

## Original Research Article

# COVID-19 mRNA vaccination: implications for the central nervous system

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## ABSTRACT

**Background:** Neuroinflammatory conditions involving the central nervous system (CNS) are on the rise and while the etiology is currently unknown the parallel rise in cases to mass COVID-19 vaccination is of particular interest. This study explores the association between the CNS infection rate and vaccination.

**Methods:** This is a retrospective study. Retrospective data were utilized from the U. S. centers for disease control and prevention (CDC) and the U.S. food and drug administration (FDA) vaccine adverse event reporting system (VAERS). Adverse events (AEs) encompassing CNS conditions following all vaccines were queried from January 1, 1990, through November 30, 2024. The timeframe for all vaccines except COVID-19 vaccines was 419 months and the timeframe for COVID-19 vaccines was 47 months (January 1, 2021, to November 30, 2024). Observed AEs are presented as odds ratios (ORs) by time which compare these events occurring after COVID-19 vaccination to those after influenza vaccination and to those after all other vaccines.

**Results:** Comparing COVID-19 vaccination to annual influenza vaccinations and all vaccines combined, the CDC/FDA's safety signal thresholds were breached for the multiple outcomes. Data are expressed as OR, 95% confidence interval (CI), p value, Z score. All CNS categories reviewed produced a safety signal when comparing events after COVID-19 vaccination to influenza vaccination (referent). Thirty-nine events were categorized as CNS infection (29.4, 21.6-40.1, <000.1, 21.4); 11 events grouped as herpetic CNS Infection (171, 93.9-312, <000.1, 16.8); and 4 categorized as CNS abscess (107, 40.9-280, <000.1, 9.53). Similarly, CNS Infections, herpetic CNS infection, and CNS abscess categories also produced a safety signal when comparing events after COVID-19 vaccination to all vaccines combined (referent) (except COVID-19): 39 events categorized as CNS Infections (4.11, 3.03-5.57, <000.1, 9.09); 11 events grouped as herpetic CNS Infection (22.3, 15.4-32.4, <000.1, 16.4) and; 4 events noted as CNS abscess (17.8, 10.5-30.4, <000.1, 10.6). When comparing COVID-19 vaccination to influenza vaccination as well as all vaccines combined, 7 of 9 events in the uncommon neurological disease grouping exceeded safety thresholds for both comparisons.

**Conclusions:** All safety signals reported are concerning and support an immediate global ban on the COVID-19 vaccination program.

**Keywords:** COVID-19 vaccines, Central nervous system disorder, Central nervous system infection, Central nervous system herpes infection, Central nervous system abscess, Prion disease, Demyelinating disease

## INTRODUCTION

The rushed global rollout of the COVID-19 mRNA vaccines in December 2020 was unprecedented. It was based on novel technology with inclusion of pseudo-uridylylated mRNA sequences carried throughout the body within a lipid nanoparticle carrier system. Despite mRNA being studied for decades, there were no preclinical reports of pharmacokinetics, pharmacodynamics, teratogenicity, oncogenicity, or genotoxicity. It is now known that synthetic mRNA coding for the spike protein without the ability to shut down protein synthesis leads to accumulation of spike protein causing nonfatal and fatal spike protein syndromes. The bio-pharmaceutical development programs for mRNA failed to recognize that the viral spike protein encoded by the “vaccine” was, by itself, a highly toxic molecule that could quickly cross the blood-brain barrier (BBB) and linger indefinitely.

Central nervous system (CNS) infections involve focal or widespread conditions of infectious and/or inflammatory conditions of the brain and/or spinal cord. They often begin as a common sinusitis, otitis, or oral cavity infection that crosses the BBB, subsequently altering the course of an otherwise self-limited infection. The homeostatic conditions maintained by the BBB are crucial to protect the CNS from vulnerabilities. Although the pathogenesis of BBB dysfunction is not well understood, it is believed that the spike protein itself is contributory to this process. Under otherwise normal circumstances it is posited that the inoculum of bacteria in the blood must reach a certain threshold for the BBB to be breached or that pathogens spread from a contiguous source such as the sinuses or inner ear. BBB disruption by spike protein and its related local vascular inflammation creates a susceptibility for patients to develop meningitis, encephalitis, and pericranial abscess formation.<sup>1</sup>

Historically, severe inflammatory pathologies involving the CNS are considered rare events that are most often associated with tissue infections involving a small understood group of viruses, bacteria, fungi and parasites. Less elucidated are the group of CNS inflammatory conditions based on an autoimmune etiology. Nevertheless, since 2021, there has been an explosive increase in the number of sporadic cases.<sup>2,3</sup> This has been accompanied by an increased incidence of even more rare CNS disorders such as Creutzfeldt-Jakob disease (CJD), progressive multifocal leukoencephalopathy (PML), and an assortment of atypical demyelinating conditions over this same time frame as witnessed and recorded in the Vaccine Adverse Event Reporting System (VAERS).<sup>4</sup> This database is co-managed by the U. S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). The VAERS database implies the vaccine has played a causal role in the development of the AE by proxy of reporting. Meaning, the reporting physician or health care provider is asked to report a health event when he or she has clinically determined it may be related to the vaccine administered.

Otherwise, if deemed unrelated, would not be entered into the system. CNS pathology infections can be severe and associated with significant morbidity and mortality with often devastating long-term consequences for the quality of life in those affected.<sup>5</sup>

The purpose of this study is to examine the relationship between COVID-19 mRNA vaccines and CNS infections, as compared to other vaccines, based on existing data from VAERS.

## METHODS

This retrospective study used the MedAlerts.org platform for VAERS data extraction.<sup>6</sup> This platform is co-owned and managed by the U. S. CDC and prevention and the FDA. The system utilizes MedDRA (Medical dictionary for regulatory activities) which is clinically validated international medical terminology used for regulatory and biopharmaceutical purposes. For this publication the data in VAERS from January 1, 1990, through November 30, 2024 involving relevant MedDRA “lowest level terms” (LLT’s) were analyzed. The MedDRA LLTs are formatted in British English, which leads to spelling variations in standard English search terms resulting in obfuscation and challenges to researchers. This should be taken into account to facilitate researchers' queries and ensure our results can be accurately duplicated. The following 63 “symptoms” were extracted from VAERS using the MedDRA LLT’s referred to hereafter as CNS AEs, and were divided into four clinically distinct and separate categories for the analytics: CNS infection, herpetic CNS infection, CNS abscess and uncommon neurological disease they are as follows.

