Safety Signal

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***Abstract*—**

Aim

The primary aim of this study is to detect safety signals for all vaccines in the VAERS database using the Proportional Reporting Ratio (PRR), and to create a public search engine for vaccine safety signals.

PRR is a metric used by both the European Medical Association and by the Centre for Disease Control for detecting safety signals. However, both the EMA and the CDC have failed to publish their PRR analyses, even though this information is vital for informed choice. This study seeks to carry out an independent PRR analysis of all of the VAERS data available. A single dataset is created by concatenating the VAERS datasets for every year from 1990 to 2023, and the proportional reporting ratios are calculated for each symptom associated with each vaccine. The result is a useful look-up tool called "Safety Signal", where a user can look-up all the safety signals for any vaccine in rank order.

The null hypothesis : The "Safety Signal" dataset is used to investigate if any vaccines generate a safety signal for the symptom of thrombosis. The null hypothesis is that all vaccines are equally safe, and so there will be no significant differences between vaccines in the PRR values for thrombosis. (95 % confidence interval). Any significant PRR values are confirmed by 5 new criteria for safety signal detection – MSC (multiple sample consistency), SSC (Same Symptom Consistency), RSC (Related Symptom Consistency), RBC (Related Biomarker Consistency), and RTC (Related Treatment Consistency. The conclusion : High PRR values for thrombotic events following COVID-19 vaccination are found, and these high PRR values are consistent across multiple related symptoms and treatments, so the null hypothesis is rejected.

Resources

Safety signal detection is of critical interest to the public, so the data has been made accessible through downloadable CSV files and as an online search engine.

Safety Signal (online) : [1]
Downloadables (csv — excel) : [2]
Coding (python) : [3]

***Index Terms*—safety signals, vaccines, pharmacovigilance, adverse effects, proportional reporting ratio, VAERS, Eudravigilance, YellowCard, Vigiaccess**

I. Introduction

A. What is the PRR ratio ?

PRR calculates the percentage of reports where a particular symptom is recorded following administration of a drug A, and sees if this varies significantly from the percentage of reports where the same symptom is recorded after administration of drug B.

The PRR is defined as the ratio between the frequency with which a specific adverse event is reported for the drug of interest (relative to all adverse events reported for the drug) and the frequency with which the same adverse event is reported for all drugs in the comparison group.

> *For example, suppose that nausea was reported 83 times for a given drug of interest, out of 1356 adverse events reported for the drug. Thus the proportion of adverse events of nausea for this drug is 83/1356 = 0.061. Suppose that we wish to compare the drug of interest to a class of drugs, for which nausea was reported as an adverse event 1489 times, out of 53789 total adverse events reported for drugs in the class. Thus, nausea was reported with proportion 1489 / 53789 = 0.028 for the class of drugs. The PRR in this case is 0.061 / 0.028 = 2.18. This tells us that nausea was reported more than twice as frequently (among all adverse event reports) for the drug of interest compared to drugs in the comparison group.*

[4]

Cases	Drug of interest	Comparator
Event of interest	a	c
Other events	b	d

$$PRR = \frac{a/(a+b)}{c/(c+d)}$$

B. Who uses PRR ratio for Signal Detection?

PRR is used for the detection of serious drug reactions (SDRs) by "the European Medical Association (EMA) in their EudraVigilance Data Analysis System

> *Different statistical methods to generate SDRs are in use. In the EudraVigilance Data Analysis System, the Proportional Reporting Ratio (PRR) has been implemented in the first release. Other methods will be considered for future implementation.*

European Medicines Agency,(2006), "Guideline on the Use of Statistical Signal Detection Methods in the Eudravigilance Data Analysis System" [5]

This method is also used by the Center for Disease Control (CDC) in the USA. On January 29th of 2021 the CDC released a document titled 'Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19' (for official use only) which announced the CDC's intention:

> *CDC will perform Proportional Reporting Ratio (PRR) analysis [...], excluding laboratory results, to identify AEs that are disproportionately reported relative to other AEs. [...] To determine if results need further clinical review, consider if clinically important, unexpected findings, seriousness, specific syndrome or diagnosis rather than non-specific symptoms*

Centers for Disease Control and Prevention, (2021), "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021) [6]

C. What Criteria Define a Strong Signal ?

The CDC [7] uses the following criteria –

1) Symptom events greater than or equal to 3
2) PRR greater than or equal to 2
3) Chi-squared greater than or equal to 4

These are exactly the same criteria that were used by Evans and his team who introduced the PRR signal detection method in 2001 [8]. In 2002 Puijenbroek [9] found that symptom events greater than 10 resulted in greater consistency across different methods for detecting safety signals.

