Covid-19 injectable products in younger populations, owing to the low likelihood of risk from Covid-19 and the increased risk of product-related injury, disability, and death for these populations. Cardiovascular events were much higher than any previously approved products in use, based on analyses of the various pharmacovigilance schemes. Several nations discontinued vaccination in younger people,

notably Denmark [21].

Immune activation cascades occurring in the circulatory system, either in the blood through thrombosis or thrombocytopenia, or in the epithelial cells of the vasculature, can alter the normal flow of blood. In extreme cases, this can lead to a stroke. Given the fact that the Covid-19 injectable products reveal a safety signal consistent with alterations in blood properties, it is reasonable to examine the possibility for carry-over effects into blood transfusion.

Given the focus on cardiovascular risks associated with the Covid-19 injectable products and the apparent persistence of spike protein in blood, it may be possible that recipients of blood transfusions and organ transplants from vaccinated donors are exposed to artefacts from the Covid-19 injectable products. Limited literature exists on the comparisons between the blood of injected people and that of uninjected people [22,23]; nonetheless, despite the paucity of evidence, many blood banks claim that there are no significant differences [24-26].

Methods

We propose that the question of secondary exposure to injectable product particles is yet unresolved and requires further investigation. This is based on three classes of argument:

-Firstly, the persistence of modified mRNA/adenoviral DNA lipid nanoparticles and their by-products (ie spike protein) for extended periods of time following injection lends plausibility to this mechanism of harm. This review of the literature evidence establishes biological plausibility. As injectable product particles and altered blood parameters can be found months after injection, these may potentially be passed onto a blood donation recipient.

-Secondly, the case report literature demonstrates many circulatory disorders manifesting in differed blood characteristics in cases of the primary

recipient of the injection, as well as adverse events following exposure to the bodily fluids of injectees. The modalities of transmission for which there is a pharmacovigilance signal are blood transfusion and breastfeeding. These establish a pharmacovigilance signal from exposure to injectee blood (in the case of blood donation) and breastmilk, in the case of breastfeeding.

-Lastly, recipients of organ transplant from donors deceased due to Vaccine Induced Thrombosis and Thrombocytopenia (VITT), encountered blood clotting and thrombotic events, suggesting a possible danger for organ donation, as well as blood transfusion. National monitoring for adverse events following organ transplantation also showed an increased rate of adverse events in temporal relationship to mass injection, but others show no increase.

Results

Mechanisms of Harm

The conditions of natural infection and vaccination are similar and distinct in several important ways. They are similar in that both conditions involve the expression of the spike protein in the cells via the injected or viral RNA. The spike protein is identified as the etiological agent for a significant portion of the cardiovascular damage of both SARS-CoV-2 infection [1,27] and in the context of the Covid-19 injectable products [28,29].

The first Covid-19 injectable product to be investigated for cardiovascular damage was the AstraZeneca product, which was determined to cause clotting disorders in several recipients [30] leading to its restriction in several countries [31]. Afterwards, the Johnson and Johnson injectable products [32], as well as the Moderna modified mRNA COVID-19 injectable products [33]

demonstrated cardiovascular safety signals, leading to their suspensions in the USA [34] and in Scandinavian nations (for young people) [35] respectively.

The proposed mechanism for cardiovascular injury from Covid-19 injectable products has been advanced in recent reviews [36,37]. Spike protein-induced clotting, being an unanticipated side effect of the products, warrants attention and caution when transfusing blood from one person to the other, depending on the time since injection, as there may still be LNP particles, aberrant proteins or spike protein present in the blood. It was previously assumed that the LNPs would remain at the site of injection [38] and break down rapidly [39]. However, both vaccine spike antigen and mRNA have been found in vaccine recipients 60 days [40] post-vaccination and spike protein antigen has been found 120 days post-vaccination [41]. The Red Cross claimed in a wishful public statement that vaccine particles do not enter the bloodstream [42], which has been contradicted by biodistribution studies [43]. It is possible that some of the Covid-19 product modified mRNA could be reverse-transcribed via LINE-1 to stably transfet the cell which would result in the observed continued production of spike protein [44].