### *CNS infection LLTs (n=39)*

Acute disseminated encephalomyelitis, acute hemorrhagic leukoencephalitis, autoimmune encephalopathy, Bickerstaff's encephalitis, CNS infection, CNS viral infection, cerebral fungal infection, cerebral septic infarct, cerebral toxoplasmosis, CNS ventriculitis, cranial nerve infection, CSF white blood cell count, encephalitis, encephalitis autoimmune, encephalitis brain stem, encephalitis meningococcal, encephalitis post immunisation, encephalitis viral, encephalomyelitis, limbic encephalitis, meningitis, meningitis aseptic, meningitis bacterial, meningitis pneumococcal, meningitis tuberculous, meningitis viral, meningoencephalitis bacterial, meningoencephalitis viral, meningococcal infection, meningoradiculitis, neuroborreliosis, neurological infection, neurosyphilis, noninfective encephalitis, pachymeningitis, PML, spinal cord infection, tick-borne viral encephalitis, and roxic encephalopathy.

### *CNS herpes infection LLTs (n=11)*

Herpes simplex encephalitis, herpes simplex meningitis, herpes simplex meningoencephalitis, herpes zoster infection neurological, herpes zoster meningitis, herpes

zoster meningoencephalitis, herpes zoster meningomyelitis, herpes zoster meningoradiculitis, meningitis herpes, meningoencephalitis herpetic, and varicella meningitis.

#### **CNS abscess LLTs (n=4)**

Brain abscess, extradural abscess, spinal cord abscess, and subdural abscess.

#### **Uncommon neurological disease LLTs (n=9)**

CJD, myelitis, myelitis transverse, noninfectious myelitis, poliomyelitis, post polio syndrome, prion disease, vaccine associated paralytic poliomyelitis, and viral myelitis.

Using the AEs above, the VAERS database was analyzed from January 1, 1990, through November 30, 2024, thus yielding 47 months of COVID-19 vaccine data and 419 months for all other vaccines. Statistical analysis performed in this study were based on Poisson distribution and Monte Carlo simulations used in a previous publication and included OR based on AEs per time, per dose number of a multiple vaccination schedule, and per individual vaccinated. Because the AE ORs per inoculation and per individual vaccinated were similar to those per time, these analytics were not repeated.<sup>7</sup>

The AEs from the COVID-19 vaccines were compared to those from the influenza vaccines and to all vaccines combined (except for the COVID-19 vaccine). ORs and 95% confidence intervals were reported using MedCalc statistical software.<sup>8</sup> The Z-score is statistical measurement that indicates how many standard deviations a data point is from the mean of a data set. It can be positive (above the mean) or negative (below the mean). The Z-score provides more detailed insight than a p-value in understanding the degree of deviation from an expected value within a given distribution. MedCalc® Statistical Software version 23.1.5 reports  $p < 0.0001$  or as a specific number if the  $p \geq 0.0001$ .

## **RESULTS**

The authors grouped the VAERS LLTs to be studied into four categories as portrayed in Tables 1-4 below: CNS infection LLTs (n=39), herpetic CNS infection LLTs (n=11), CNS abscess LLTs (n=4) and uncommon neurological disease LLTs (n=9), respectively.

As exhibited in Tables 1-4, notable safety concerns as defined by the CDC/FDA with an OR of 2 or greater were present for CNS infections as reported in VAERS. These safety concerns included CNS infections, herpetic CNS infection, CNS abscess and a separate category for Uncommon neurological diseases. A full listing of all symptoms extracted from the VAERS system and ORs for the COVID-19 vaccine, influenza vaccine, and all vaccines combined are listed in Tables 1-4 and all symptom titles are written exactly as included in VAERS. Two of the 39 LLT's in Table 1 and two of the 9 LLT's in

Table 4 did not achieve statistical significance (p value greater than 0.05).

#### **Findings related to CNS infection**

In total, there were 39 LLT identified in VAERS as correlated to CNS infection. Data are expressed as OR, CI, p value, Z score. In total all 39 LLTs combined was 29.4, 21.6-40.1,  $< 0.0001$ , 21.4 when the COVID-19 vaccines were compared to influenza vaccines and 4.11, 3.03-5.57,  $< 0.0001$ , 9.09 when the COVID-19 vaccines were compared to all other vaccines combined. Some specific LLT ORs in the CNS infection grouping include:

Bickerstaff's encephalitis: 68.3, 19.8-236,  $< 0.0001$ , 6.68 and 41.0, 14.9-113,  $< 0.0001$ , 7.19; CNS ventriculitis: 97.1, 5.29-1780, =0.0021, 3.08 and 11.1 (2.89-42.9, =0.0005, 3.50; CSF white blood cell count: 273, 127-587,  $< 0.0001$ , 14.4 and 37.7, 24.8-57.1,  $< 0.0001$ , 17.1; encephalitis autoimmune: 78.9, 45.4-137,  $< 0.0001$ , 15.5 and 14.9, 10.1-21.9,  $< 0.0001$ , 13.7; limbic encephalitis: 146, 43.7-485,  $< 0.0001$ , 8.11 and 87.4, 33.2-230,  $< 0.0001$ , 9.05; meningoradiculitis: 80.2, 18.1-357,  $< 0.0001$ , 5.76 and 16.0, 7.00-36.8,  $< 0.0001$ , 6.56; neuroborreliosis: 321, 43.0-2390,  $< 0.0001$ , 5.63 and 35.7, 16.2-78.6,  $< 0.0001$ , 8.87; neurosyphilis: 44.6, 5.10-390, =0.0006, 3.43 and 11.1, 2.89-42.9, =0.0005, 3.50; noninfective encephalitis: 74.5, 41.4-134,  $< 0.0001$ , 14.4 and 12.7, 8.52-18.8,  $< 0.0001$ , 12.6; pachymeningitis: 152 (19.7-1160),  $< 0.0001$ , 4.83 and 30.3, 10.7-85.9),  $< 0.0001$ , 6.42; spinal cord infection: 89.1 (20.2-393),  $< 0.0001$ , 5.93 and 16.2, 7.32-35.9,  $< 0.0001$ , 6; toxic encephalopathy: 157, 69.1-355,  $< 0.0001$ , 12.1 and 57.7, 32.7-102,  $< 0.0001$ , 14.0.

