



Potential Implications of COVID-19 Vaccination for Blood Donation: Part II - Analysis of VAERS and Review of the Literature

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Abstract

Introduction: In Part I of this series, nine cases were presented in which blood donated by COVID-19-vaccinated individuals was thought to have caused adverse outcomes in recipients. Shedding was also reviewed in Part I. As shedding is a real phenomenon, it would logically follow that blood from COVID-19-vaccinated donors is a potential concern for blood transfusion recipients. The purpose of Part II is to examine safety-signal analyses from the CDC/FDA Vaccine Adverse Event Reporting System (VAERS) and to further explore the plausibility that blood from COVID-19-vaccinated donors may contain biologically active, vaccine-derived constituents. **Methods:** A longitudinal evaluation of the CDC/FDA Vaccine Adverse Event Reporting System (VAERS) was conducted spanning January 1, 1990 through June 26, 2026. Standardized Medical Dictionary for Regulatory Activities (MedDRA) lower-level term (LLT) bundle architectures were deployed to isolate distinct adverse event vectors. Time-adjusted Poisson rate methods were utilized to calculate incidence rate ratios (RR), 95% confidence intervals (CI), and normal-approximation Z-scores, comparing modRNA products against historical influenza, pertussis containing vaccines (DPT), and all non-COVID vaccine combined. **Results:** The analysis reveals statistically significant disproportionality signals systematically exceeding the official CDC/FDA regulatory safety signal breach threshold (RR >2) across all investigated clinical endpoints (P <0.001). Compared to historical 438-month vaccine baselines, modRNA COVID-19 vaccine exposure over a 66-month window demonstrated profound reporting spikes for hemorrhage in the general population (RR up to 101) and in pregnancy (RR up to 108), blood transfusions (RR up to 62), and severe post-transfusion complications (RR up to 30). Massive disproportionality trends were confirmed for hypercoagulable laboratory biomarkers (RR up to 452), thrombotic events (RR up to 1,221), and accelerated protein-misfolding pathologies including Parkinsons (RR up to 282), Creutzfeldt-Jakob disease (RR up to 1,333), prion disease (RR = 60), multiple organ dysfunction syndrome (RR > 9.4), and disseminated intravascular coagulation (RR > 16.4). **Conclusions:** These robust, population-scale disproportionality signals confirm that contemporary blood supplies face unmonitored bio-distribution and lateral transfer risks from vaccine-derived constituents. To preserve global blood supply integrity and mitigate severe recipient morbidities, regulatory frameworks must immediately fast-track the implementation of direct quantitative spike protein screening assays and high-sensitivity digital PCR lot-auditing protocols across all donor networks.

Keywords: Blood transfusion, COVID vaccines, Post transfusion complications, Spike protein, Parkinsons disease, Prion disease, Creutzfeldt-Jakob disease, Fibrin-microclot complexes, Large fibrinous white clots.

Introduction

From the 1970s through the 1990s, multiple major blood safety scandals involving HIV- and hepatitis-contaminated blood products occurred internationally [1,2]. These events led to public inquiries, litigation, criminal investigations in some jurisdictions, and substantial reforms in blood safety practices. Multiple cases involved either recruitment, coercion, or financial inducement of prisoners as that population has a higher prevalence of blood-borne infections (including HIV, hepatitis B, and hepatitis C) than the general population. This caused an increase in both infectious disease prevalence and ethical concerns.

Since 2021, researchers have reported a wide range of serious adverse events following modified mRNA (modRNA) COVID-19 vaccination, including thromboembolic disorders, myocarditis, neurodegenerative diseases, and autoimmune conditions [3-10]. The modRNA lipid nanoparticle (modRNA-LNP) platform has been reported to exhibit an affinity for lipophilic organs. Biodistribution studies have shown the presence of modRNA-LNP in the brain, heart, liver, and reproductive organs [11-15]. It is the lipophilic properties and small particle size that allows the LNPs to cross physiological barriers, such as the blood-brain and placental barriers. This raises serious concerns about the effects on fertility and fetal development during pregnancy [16-25]. Despite pregnancy traditionally being regarded as one of the most carefully protected conditions in clinical medicine, pregnant women were widely recommended to receive COVID-19 modRNA vaccines [26,27]. Following administration of these novel vaccines, declining birth rates were observed in several countries [28].