One potential cause for concern is the observation that anti-platelet factor 4 antibodies have been measured and are elevated 7 months post injection in a subset of recipients [44]. Other studies show a small percentage of injected individuals maintain elevated levels long term [45,46]. Most patients have a transient response [47-49], but approximately 1% of patients maintain elevated anti-PF4 levels [45], which can lead to clotting [50]. This remains cause for concern, as the triggering of this immune response can well lead to a clotting cascade [51].

Pharmacovigilance

The large-scale administration of Covid-19 injectable products requires post-marketing surveillance to monitor any safety signal emerging from adverse event reports. Pharmacovigilance databases have observed an unprecedented number of adverse event (AE) reports since the rollout of the Covid-19 injectable products. These include the USA Vaccine Adverse Events Reporting System (VAERS) [52], the US-based V-safe database [53], the UK based yellow card scheme [54], the European EudraVigilance system [55] and the World Health Organization's (WHO's) VigiBase [56]. These resources were developed for the purpose of monitoring the safety profile of biological products following FDA approval. Despite a disproportionately high number of AE reports for the Covid-19 injectable products [57], these products are still approved for use and recommended in the USA and other countries as of July 3, 2024.

Case Reports of Blood Manifestations

Recent reviews cover cardiovascular adverse

events, finding an increased rate compared to previous vaccines [58–62]. In addition to these monitoring systems, there are also hundreds of case reports in the medical literature which have been linked to the vaccine by the medical provider (Table 1). These can broadly fall into the categories of VITT [12,14,30,37,44,45,61,63–358], Stroke [36,78,79,88,98,101,108,146,359–388], Hemolysis [92,389–403], vasculitis [4,360,404–540], anemia [541–564], cold agglutin disease [565,566], and hepatitis [135,567].

Postmortem data also supports a causative role for the Covid-19 injectable products regarding patient death. Autopsies can include immunohistochemical staining of both spike (S) protein and nucleocapsid (N) protein, and can thus be used to distinguish a Covid-19 injectable product-related death, and a SARS-CoV-2 infection-related death [568]. As the Covid-19 injectable products only result in the production of spike proteins, whereas natural infection results in the production of both S and N proteins, observing S in the absence of N protein using immunohistochemical staining highly suggests that the proteins came from the injectable products, and not SARS-CoV-2 infection [569].

Condition	Case Reports
VITT	[12,14,30,37,44,45,61,63–358]
Stroke	[36,78,79,88,98,101,108,146,359–388]
Hemolysis	[92,389–403]
Vasculitis	[4,360,404–540]
Anemia	[541–564]
Cold agglutinin disease	[565,566]
Hepatitis	[135,567]

Table 1. An overview of case reports for blood conditions related to Covid-19 injectable products.

Blood Transfusions

Since Covid-19 injectable product and their downstream manifestations (e.g. microclots) remain in the bloodstream for long periods of time [41], blood transfusion is a potential (secondary) route of exposure to injection by-products.

There are 1352 transfusion reports in VAERS as of May 15, 2023 (Figure 1). As of May 25, 2023, according to the Worldometer [570], the population in the United States is 336,688,028. And according to Our World in Data, the number of Americans who have received at least one dose of the Covid-19

injectable products is 270,230,000, or 80% of the US population [571]. Considering the time course of injection, from the period of 1st March, 2021 to May 25, 2023, the time-averaged injection percentage is 70% [571]. A 2019 statistic puts the number of blood transfusions occurring yearly in the USA at 10,852,000 [572], putting the approximate number of blood transfusions during the above period at 24.2 million. Of the 24.2 million, approximately 17 million would have received a Covid-19 vaccine. Using the number of individuals who had received both an injection and a transfusion, and the number of reports of adverse events in VAERS of transfusions, we get a rate of 1/12,570 and with an under-reporting of 31, this becomes 1/405.