#### **Findings related to herpetic CNS infection**

In total, there were 11 LLT identified in VAERS as correlated to herpetic CNS infection. Data are expressed as OR, CI, p value, Z score. In total, the OR of all 11 LLTs combined was 171, 93.9-312,  $< 0.0001$ , 16.8 when the COVID-19 vaccines were compared to influenza vaccines, and 22.3, 15.4-32.4,  $< 0.0001$ , 16.4 when the COVID-19 vaccines were compared to all other vaccines combined. Specific LLT ORs in the herpetic CNS infection grouping include: Herpes simplex encephalitis: 43.3, 18.2-103,  $< 0.0001$ , 8.51 and 20.2, 10.3-39.8,  $< 0.0001$ , 8.69; herpes simplex meningitis: 132, 7.45-2360, =0.0009, 3.33 and 31.2, 6.30-155,  $< 0.0001$ , 4.21; herpes simplex meningoencephalitis: 120, 6.52-2210, =0.0013, 3.22 and 27.6, 5.18-147, =0.0001, 3.89; herpes zoster infection neurological: 680, 41.1-11200,  $< 0.0001$ , 4.56 and 28.2, 13.8-57.7,  $< 0.0001$ , 9.15; herpes zoster meningitis: 1260, 77.0-20700,  $< 0.0001$ , 5.00 and 28.8, 16.3-50.6,  $< 0.0001$ , 11.6; herpes zoster meningoencephalitis: 339, 45.5-2520,  $< 0.0001$ , 5.69 and 12.5 7.04-22.4,  $< 0.0001$ , 8.58; herpes zoster meningomyelitis: 79.5, 4.21-1500, =0.0035, 2.92 and 17.8, 3.18-100, =0.0011, 3.28; herpes zoster meningoradiculitis: 150, 8.53-2640, =0.0006, 3.43 and 71.3, 8.73-583,  $< 0.0001$ , 3.98; meningitis herpes: 38.6, 10.6-140,  $< 0.0001$ , 5.55 and 23.2, 7.91-67.9,  $< 0.0001$ ,

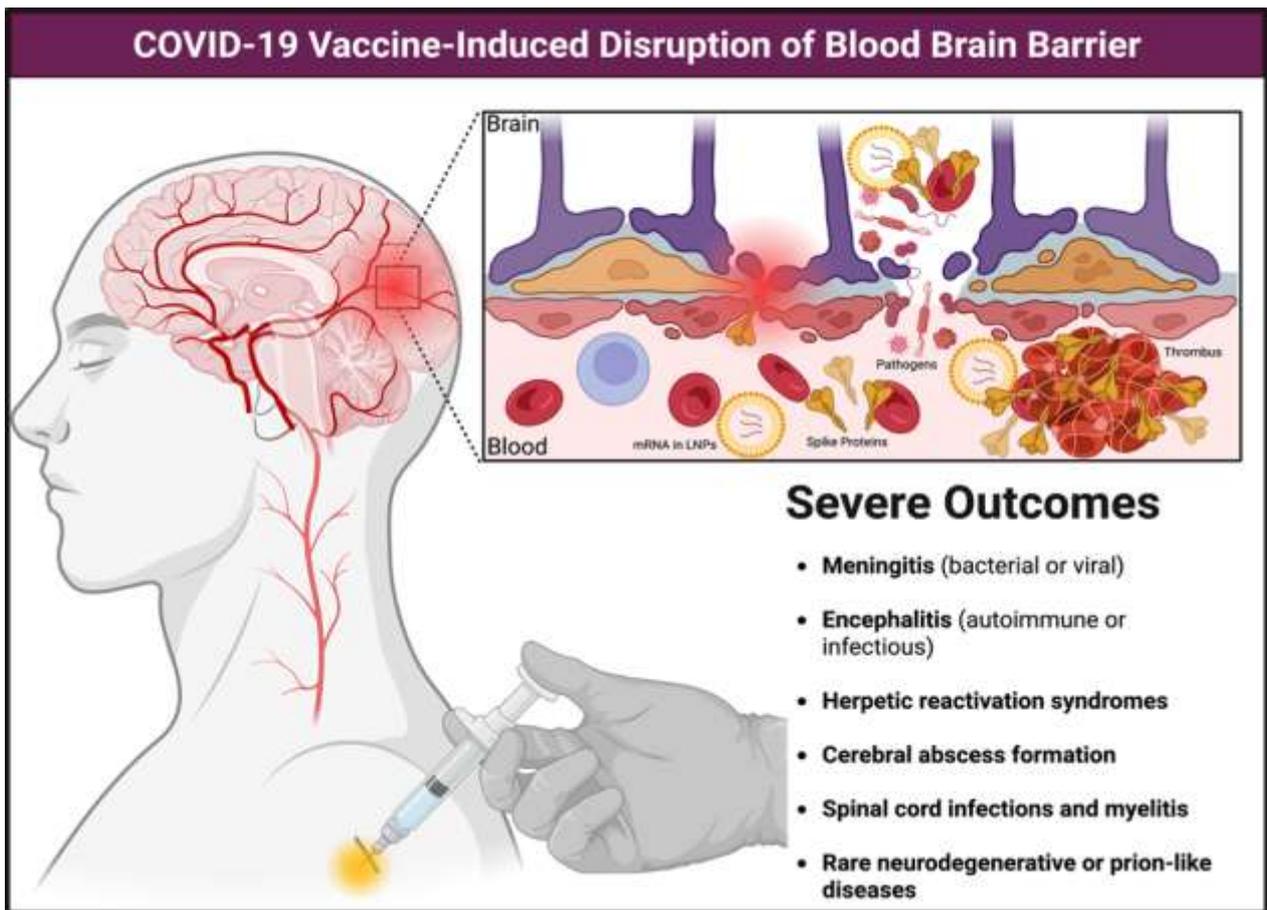
5.73; meningoencephalitis herpetic: 136, 47.3-391, <0.0001, 9.12 and 25.9, 14.5-46.3, <0.0001, 11.0; varicella meningitis: 168, 9.61-2930, =0.0004, 3.51 and 13.4, 4.56-39.2, <0.0001, 4.72.