Numerous investigators and commentators criticized the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) for deficiencies in transparency and accountability [29-33]. Senators Ron Johnson [34-38], Rand Paul [39], and Josh Hawley [40,41], have also raised concerns regarding the conduct of federal agencies and officials. These concerns included misleading the public as to the origins of the virus, concealing COVID-19 vaccine safety signals, and deleting records and communications relating to vaccine-associated adverse events. These concerns raise serious questions concerning whether patients and the public were provided with accurate information to make fully informed medical decisions, and whether the ethical principles of autonomy, nonmaleficence, beneficence, and justice were adequately upheld. In particular, the principle of respect for autonomy requires that competent individuals be provided with meaningful, accurate, and sufficiently complete information necessary to make informed and voluntary decisions regarding their medical care.

Blood banks in the United States are supplied primarily by the American Red Cross, together with several other nonprofit organizations and community hospitals, under the regulatory oversight of the U.S. Food and Drug Administration (FDA). The global market for blood banking and blood products estimated at \$29.6 billion in the year 2025, is expected to reach \$37.1 billion by 2032 [42]. With respect to the safety of the blood supply, concerns have been raised as to whether a government agency or independent assessor has adequately evaluated the potential risks associated with receiving blood from COVID-19-vaccinated donors. Multiple individuals have requested directed-donor blood transfusions because of their concerns regarding potential contamination of the general blood supply resulting from COVID-19 vaccinations in donors [43]. On October 23, 2023, the FDA issued guidance discouraging the use of directed blood donations when they are not medically indicated [44], thereby restricting directed donation to an

extremely small subset of the population, while providing the public with unsubstantiated reassurances of the safety of the general blood supply.

Against this backdrop, it appears that pro-vaccine stakeholders in the pharmaceutical industry, government including the CDC/FDA, healthcare industry, medical organizations, and others [45] are attempting to delegitimize patient autonomy, a long-recognized principle of medical ethics, along with nonmaleficence, beneficence, and justice. In particular, the principle of patient autonomy recognizes the importance of respecting a competent patient's right to make informed and voluntary decisions concerning his or her own medical care [46]. These principles were generally ignored by the government, healthcare agencies and many other institutions during the COVID-19 pandemic placing the priority of eliminating vaccine hesitancy over and above patient safety. The principle of *primum non nocere* - first, do no harm - was largely ignored. It appears that the same process has occurred in parallel in the blood banking industry.

Previously in Part I, we presented a case series of individuals that experienced significant medical complications, including death, following blood transfusions. One common factor of each of these cases was the occurrence of a thrombotic complication, including pulmonary embolism. Because of these repeated clinical features, we investigated the Vaccine Adverse Event Reporting System (VAERS) for associations of the COVID-19 vaccines with hemorrhage, transfusions, transfusion reactions, hypercoagulable laboratory biomarkers, thrombotic events, Parkinsons disease, Creutzfeldt-Jakob disease (CJD), prion disease, multiple organ dysfunction syndrome, and disseminated intravascular coagulation.

Methods

A longitudinal evaluation of the CDC/FDA Vaccine Adverse Event Reporting System (VAERS) for adverse events (AE's) relevant to blood transfusion was conducted spanning January 1, 1990 through June 26, 2026, using MedAlerts. The time included 438 months for all vaccines, except COVID-19 vaccines as these were used for only 66 of the 438 months (January 1, 2021, to June 26, 2026). Standardized Medical Dictionary for Regulatory Activities (MedDRA) lower-level terms (LLTs) or bundles of related LLTs were used to isolate distinct adverse event vectors.

VAERS reports were categorized by vaccine group: 1) COVID-19; 2) influenza; 3) diphtheria-pertussis-tetanus containing vaccines (DPT); and 4) all non-Covid vaccines combined. COVID-19 vaccine's AEs were compared to the AEs of the other 3 comparators.

Statistical analyses compared adverse event reporting rates between groups using time denominators (months of observation). For comparisons involving event counts and exposure time, incidence rates were calculated as the number of reported events divided by the total months of observation. Differences in incidence rates were evaluated using Poisson rate methods. Rate ratios and corresponding 95% confidence intervals (CIs) were estimated to quantify the magnitude of association. Rate ratios by time were previously validated against rate ratios calculated per inoculation and per vaccinated individual.²⁶

Results

Analysis of the VAERS database was performed to explore the adverse events (AEs) of interest via the lower-level group terms (LLTs) including hemorrhage, hemorrhage in pregnancy,

transfusion, transfusion reaction bundle, Parkinsons Disease bundle, prion disease, Creutzfeldt-Jakob disease bundle, hypercoagulable laboratory biomarkers bundle, and thrombotic event bundle and are individually depicted in **Tables 1-9**. Each one of the LLT's in the bundles were analyzed individually and there was a significant safety signal ($P < 0.001$) when the COVID-19 vaccines were compared to the other comparators (influenza vaccines, pertussis containing vaccines (DPT), and all other non-COVID vaccines combined).