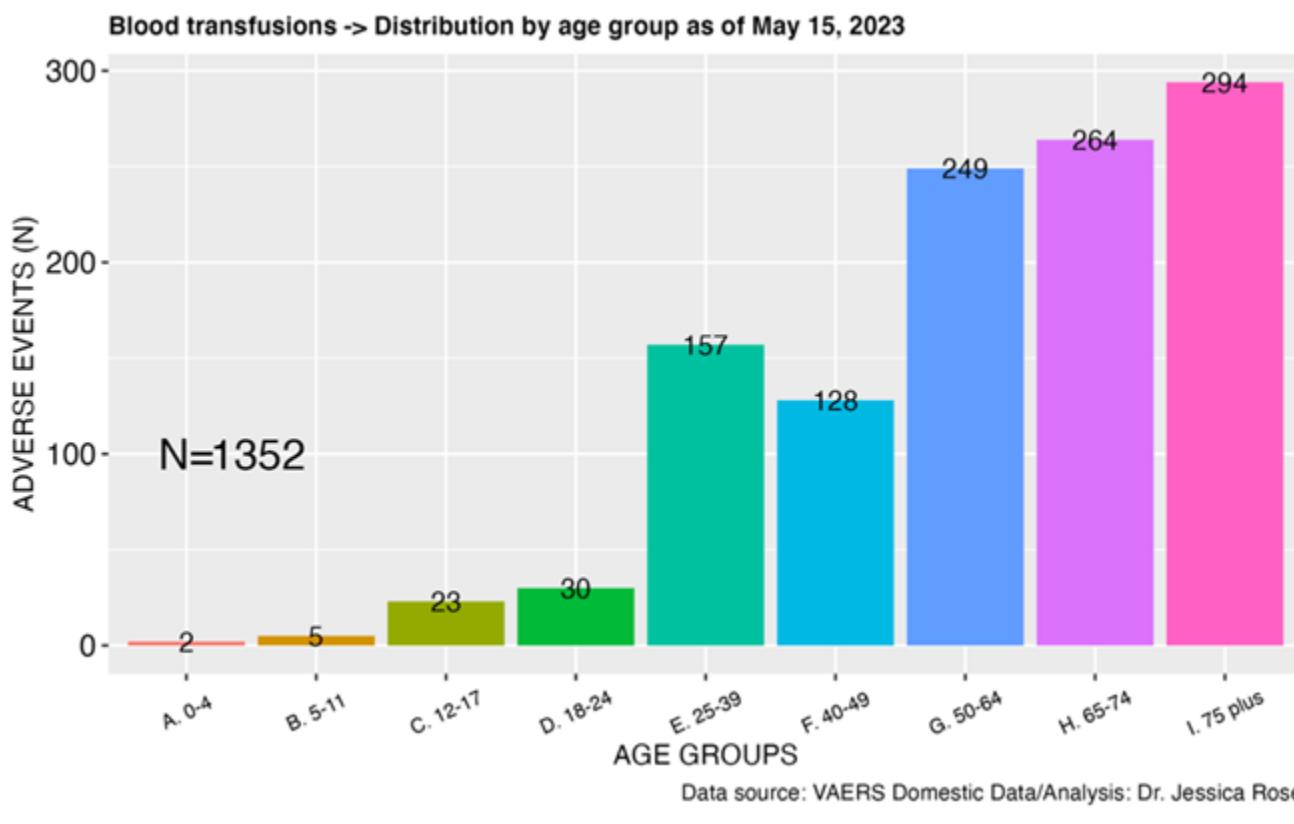


Figure 1. VAERS domestic and foreign reports as of May 15, 2023 queried using keyword "transfusions." Original figure with data source (<https://vaers.hhs.gov>).

