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]

1 Introduction

1.1 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.*
>
> **Wikipedia, (2023), "Proportional Reporting Ratio"** [4]

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

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

Figure 1: PRR formula

1.2 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]

1.3 What Criteria Define a Strong Signal ?

1.3.1 CDC Criteria :

The CDC uses the following criteria –

1. Symptom events >= 3
2. PRR >= 2
3. Chi-squared >= 4 OR
4. Lower limit of 95% confidence interval of PRR >= 2

Ref : [7] Excel spread sheets released by CDC through Freedom of Information request

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 >= 10 resulted in greater consistency across different methods for detecting safety signals.

1.3.2 PRR >= 2

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 >= 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]

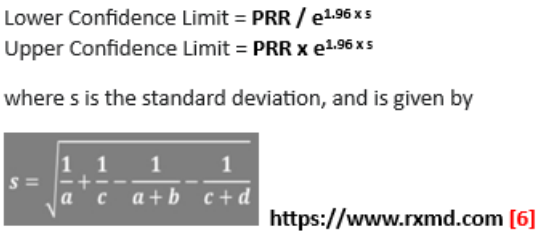

Figure 2: Confidence limits for PRR

1.4 What Criteria Confirm a Strong Signal ?

1.4.1 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.

1.4.2 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.

1.4.3 Same Symptom Consistency (SSC) :

This is where different forms of the same symptom are consistently reported with a high PRR. The table below shows 25 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 (> 2) across 43 different symptoms of thrombosis.

In addition to this, COVID 19 vaccines have an INF score across 46 additional symptoms (shown on the next page). 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 (>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.

1.4.4 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.

1.4.5 Related Biomarker Consistency (RBC)

In addition, any particular illness or condition is evidenced by several biomarkers 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.

1.4.6 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.

1.5 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 of Dis-proportionality with COVID Vaccines : 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] and here [**?**]

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.

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 >= 2, minimum number of symptom records > 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.

2 Data Preparation

2.1 Data Source

Vaers Vax csv files and **Vaers Symptoms** csv files were downloaded from the VAERS-AWARE website [19] 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 [20]

2.2 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.

2.3 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.

2.4 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 [21]

3 Data Search

3.1 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.

3.2 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.

3.3 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.

3.4 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”
5. ”haemorrhage”
6. ”bleeding”
7. ”ischaemia”
8. ”haematoma”
9. ”stroke”
10. ”arteriosclerosis”
11. ”phlebitis”

Additional terms that could be used are -

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

3.5 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”

3.6 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”

4 Results

The VAERS data for COVID 19 monovalent vaccines, shows that there are 483 adverse symptoms that qualify as safety signals. These symptoms fall into general categories. Here are the number of safety signals for each of the top 3 categories -

Vascular Disorders	164
Cardiac Disorders	85
Infections	28

This shows that cardio-vascular damage defines the nature of the largest group of safety signals associated with COVID monovalent vaccines– accounting for about 50% of all the safety signals.

In the following pages you will see that COVID 19 monovalent vaccines are associated with safety signals for every form of vascular disease including thrombosis, infarctions, embolisms, aneurysms, occlusions, strokes, haematomas, ischaemias, bleeding haemorrhages and arteriosclerosis.

In fact, out of all 99 vaccines in the VAERS database, COVID 19 monovalent vaccines have the highest LCI (lower confidence limit of the PRR) for each of these symptoms.

4.1 PRR for Thrombosis

Here are the results comparing the COVID 19 vaccine with the other 98 vaccines for the symptom of "thrombosis" (as a single word). Covid 19 vaccine has a very high PRR score of 8.76 for Thrombosis. It is the only vaccine where the lower confidence limit (LCI) exceeds 2.

VAX_TYPE	PRR	LCI
COVID19	8.76105081	7.96799892
EBZR	4.602034548	0.651511966
MER	1.862205966	0.26282777
6VAX-F	0.999910757	0.140989555
UNK	0.809453261	0.62399788
HPV4	0.577844959	0.476370055
COVID19-2	0.406311707	0.311744976
FLUR4	0.388896871	0.125435651
HEPAB	0.367340078	0.175104015
ANTH	0.324572566	0.179709134
RUB	0.287159812	0.040457975
FLUX(H1N1)	0.267369026	0.086231048
FLUC3	0.236704065	0.033347384
IPV	0.209187694	0.052317596
FLUN(H1N1)	0.201686561	0.050441273
HPV9	0.192423651	0.100098184
FLUA3	0.191370325	0.04786082
HPVX	0.178919365	0.044746455
SMALLMNK	0.178164003	0.025098494
HPV2	0.175442996	0.078806372
PNC20	0.167236878	0.02355887
FLUN4	0.160282063	0.04008481
FLUA4	0.146550403	0.020644264
LYME	0.132478325	0.03313067
FLUX	0.132026433	0.080854993
MEN	0.128506388	0.018102076

Figure 3: Vaccines sorted by PRR for thrombosis

4.2 Multiple Sample Consistency (MSC)

Here are the results comparing 100 random samples for COVID vaccine with 100 random samples for FLU vaccine (each sampl of size 40,000 symptoms). The figure below exhibits the results for the first 25 samples. The PRR > 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

Figure 4: 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.