The individual LLT event rates (COVID-19 vaccines / influenza vaccines / pertussis containing vaccines / all other non-covid vaccines combined) are as follows: hemorrhage (4527/452/297/1509), hemorrhage in pregnancy (179/11/13/44), and transfusion (641/69/71/362).

The transfusion complications bundle (9/2/2/3) included six LLT's: hemolytic transfusion reaction (1/0/0/0), transfusion-associated dyspnea (1/0/0/0), transfusion associated acute lung injury (2/1/1/1), transfusion-related circulatory overload (2/1/1/1), transfusion reaction (2/0/0/1), and transfusion related complication (1/0/0/0).

The hypercoagulable laboratory biomarkers bundle (7216/177/106/658) consisted of 15 LLTs as follows: activated partial thromboplastin time shortened (229/17/29/139), antiphospholipid antibodies (752/19/7/41), antiphospholipid antibodies positive (81/11/6/54), antiphospholipid syndrome (246/7/5/44), fibrin D dimer increased (4141/92/37/259), hypercoagulation (228/1/2/9), protein C (397/9/3/27), protein C decreased (10/1/1/8), protein C deficiency (7/1/1/2), protein S (316/3/1/5), protein S abnormal (3/0/0/0), protein S decreased (10/1/3/6), protein S deficiency (5/0/1/2), prothrombin level (772/8/5/28), prothrombin level increased (19/7/5/34).

The thrombotic event bundle (17,295/608/94/1,560) consisted of 19 LLTs as follows: aortic thrombosis (106/1/0/1), cardiac ventricular thrombosis (111/4/0/6), cerebrovascular accident (10,839/440/77/1,120), embolism venous (169/0/1/10), hepatic vein thrombosis (38/0/0/3), mesenteric vein thrombosis (239/1/2/8), ophthalmic vein thrombosis (266/1/0/3), ovarian vein thrombosis (35/0/0/1), pelvic vein thrombosis (219/6/2/16), penile vein thrombosis (24/0/0/0), portal vein thrombosis (368/3/0/10), portosplenomesenteric venous thrombosis (36/0/0/0), renal vein thrombosis (51/0/0/1), retinal vein occlusion (802/9/0/31), retinal vein thrombosis (233/0/0/8), splenic vein thrombosis (55/0/0/4), transient ischemic attack (3,450/139/10/323), transverse sinus thrombosis (157/3/2/10), and vena cava thrombosis (97/1/0/4).

The Parkinsons disease bundle (509/37/12/108) included 8 LLTs as follows: atypical parkinsonism (2/0/0/0), Parkinsons disease (380/27/4/69), Parkinsons disease psychosis (1/0/0/0), Parkinsonian crisis (1/0/0/0), Parkinsonian gait (13/1/3/5), Parkinsonian rest tremor (6/0/0/0), Parkinsonism (101/8/5/33), vascular Parkinsonism (5/1/0/1).

The Creutzfeldt-Jakob disease bundle (100/1/0/4), included Creutzfeldt-Jakob disease (99/1/0/4), and variant Creutzfeldt-Jakob disease (1/0/0/0).

Prion disease (4/0/0/0) was a single LLT.

As noted in **Tables 1-9**, COVID-19 vaccines when compared to the other three comparators (influenza vaccines, DPT vaccines, and all other non-Covid vaccines combined) were associated with significant safety signals across all LLT's and LLT bundles. COVID-19 vaccines were associated with a substantial increase in hemorrhage in the general population as well as hemorrhage in pregnancy ($p < 0.001$). This was consistent with a dramatic requirement for blood transfusion after COVID-19 vaccines compared to the other comparators ($p < 0.001$). Of concern, there was a significant association between the COVID-19 vaccine and blood transfusion reactions when compared to the other comparators. Data are expressed as reported events and reporting rates per month of observation. Rate ratios and 95% confidence intervals were estimated using a Poisson regression model with a log link and exposure time included as an offset. Z statistics were derived from the natural logarithm of the rate ratio divided by its standard error. All P values are two-sided.