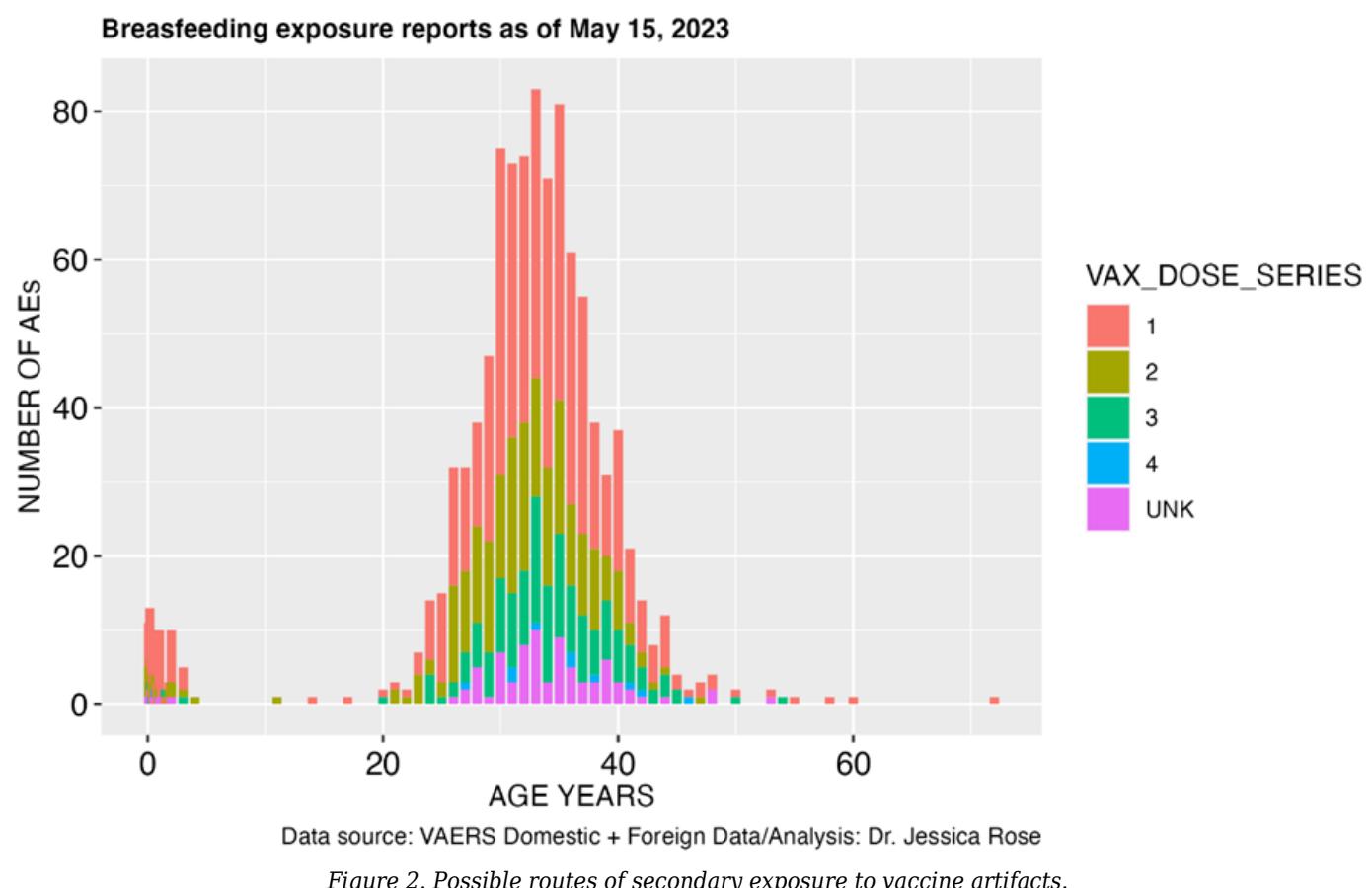
Breastfeeding and other routes of exposure

Given that Covid-19 injectable product contents have

been observed in breast milk [573], breastfeeding presents a possible, albeit likely transient, route of

secondary exposure for nursing babies. In VAERS as of May 15, 2023, the search terms (“Breast feeding,” “Breast milk discoloration,” “Exposure via breast

milk,” “Maternal exposure during breast feeding”) return $N = 1,835$ total reports of adverse events (Figure 2).