The higher the value of PRR, the stronger the signal. A PRR greater than 2 means that a symptom occurs at more than twice the frequency with the drug of interest compared to the comparator drug/s. This is regarded by the CDC as a strong signal, so PRR greater than or equal to 2, is the level used by the CDC to detect a safety signal.

We can calculate the limits of random variation of the PRR. If the lower limit of variation is still ¿ 2, then we can be confident that the PRR exceeds 2 by a significant margin. The lower limit of variation is called the lower confidence limit, and it is given by the equation – [10]

Lower Confidence Limit = $\mathbf{PRR} / e^{1.96 \times s}$
Upper Confidence Limit = $\mathbf{PRR} \times e^{1.96 \times s}$

where s is the standard deviation, and is given by

$$s = \sqrt{\frac{1}{a} + \frac{1}{c} - \frac{1}{a+b} - \frac{1}{c+d}}$$

D. What Criteria Confirm a Strong Signal ?

*1) **Large samples**:* A signal is regarded as strong if it is based on a large sample of data. CDC accepts a signal if the number of reports of a symptom (symptom events) is greater than or equal to 3. The larger the number of symptom reports, the greater our confidence.

*2) **Multiple Sample Consistency (MSC) ::*** Sample variation is a possible cause of a high PRR. To rule this out we can take multiple independent samples of equal size to see if there is consistency in the PRR across samples. If the PRR remains consistently high across all samples then we can have greater confidence in the PRR score. (See Results : Fig.2).

*3) **Same Symptom Consistency (SSC) ::*** This is where different forms of the same symptom are consistently reported with a high PRR. (Results : Fig. 3-7) show 94 different forms of thrombosis. If a medication has a high PRR score for causing cerebral thrombosis, then our confidence in that score is increased if the medication also has high scores for many other forms of thrombosis. This consistency is strong evidence that the effect is real.

Same Symptom Consistency may be quantified by the number of symptoms that it is consistent across. In this example, COVID 19 vaccines produce high PRR scores (greater than 2) across 43 different symptoms of thrombosis.

In addition to this, COVID 19 vaccines have an INF score across 46 additional symptoms (Results : Fig. 5,6). An INF score is where COVID 19 vaccines are THE ONLY vaccines in the database producing that particular symptom. We may therefore add this score to the previous one, and the total score comes to 89.

In the database there are only 94 symptoms in total containing the word thrombosis, and COVID 19 has high PRR scores (greater than 2) for 89 of them. Other vaccines never have more than 4. The consistent occurrence of a high

PRR across many related symptoms supports the conclusion that a symptom is occurring disproportionately.

*4) **Related Symptom Consistency (RSC):*** This is where related symptoms are consistently reported with a high PRR. Related symptoms would include terms such as clots, infarctions, occlusions, and embolisms. (Results : Fig. 8-11)

*5) **Related Biomarker Consistency (RBC):*** In addition, any particular illness or condition is evidenced by several bio-markers or biological indicators. Consequently, if a high PRR is obtained for a particular condition, then we would expect bio-markers and effects for that condition to have high PRR scores also. When multiple biomarkers for a condition have high PRR scores, then we can have greater confidence in the high PRR score for the condition.

*6) **Related Treatment Consistency (RTC):*** Every condition requires different medical treatments. For example a cardiac disorder may be treated with chest X-rays, electrocardiogram, cardiac imaging, cardiac operation, cardiac pacemaker, cardiac stress test, cardiac rehabilitation therapy, cardiac ventriculogram, assays etc. So, when associated treatments also have high PRR scores, then our confidence in a high PRR score for a particular condition increases. (Results : Fig. 12-17)

E. Previous Studies

Clinical Studies : The possibility of finding serious levels of dis-proportionality in symptoms for COVID vaccines is suggested by several clinical studies - which show that COVID vaccines induce the body to produce a spike protein that acts as a cardio-vascular toxin. [11] [12] [13]

Previous Studies of Dis-proportionality with COVID Vaccines : In previous studies significant dis-proportionality has been found when comparing COVID vaccines with flu vaccines using data from the VAERS database for 2021 [14] . The vaccines were compared using cardiovascular symptoms. In a second study, COVID vaccines were compared with Flu vaccines using data from the World Health Organisation. Once again the vaccines were compared using cardiovascular symptoms, and significant dis-proportionality was found. [15]

These findings led to a third study were COVID vaccines have also been compared to flu vaccines using full range of symptom categories. World Health Organisation data was used in this study. Significant dis-proportionality was found for reproductive, cardiac and endocrine symptoms [16].