**Findings related to CNS abscess**

In concert with the VAERS associated increases in bacterial meningitis, is the fact that in total, there were 4 LLTs were identified in VAERS as correlated to CNS abscess. Data are expressed as OR, CI, p value, Z score. In total, the OR of all 4 LLTs combined was 107, 40.9-280, <0.0001, 9.53 when the COVID-19 vaccines were compared to influenza vaccines and 17.8, 10.5-30.4, <0.0001, 10.6 when the COVID-19 vaccines were compared to all other vaccines combined. Specific LLT ORs in the CNS abscess grouping include: brain abscess: 120, 27.7-522, <0.0001, 6.40 and 15.0, 7.56-29.9, <0.0001, 7.72; extradural abscess: 169, 22.2-1290, <0.0001, 4.95 and 28.2, 10.7-74.2, <0.0001, 6.78; spinal cord abscess: 89.1, 11.2-712, <0.0001, 4.24 and 17.8, 5.85-54.4, <0.0001, 5.06; subdural abscess: 35.7, 3.90-326, =0.0015, 3.17 and 11.9, 2.58-54.7, =0.0015, 3.18.

**Findings related to CNS uncommon neurological disease**

Due to the degree of heterogeneity in this grouping, the authors did not conduct a total OR but rather listed the ORs out separately. Data are expressed as OR, 95% confidence interval, CI, p value, Z score. Listed below are the calculated ORs comparing the COVID-19 vaccines to influenza vaccines as well as COVID-19 vaccines to all other vaccines combined: CJD: 847, 115-6220, <0.0001, 6.63 and 169, 65.6-437, <0.0001, 10.6; myelitis transverse: 20.8, 15.0-29.0, <0.0001, 18.0 and 8.93, 6.49-12.3, <0.0001, 13.5; noninfectious myelitis: 132, 7.45-2360, =0.0009, 3.33 and 15.6 (4.40-55.3), <0.0001, 4.26; poliomyelitis: 32.7, 8.80-121, <0.0001, 5.21 and 1.02, 0.511-2.04, =0.952, 0.0602; post-polio syndrome: 97.1, 5.29-1780, =0.0021, 3.08 and 5.57, 1.75-17.7, =0.0036, 2.91; prion disease: 61.8, 3.15-1220, =0.0066, 2.71 and 61.8, 3.15-1220, =0.0066, 2.71; vaccine associated paralytic poliomyelitis: 44.2, 2.09-934, =0.0150, 2.43 and 2.55, 0.514-12.6, =0.2521, 1.15; viral myelitis: 115, 6.37-2070, =0.0013, 3.22 and 13.4, 3.64-49.1, =0.0001, 3.91.



**Figure 1: COVID-19 vaccine-induced disruption of the blood–brain barrier and pathogenic outcomes.**

\*Illustration of the proposed mechanism by which mRNA vaccine lipid nanoparticles (LNPs) and spike proteins contribute to disruption of the BBB. Once BBB integrity is compromised, pathogens, vaccine components and inflammatory mediators can enter the CNS, leading to vascular inflammation, thrombus formation, and secondary infections. Severe outcomes include bacterial or viral meningitis, autoimmune or infectious encephalitis, herpetic reactivation syndromes, cerebral abscess formation, spinal cord infections and myelitis, and rare neurodegenerative/prion-like conditions. Created with Biorender.com

**Table 1: CNS infections reported to VAERS following COVID-19 vaccination compared with influenza and all other vaccines.**

