Review

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

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Review

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

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Abstract: Exposure to vaccine lipid nanoparticles, mRNA, adenoviral DNA, and or Spike protein from one of the approved Covid-19 vaccines, or through secondary exposure, as through blood transfusion, is a potential source of harm. Blood reactions are an acknowledged side-effect of Covid-19 vaccination, not limited to hemolysis, paroxysmal nocturnal hemoglobinuria, chronic cold agglutinin disease, immune thrombocytopenia, haemophagocytosis, hemophagocytic lymphohistiocytosis, and many other blood related conditions. The observation of adverse events has motivated investigation into the cardiovascular mechanisms of harm by Covid-19 vaccines, and the biodistribution of vaccine contents. Biodistribution may not be limited to the body of the vaccine recipient, as a growing body of evidence demonstrates the possibility of secondary exposure to vaccine particles. 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 vaccines are associated with an increased risk of stroke, the persistence of vaccine artifacts in the blood presents a possible threat to a recipient of a blood donation from a vaccinated donor who suffered from vaccine induced thrombosis or thrombocytopenia. (VITT) We assess the feasibility and significance of these risks through an overview of the case report literature of blood disorders in vaccinated individuals, pharmacovigilance reports from the US Vaccine Adverse Events Reporting System (VAERS) and a meta-analysis of the available literature on organ transplants from vaccinated organ donors. Our analysis establishes biological mechanistic plausibility, a coherent safety signal in pharmacovigilance databases for secondary vaccine contents 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 vaccine artifacts is a potential explanation for some of the cases put forth, and requires a deeper investigation.

Keywords: Covid-19 vaccination; mRNA vaccine; lipid nanoparticles; blood transfusion; breastfeeding exposure; pharmacovigilance; VAERS

1. Introduction

Since the introduction of Covid-19 vaccines, much attention has been given to the safety signal of myocarditis, as well as 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]. Vaccines developed during 2020 showed promising levels of protection in the clinical trials leading to their approval in many nations[10,11], however, a cardiovascular safety signal emerged, first with the AstraZeneca vaccine[12–14], leading to its suspension in several nations[15]. A thrombotic safety signal was also found in the Johnson and Johnson adenovirus-vectored vaccine[16–18], leading to its suspension in the USA[19].

Later on, a similar safety signal was observed for the Moderna and Pfizer mRNA vaccines[20], both messenger RNA (mRNA) vaccines encapsulated in lipid nanoparticles (LNPs). Currently, several countries no longer promote the use of Covid-19 vaccines in younger populations, owing to the low likelihood of risk from Covid-19 and the increased risk of vaccine injury, disability, and death

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for these populations. Cardiovascular events were much higher than any previously approved vaccines 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 vaccines show 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 from the vaccines, and one route of exposure, albeit uncommon, to Covid-19 vaccine products and their after-effects is via blood transfusion and organ transplantation. Limited literature exists on the comparisons between the blood of vaccinated people and that of unvaccinated people[22,23]; nonetheless, despite the paucity of evidence, many blood banks claim that there are no significant differences[24–26].

Materials and Methods

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

1. Firstly, the persistence of vaccine mRNA/adenoviral DNA lipid nanoparticles and their products (ie spike protein) for long periods following vaccinations lends plausibility to this mechanism of harm. This review of the literature evidence establishes biological plausibility. As vaccine particles and altered blood parameters are found months after inujection, these may potentially be passed onto a blood donation recipient.
2. 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 vaccinees. The modalities of transmission for which there is a pharmacovigilance signal are blood transfusion and breastfeeding. These establish a pharmacovigilance signal from exposure to vaccinees blood (in the case of blood donation) and breastmilk, in the case of breastfeeding.
3. 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 vaccination, but others show no increase.

2. Results

2.1. 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 vaccine 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 vaccination against Covid-19[28,29].

The first Covid-19 vaccine to be investigated for cardiovascular damage was the AstraZeneca vaccine, which caused clotting disorders in several of its recipients[30], and leading to its restriction in several countries[31]. Afterwards, the Johnson and Johnson vaccines[32], as well as the Moderna mRNA COVID-19 vaccines[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 vaccines has been advanced in recent reviews[36,37]. Spike protein induced clotting, being an unanticipated side effect of the vaccines, warrants attention and caution when transfusing blood from one person to the other, depending on the time since vaccination, there may still be vaccine particles or spike protein present in the blood. It was previously assumed that the vaccine particles would remain at the site of

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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].