COVID vaccines have been compared with 7 other vaccines, and with common medications such as paracetamol and aspirin. The drugs were compared for the full range of symptom categories. Significant dis-proportionality was found - especially for reproductive and cardiac symptoms. [17]

CDC Analysis : The CDC itself released results of their own PRR analysis of COVID vaccines (2020-2022 compared to all non-mRNA vaccines (2009-2022) in the VAERS database. Their analysis was not published publicly, but was obtained through legal coercion using Freedom of Information. Very high dis-proportionality was found. Their analyses can be viewed here. [7]. Their spreadsheets can be viewed here [18].

Prelude to the Current Study : Since COVID vaccine have been found to be associated with serious symptoms, this suggested that other vaccines might also have serious side-effects. Consequently, all 98 vaccines in the VAERS database were compared using the symptom of mortality (death) for the period 1990 to 2022. Significant differences in mortality were found between them [19]

Current Study : In the current study, I create a dataset of PRR values for every symptom of every vaccine recorded in the VAERS database, then demonstrate the dataset by using it to determine if safety signals are generated with COVID-19 vaccines for the symptom of thrombosis.

1) **Safety Signal Definition :** A safety signal is **defined** by - PRR greate than or equal to 2, minimum number of symptom records greater than 3.
2) **Safety Signal Confirmation :** A safety signal is **confirmed** by consistency of PRR across samples, symptoms and treatments - MSC, SSC, RSC, RBC and RTC.

Due to the critical nature of the information uncovered, the data for all vaccines has been made publicly available through downloadable CSVs and an online interface (Safety Signal) enabling users to read off the symptoms for each vaccine, sorted by PRR, and read off the vaccines for each symptom, sorted by PRR.

II. Data Preparation

A. Data Source

Vaers Vax csv files and **Vaers Symptoms** csv files were downloaded from the VAERS-AWARE website [20] for all years from 1990 to 2023, and read into a Jupyter Notebook using Python. The same files can also be downloaded from the VAERS website [21]

B. Concatenation and Data Preprocessing

Vaers Vax files were concatenated into a single data file called **"datasetvax"**, with two columns – VAERS ID and VAX TYPE. Rows with duplicate VAERS IDs were removed entirely, because they represent instances where a person received two or more different vaccines at the same time. Taking multiple medicines makes it hard to attribute adverse effects to a particular medicine, so these records were removed.

Vaers Symptom files were concatenated into a single data file called **"datasetsymptoms"**, with two columns – VAERS ID and SYMPTOM1. Rows where SYMPTOM1 was null were removed.

C. Merging

The datsetvax table was merged with the datasetsymptoms table on the common field of VAERS ID, so we end up with -

1) 9020372 records
2) 2144512 unique VAERS IDs
3) 16849 unique symptoms
4) 99 unique vaccines
5) averaging 4.2 symptoms per VAERS ID

The resulting dataset lists every symptom and its associated vaccine, and the strength of the safety signal for that symptom.

D. Converting Raw Data into Safety Signals

1) **Counting :** A count of each symptom for each vaccine was obtained by creating a pivot table.
2) **Converting Counts to PRR Scores :** The symptom frequencies were then converted into PRR scores. The resulting dataset lists every vaccine as a separate column, and each row is a different symptom.
3) **Transposing :** This dataset was then transposed to generate a dataset where every symptom is a separate column, and each row is a different vaccine.

The datasets created above can be downloaded as spreadsheets and CSV files here [2]

Finally, an online interface was created that enables users to enter a vaccine, then view all its symptoms ranked by PRR. They can also enter a symptom, and see all the vaccines with that symptom ranked by PRR. The interface can be viewed here [1]

A webpage showing the python code used in this study is available online here [22]

III. Data Search

A. *PRR Magnitude (PRR)*

The Transposed Dataset was used. The symptom column for "thrombosis" was selected and sorted by PRR from high to low to show those vaccines with the highest PRR for thrombosis. The PRR scores were recorded.