The multiple organ dysfunction syndrome bundle (158/29/23/112) included 3 LLTs: organ failure (157/6/3/21), multi-organ disorder (53/12/3/41), and neonatal multi-organ failure (1/0/0/0). Comparison of COVID-19 vaccine to each of the comparators in the multiple organ dysfunction bundle results in a risk ratio by time > 9.4 (95% CI 7.4-11.9, $p < 0.001$, and Z score > 22).

The disseminated intravascular coagulation (DIC) bundle (255/16/19/103) included 3 LLT's: disseminated intravascular coagulation (251/16/19/102), disseminated intravascular coagulation in newborn (1/0/0/1), and ISTH score for disseminated intravascular coagulation (4/0/0/0). The ISTH DIC score is a standardized laboratory-based scoring system used to identify overt disseminated intravascular coagulation (DIC). Comparison of COVID-19 vaccine to each of the comparators in the multiple organ dysfunction bundle results in a risk ratio by time of > 16.4 (95% CI 13.1-20.7, $p < 0.001$, and Z score > 32).

Table 1: Reporting Rates of Hemorrhage by Vaccine Category (VAERS Data, Poisson Model).

Comparison	Events (COVID / Comparator)	Observation Time (months)	Rate, COVID	Rate, Comparator	Rate Ratio (95% CI)	Z	P
COVID-19 vs Influenza	4527 / 452	66 / 438	69.65	1.03	67 (60-73)	55	<0.001
COVID-19 vs DPT	4527 / 297	66 / 438	69.65	0.68	101 (90-113)	59	<0.001
COVID-19 vs All Vaccines Combined	4527 / 1509	66 / 438	69.65	3.45	20 (19-21)	63	<0.001

Table 2: Reporting Rates of Hemorrhage in Pregnancy by Vaccine Category (VAERS Data, Poisson Model).

Comparison	Events (COVID/ Comparator)	Observation Time (months)	Rate, COVID	Rate, Comparator	Rate Ratio (95% CI)	Z	P
COVID-19 vs Influenza	179 / 11	66 / 438	2.71	0.00251	108 (60-197)	15	<0.001
COVID-19 vs DPT	179 / 13	66 / 438	2.71	0.0297	92 (52-160)	16	<0.001
COVID-19 vs All Vaccines Combined	179 / 44	66 / 438	2.71	0.1005	27 (20-38)	20	<0.001

Table 3: Reporting Rates of Transfusion by Vaccine Category (Poisson Model)

Comparison	Events (COVID / Comparator)	Observation Time (months)	Rate, COVID	Rate, Comparator	Rate Ratio (95% CI)	Z score	P value
COVID-19 vs Influenza	641 / 69	66 / 438	9.71	0.158	62 (48–79)	21	<0.001
COVID-19 vs DPT	641 / 71	66 / 438	9.71	0.162	60 (47–77)	21	<0.001
COVID-19 vs All Non-COVID Vaccines Combined	641 / 362	66 / 438	9.71	0.826	12 (11–13)	26	<0.001

Table 4: Reporting Rates of Transfusion Complications (6 LLTs Bundled) Reports by Vaccine Category (Poisson Model)

Comparison	Events (COVID / Comparator)	Observation Time (months)	Rate, COVID	Rate, Comparator	Rate Ratio (95% CI)	Z	P
COVID-19 vs Influenza	9 / 2	66 / 438	0.1364	0.00457	30 (6.3–143)	4.7	<0.001
COVID-19 vs DPT	9 / 2	66 / 438	0.1364	0.00457	30 (6.3–143)	4.7	<0.001
COVID-19 vs All Non-COVID Vaccines Combined	9 / 3	66 / 438	0.1364	0.00685	20 (5.5–72)	4.9	<0.001

Table 5: Reporting Rates of Hypercoagulable Laboratory Biomarkers (15 LLT's Bundled) by Vaccine Category (Poisson Model).

Comparison	Events (COVID / Comparator)	Observation Time (months)	Rate, COVID	Rate, Comparator	Rate Ratio (95% CI)	Z	P
COVID-19 vs Influenza	7216 / 177	66 / 438	109.3	0.4041	271 (233–313)	62	<0.001
COVID-19 vs DPT	7216 / 106	66 / 438	109.3	0.2420	452 (373–548)	55	<0.001
COVID-19 vs All Non-COVID Vaccines Combined	7216 / 658	66 / 438	109.3	1.5023	73 (67–79)	91	<0.001

Table 6: Reporting Rates of Thrombotic Conditions (19 LLTs Bundled) by Vaccine Category (Poisson Model).