CNS infections	COVID	Influenza	All vax	COVID vs flu vax OR (95% confidence interval), p value, Z score	COVID vs all vax OR (95% confidence interval), p value, Z score
Acute disseminated encephalomyelitis	310	210	541	13.2 (9.29-18.7), <0.0001, 14.5	5.11 (3.66-7.12), <0.0001, 9.62
Acute hemorrhagic leukoencephalitis	3	6	10	4.46 (1.08-18.4), =0.0389, 2.07	2.67 (0.711-10.1), =0.1456, 1.46
Autoimmune encephalopathy	27	1	55	241 (32.0-1810), <0.0001, 5.32	2.52-7.59), <0.0001, 5.26
Bickerstaff's encephalitis	23	3	5	68.3 (19.8-236), <0.0001, 6.68	41.0 (14.9-113), <0.0001, 7.19
CNS infection	16	2	27	71.3 (15.9-320), <0.0001, 5.57	5.28 (2.66-10.5), <0.0001, 4.74
CNS viral infection	4	2	7	17.8 (3.18-100), =0.0011, 3.28	5.09 (1.44-18.0), =0.0116, 2.52
Cerebral fungal infection	1	0	0	5.09 (1.44-18.0), =0.0116, 2.52	5.09 (1.44-18.0), =0.0116, 2.52
Cerebral septic infarct	1	0	0	5.09 (1.44-18.0), =0.0116, 2.52	5.09 (1.44-18.0), =0.0116, 2.52
Cerebral toxoplasmosis	1	0	1	5.09 (1.44-18.0), =0.0116, 2.52	8.91 (0.549-145), =0.1241, 1.54
CNS ventriculitis	5	0	4	97.1 (5.29-1780), =0.0021, 3.08	11.1 (2.89-42.9), =0.0005, 3.50
Cranial nerve infection	5	0	2	97.1 (5.29-1780), =0.0021, 3.08	22.3 (4.21-118), =0.0003, 3.65
CSF white blood cell count	245	8	58	273 (127-587), <0.0001, 14.4	37.7 (24.8-57.1), <0.0001, 17.1
Encephalitis	784	334	1848	20.9 (15.1-29.0), <0.0001, 18.2	3.78 (2.77-5.17), <0.0001, 8.33
Encephalitis autoimmune	177	20	106	78.9 (45.4-137), <0.0001, 15.5	14.9 (10.1-21.9), <0.0001, 13.7
Encephalitis brain stem	24	10	31	21.4 (9.64-47.5), <0.0001, 7.53	6.90 (3.74-12.7), <0.0001, 6.18
Encephalitis meningococcal	4	0	4	79.5 (4.21-1500), =0.0035, 2.92	8.91 (2.16-36.8), =0.0025, 3.02
Encephalitis post immunization	15	14	54	9.55 (4.34-21.0), <0.0001, 5.61	2.48 (1.30-4.73), =0.0060, 2.75
Encephalitis viral	45	31	144	12.9 (7.48-22.4), <0.0001, 9.16	2.79 (1.78-4.37), <0.0001, 4.46
Encephalomyelitis	95	28	89	30.2 (18.0-50.8), <0.0001, 12.9	9.52 (6.27-14.5), <0.0001, 10.6
Limbic encephalitis	49	3	5	146 (43.7-485), <0.0001, 8.11	87.4 (33.2-230), <0.0001, 9.05
Meningitis	411	107	1653	34.2 (23.7-50.0), <0.0001, 18.8	2.22 (1.61-3.05), <0.0001, 4.87
Meningitis aseptic	231	39	244	52.8 (33.5-83.1), <0.0001, 17.1	8.44 (5.94-12.0), <0.0001, 11.9
Meningitis bacterial	40	10	180	35.7 (16.7-76.0), <0.0001, 9.27	1.98 (1.26-3.13), =0.0033, 2.94
Meningitis pneumococcal	10	4	730	22.3 (6.73-73.9), <0.0001, 5.08	0.122 (0.0611-0.244), <0.0001, 5.95
Meningitis tuberculous	4	1	7	35.7 (3.90-326), =0.0015, 3.17	5.09 (1.44-18.0), =0.0116, 2.52
Meningitis viral	116	42	217	24.6 (15.5-39.2), <0.0001, 13.5	4.77 (3.27-6.94), <0.0001, 8.13
Meningoencephalitis bacterial	6	2	11	26.7 (5.25-136), <0.0001, 3.96	4.86 (1.72-13.7), =0.0029, 2.98
Meningoencephalitis viral	11	5	22	19.6 (6.53-58.9), <0.0001, 5.31	4.46 (2.04-9.76), =0.0002, 3.74
Meningococcal infection	5	5	370	8.91 (2.49-31.9), =0.0008, 3.36	0.121 (0.0474-0.306), <0.0001, 4.45
Meningoradiculitis	18	2	10	80.2 (18.1-357), <0.0001, 5.76	16.0 (7.00-36.8), <0.0001, 6.56
Neuroborreliosis	36	1	9	321 (43.0-2390), <0.0001, 5.63	35.7 (16.2-78.6), <0.0001, 8.87
Neurological infection	7	3	11	20.8 (5.20-83.2), <0.0001, 4.29	5.67 (2.10-15.3), =0.0006, 3.42
Neurosyphilis	5	1	4	44.6 (5.10-390), =0.0006, 3.43	11.1 (2.89-42.9), =0.0005, 3.50
Noninfective encephalitis	142	17	100	74.5 (41.4-134), <0.0001, 14.4	12.7 (8.52-18.8), <0.0001, 12.6
Pachymeningitis	17	1	5	152 (19.7-1160), <0.0001, 4.83	30.3(10.7-85.9), <0.0001, 6.42
PML	10	2	9	44.6 (9.48-210), <0.0001, 4.81	9.91 (3.83-25.6), <0.0001, 4.73
Spinal cord infection	20	2	11	89.1 (20.2-393), <0.0001, 5.93	16.2 (7.32-35.9), <0.0001, 6.87
Tick-borne viral encephalitis	8	1	13	88.4 (10.8-726), <0.0001, 4.17	5.49 (2.16-13.9), <0.0003, 3.58
Toxic encephalopathy	123	7	19	157 (69.1-355), <0.0001, 12.1	57.7 (32.7-102), <0.0001, 14.0
<b>Total CNS infection</b>	<b>3044</b>	<b>922</b>	<b>6607</b>	<b>29.4 (21.6-40.1), &lt;0.0001, 21.4</b>	<b>4.11 (3.03-5.57), &lt;0.0001, 9.09</b>

**Table 2: Herpetic CNS infections reported to VAERS following COVID-19 vaccination compared with influenza and all other vaccines.**

Herpetic CNS infection	COVID	Influenza	All vax	COVID vs flu vax OR (95% confidence interval), p value, Z score	COVID vs all vax OR (95% confidence interval), p value, Z score
Herpes simplex encephalitis	34	7	15	43.3 (18.2-103), <0.0001, 8.51	20.2 (10.3-39.8), <0.0001, 8.69
Herpes simplex meningitis	7	0	2	132 (7.45-2360), =0.0009, 3.33	31.2 (6.30-155), <0.0001, 4.21
Herpes simplex meningoencephalitis	5	0	2	120 (6.52-2210), =0.0013, 3.22	27.6 (5.18-147), =0.0001, 3.89
Herpes zoster infection neurological	38	0	12	680 (41.1-11200), <0.0001, 4.56	28.2 (13.8-57.7), <0.0001, 9.15
Herpes zoster meningitis	71	0	22	1260 (77.0-20700), <0.0001, 5.00	28.8 (16.3-50.6), <0.0001, 11.6
Herpes zoster meningoencephalitis	38	1	27	339 (45.5-2520), <0.0001, 5.69	12.5 (7.04-22.4), <0.0001, 8.58
Herpes zoster meningomyelitis	4	0	2	79.5 (4.21-1500), =0.0035, 2.92	17.8 (3.18-100), =0.0011, 3.28
Herpes zoster meningoradiculitis	8	0	1	150 (8.53-2640), =0.0006, 3.43	71.3 (8.73-583), <0.0001, 3.98
Meningitis herpes	13	3	5	38.6 (10.6-140), <0.0001, 5.55	23.2 (7.91-67.9), <0.0001, 5.73
Meningoencephalitis herpetic	61	4	21	136 (47.3-391), <0.0001, 9.12	25.9 (14.5-46.3), <0.0001, 11.0
Varicella meningitis	9	0	6	168 (9.61-2930), =0.0004, 3.51	13.4 (4.56-39.2), <0.0001, 4.72
Total herpetic CNS infection	288	15	115	171 (93.9-312), <0.0001, 16.8	22.3 (15.4-32.4), <0.0001, 16.4