4.3 Same Symptom Consistency (SSC)

There are 94 "thrombosis" symptoms listed in the database, and COVID 19 vaccines generate a safety signal for 32 of them, where PRR >= 2 and lower confidence limit (LCI) >=2.

SYMPTOM	PRR	LCI
Venous thrombosis limb	43.68344	21.77704
Cerebral venous sinus thrombosis	32.09543	17.70948
Deep vein thrombosis	11.03028	9.841463
Superficial vein thrombosis	14.81228	8.711423
Ophthalmic vein thrombosis	26.40244	8.44313
Thrombosis	8.761051	7.967999
Peripheral artery thrombosis	19.02568	7.846996
Venous thrombosis	9.668733	6.428007
Cerebral venous thrombosis	10.68549	6.142614
Jugular vein thrombosis	15.92107	5.903055
Cerebral thrombosis	8.509538	5.863888
Mesenteric vein thrombosis	13.13488	5.830326
Portal vein thrombosis	10.5658	5.787114
Retinal vascular thrombosis	40.99676	5.720189
Pulmonary thrombosis	7.244087	5.521997
Retinal vein thrombosis	11.59964	5.460618
Transverse sinus thrombosis	15.39037	4.891978
Superior sagittal sinus thrombosis	35.02635	4.879274
Arterial thrombosis	10.50791	4.302274
Coronary artery thrombosis	7.4431	3.939785
Aortic thrombosis	15.52304	3.814239
Thrombosis with thrombocytope	7.120256	3.638601
Carotid artery thrombosis	9.254122	3.401501
Pelvic venous thrombosis	5.937232	3.309456
Pulmonary artery thrombosis	23.48358	3.253598
Cardiac ventricular thrombosis	10.21602	3.223661

Figure 5: Same Symptom Consistency (COVID monovalent : thrombosis)

In comparison to COVID 19 monovalent, other vaccines have a safety signal for only one or two symptoms of thrombosis.

1. **COVID 19 (bivalent)** generates a safety signal for only 2 of these symptoms, where lower confidence limit >= 2.

SYMPTOM	COVID19-2	COVID19-22
Ophthalmic vascular thrombosis	37.70572639	3.418900119
Postoperative thrombosis	25.13715092	2.614678376

Figure 4: COVID bivalent : thrombosis

2. **DTAPIPV vaccine** has a high PRR and LCI for injection site thrombosis (LCI = 6.71) only.
3. **FLUN(H1N1)**, the Swine Flu vaccine, has a strong safety signal for Cavernous Sinus Thrombosis (LCI = 7) only.
4. **HEP vaccines** are associated with injection site thrombosis (LCI = 2.1) and with arterial limb thrombosis. Arterial limb thrombosis is much higher for HEPAB (LCI = 15) compared to HEP A (LCI = 6.69).
5. **HPV2 vaccine** is associated with brainstem thrombosis (LCI = 2) only
6. **HPV4 vaccine** is associated with Intercranial venous sinus thrombosis (LCI = 28.9) only. [suggesting that HPV vaccines affect the brain]
7. **Meningitis vaccines (MEN)** are associated with hepatic vein thrombosis only (LCI = 5.39)
8. **Pneumonia vaccine (PNC13)** is associated with Intercranial venous sinus thrombosis only (LCI = 2.47)
9. **TDAP** is associated with umbilical cord thrombosis only (LCI = 5.94)

So, all the vaccines except COVID monovalent, have only 1 or 2 safety signals for thrombosis that are significant at the 5%level. COVID monovalent has 32 signals that are significant !

4.4 PRR for Infarction

There are 39 ”infarction” symptoms listed in the database, and COVID 19 monovalent vaccines generate safety signals for 14 of these symptoms (LCI >= 2). 8 of these infarction symptoms are cerebral - causing significant brain damage, cognitive deficit and ”brain fog”.