B. *Multiple Sample Consistency (MSC)*

Python code was used to generate 100 random samples of COVID vaccine symptoms (each sample size = 40,000 symptoms), and these were compared to 100 random samples of FLU vaccine symptoms (each sample size = 40,000 symptoms), so they were matched exactly on size. The aim was to see if the high PRR for thrombosis following COVID19 vaccination was consistent across multiple samples.

C. *Same Symptom Consistency (SSC)*

The PRR Dataset was used. The symptoms column was filtered for "thrombosis".The PRR scores were then read from the COVID19 column and recorded. Same symptoms included -

1) "Venous thrombosis limb"
2) "Retinal vascular thrombosis
3) "Superior sagittal sinus thrombosis
4) "Cerebral venous sinus thrombosis
5) "Ophthalmic vein thrombosis
6) "Pulmonary artery thrombosis
7) "Peripheral artery thrombosis
8) "Atrial thrombosis
9) etc.

D. *Related Symptom Consistency (RSC)*

The PRR Dataset was used. The symptom column was filtered for terms related to thrombosis. The PRR scores were then read from the COVID19 column and recorded. Related terms included -

1) "embolism"
2) "infarction"
3) "occlusion"
4) "aneurysm"

Additional terms that could be used are -

1) "stroke"
2) "coagulation"
3) disorders with key word "vascular"
4) disorders with key word "arterial"
5) disorders with the key word "alveolar"
6) disorders with the key word "capillary"
7) "red blood cell agglutination"
8) "abnormal clotting factor"

E. *Related Biomarker Consistency (RBC)*

The PRR Dataset was used. The symptom column was filtered for the tests and indicators used to identify thrombosis. Each element of the clotting cascade involves specific molecules that can be tested for. The PRR scores were then read from the COVID19 column and recorded. Indicators included -

1) "d-dimer"
2) "coagulation test"

Additional terms that could be used are -

1) "fibrin"
2) "coagulation factor V"
3) "coagulation factor VII"
4) "coagulation factor VIII"
5) "coagulation factor inhibitor assay"
6) "coagulation time"
7) "duplex ultrasound"
8) "venography"
9) "vascular imaging"
10) "vascular resistance"
11) "vascular insufficiency"

F. *Related Treatment Consistency (RTC)*

The PRR Dataset was used. The symptom column was filtered for treatments used to treat thrombosis. The PRR scores were then read from the COVID19 column and recorded. Treatments included -

1) ”thrombectomy”
2) ”anticoagulant therapy”
3) ”catheters”
4) ”stents”

Additional terms that could be used are -

1) ”blood thinners”
2) ”thrombolytics”
3) ”vena cava filter”
4) ”stockings”
5) ”compression”
6) ”graft”
7) ”vascular operation”
8) ”vascular procedure complication”
9) ”shunt”

IV. Results

A. *PRR for Thrombosis*

Here are the results comparing the COVID 19 vaccine with the other 98 vaccines for the symptom of thrombosis (Fig. 1). Covid 19 vaccine has a very high PRR score of 8.76 for Thrombosis. It’s the highest out of all 99 vaccines.

VAX_TYPE	Thrombosis
COVID19	8.76
EBZR	4.60
MER	1.86
6VAX-F	1.00
UNK	0.81
HPV4	0.58
COVID19-2	0.41
FLUR4	0.39
HEPAB	0.37
ANTH	0.32
RUB	0.29
FLUX(H1N1)	0.27
FLUC3	0.24
IPV	0.21
FLUN(H1N1)	0.20
HPV9	0.19
FLUA3	0.19
HPVX	0.18
SMALLMNK	0.18
HPV2	0.18
PNC20	0.17
FLUN4	0.16
FLUA4	0.15
LYME	0.13

Fig. 1. Vaccines sorted by PRR for thrombosis

B. *Multiple Sample Consistency (MSC)*

Here are the results comparing 100 random samples for COVID vaccine with 100 random samples for FLU vaccine (each sample of size 40,000 symptoms). Fig 2 shows the results for the first 25 samples. The PRR is greater than 7 for all 100 samples.