**Table 3: CNS abscesses reported to VAERS following COVID-19 vaccination compared with influenza and all other vaccines.**

CNS abscess	COVID	Influenza	All vax	COVID vs flu vax OR (95% confidence interval), p value, Z score	COVID vs all vax OR (95% confidence interval), p value, Z score
Brain abscess	27	2	16	120 (27.7-522), <0.0001, 6.40	15.0 (7.56-29.9), <0.0001, 7.72
Extradural abscess	19	1	6	169 (22.2-1290), <0.0001, 4.95	28.2 (10.7-74.2), <0.0001, 6.78
Spinal cord abscess	10	1	5	89.1 (11.2-712), <0.0001, 4.24	17.8 (5.85-54.4), <0.0001, 5.06
Subdural abscess	4	1	3	35.7 (3.90-326), =0.0015, 3.17	11.9 (2.58-54.7), =0.0015, 3.18
Total CNS abscess	60	5	30	107 (40.9-280), <0.0001, 9.53	17.8 (10.5-30.4), <0.0001, 10.6

**Table 4: Uncommon neurological diseases reported to VAERS following COVID-19 vaccination compared with influenza and all other vaccines.**

Uncommon neurological disease	COVID	Influenza	All vax	COVID vs flu vax OR (95% confidence interval), p value, Z score	COVID vs all vax OR (95% confidence interval), p value, Z score
CJD	95	1	5	847 (115-6220), <0.0001, 6.63	169 (65.6-437), <0.0001, 10.6
Myelitis	640	182	616	31.3 (22.2-44.2), <0.0001, 19.7	33.2 (23.5-46.9), <0.0001, 19.9
Myelitis transverse	713	305	712	20.8 (15.0-29.0), <0.0001, 18.0	8.93 (6.49-12.3), <0.0001, 13.5
Noninfectious myelitis	7	0	4	132 (7.45-2360), =0.0009, 3.33	15.6 (4.40-55.3), <0.0001, 4.26
Poliomyelitis	11	3	96	32.7 (8.80-121), <0.0001, 5.21	1.02 (0.511-2.04), =0.952, 0.0602
Post polio syndrome	5	0	8	97.1 (5.29-1780), =0.0021, 3.08	5.57 (1.75-17.7), =0.0036, 2.91
Prion disease	3	0	0	61.8 (3.15-1220), =0.0066, 2.71	61.8 (3.15-1220), =0.0066, 2.71
Vaccine associated paralytic poliomyelitis	2	0	7	44.2 (2.09-934), =0.0150, 2.43	2.55 (0.514-12.6), =0.2521, 1.15
Viral myelitis	6	0	4	115 (6.37-2070), =0.0013, 3.22	13.4 (3.64-49.1), =0.0001, 3.91

## DISCUSSION

The anatomically complex BBB plays a critical role in maintaining CNS homeostasis by restricting toxin and pathogen entry into the brain. Overt CNS infections generally result from a common pericranial infection such as sinusitis, otitis, or infections of the oral cavity that unusually deviate from a typical indolent course by crossing the BBB causing a life-threatening illness. The mRNA, lipid nanoparticle, and unchecked production of spike protein likely was the root cause of BBB dysfunction and incipient infection. Although the pathogenesis of BBB dysfunction is not well understood, it is believed that the pathogen inoculum must reach a minimum threshold or that a contiguous pathogen spread occurs from a nidus of chronic infection in the sinuses or inner ear. This attack on the BBB creates a vulnerability for patients to develop meningitis, encephalitis, and pericranial abscess formation.<sup>1</sup> Inflammation of the BBB compromises the structural integrity, allowing substances to enter the brain that are normally excluded from the systemic circulation. The spike protein, in particular, has the potential to induce inflammation in endothelial cells throughout the body, including those that comprise the BBB vasculature resulting in loss of barrier integrity, thrombosis, and hemorrhage.<sup>9-11</sup> The proposed mechanism of COVID-19 vaccine-induced disruption of the BBB and its potential downstream sequelae, is illustrated in Figure 1.

CNS infection syndromes are grouped based on the anatomical location affected. Meningitis indicates inflammation of the meninges, the three protective membranes encasing the CNS including the dura mater, arachnoid mater, and the pia mater, while encephalitis refers to an involvement of the actual brain parenchyma. Myelitis generally refers to the involvement of the insulative myelin surrounding the peripheral or cranial nerves, or actual spinal cord. These diagnoses may be further differentiated based on the causative organism or mechanism of disease. It is acknowledged that there may be some symptom overlap in the presentation of these conditions.

Bacterial meningitis generally has an acute severe clinical onset, can be rapidly diagnosed, and is often lethal. Although historically considered rare in the developed countries, between 600-1000 people are diagnosed with meningococcal disease each year in the US, of which 10-15% will die despite appropriate treatment and 20% of survivors may live with permanent disabilities.<sup>12</sup> Autoimmune meningitis and encephalitis are usually milder and may be triggered by medication, viruses, vaccination, or even cancer.<sup>6</sup> Encephalitis tends to portend a poorer prognosis than meningitis. Enteroviruses are often implicated in both meningitis and encephalitis with herpes simplex and herpes zoster viruses also frequently identified as the causative organism in encephalitis cases.<sup>13</sup> The authors believe the increase in bacterial meningitis cases found in our VAERS queries may have a causal link to the COVID-19 mRNA “vaccines”. Further investigation

is required, possibly to involve some preliminary opsonization and phagocytosis studies of the innate immune system in these patients.