One potential cause for concern is the observation that anti-platelet factor 4 antibodies have been measured are elevated 7 months post vaccination in a subset of vaccine recipients[44], and other studies show a small percentage of vaccinated patients 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].

2.2. Pharmacovigilance

The large-scale administration of covid-19 vaccine 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 vaccines. 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 vaccines after approval. Despite a large number of AE reports for the Covid-19 vaccines[57], the vaccines are still approved for use and recommended in the USA and other countries as of this writing (July 30, 2023).

2.2.1. 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[63],

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

Condition	Case Reports
VITT	12,14,30,37,44,45(p4),61,63–101,102(p1),103–233
Stroke	36,78,79,88,98,101,108,146,234–250,251(p284),252–258
Hemolysis	92,259–267
Vasculitis	4,268,269
Anemia	270
Cold agglutinin disease	271
Hepatitis	135,272

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Postmortem data also supports a causative role for the vaccine in the death of the patient. These autopsies, by immunohistochemically staining for both spike (S) protein and nucleocapsid (N) protein, can determine if a case is vaccine caused or caused by SARS-CoV-2 infection[273]. As the vaccines mentioned above only contain the spike protein, whereas natural infection results in both S and N proteins, observing S in the absence of N protein highly suggests that the proteins came from vaccines, and not SARS-CoV-2 infection[274].

2.2.2. Blood Transfusions

Since vaccine contents 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 vaccine particles.

There are 1352 transfusion reports in VAERS as of May 15, 2023 (Figure 1). In 2019, there were 10,852,000 blood transfusions performed in the USA[275]. Taking that as the per-year rate, roughly 24 million blood transfusions were performed since the beginning of mass-vaccination campaigns in Spring 2021. If roughly ¾ of the donors were vaccinated, that makes the denominator 18, 000, 000 transfusions. The adverse event rate is roughly 1/13 000 transfusions, or 1/429 taking into account the under reporting factor of 31 as estimated by Rose[276].

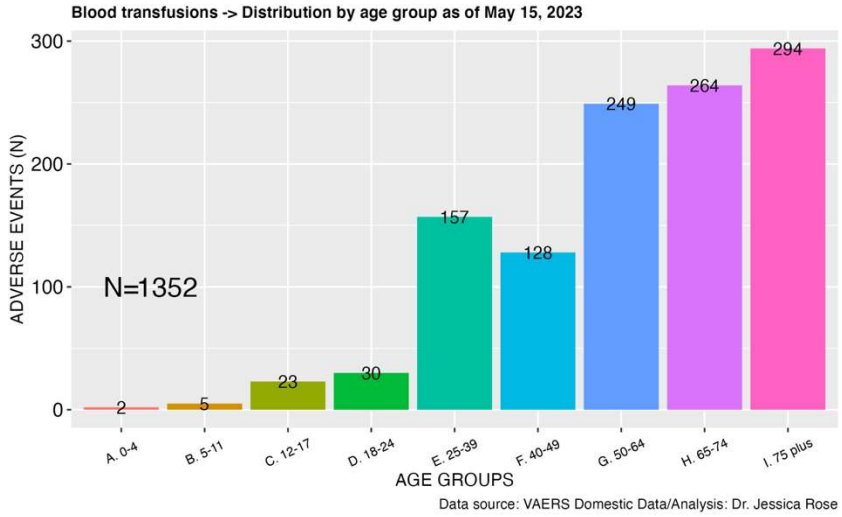

Figure 1. VAERS domestic and foreign reports as of May 15, 2023 queried using keyword 'transfusions'. Source: https://vaers.hhs.gov.

As of May 25, 2023, according to the Worldometer[277], 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[278]. Considering the time course of vaccination; from the period of 1st March, 2021 to May 25, 2023, the time-averaged vaccination percentage is 70%[278]. A 2019 statistic puts the number of blood transfusions occurring yearly in the USA at 10,852,000[275], 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.

2.2.3. Breastfeeding and Maternal Exposure

Given that vaccine contents have been observed in breast milk[279], breastfeeding presents a possible, albeit likely transient, route of secondary exposure for nursing babies.