PRR	Covid Flu
23.00	Counts = 69 | 3
11.60	Counts = 58 | 5
20.67	Counts = 62 | 3
7.88	Counts = 63 | 8
13.50	Counts = 54 | 4
7.00	Counts = 56 | 8
4.91	Counts = 54 | 11
18.67	Counts = 56 | 3
17.25	Counts = 69 | 4
12.60	Counts = 63 | 5
10.00	Counts = 50 | 5
13.50	Counts = 54 | 4
10.50	Counts = 63 | 6
12.50	Counts = 50 | 4
7.57	Counts = 53 | 7
7.50	Counts = 60 | 8
19.33	Counts = 58 | 3
11.86	Counts = 83 | 7
11.00	Counts = 55 | 5
19.33	Counts = 58 | 3
14.20	Counts = 71 | 5
10.33	Counts = 62 | 6
32.00	Counts = 64 | 2
9.50	Counts = 57 | 6
18.25	Counts = 73 | 4

Fig. 2. Multiple Sample Consistency (COVID vax vs Flu vax : Counts for symptom of thrombosis for each random sample of symptoms (n = 40,000)

These samples are drawn randomly from a dataset of 6,452,217 COVID 19 vaccination symptoms and 269,177 Flu vaccination symptoms.

C. *Same Symptom Consistency (SSC)*

There are 94 ”thrombosis” symptoms listed in the database, and COVID 19 vaccines has a high PRR (PRR greater than 2) for 89 of them. COVID 19 (bivalent) has a high PRR for 9 of them. None of the other 97 vaccines in the database have high PRR scores for more than 4 of 94 thrombosis symptoms. Most only show 1 symptom. COVID19 shows safety signals for 89 ! (See Figs 3,4,5,6,7)

COVID 19 Bivalent vaccines have a high PRR scores (PRR greater than 2) for 9 thrombosis symptoms.

SYMPTOM	COVID19
Venous thrombosis limb	43.68
Retinal vascular thrombosis	41.00
Superior sagittal sinus thrombosis	35.03
Cerebral venous sinus thrombosis	32.10
Ophthalmic vein thrombosis	26.40
Pulmonary artery thrombosis	23.48
Peripheral artery thrombosis	19.03
Atrial thrombosis	16.32
Jugular vein thrombosis	15.92
Aortic thrombosis	15.52
Transverse sinus thrombosis	15.39
Superficial vein thrombosis	14.81
Mesenteric vein thrombosis	13.13
Retinal vein thrombosis	11.60
Deep vein thrombosis	11.03
Cerebral venous thrombosis	10.69
Portal vein thrombosis	10.57
Arterial thrombosis	10.51
Vascular stent thrombosis	10.35
Cardiac ventricular thrombosis	10.22
Brachiocephalic vein thrombosis	9.95
Venous thrombosis	9.67
Thrombosis in device	9.55
Carotid artery thrombosis	9.25
Thrombosis	8.76

Fig. 3.

SYMPTOM	COVID19
Cerebral artery thrombosis	8.66
Cerebral thrombosis	8.51
Retinal artery thrombosis	8.16
Splenic vein thrombosis	7.56
Coronary artery thrombosis	7.44
Pulmonary thrombosis	7.24
Vertebral artery thrombosis	7.16
Thrombosis with thrombocytopenia syndrome	7.12
Basilar artery thrombosis	6.77
Axillary vein thrombosis	6.67
Hepatic vein thrombosis	6.57
Mesenteric artery thrombosis	6.57
Pelvic venous thrombosis	5.94
Splenic artery thrombosis	5.57
Subclavian vein thrombosis	5.57
Vena cava thrombosis	4.38
Brain stem thrombosis	3.78
Cavernous sinus thrombosis	3.58
Injection site thrombosis	2.79
Truncus coeliacus thrombosis	1.79
Postoperative thrombosis	1.19
Ophthalmic vascular thrombosis	0.80
Umbilical cord thrombosis	0.80
Arterial thrombosis limb	0.00
Iliac artery thrombosis	0.00
Intracranial venous sinus thrombosis	0.00

Fig. 4.

SYMPTOM	COVID19
Aneurysm thrombosis	inf
Application site thrombosis	inf
Arteriovenous fistula thrombosis	inf
Arteriovenous graft thrombosis	inf
Catheter site thrombosis	inf
Cerebellar artery thrombosis	inf
Coronary bypass thrombosis	inf
Deep vein thrombosis postoperative	inf
Device related thrombosis	inf
Foetal placental thrombosis	inf
Graft thrombosis	inf
Hepatic artery thrombosis	inf
Hepatic vascular thrombosis	inf
Infective thrombosis	inf
Intrapericardial thrombosis	inf
Medical device site thrombosis	inf
Ophthalmic artery thrombosis	inf
Ovarian vein thrombosis	inf
Paraneoplastic thrombosis	inf
Penile vein thrombosis	inf
Peripheral vein thrombosis	inf
Portosplenomesenteric venous thrombosis	inf
Postpartum thrombosis	inf
Postpartum venous thrombosis	inf

Fig. 5.