SYMPTOM	PRR	LCI
Embolic cerebral infarction	19.503311	2.693080723
Thrombotic cerebral infarction	16.319097	2.244713958
Pulmonary infarction	13.1961178	7.600249323
Haemorrhagic cerebral infarction	11.1447492	1.516304349
Thalamic infarction	10.3486956	4.578871093
Splenic infarction	9.68531772	4.280926641
Ischaemic cerebral infarction	8.6371806	4.582070772
Cerebellar infarction	8.55757525	4.539250124
Haemorrhagic infarction	8.35856187	1.124302621
Basal ganglia infarction	8.22588629	2.582159969
Brain stem infarction	7.86102843	3.863708514
Cerebral infarction	6.64104916	5.619682678
Lacunar infarction	5.97040134	3.328283954
Acute myocardial infarction	4.50679114	3.964169684
Myocardial infarction	4.2085862	3.822881704
Infarction	3.72439321	2.522400708

Figure 5: Related Symptom Consistency (COVID monovalent : infarctions)

COVID 19 monovalent vaccines have the **highest LCI** for ”infarction” compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term ”Infarction”

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	2.5224007083448314
PNC13	0.5316210738764172
TTOX	0.4869591919022633
DTP	0.465250118878941
FLUN4	0.3994817974910356
FLUX	0.2833816274189712
HEPAB	0.2614491780813454
SMALL	0.2605596772395959
RV5	0.1412235021216178
FLU4	0.1344344720989727

Figure 6: Related Symptom Consistency (All vaccines : ”infarction”)

Besides COVID 19 monovalent vaccines, only three other vaccines have symptoms for infarction that are significant at the 5% level. These are COVID bivalent, HEPAB and HPV2

1. **COVID bivalent** has a safety signal for 2 symptoms - acute myocardial infarction (LCI = 4.05) and post-infarction angina (LCI = 3.41)
2. **HEPAB** has a safety signal for haemorrhagic cerebral infarction only (LCI = 2.61)
3. **HPV2 vaccine** has a safety signal for optic nerve infarction only (LCI = 2.22).

So, there appears to be some consistency, with COVID bivalent, HEPAB and HPV2 having safety signals for both thrombosis and for infarction. COVID monovalent remains the highest risk, with 14 safety signals for infarctions!

4.5 PRR for Embolisms

. There are 32 ”embolism” symptoms listed in the database, and COVID 19 monovalent vaccine generates a safety signal for 7 of them.

SYMPTOM	PRR	LCI
Peripheral embolism	42.19083611	5.888375
Microembolism	15.12501672	2.076593
Embolism	12.97567224	7.762506
Pulmonary embolism	12.35621895	11.20169
Retinal artery embolism	8.756588627	1.180286
Embolism arterial	7.960535115	2.916243
Embolism venous	5.49276923	2.890888
Coronary artery embolism	4.776321069	0.621039
Cerebral artery embolism	4.599420289	2.327782

Figure 7: Related Symptom Consistency (COVID monovalent : embolisms)

COVID 19 monovalent vaccines have the **highest LCI** for ”embolism” compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term ”embolism”

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	7.76250638183344
FLUN(H1N1)	0.289237522041059
TYP	0.1992864107598517
HEPAB	0.1504329109448139
SMALL	0.1499211089662782
UNK	0.1440155180625095
FLU3	0.0972332967298484
COVID19-2	0.0749323725245225
HEP	0.0561901219759421
HPV4	0.0157761423434675

Figure 8: Related Symptom Consistency (All vaccines : ”embolism”)

Besides COVID 19 monovalent vaccines, only three other vaccines have symptoms for embolism that are significant at the 5% level. These are HEPAB, HPVX and FLUX

1. **HEPAB** has a safety signal for cerebellar embolism only (LCI = 12.57)
2. **HPVX vaccine** has a safety signal for venous embolism only (LCI = 6.05)
3. **FLUX vaccine** has a safety signal for air embolism only (LCI = 3.83)

So, there appears to be some consistency, with HEPAB and HPV having safety signals for thrombosis, infarction and for embolism. COVID monovalent remains the highest risk, with 7 safety signals for embolism !

4.6 PRR for Stroke

. There are 18 "stroke" symptoms listed in the database, and COVID 19 monovalent vaccines generate a safety signal for 7 of them (LCI >= 2).