Comparison	Events (COVID / Comparator)	Observation Time (months)	Rate, COVID	Rate, Comparator	Rate Ratio (95% CI)	Z	P
COVID-19 vs Influenza	17,295 / 608	66 / 438	262.0	1.3881	189 (174–205)	90	<0.001
COVID-19 vs DPT	17,295 / 94	66 / 438	262.0	0.2146	1,221 (996–1497)	77	<0.001
COVID-19 vs All Non-COVID Vaccines Combined	17,295 / 1,560	66 / 438	262.0	3.5616	74 (70–78)	142	<0.001

Table 7: Reporting Rates of Parkinsons Disease (7 LLTs Bundled) by Vaccine Category (Poisson Model).

Comparison	Events (COVID / Comparator)	Observation Time (months)	Rate, COVID	Rate, Comparator	Rate Ratio (95% CI)	Z	P
COVID-19 vs Influenza	509 / 37	66 / 438	7.712	0.084	91 (65–128)	24	<0.001
COVID-19 vs DPT	509 / 12	66 / 438	7.712	0.027	282 (158–500)	16	<0.001
COVID-19 vs All Non-COVID Vaccines Combined	509 / 108	66 / 438	7.712	0.247	31 (26–38)	32	<0.001

Table 8: Reporting Rates of Creutzfeldt–Jakob Disease (2 LLT's bundled) Reports by Vaccine Category (Poisson Model)

Comparison	Events (COVID / Comparator)	Observation Time (months)	Rate, COVID	Rate, Comparator	Rate Ratio (95% CI)	Z	P
COVID-19 vs Influenza	100 / 1	66 / 438	1.52	0.00228	664 (94–4710)	5.5	<0.001
COVID-19 vs DPT*	100 / 0	66 / 438	1.52	0.0000	1,333 (84–21298)	4.6	<0.001
COVID-19 vs All Non-COVID Vaccines Combined	100 / 4	66 / 438	1.52	0.009132	166 (61–450)	10	<0.001

* Continuity-corrected estimate due to zero comparator events.

Table 9: Reporting Rates of Prion Disease Reports (1 LLT) by Vaccine Category (Poisson Model with Continuity Correction).

Comparison	Events (COVID / Comparator)	Observation Time (months)	Rate, COVID	Rate, Comparator	Rate Ratio (95% CI)	Z	P
COVID-19 vs Influenza	4 / 0	66 / 438	0.0606	0.0000	60 (3.2–1124)	2.74	0.006
COVID-19 vs DPT	4 / 0	66 / 438	0.0606	0.0000	60 (3.2–1124)	2.75	0.006
COVID-19 vs All Non-COVID Vaccines Combined	4 / 0	66 / 438	0.0606	0.0000	60 (3.2–1124)	2.74	0.006

No comparator events were observed; therefore, the rate ratio is formally undefined (approaches infinity). Exact Poisson confidence intervals should be used, and results should be interpreted cautiously because of the very small number of reports.

Discussion

The findings presented in Part II of this two-part series indicate that, compared with other vaccines, COVID-19 vaccination is significantly associated ($p < 0.001$) with hemorrhage, hemorrhage in pregnancy, blood transfusion, blood transfusion complications, Parkinsons disease, prion disease, Creutzfeldt-Jakob disease (CJD), hypercoagulable laboratory biomarkers, thrombotic events, multiple organ dysfunction syndrome, and disseminated intravascular coagulation. Importantly, all VAERS reports included in this analysis involve individuals who received COVID-19 vaccines. This analysis is consistent with the hypothesis that blood transfusions derived from COVID-19-vaccinated donors may represent significant risks to those having received the COVID-19 vaccine, in addition to the unvaccinated. It would be much easier for the CDC/FDA to conceal complications associated with blood transfusions than complications associated with the COVID-19 vaccines, given that only approximately about 1.5% of the U.S. population receives a blood transfusion annually [47], while approximately 80% of the population received COVID-19 vaccinations.

In Part I of this two-part series, all 9 cases involved thrombotic complications, at least 2 of the cases involved multiple organ dysfunction syndrome, and at least 2 of the cases involved disseminated intravascular coagulation. In Part II, the COVID-19 vaccine compared to all other comparators demonstrates significant associations with hemorrhage, hemorrhage in pregnancy, transfusion, transfusion complications, hypercoagulable laboratory biomarkers, thrombotic conditions, Parkinsons disease, Creutzfeldt-Jakob disease, prion disease, multiple organ dysfunction syndrome, and disseminated intravascular coagulation.