It is of note that the rates of meningococcal meningitis/encephalitis had been in decline prior to 2021. CDC documents demonstrate that there has been a sharp increase in cases since the introduction of the COVID-19 mRNA vaccines and numerous outbreaks of meningococcal disease have made national headlines over the past few years. Specifically, the CDC has noted that 438 cases were reported in 2023, the highest number of cases in over a decade.<sup>2</sup> In 2022, ABC News reported on an unusual outbreak of meningococcal disease in Florida involving 26 individuals, with 7 dead. The CDC described this as one of the worst outbreaks in history with this particular case exceeding the state’s five-year average.<sup>3</sup> Most of the individuals affected were gay or bisexual, with 10 documented as having HIV/AIDS. Several investigators demonstrate that the COVID-19 vaccinations have caused vaccine induced acquired immune deficiency syndrome also referred to as VAIDS.<sup>14-16</sup> Epidemiologist Nic Hulscher recently reviewed eight published articles documenting the VAIDS phenomenon which detailed dramatic increases in infection associated with mRNA COVID-19 vaccines.<sup>17</sup>

A statewide outbreak in Virginia between August 2022 through March 2024 reported 36 cases of meningitis including 7 deaths.<sup>18</sup> Although Colorado meningitis cases generally average 6 per year, by April 2023 there were news reports of 6 cases in just the first four months of the year.<sup>19</sup> In 2024, US officials reported 143 cases of meningococcal disease, a 75% increase from 2023.<sup>20</sup> None of these cases were investigated with respect to antecedent mRNA COVID-19 vaccination as a common predisposing factor.

The suggestion that COVID-19 anti-viral mRNA “vaccination” might have an unwarranted side-effect on the innate human immune system responsible for mediating bacterial infections is alarming and it is a finding that requires further preclinical and clinical investigation. In the Australian COVID-19 inquiry, the term “vaccine associated immunodeficiency syndrome” was accepted and under investigation given concerns over higher rates of both common and unusual infections among those vaccinated for SARS-CoV-2.

Others have found increases in herpetic CNS infections, confirming our findings. A publication by Shafiee et al documents such evidence regarding reactivation of herpes viruses after receipt of the COVID-19 vaccine.<sup>21</sup> The authors conducted a systematic search which included observational studies, case reports and series. Within the 80 articles meeting the eligibility criteria reporting herpes virus reactivation, results noted a reactivation of varicella-zoster virus of 14 persons per 1000 vaccinations (95% CI 2.97-32.80) and reactivation of herpes simplex virus of 16 persons per 1000 vaccinations (95% CI 1.06-46.4). A

noteworthy finding by Fathy et al observed an increase in dermatologic reactions after receiving a COVID-19 vaccination.<sup>22</sup> The authors reviewed a national registry (American academy of dermatology and the international league of dermatologic societies' COVID-19 dermatology registry) and found 672 incidences of dermatologic reactions reports recorded by healthcare professionals (dermatologists, physicians and nurse practitioners) as of April 2021. Of the 672 reports, the authors reviewed the first 40 cases of varicella-zoster and herpes simplex virus reactivation reports and found that 77% occurred after the first COVID-19 vaccination.

Brain abscesses occur when a focal pocket of purulent material becomes encapsulated in the brain parenchyma resulting in tissue necrosis. The vast majority of cases occur after a nearby pericranial infection, but a small number can also result via hematogenous spread from a distant site.<sup>23</sup> Paranasal sinusitis is implicated in 30-50% of these cases. Some 1500-2500 cases of brain abscess are diagnosed in the United States annually and this condition is more prevalent in patients with AIDS.<sup>24</sup> Like meningitis and encephalitis, this diagnosis carries a high mortality and disability rate.

In the morbidity and mortality weekly report of August 2022, the CDC noted an approximate 100% increase in brain abscesses across eight pediatric hospitals between 2020-2022.<sup>25</sup> CNN covered an investigation in April 2023 out of Clark County, Nevada of an "alarming cluster of mysterious brain infections" in pediatric patients. Notably the news anchor reported that prior to 2020, only 4 cases of brain abscesses were historically diagnosed annually. In 2022 these numbers saw a dramatic increase to 18 cases diagnosed within the year.<sup>26</sup>

Nerve demyelination occurs when the immune system is triggered to inappropriately attack the outside myelinated structures around the nerve cell axons in the CNS. This results in a variety of debilitating diseases. When demyelination occurs after COVID-19 mRNA vaccination, it has been found to occur most often within 1-2 weeks of inoculation. However, delayed presentations have been documented to occur as far out as between 4 weeks and 5 months post-inoculation.<sup>27</sup> A large global observational study evaluated 99 million vaccinated individuals and documented a 378% increased general risk for developing a devastating acute disseminated encephalomyelitis (ADEM) demyelination following COVID-19 mRNA "vaccination".<sup>28</sup>

The study, published by Faksova et al examined the association between COVID-19 vaccines and AEs of special interest.<sup>28</sup> This CDC-funded global study utilized 10 sites in 8 countries and reviewed data of 99 million vaccinated participants obtained from the global COVID vaccine safety (GCoVS) project. The authors found statistically significant safety signals for acute disseminated encephalomyelitis and transverse myelitis, among others.