SYMPTOM	COVID19
Precerebral artery thrombosis	inf
Prosthetic cardiac valve thrombosis	inf
Pulmonary venous thrombosis	inf
Renal artery thrombosis	inf
Renal vascular thrombosis	inf
Renal vein thrombosis	inf
Shunt thrombosis	inf
Sigmoid sinus thrombosis	inf
Spinal artery thrombosis	inf
Splenic thrombosis	inf
Subclavian artery thrombosis	inf
Thrombosis corpora cavernosa	inf
Thrombosis mesenteric vessel	inf
Thrombosis prophylaxis	inf
Tumour thrombosis	inf
Vaccination site thrombosis	inf
Vascular access site thrombosis	inf
Vascular graft thrombosis	inf
Venous thrombosis in pregnancy	inf
Visceral venous thrombosis	inf

Fig. 6.

SYMPTOM	COVID19	COVID19-2
Ophthalmic vascular thrombosis	0.80	37.71
Postoperative thrombosis	1.19	25.14
Umbilical cord thrombosis	0.80	9.43
Truncus coeliacus thrombosis	1.79	7.54
Vena cava thrombosis	4.38	3.77
Brain stem thrombosis	3.78	3.77
Cardiac ventricular thrombosis	10.22	2.94
Cerebral artery thrombosis	8.66	2.57
Mesenteric artery thrombosis	6.57	2.22

Fig. 7.

D. Related Symptom Consistency (RSC)

There are 39 ”infarction” symptoms listed in the database, and COVID 19 vaccines have a high PRR (PRR greater than 2) for 35 of them. COVID19-2 (bivalent) is next highest with 4 of 39 infarction symptoms where PRR greater than 2 (Fig. 8). None of the other 97 vaccines in the database have high PRR scores for more than 3 of 39 infarction symptoms.

SYMPTOM	COVID19	COVID19-2
Embolic cerebral infarction	19.50	0.00
Thrombotic cerebral infarction	16.32	0.00
Pulmonary infarction	13.20	0.69
Haemorrhagic cerebral infarctior	11.14	0.00
Thalamic infarction	10.35	0.94
Splenic infarction	9.69	1.01
Ischaemic cerebral infarction	8.64	0.33
Cerebellar infarction	8.56	0.34
Haemorrhagic infarction	8.36	0.00
Basal ganglia infarction	8.23	1.18
Brain stem infarction	7.86	0.00
Cerebral infarction	6.64	0.38
Lacunar infarction	5.97	1.60
Acute myocardial infarction	4.51	4.71
Myocardial infarction	4.21	0.58
Infarction	3.72	0.52
Bone infarction	2.79	0.00
Embolic cerebellar infarction	2.79	0.00
Spinal cord infarction	2.32	0.00
Omental infarction	2.26	8.38
Retinal infarction	1.72	5.03
Optic nerve infarction	1.49	0.00
Postinfarction angina	0.80	37.71
Haemorrhagic cerebellar infarcti	0.00	0.00

Fig. 8.

There are 49 ”occlusion” symptoms listed in the database, and COVID 19 vaccines has a high PRR (PRR greater than 2) for 41 of them (Fig. 9). COVID 19-2 bivalent has a high PRR for 10 of them. No other vaccine in the database has a high PRR score for more than 2 of 49 occlusion symptoms. The bivalent has high PRR for intestines (mesenteric), brain (cerebral and cerebellum), spine and retina. It causes a particularly high incidence of occlusions in the mesenteric arteries that feed the intestines, and in the cerebral arteries.

E. Related Treatment Consistency (RTC)

There are 42 ”catheter” treatments listed in the database, and COVID 19 vaccines has a high PRR (PRR greater than 2) for 25 of them (Fig.14). COVID 19-2 bivalent has a high PRR for 11 of them. No other vaccine in the database has a high PRR score for more than 4 of 42 catheter treatments.