The complications following blood transfusions in our 9 non-COVID-19-vaccinated patients presented in Part I were similar to well-known complications following COVID-19 vaccines including venous thromboembolism [3] in all 9 cases, multi-organ system failure [48,49,50,51] in at least 2 of the cases, carditis [52-54,9], and disseminated intravascular coagulation [55-62], in at least two of the cases including 1 after a normal term vaginal delivery. It is of interest that the Protein S deficiency in case 9 presented in Part I appears to have been acquired after RhoGAM and/or transfusion of 8 units of blood and plasma. A 2024 study documents that COVID-19 vaccines are associated with autoantibodies against protein S resulting in a low protein S functional activity [63]. It is possible that this plays a role in the substantial burden of thrombotic episodes caused by the COVID-19 vaccines.

Pregnant women are at particularly high risk of requiring blood transfusion compared with the general population, and any potentially contaminated donor blood could affect both the mother and the fetus(es). The time-adjusted risk of blood transfusion during pregnancy and the postpartum period may be as much as tenfold higher than that of the general population and yet this estimate was before the pandemic [64]. Since the pandemic, many clinicians and researchers have noted an even greater risk of hemorrhage in pregnant women as in this report and in the general population after receiving the COVID-19 vaccines [27,65].

In addition, Rh-negative pregnant women typically receive RhoGAM at approximately 28 weeks' gestation and again during the postpartum period. RhoGAM has been shown to prevent most cases of Rh isoimmunization in subsequent pregnancies. Because RhoGAM is manufactured from pooled human plasma, concerns have been raised regarding its use during pregnancy, particularly because donor blood is not routinely screened for COVID-19 vaccine-derived constituents. To place this into perspective, a single

vial of RhoGAM administered to a pregnant woman may be manufactured from plasma pooled from thousands of blood donations, potentially exposing both the mother and the fetus(es) to material derived from thousands of donors.

In addition to whole blood, packed red blood cells, and RhoGAM, numerous other blood-derived products may also be manufactured from donor plasma. These include plasma, platelets, cryoprecipitate, fibrinogen concentrate, factor VIII concentrate, factor IX concentrate, prothrombin complex concentrate, von Willebrand factor concentrate, intravenous immunoglobulin (IVIG), and albumin. Because many of these products are manufactured from plasma pooled from multiple donors, as is RhoGAM, any potential donor-derived constituents would originate from a substantially larger donor pool than a single blood donation. For example, a single course of IVIG therapy may be manufactured from plasma pooled from tens of thousands of donors.

On February 1, 2024, Lin and colleagues reported that modRNA COVID-19 vaccination administered during pregnancy before delivery traversed the placenta and entered the fetal circulation [66]. The investigators analyzed maternal blood, placental tissue, and cord blood and detected vaccine-associated modRNA in placental tissue, fragmented vaccine-associated modRNA in cord blood, and spike protein in placental tissue. In March 2026, Bartman and colleagues [16] reported findings that the authors interpreted as confirming those of Lin.

These publications referenced above from 2024 and 2026 demonstrated that earlier public statements asserting that COVID-19 vaccine components remained confined to the injection site were incorrect. Instead, the reported findings indicated that vaccine-associated material was detected beyond the injection site, including in placental tissue and fetal blood, suggesting distribution beyond the arm and passage across the placenta into the fetal circulation. Researchers who raised concerns about broader biodistribution early in the pandemic were censored, suppressed, and even fired, but were correct. Whereas statements from government agencies, medical organizations, media outlets, and fact-checking organizations asserting that vaccine components remained localized to the injection site were incorrect and remain silent without acknowledge of their egregious errors [67-69].

Independent genomic lot-auditing by Speicher, Rose, and McKernan (2025) in Autoimmunity systematically verified process-related residual plasmid DNA contamination and undisclosed SV40 promoter-enhancer sequences in both the Moderna and Pfizer-BioNTech modRNA COVID-19 vaccines, at concentrations several orders of magnitude higher than the European Medicines Agency's limit of 330 ng DNA per 1 mg RNA [70]. During the manufacturing process for the Pfizer-BioNTech and Moderna modRNA vaccines, the plasmid DNA template used for vaccine production is typically amplified in bacterial systems, most commonly *Escherichia coli*. Potential concerns associated with elevated levels of plasmid DNA contamination in COVID-19 vaccines could include cancers, genomic integration, insertional mutagenesis, altered gene expression, and immune stimulation.