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In VAERS as of May 15, 2023, the search terms ("Breast feeding", "Breast milk discolouration", "Exposure via breast milk", "Maternal exposure during breast feeding") return N = 1,835 total reports of adverse events (Figure 2).

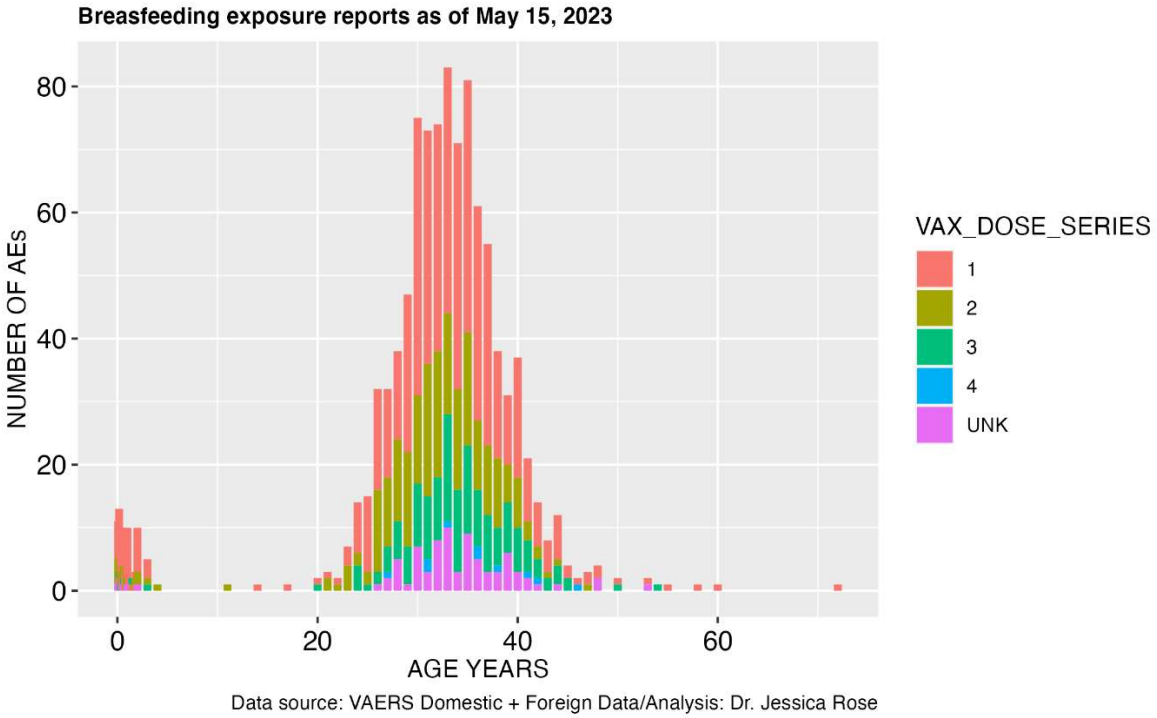

Figure 2. VAERS domestic and foreign reports as of May 15, 2023 queried using MedDRA keywords "Breast feeding", "Breast milk discolouration", "Exposure via breast milk", "Maternal exposure during breast feeding". Source: https://vaers.hhs.gov.

Although the absolute count of reports is not very high, the under-reporting factor is not accounted for here. If we use the under-reporting factor of 31 as estimated by Rose[276], the number of incidents becomes N = 56,885. This means that of the population of women who were injected who were also breast-feeding at the time, a likely meaningful proportion reported an adverse event to VAERS. 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[280]. The age groups 18-24 and 25-49, as per the CDC grouping, span the child-bearing years appropriately.

Since 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[281], 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)[282]. 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 it *is* based on recent data provided by the CDC. If we use this number and compare it with the number of reports in VAERS using an under-reporting factor of 31, we get 56,885 women succumbing to adverse events out of 6,911,289. That's a rate of 1/121, approximately. Even without the under-reporting factor, we still get a reporting rate of 1/3766.