To estimate the denominator of total number of (injected) mother-baby pairs, between December 14, 2020 and May 10, 2023, 60,615,370 women between the ages of 18 and 49 were reported to have been injected with at least one dose of the COVID products [574]. The age groups 18-24 and 25-49, as per the CDC grouping, span the child-bearing years appropriately.

The estimated fertility rate for women of childbearing age [15-44 years] in the United States in 2021 was 56.3 births per thousand women per year [575], therefore we can estimate that the number of women who gave birth (in the window of December 14, 2020 to May 10, 2023) of the number

injected was 8,326,855. We can also estimate the number of women breastfeeding of those births since ~83% of infants are breastfed immediately, according to the CDC breastfeeding report card released in 2022 (based off 2019 data) [576]. Therefore, by these rates, there were approximately 6,911,289 women breastfeeding at the time of injection with COVID products. This is a rough estimate, but based on recent data provided by the CDC. Using this number to compare it with the number of reports in VAERS, we get 1,835 reports of adverse events out of approximately 7 million mother-infant pairs (with the mother having received a Covid-19 injectable biological product), or

approximately 1/3800. While seemingly low, this estimate does not account for underreporting, where the underreporting factor is estimated to be 31 [577].

Mechanistically, adverse events through breastfeeding exposure are plausible given that breast milk of recently injected mothers may contain SARS-CoV-2 antibody proteins [578,579] and traces of the injection materials [573].

While dosage would likely be minimal, it is possible that others may be exposed to injection particles via other routes. Shedding is observed in adenovirus vectored products [581], which would apply to Johnson & Johnson and AstraZeneca [581]. One important distinction is that while viral shedding can be ruled out with modified mRNA injectable products, because they lack a viral vector, exposure to the injection particles and their artifacts can occur, albeit in smaller quantities than the original injection.

In households where one person was injected, other family members developed spike protein antibodies [582]. While the cited article explained this in terms of the transfer of antibodies themselves, this would likely not be persistent. In cases where the antigen (spike protein) is transferred, this may possibly explain the presence of anti-spike antibodies in the serum of uninjected and unexposed (to SARS-CoV-2) individuals.

Sexual intercourse is a possible mode of transmission as spike protein RNA has been observed in semen during SARS-CoV-2 infection [583]. Inactivated viral vector Covid-19 injectable products have been observed to impair sperm morphology [584], motility [585], and increase DNA fragmentation [584]. Conflicting information exists on the impact of mRNA injections on semen parameters, with a study showing impaired semen concentration and sperm counts [586], and two

studies seeing no impact [587,588]. It may be of interest that sperm motility decreased 22% at a sperm bank in Denmark from 2019 to 2022 [589], and the drop in quality may be due to Covid-19, Covid-19 biological products, or it may be spurious.

Transfer through either exhalation or skin-to-skin contact has anecdotal accounts supporting it, but limited published evidence exists. Mechanistically, the lipid nanoparticles of the mRNA injections are very similar to endogenous exosomes, which can be transmitted trans-dermally, via inhalation, via breast milk, and across the placenta (Figure 2) [590].

Spike protein can importantly be packaged into exosomes [591], and precedent exists for the presence of RNA-containing exosomes in breath [592-594]. A recent review has summarized the persistence of Covid-19 injection components in different bodily fluids [595], finding evidence for persistence of spike protein in lymph nodes [40], on skin [596] and in blood [40,597], and persistent spike protein mRNA in lymph nodes [40], and in blood plasma [598].

Organ Transplant Safety

Another source of information on the safety of blood transfusions is the organ transplant literature. Blood type matching is necessary for organ transplantation, in addition to other criteria, such as organ size. Current approaches are lowering the risk of transplant rejection by matching donor and recipient human leukocyte antigen (HLA) [599-601].