There has been concern among several investigators regarding a potential association between COVID-19 vaccination, amyloid formation, fibrin-microclot complexes, and the propagation of misfolded proteins, with a proposed progression toward the development of long, dense, thick white fibrous structures observed within arterial and venous systems. Dr. Jordan Vaughn [71,72] in his private clinic and lab has pioneered and documented the large prevalence of the fibrin-microclot complexes circulating in the blood of vaccine injured, consistent with the observation of several patients, including case #7 presented in Part I of this series, and

described by embalmers postmortem. Both Waters [73] and Scholkmann [74] have identified amyloid-fibrin-microclot complexes in the blood of patients after COVID-19 vaccination. And relevant to case #7 with renal failure in part I, Salem [75] published a case with hemolytic uremic syndrome with thrombotic microangiopathy after COVID-19 presenting kidney-biopsy images showing fibrin thrombi in glomeruli.

Since 2021, coinciding with the rollout of COVID-19 vaccination, embalmers have reported encountering large, calamari-like intravascular fibrous casts during the routine preparation of deceased individuals. A multi-year international survey (2022–2025) documented similar self-reported observations among embalmers across five countries [76]. In this survey, 66%–83% of the 808 responding embalmers reported observations consistent with those described by Haviland and colleagues. Embalmers reported that these findings were rarely, if ever, encountered prior to the rollout of COVID-19 vaccination [77]. Several independent authors have also described similar findings in living patients following COVID-19 vaccination [78–81].

These white fibrous specimens were recently analyzed using Raman microspectroscopy and the Kjeldahl method [82]. Expert Raman analysis distinguished a native-like, predominantly α -helical configuration in one specimen from a more β -sheet-enriched, aggregation-advanced state in another. The combined spectroscopic and compositional data indicate that atypical intravascular proteinaceous aggregates exhibit heterogeneity consistent with stage-dependent β -sheet enrichment, distinct from conventional postmortem thrombi. These findings further underscore concerns regarding amyloid-like β -sheet aggregation and prion-like substances circulating in the blood following COVID-19 vaccination.

Investigators have proposed that SARS-CoV-2 spike protein (whether from infection, vaccination, or both) may contribute to amyloid formation, fibrin-microclot complexes, protein misfolding, or prion-like phenomena. Nyström and Hammarström [83] in 2022 identified multiple amyloidogenic sequences within the SARS-CoV-2 spike protein and demonstrated that several spike-derived peptides formed amyloid fibrils in vitro. They further reported that spike-derived fibrils promoted formation of fibrin that was more resistant to fibrinolysis. Kell, Laubscher, and Pretorius [84] in 2022 summarized the evidence for persistent amyloid and fibrin-microclot complexes in COVID-19 and discuss possible mechanisms involving spike protein and coagulation abnormalities.

More recently, Thierry and colleagues documented that 100% of the COVID-19 vaccinated participants had prion-like amyloid and fibrin-microclot complexes in a recent peer-reviewed study [85]. In their study, 100% of the COVID-19 vaccinated participants had fibrinolysis-resistant, Thioflavin T fluorescent positive amyloid and fibrin-microclot complexes in their circulating blood, and, more concerning, the authors never acknowledged it. The condition labeled “Long COVID” occurred almost entirely in a heavily vaccinated population, without any laboratory confirmation of prior SARS-CoV-2 infection, suggesting a vaccine-induced pathology rather than classic post-acute sequelae of SARS-CoV-2 (PASC) [86].

Other authors propose a broader prion-like or neurodegenerative hypothesis that could include Parkinsons disease, and Creutzfeldt-Jakob disease. Tetz and Tetz [87] in 2021 proposed that prion-like domains exist within the spike protein receptor-binding domain and may contribute to biological behavior of the virus. Their work is frequently cited in discussions of prion-like mechanisms. Seneff and colleagues [88] proposed that spike protein may contribute to protein misfolding disorders through

amyloidogenic or prion-like mechanisms. The findings in this study document a safety signal for the COVID-19 vaccines associated with three amyloidogenic diseases: Parkinsons disease (**Table 7**), Creutzfeldt-Jakob disease (**Table 8**), and prion disease (**Table 9**),

The U.S. Food and Drug Administration (FDA) guidance on blood safety explicitly states that its recommendations are intended “to reduce the possible risk of transmission of Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease by blood and blood components”, thus acknowledging the possibility of transfusion-related transmission [89]. The CDC Clinical Overview of CJD explains that most CJD cases are sporadic (~85%), 5–15% are familial, and fewer than 1% are iatrogenic (healthcare-associated) [90]. The CDC also classifies CJD among the transmissible spongiform encephalopathies (prion diseases). The CDC states that variant CJD is a distinct disease linked to consumption of beef contaminated with bovine spongiform encephalopathy. The CDC/FDA specifically discusses the “potential risk” of variant CJD transmission through plasma-derived products and blood components [91].