Of the 1,835 reports, 6.6% are made for infants 4 years of age or less and of these reports, 25% are considered severe adverse events (SAEs). The VAERS handbook states that approximately 7% of reported AEs are classified as severe[283], so here the proportion of serious events to total events is 18 percentage points above the norm. To be clear, neither these infants nor their mothers required the COVID-19 injections since the Infection Fatality Rate (IFR) is 0.05% for individuals less than 70 years of age[284]. The infants would have inherited existing immunity from neutralizing IgA antibodies, for example, from their mother's milk since their mother likely would have generated robust and long-

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lasting immunity involving both antibody and T cell responses from exposure to SARS-CoV-2[285]. Instead, it appears as though they are suffering from severe adverse events from their mother's milk that contains not only SARS-CoV-2 antibody proteins[286,287] but traces of the injection materials[279] and likely spike proteins as well. It is critical that we examine the connection between the emergence of these SAEs in infants due to exposure to the COVID-19 injectable products via breast milk.

2.2.4. Other routes of exposure

While dosage would likely be minimal, it is possible that others be exposed to vaccine particles via other routes. Shedding is observed in adenovirus vectored vaccines[288], which would apply to Johnson & Johnson and the AstraZeneca vaccines[289]. One important distinction is that while viral shedding can be ruled out with mRNA vaccines, because they only contain the mRNA encoding the spike protein, exposure to the vaccine particles themselves can occur, albeit in very miniscule quantities.

In households where one person was vaccinated, other family members developed spike protein antibodies[290]. 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 unvaccinated 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[291]. Inactivated viral vector Covid-19 vaccines have been observed to decrease sperm morphology[292] and motility[293], and increase DNA fragmentation[292], though studies do not see this effect with mRNA vaccines[294,295].

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 3)[296].

Spike protein can importantly be packaged into exosomes[297], and precedent exists for the presence of RNA-containing exosomes in breath [298–300]. A recent review has summarized the persistence of vaccine components in different bodily fluids [301], finding evidence for persistence of spike protein in lymph nodes[40], on skin[302] and in blood[40,303], and persistent spike protein mRNA in lymph nodes[40] and in blood plasma[304].

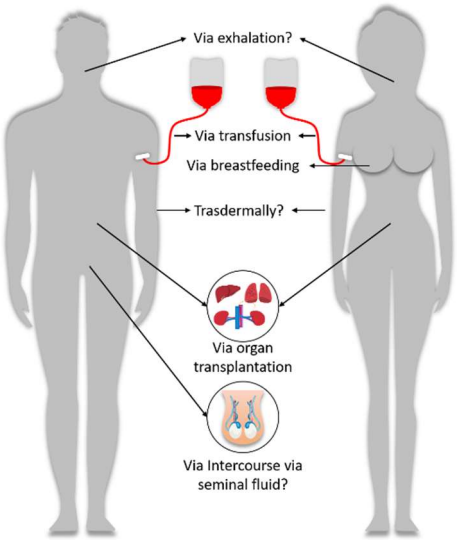

Figure 3. Possible routes of secondary exposure to vaccine artifacts.

2.3. 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,

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such as organ size. Current approaches are lowering the risk of transplant rejection by matching donor and recipient human leukocyte antigen (HLA)[305–307].

There are several case reports of transplants from vaccinated 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[308–313]. Several centers have refused to provide transplants to unvaccinated prospective recipients.

Our search returns 8 articles focusing on transplants from donors deemed deceased from VITT[314–320] (Table 2).

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

Study	Donor	Organ	Recipient	Outcome	Thrombotic AE rate [AE rate including microthrombi, organ/graft rejection and Positive anti-PF4]
[314]	50 year female with VITT	Heart	Unknown	No thrombosis or thrombocytopenia Anti-PF4 antibodies negative 3 weeks after transplantation	0/1 [0/1]
[321]	18 year old brain-dead female who dies from VITT-related	Liver	58 year old female	Rapid drop in platelet count from $104x10^9$/liter to $30x10^9$/liter	1/1 [1/1]

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	intracranial hemorrhage			Anti-PF4 IgG strongly positive Grade 3 (severe) thrombocytopenia	
315	(*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]
316	N=16 Median age 44	Kidney	N=30 Median age 48	2 recipients with anti-PF4 antibodies	3/30 [5/30]

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	75% female	Microthrombi observed in 4/11 biopsies	47% female	but no clinical disease Major hemorrhagic complications in 3 recipients w/ independent risk factors	
318	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]
319	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	2/17 [4/17]