There are several case reports of transplants from Covid-19 injected donors. This literature focuses mostly on donors who died due to VITT. In the case of organ transplantation, with few exceptions, such as the kidney, the donor must be deceased. Considering these donors were classified as having

died from VITT by a medical professional, these donations are more likely to present safety issues than blood donation, where the donor does not have manifested VITT, as this would deem them ineligible or at the very least reluctant to donate.

Vaccination mandates with respect to transplantation, especially for recipients, have been a source of controversy during the Covid-19 pandemic [602-607]. Several centers have refused to provide transplants to uninjected prospective recipients.

Our search returns 8 articles focusing on transplants from donors deemed deceased from VITT [608-616] (Table 2).

Several people, having died from likely VITT, have donated their organs for medical transplantation. While the blood used during a transplant operation is typically given by a separate donor, still, this high rate of complications in recipients is cause for concern. Transplantation of organs from those suffering stroke is a common occurrence and has a low failure rate. In a Canadian study of kidney transplant recipients, where the donor died of stroke, only 5% of recipients were on dialysis after 1 year and there were no deaths in hospital [617], so the vast majority of the kidney transplants worked.

A study calculated the rate of microthrombi formation in recipients where the donor dies from a cardiac death (DCD) as 3.3% [618]. This was not significantly different from the rate of microthrombi formation in recipients where the donor dies due to brain death (DBD), which is 11.3% [618]. The rate of microthrombi and thrombotic complications is much higher in recipients of donors deceased due to VITT, at 30% of recipients (Table 2). Another study observed rates of vascular complications in the recipients of liver transplants from donors deceased due to cardiovascular events in 7% to 14% of transplant recipients [619]. The uncertainty is due to

there being two categories of vascular complications, “hepatic artery thrombosis” and “other,” and it is not specified what the degree of overlap (recipients experiencing both types of complications) there is. Another study of liver transplant recipients from DCD cases showed a rejection rate due to thrombotic complications of 2%, comparable with 3% of recipients of DBD [620]. Another Swedish study reported rates of hepatic artery thrombosis in 8 of 24 liver graft recipients from DCD donors, or 33% [621]. A large meta-analysis found vascular thrombosis of 3% in DCD liver graft recipients, and 2% in DBD liver graft recipients [622]. The same meta-analysis observed rates of vascular stenosis of 4% in DCD and 2% in DBD liver graft recipients.

These operations have mixed successes, as many of these transplantations are successful, still, there remain several cases where the recipient experienced thrombotic events which persisted over long term. All considered, the risks of organ transplantation may be outweighed by the definite dangers of not going through with a transplant.

Data monitoring for increases in transfusion reactions is limited. Several national hemovigilance systems do not observe a significant increase in adverse event rates in 2021 compared to previous years [623,624]. Other systems have not yet published hemovigilance for 2021 [625], though Austria reported a 49% increase in transfusion reactions from 49 in 2020 to 73 in 2021 [626], Denmark saw a significant increase in adverse reactions between 2020 and 2021 [627] and UK hemovigilance data shows an increase in blood component issues from 2020 to 2021 [628]. Additionally, transplantation AE rates in Canada rose significantly, from less than 3 transfusion adverse events per year to 12 between 2020 and 2021 [629]. In Japan there was a slight increase of 7% from 2020

to 2021 [630].