In addition to this, COVID 19 monovalent and bivalent vaccines have the highest PRR scores for arterial and vascular catheterisation out of all 99 vaccines in the VAERS database (Fig. 15)

There are 26 ”stent” treatments listed in the database, and COVID 19 vaccines has a high PRR (PRR greater than 2) for 20 of them (Fig. 16). COVID 19-2 bivalent has a high PRR

SYMPTOM	COVID19	COVID19-2
Peripheral artery occlusion	13.80	0.00
Retinal vein occlusion	11.13	0.69
Venous occlusion	9.75	0.75
Aortic occlusion	7.96	0.00
Retinal artery occlusion	6.46	1.42
Peripheral vein occlusion	5.57	2.60
Malocclusion	4.78	0.00
Coronary artery occlusion	4.66	2.03
Basilar artery occlusion	4.58	0.00
Device occlusion	3.98	3.59
Vascular graft occlusion	3.98	7.54
Carotid artery occlusion	3.92	2.77
Retinal vascular occlusion	3.64	2.19
Jugular vein occlusion	3.58	0.00
Mesenteric arterial occlusion	3.58	8.38
Cerebral artery occlusion	3.47	6.31
Subclavian vein occlusion	2.79	0.00
Cerebellar artery occlusion	2.59	5.39
Vascular occlusion	2.08	0.88
Vertebral artery occlusion	1.93	3.87
Cerebral vascular occlusion	1.19	0.00
Renal artery occlusion	1.19	0.00
Arteriovenous fistula occlusion	0.40	0.00
Reocclusion	0.40	0.00
Shunt occlusion	0.40	0.00
Superior vena cava occlusion	0.20	0.00

Fig. 9.

SYMPTOM	COVID19	COVID19-2
Jugular vein embolism	inf	0.00
Paradoxical embolism	inf	0.00
Portal vein embolism	inf	0.00
Post procedural pulmonary embc	inf	0.00
Renal embolism	inf	0.00
Septic cerebral embolism	inf	0.00
Spinal artery embolism	inf	0.00
Splenic embolism	inf	0.00
Subclavian artery embolism	inf	0.00
Vena cava embolism	inf	0.00
Peripheral embolism	42.19	0.00
Microembolism	15.13	0.00
Embolism	12.98	0.30
Pulmonary embolism	12.36	0.91
Retinal artery embolism	8.76	0.00
Embolism arterial	7.96	2.79
Embolism venous	5.49	0.51
Coronary artery embolism	4.78	0.00
Cerebral artery embolism	4.60	1.36
Femoral artery embolism	3.58	0.00
Septic pulmonary embolism	2.79	10.77
Cerebellar embolism	1.99	0.00
Mesenteric artery embolism	1.99	0.00
Iliac artery embolism	1.19	0.00
Air embolism	0.80	0.00
Renal vein embolism	0.00	0.00

Fig. 10.

SYMPTOM	COVID19	COVID19-2
Ophthalmic artery aneurysm	inf	0.00
Peripheral artery aneurysm	inf	0.00
Peripheral artery aneurysm rupture	inf	0.00
Pulmonary artery aneurysm	inf	0.00
Renal aneurysm	inf	0.00
Retinal aneurysm rupture	inf	0.00
Subclavian artery aneurysm	inf	0.00
Vascular pseudoaneurysm	inf	0.00
Vascular pseudoaneurysm ruptured	inf	0.00
Venous aneurysm	inf	0.00
Aortic aneurysm rupture	9.15	0.00
Aneurysm ruptured	6.87	0.00
Ruptured cerebral aneurysm	5.73	0.00
Cerebral endovascular aneurysm repair	4.78	6.28
Carotid artery aneurysm	4.38	3.28
Splenic artery aneurysm	3.98	7.54
Cardiac aneurysm	3.98	0.00
Aortic aneurysm	3.67	2.78
Retinal aneurysm	3.58	0.00
Aneurysm	2.69	1.24
Intracranial aneurysm	2.52	1.75
Vertebral artery aneurysm	2.39	12.57
Aortic aneurysm repair	2.19	6.28
Mesenteric artery aneurysm	1.19	0.00
Coronary artery aneurysm	0.71	3.14
Carotid aneurysm rupture	0.20	0.00

Fig. 11.

VAX_TYPE	Anticoagulant therapy
PNC15	6.89
COVID19-2	5.03
COVID19	3.72
FLUA4	1.62
RSV	1.39
PNC20	1.39
UNK	1.38
FLUC4	0.38
FLU4	0.36
YF	0.31
FLUX	0.25
FLUX(H1N1)	0.25
PNC13	0.21
TYP	0.19
VARZOS	0.15
HEPAB	0.15
RAB	0.12
HPV9	0.12
HPV2	0.08
PPV	0.07
FLU3	0.06
HPV4	0.03
TDAP	0.03
DTP	0.00

Fig. 12.