CNS prion diseases cause rapid and terminal neurodegeneration as a result of the accumulation of abnormal folding of proteins. The proteins change from a loose, uncompiled form into precisely organized, self-arranging, composite entities. These devastating cases are extremely rare with only roughly 300 cases reported in the US each year.<sup>29</sup> At present there are only two well documented types of CNS prion disease, the classical PrP<sup>sc</sup> protein involved in both CJD and variant "mad cow disease" and a recently outlined  $\alpha$ -synuclein CNS amyloid variant.<sup>30</sup>

Some researchers such as Tetz and Tetz and Seneff and Nigh suggest a link between COVID-19 vaccination and the onset of CJD due to prion development.<sup>31,32</sup> 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-19 mRNA vaccine known as a "GxxxG" motif, a three-amino acid sequence surrounded by glycine residue which may promote the abnormal folding of the protein into the organized entities mentioned above.<sup>32</sup> Thorp and colleagues not only reaffirm the previously discussed hypothesis but also introduce an additional theory linking COVID-19 infection and/or vaccination to an energy-depleted physiological state. They suggest that such a state may impair intracellular energy dynamics, potentially exacerbating the development of protein misfolding disorders such as CJD.<sup>33</sup>

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.<sup>4</sup>

However, in 2021, Nobel Prize laureate Luc Montagnier and colleagues reported 26 cases of apparent Creutzfeldt-Jacob disease, with symptoms beginning approximately 11 days after a Pfizer, Moderna, or AstraZeneca COVID-19 vaccine. Twenty of the 26 individuals were deceased within 4.76 months after the vaccination.<sup>4</sup> Unfortunately, a confirmatory diagnosis was not made using classic histology, and brain tissues were never stained for the COVID-19 spike protein. This results in uncertainty as to whether a cytokine-driven inflammation directed against the mRNA vaccine-generated spike protein in the CNS drove the acceleration of a very early pre-existing CJD, or if abnormal amyloid deposits of the vaccine-induced spike protein itself in the brain were causing a clinically similar presentation. The matter remains unresolved at this time.

In addition to their observations on prion disease and CJD, Thorp et al highlight alarming safety signals related to neuropsychiatric outcomes following COVID-19 vaccination, particularly when compared to both the influenza vaccine and all vaccines combined.<sup>34</sup> Their analysis focused on 47 AEs reported in VAERS, and categorized into cognitive decline, psychiatric disorders, and suicidal/homicidal behavior groupings. A few notable symptoms included acute psychosis, brain fog, dementia,

homicidal ideation, mania, panic attacks, schizophrenia, and suicidal ideation. Based on these findings, authors raise significant concerns about potential long-term neuropsychiatric effects associated with COVID-19 vaccine.

A case series published by Ballout et al review the findings of new onset CNS inflammatory disorders temporally associated with the COVID-19 vaccines.<sup>35</sup> It should be noted that the temporality, strength of association, consistency, specificity, coherence, and biological plausibility demonstrated in these findings fulfill six of the nine Bradford Hills criteria for causation.<sup>36</sup> The authors studied 5 patients all of whom were part of a single health system comprised of 23 hospitals. All 5 patients developed a new onset CNS condition within 2 weeks of receipt of a COVID-19 vaccine (all mRNA-based), including 1 fatal case of acute disseminated encephalitis and 1 diagnosis of meningoencephalitis. Although the sample size is small, the temporal association between vaccine administration and the onset of these rare conditions must be considered.

The limitations to this study are those intrinsic to the CDC/FDA's VAERS database. Because VAERS is a passive reporting system, it is subject to underreporting, differential reporting rates, and varying data quality.

The COVID-19 mRNA "vaccines" are now known to downregulate a number of critical pathways related to infection control and cellular homeostasis.<sup>37</sup> Capillary endothelial mRNA and spike protein likely disrupt the BBB and in certain individuals, increase the risk for devastating CNS infections. We found an increase in the incidence of life-threatening CNS bacterial infections including brain abscess formation as detected in the VAERS data. This implies a gross breach of the BBB and possibly impairment of opsonization and neutrophil/macrophage phagocytosis.<sup>38</sup> Further study is urgently needed concerning the negative influence of the COVID-19 mRNA vaccines on the human immunological response to bacterial infections.

COVID-19 mRNA vaccines represent the most widely utilized genetic product in human history. Lack of preclinical and clinical study to guide safe development of this technology has led to concerning reports of AE and SAE's month to years after administration. Key shortcomings in the development process included the rushed speed of manufacturing; the use of unproven mRNA technology in the first operational "vaccine"; reliance on nanometer-scale lipid nanoparticle delivery systems containing polyethylene glycol (PEG); and the unstable character of the initial product, which required a complex cold-chain for storage and distribution (Process 1). These problems were compounded by the shift to large-scale commercial production (Process 2), which used *E. coli* plasmids as the DNA template and led to contamination of finished vials with residual plasmid DNA fragments, raising additional safety concerns.<sup>39</sup> The suspected side effect of PEG as a high-risk allergen alone mandated that the closest adverse event supervision

possible be conducted, which was neglected during the rollout process.<sup>40</sup>

Data recovered after the vaccine rollout revealed serious irregularities in the clinical and safety trials of the experimental mRNA "vaccines".<sup>41,42</sup> These data recovered by lawsuits include the rapid systemic dissemination of the genetically active highly inflammatory lipid nanoparticles throughout the body with their prolonged deposition in critical organs.<sup>43-45</sup> The implications of this information is vast for the overall US healthcare system given that approximately 81% of Americans have taken at least one COVID-19 vaccine.<sup>46</sup> An alarming study by a group of Yale researchers has demonstrated that in some individuals, the resultant spike protein production has continued for years after "vaccination" along with definitive laboratory evidence of T-cell exhaustion in these patients.<sup>47</sup>

In 2024, a second edition of the book "toxic shot" was independently published by Amazon. Authored by Dr. Byram Bridle and Dr. Harvey Risch at Yale, individual chapters in the book were written by national experts in their fields. It essentially summarized that in early 2020, the US had two highly effective and safe early outpatient drug treatments for COVID-19 which should have nullified the use of the emergency use authorization by our regulatory agencies to bring this product to market. Consequently, not a single human being should have ever received a COVID-19 mRNA "vaccine" injection, particularly children and infants.

There are now eight published peer reviewed papers that describe an overall negative risk-benefit ratio for the COVID-19 mRNA "vaccines".<sup>17</sup> The first of these papers examined the original clinical trial data from two pharmaceutical manufacturers. The authors concluded that it was safer to contract COVID-19 with subsequent hospitalization than to take a mRNA "vaccine".<sup>48</sup>

## CONCLUSION

At the time of this publication, 4.5 years have passed since the initiation of the mass COVID-19 mRNA "vaccination" campaign and yet the long-term effects of this program are still being elucidated. Our data join the work of others to firmly conclude the COVID-19 vaccines and their boosters are not safe for human use and should be urgently removed from the market.

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