Study	Donor	Organ	Recipient	Outcome	Thrombotic AE rate (AE rate including microthrombi, organ/graft rejection and Positive anti-PF4)
[608]	50-year female with VITT	Heart	Unknown	No thrombosis or thrombocytopenia Anti-PF4 antibodies negative 3 weeks after transplantation	0/1 (0/1)
[615]	18-year-old brain-dead female who dies from VITT-related intracranial hemorrhage	Liver	58-year-old female	Rapid drop in platelet counts from $104 \times 10^9/\text{liter}$ to $30 \times 10^9/\text{liter}$ Anti-PF4 IgG strongly positive Grade 3 (severe) thrombocytopenia	1/1 (1/1)
[609]	(n = 8, aged between 22 and 55 years) Died of catastrophic intracerebral hemorrhage or thrombosis, had received the first dose of ChAdOx1 nCOV-19 vaccine 9 to 19 days before hospital admission, and had detectable anti-PF4, low fibrinogen and elevated D-Dimers	Liver	(n = 9, aged 2–43 years)	Four recipients with positive anti-PF4 antibodies without bleeding or thrombotic complications Two recipients with severe thrombotic events, requiring emergency retransplantation. Anti-PF4 antibodies negative.	2/9 (6/9)
[610]	N=16 Median age 44 75% female	Kidney	N=30 Median age 48 47% female	2 recipients with anti-PF4 antibodies but no clinical disease Major hemorrhagic complications in 3 recipients w/ independent risk factors	3/30 (5/30)
[612]	Male, 41 Female, 69 Male, 67 All deceased from VITT	Heart Kidney Liver Lungs	N=9 Median age 58 (40-70) 44% female	Glomerular microthrombi in 2 kidney recipients Pulmonary embolism in lung recipient No anti-PF4 antibodies observed	1/9 (3/9)
[613]	N=6 Aged 37-72 years 50% female	Liver Kidney Lung Heart	N=17 Aged <1 to 77 years 42% female	Liver cell necrosis and re-transplantation in one recipient Microangiopathy in one kidney recipient Two recipients (11.8%) developed thrombosis-related complications	2/17 (4/17)
[614]	32-year-old female deceased from VITT-induced stroke	Liver	69-year-old female	No adverse events, operation successful	0/1 (0/1)
[611]	N=13 Median age 34 (21 to 63) 85% female	Kidney Liver Heart Lung Pancreas	N=26 Median age 40 (2 to 63)	Thrombosis Thromboembolism in 7/26 recipients (3 liver recipients and 4 Kidney/SPK/islet recipients) Graft dysfunction in 4/26 recipients Anti-PF4 antibodies positive in 3/13 (23%) tests with results	7/26 (10/26)
[616]	Female aged 60-69	Liver & Heart Lungs Right Kidney Left Kidney	63-year-old male 58-year-old woman 70-year-old man 52-year-old man	No AEs No AEs Thrombi in pre-implantation biopsy, uneventful transplantation Glomerular inflammation and hemorrhagic suffusion	0/4 (2/4)
Summary					16/98, 16% (29/98, 30%)

Table 2. A summary of transplantation trials from donors deceased from VITT.

Discussion

In total, we found evidence to support Covid-19 injectable product by-product transfer between injected and uninjected recipients, and this calls into question the safety of blood donation from injected individuals, especially in temporal proximity to actual injection date. Questions remain over the safety of associated blood products and secondary exposure to injection by-products. Circulatory AEs associated with Covid-19 injection far outnumber those for any vaccine historically monitored, and may be cause for concern, as clotting can exist at a subclinical level and evade detection for many years, unless explicitly tested for, through measurements of D-dimer or troponin, for example.

It has been brought to attention that with regard to the injectable Covid-19 biological products, these may be better classified as gene therapies as opposed to vaccines [631]. Additional testing for the shedding of the gene therapy product is required by both the US Food and Drug Administration [632] and the European Medicines Agency [633].

One open question is if the waiting period to donate blood post injection is sufficient to ensure the safety for the recipient, and if there is a definitive safe waiting period at all. Most countries have limited or nonexistent waiting periods for donations post-Covid-19 injection, though some ask their donors to refrain from donating blood for a few weeks afterwards. Given that injection by-products are, in principle, non-replicating, we expect them to decay once in the body, where their concentration gradually drops. The time curve of injection by-product decay still requires more investigation in the context of the LNPs, the modified mRNA, potential DNA, aberrant proteins produced to frameshifting, and the spike protein, as studies observe both circulating spike protein at least two months after injection [41].