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				thrombosis-related complications	
[320]	32-year-old female deceased from VITT-induced stroke	Liver	69-year-old female	No adverse events, operation successful	0/1 [0/1]
[317]	N=13 Median age 34 (21 to 63) 85% female	Kidney Liver Heart Lung Pancreas	N=26 Median age 40 (2 to 63)	Thrombsis 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]
[322]	Female aged 60-69	Liver & Heart Lungs Right Kidney	63-year-old male 58-year-old woman	No AEs No AEs Thrombi is pre-implantation biopsy,	0/4 [2/4]

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		Left Kidney	70-year-old man 52-year-old man	uneventful transplantation Glomerular inflammation and hemorrhagic suffusion	
Summary					16/98, 16% [29/98, 30%]

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[323], 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%[324]. 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% [324]. 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[325]. The uncertainty is because there are 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 recipients of liver transplants from DCD cases showed a rejection rate due to thrombotic complications of 2%, comparable with 3% of recipients of DBD[326]. Another Swedish study reported rates of hepatic artery thrombosis in 8 of 24 liver graft recipients from DCD donors, or 33%[327]. A large meta-analysis found vascular thrombosis of 3% in DCD liver graft recipients, and 2% in DBD liver graft recipients[328]. The same meta-analysis observed rates of vascular stenosis of 4% in DCD and 2% in DBD liver graft recipients.

These operations have mixed success, as many of these transplantations are successful, still, there remain several cases where the recipient experienced thrombotic events which persisted over long term. Still, 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 [329,330]. Other systems have not yet published hemovigilance for 2021[331], though Austria reported a 49% increase in transfusion reactions (49 in 2020 to 73 in 2021) from 2020 to 2021[332], Denmark saw a significant increase in adverse reactions between 2020 and 2021[333] and UK hemovigilance data shows an increase in blood component issues from 2020 to 2021[334]. Additionally transplantation adverse event rates in Canada rose significantly, from less than 3 transfusion adverse events per year to 12 between 2020 and 2021[335]. In Japan there was a slight increase of 7% from 2020 to 2021[336]

3. Discussion

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In total, we did not find evidence to support the safety of COVID-19 vaccine recipients to donate blood.. Questions remain over the safety of associated blood products and secondary exposure to vaccine particles. Circulatory AEs associated with C19 vaccination far outstrip any previous vaccine, 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.

One open question is if the waiting period to donate blood post vaccination is sufficient to ensure the safety for the recipient. Most countries have limited or nonexistent waiting periods for donations post vaccination, though some ask their donors to refrain from donating blood for a few weeks after vaccination. Given that vaccine particles are in principle non-replicating, we expect them to decay once in the body, where their concentration gradually drops. The time curve of vaccine particle decay still requires more investigation, as studies observe both circulating spike protein at least two months after vaccination[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 adverse events from vaccinated donors should be addressed in a passive monitoring study whereby donors voluntarily provide their Covid-19 vaccination study on an intake form. Comparisons of vaccinated and unvaccinated blood should be made at two levels, both the properties of the blood itself as well as its interaction with its recipient. Summary statistics on both types of measurements can be calculated to determine if there exist any statistically significant differences between blood products from vaccinated and unvaccinated donors. Reporting of donor's vaccination 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 vaccinated 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 vaccination 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 vaccine particles via injection, but also of secondary exposure through bodily fluids. Several lines of evidence, including mechanistic understanding, pharmacovigilance, case reports of blood manifestations in vaccine recipients and case reports of autopsies from vaccinated donors suggest that it may be a possibility. Persistence of vaccine contents and/or their expression products has been observed in blood[40,41] and breast milk[279]. Additionally, there are adverse event reports which support bodily fluids exposure (via blood transfusion or breastfeeding) as an aetiological factor.

Further support is given 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 vaccine related. The rate of thrombotic complications for the case of vaccinated 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[324]. 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 [324,326,328]. One study's reported rates[327] (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 vaccinated donors.

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Abbreviations

AE: adverse events
CDC: Centers for Disease Control (USA)
HLA: human leukocyte antigen
IFR: Infection Fatality Rate
VAERS: Vaccine adverse event reporting system
VITT: vaccine-induced thrombosis and thrombocytopenia
WHO: World Health Organization

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