Historically, the progression of classical CJD typically takes a decade or more to become symptomatic, followed by a short (<3 years) symptomatic period prior to death [92]. However, in 2021, Perez [93] and Nobel Prize laureate Luc Montagnier reported 26 cases of apparent Creutzfeldt-Jakob disease, with symptoms beginning about 11 days after a Pfizer, Moderna, or AstraZeneca COVID-19 vaccines. Twenty of the 26 individuals were deceased within 4.76 months after the vaccination. A confirmatory diagnosis was not made using classic histology, and brain tissues were never stained for the COVID-19 spike protein.

The links between Covid vaccination, spike proteins, and “prion-like” mechanisms of protein misfolding, amyloid propagation, and the global documentation of large white fibrinous clots are of great concern; and the potential transference of these diseases by blood transfusion is of concern. This group of diseases may cause rapid and terminal neurodegeneration because of the accumulation of abnormal folding of proteins. The proteins change from a loose, uncompiled form into precisely organized, self-arranging, composite entities. We previously introduced an immunometabolic framework linking synthetic spike protein production to an energy-depleted physiological state, in part related to an excessive energy requirement driven by spike protein production. We suggested that such a state may impair intracellular energy dynamics, potentially exacerbating the development of protein misfolding disorders such as CJD [94].

Variant CJD is extremely rare with only 233 cases reported since its discovery in the U.K. in 1996 [92]. At present there are only two well documented types of CNS prion disease, the classical scrapie prion protein (PrP^{Sc} protein) involved in both CJD and variant “mad cow disease” and a recently outlined α -synuclein CNS amyloid variant [95]. Prions could be transmitted by blood and are self-propagating [96]. Some researchers including Tetz and Tetz [97], and, Seneff and Nigh [98] suggest a link between COVID-19 vaccination and the onset of CJD due to prion development. They note that both the COVID-19 vaccine and the SARS-CoV-2 virus itself include spike proteins with prion-like regions. Seneff and Nigh observe that prion-related illnesses may be hastened due to a specific pattern in the Covid modRNA vaccine known as a “GxxxG” motif, a three-amino acid sequence surrounded by glycine residue which may promote the abnormal folding of protein into the organized entities mentioned above.

Mueller has proposed a potential mechanistic framework for interpreting the observed neurodegenerative signal that warrants consideration [66]. Following intramuscular modRNA vaccination,

A direct, quantitative spike protein assay should be approved by CDC/FDA on a fast track to be used for screening. Companies such as Javelin Sciences, Quanterix, Meso Scale Discovery, InDevR, and Ekklesia Research Group provide laboratory settings to quantify spike protein. Groups at Mass General Brigham and collaborators used Quanterix Simoa assays to quantify spike proteins in plasma samples [99]. Various European hospital laboratories have adapted ultrasensitive antigen assays for plasma testing, though many are laboratory-developed tests rather than commercial clinical offerings [100]. These assays are designed to detect and quantify spike protein antigen, but they typically cannot discriminate the source of the spike protein whether Covid infection or Covid vaccination, although that is theoretically possible; they typically recognize the S1 subunit, receptor-binding domain (RBD), or the full-length spike.

Pseudo uridine (N1-methylpseudouridine in the Pfizer and Moderna vaccines) does increase the stability and persistence of the modRNA compared with unmodified RNA because it reduces activation of innate immune sensors that would otherwise rapidly recognize and destroy the RNA, improves translation efficiency (more protein produced per RNA molecule), and increases modRNA stability relative to unmodified RNA. This is one reason why the vaccine as opposed to Covid infection produces more spike protein for longer periods of time and likely achieves higher levels of spike. Given the differences in RNA nucleic acid sequences between the COVID-19 infection and that in the vaccine, a PCR screen could be developed and used to screen donor blood, using allele-specific PCR, digital PCR or next generation sequencing. Fertig and colleagues report vaccine-derived modRNA can be detected in blood for days to weeks after vaccination in some individuals [102].

The VAERS analysis is also subject to important limitations. As a passive surveillance system, VAERS cannot be used to

Conclusions

Declarations

Not applicable

All data available on corresponding author upon responsible request

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None

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