One recommendation of this report is the development of hemovigilance systems to provide summary statistics on blood properties during donor intake. Additionally, the passive monitoring for transfusion related AEs from injected donors should be addressed in a passive monitoring study whereby donors voluntarily provide their Covid-19 injection status on an intake form. Comparisons of injected and uninjected blood should be made at two levels: both the properties of the blood itself, and its interaction with recipient blood/physiology. Summary statistics on both types of measurements can be calculated to determine if any statistically significant differences between blood products from injected and uninjected donors exists. Reporting of donor's Covid-19 injection status can be done on a voluntary basis, out of respect for medical privacy.

Questions remain as to the safety of transfusions and transplants from Covid-19 injected donors, and this question carries significant implications for national health systems, blood banks, and organ transplant pools. A survey of blood parameters, as well as recipient adverse events would require only recording the donor injection status, and analysis of such data is straightforward from a statistical perspective. The low cost of such a study, combined with the importance of the questions that it would address is significant motivation to perform such a study. We ask the relevant authorities (blood donation clinics and transplant clinics) to consider adding an optional questionnaire for donors, on whether they have been vaccinated, and the dose schedule, and type of vaccination. This presents a completely non-invasive way to address questions of significant public health importance.

Conclusion

Concerns remain over not only primary exposure to injection by-products, but also of secondary exposure through bodily fluids. Several lines of

evidence, including mechanistic understanding, pharmacovigilance, case reports of blood manifestations in product recipients, and case reports of autopsies from Covid-19-injected donors suggest that it may be a possibility. Persistence of injection by-products have been observed in blood [40,41] and breast milk [573]. Additionally, there are AE reports that support bodily fluid exposure (via blood transfusion or breastfeeding) as an aetiological factor.

Further evidence is notable by the comparatively high rate of thrombotic complications in organ donation recipients from donors deceased due to VITT, which appears higher than rates of thrombotic complications in people dying of comparable cause, only not injection-related. The rate of thrombotic complications for the case of Covid-19 injectable product donors deceased due to VITT is 30% (Table 2), whereas a pre-Covid-19 vaccine study observed a rate of thrombotic complications of 3% in recipients of liver grafts from donors deceased due to cardiovascular complications, including stroke [618]. While different studies have found a variety of rates for thrombotic complications, the rates of thrombotic complications in recipients of organ transplants from VITT donors (30%, Table 2) are higher than most comparable historical rates of thrombotic complications in recipients of organ transplants from DCD donors [618,620,622]. One study's reported rates [621] (33%) were similar to our reported rates of thrombotic complication (30%, Table 2).

Future monitoring is important for maintaining transfusion safety, as well as the safety of breastfeeding. At this point, harms cannot be definitively ruled out and the question deserves more attention. Given these concerns, blood donors should consider refraining from donation until more information is published on the safety of blood from donors who received the Covid-19 injectable products.

Acknowledgments

We thank supporters of the World Council for Health, Frontline Covid-19 Critical Care Alliance and the McCullough Foundation for enabling this research.

Ethics approval and informed consent: This article is based on published data. No ethical approval is required.

Consent for Publication: All figures are original productions and do not require approval.

Data Availability: The datasets studied in this article are available at their respective citations.

Competing Interests: The authors declare no competing interests.

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EMA: European Medicines Agency
FDA: Food and Drug Administration
HLA: Human Leukocyte Antigen
IFR: Infection Fatality Rate
LNPs: Lipid Nanoparticles
mRNA: Messenger RNA
PF4: Platelet Factor 4
SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus 2
VAERS: Vaccine Adverse Event Reporting System
VITT: Vaccine-induced Thrombosis and Thrombocytopenia
WHO: World Health Organization

Abbreviations

AE: Adverse events
CDC: Centers for Disease Control (USA)
DBD: Donor dies from a Brain Death
DCD: Donor dies from a Cardiac Death