VAX_TYPE	Thrombectomy
RSV	13.54
COVID19	5.23
COVID19-2	3.30
DTP	2.51
FLUN3	1.43
FLUC4	1.23
UNK	1.15
HPV2	0.79
HPV4	0.45
ADEN_4_7	0.00
PNC20	0.00
FLUA4	0.00
HPV9	0.00
RV5	0.00
SMALL	0.00
PNC13	0.00
FLU4	0.00
ANTH	0.00
MENB	0.00
DTAP	0.00
HEP	0.00
PPV	0.00
TDAP	0.00
FLUX	0.00

Fig. 13.

SYMPTOM	COVID19	COVID19-2
Arterial catheterisation	9.35	1.57
Catheter directed thrombolysis	8.36	3.59
Catheterisation cardiac	6.41	0.65
Vascular catheterisation	6.37	4.71
Catheter removal	4.78	6.28
Transcatheter aortic valve implantation	4.38	6.86
Catheterisation cardiac abnormal	3.15	2.93
Biliary catheter insertion	2.79	0.00
Catheterisation cardiac normal	2.14	2.02
Bladder catheter replacement	1.59	18.85
Catheter site pain	1.59	0.00
Central venous catheterisation	1.48	3.21
Arterial catheterisation normal	1.19	0.00
Bladder catheter removal	1.19	10.77
Catheter site haemorrhage	1.06	0.00
Bladder catheterisation	1.03	2.92
Catheter placement	0.86	0.99
Bladder catheter permanent	0.80	0.00
Bladder catheter temporary	0.80	0.00
Catheter culture positive	0.40	0.00
Catheter site discharge	0.40	0.00
Swan ganz catheter placement	0.40	0.00
Ureteral catheterisation	0.40	0.00
Catheter site erythema	0.20	0.00
Catheter site phlebitis	0.00	0.00
Condom catheter placement	0.00	inf

Fig. 14.

VAX_TYPE	Arterial catheterisation
COVID19	9.35
COVID19-2	1.57
HEP	1.18
PNC15	0.00
FLUA4	0.00
RSV	0.00
PNC20	0.00

VAX_TYPE	Vascular catheterisation
COVID19	6.37
COVID19-2	4.71
HEP	0.00
PNC15	0.00
FLUA4	0.00
RSV	0.00
PNC20	0.00

Fig. 15.

for 8 of them. No other vaccine in the database has a high PRR score for more than 2 of stent treatments.

SYMPTOM	COVID19	COVID19-2
Carotid artery stent insertion	inf	0.00
Coronary artery stent removal	inf	0.00
Intestinal stent insertion	inf	0.00
Mesenteric artery stent insertion	inf	0.00
Peripheral artery stent insertion	inf	0.00
Renal artery stent placement	inf	0.00
Renal artery stent removal	inf	0.00
Stent malfunction	inf	0.00
Stent-graft endoleak	inf	0.00
Tracheobronchial stent insertion	inf	0.00
Ureteral stent removal	inf	0.00
Vascular stent occlusion	inf	0.00
Vascular stent thrombosis	10.35	0.00
Ureteral stent insertion	5.31	1.80
Vascular stent stenosis	5.17	5.80
Arterial stent insertion	4.98	2.90
Stent placement	4.43	1.01
Bile duct stent insertion	2.99	4.71
Coronary arterial stent insertion	2.91	3.57
Venous stent insertion	2.79	10.77
Aortic stent insertion	1.59	0.00
Cerebral artery stent insertion	1.59	18.85
Stent removal	1.59	18.85
Vascular stent insertion	1.59	0.00
Pancreatic stent placement	0.80	37.71
Brain stent insertion	0.40	0.00

Fig. 16.

In addition to this, COVID 19 and COVID 19-2 bivalent have the highest PRR scores for arterial stent insertion and venous stent insertion (Fig. 17).

VAX_TYPE	Arterial stent insertion
HPVX	35.31
COVID19	4.98
COVID19-2	2.90
HEP	0.00
PNC15	0.00
FLUA4	0.00

VAX_TYPE	Venous stent insertion
COVID19-2	10.77
COVID19	2.79
HPVX	0.00
HEP	0.00
PNC15	0.00
FLUA4	0.00
RSV	0.00

Fig. 17.

V. Summary

This pilot study provides a publicly accessible dataset where safety signals for any vaccine can be checked. Safety signals are defined by the magnitude of the PRR, and by consistency of the PRR across multiple samples, related symptoms, indicators and treatments.

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