SYMPTOM	PRR	LCI
Thrombotic stroke	22.2895	3.085437937
Haemorrhagic transformation stroke	15.92107	2.188672446
Ischaemic stroke	7.731164	6.425317684
Brain stem stroke	6.865962	2.505708413
Embolic stroke	5.731585	3.642837303
Haemorrhagic stroke	5.58968	3.661729795
Cerebellar stroke	3.953732	2.325022277
Spinal stroke	3.582241	0.453830104
Lacunar stroke	2.945398	1.846518783
CHA2DS2-VASc annual stroke risk high	1.592107	0.177943743
Basal ganglia stroke	1.552304	0.774918669
Thalamic stroke	1.353291	0.499272257
Post procedural stroke	0.398027	0.024894852

Figure 9: Related Symptom Consistency (COVID monovalent : stroke)

There are two types of stroke - ischaemic stroke and haemorrhagic stroke. COVID 19 monovalent vaccines have the **highest LCI** for both of these symptoms compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular terms "ischaemic stroke" and "haemorrhagic stroke"

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	6.42531768379675
COVID19-2	1.6049975682018476
FLUA3	0.2038553308106283
VARZOS	0.1432645301018799
UNK	0.1253058916120519
MEN	0.0770882864145735
YF	0.0674560837263677
PNC13	0.0637182391964651
FLUX(H1N1)	0.0534502561562702
FLUN3	0.0319525840253665

Figure 10: Related Symptom Consistency (All vaccines : "ischaemic stroke")

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	3.661729795127352
UNK	0.4068333854333099
FLUA3	0.399771293399837
VARZOS	0.2311669593866537
PNC13	0.2297183774894627
COVID19-2	0.2116780129467143
MENB	0.112452230829477
DTAP	0.098041893396788
FLU3	0.0912566172243677
FLUX	0.0344249000048456

Figure 11: Related Symptom Consistency (All vaccines : "haemorrhagic stroke")

1. **COVID bivalent** has a safety signal for 5 symptoms including basal ganglia stroke (LCI = 2.41), haemorrhagic stroke (LCI = 2.49), thalamic stroke (8.18), CHA2DS2-VASc annual stroke risk high (LCI = 2.1) and NIH stroke scale score increased (LCI = 4.7)
2. **FLU3** has a safety signal for post-procedural stroke only (LCI = 2.03)
3. **FLUA3** has a safety signal for cerebellar stroke only (LCI = 3.0)
4. **HPVX** has a safety signal for basal ganglia stroke only (LCI = 9.4)

4.7 PRR for Haemorrhage

. COVID monovalent vaccines generate safety signals for 18 symptoms of haemorrhage (LCI >= 2).

SYMPTOM	PRR	LCI
Postmenopausal haemorrhage	61.954395	42.130876
Uterine haemorrhage	7.5931258	5.11876073
Vaccination site haemorrhage	5.9058565	4.23356537
Subarachnoid haemorrhage	4.6967157	3.51899312
Conjunctival haemorrhage	4.5018199	3.44177984
Cerebral haemorrhage	3.9132087	3.36255437
Vitreous haemorrhage	6.5176881	3.19220169
Vaginal haemorrhage	3.5154042	3.1696967
Brain stem haemorrhage	12.736856	3.11766008
Haemorrhage urinary tract	4.692526	2.93772752
Eye haemorrhage	3.5303243	2.91128934
Upper gastrointestinal haemorrhage	5.2105321	2.82233712
Basal ganglia haemorrhage	11.343763	2.76941072
Urinary bladder haemorrhage	10.348696	2.52068556
Cerebellar haemorrhage	6.129612	2.4808035
Vulval haemorrhage	17.513177	2.41284492
Internal haemorrhage	3.2927668	2.40825159
Genital haemorrhage	3.2339674	2.11641273
Gastric haemorrhage	4.5773077	1.9875065
Haemorrhage in pregnancy	3.0847074	1.93628637
Haemorrhoidal haemorrhage	7.9605351	1.92387626
Subdural haemorrhage	4.1792809	1.80893281
Anal haemorrhage	2.9392745	1.64694152
Intraventricular haemorrhage	3.0756613	1.64129187

Figure 12: Related Symptom Consistency (COVID monovalent : haemorrhage)

COVID 19 monovalent vaccines have the **highest LCI** for ”brain stem haemorrhage” compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term ”brain stem haemorrhage”.

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	3.117660082583733
FLUX	0.1805046206595191
PPV	0.1154849002805949

Figure 13: Related Symptom Consistency (All vaccines : ”brain stem haemorrhage”)

4.8 PRR for Bleeding

. COVID monovalent vaccines generates safety signals for 13 symptoms of menstrual bleeding (LCI >= 2).

SYMPTOM	PRR	LCI
Premenstrual pain	52.14151	12.97148
Heavy menstrual bleeding	48.66383	40.60019
Intermenstrual bleeding	44.68436	31.88053
Polymenorrhoea	31.33797	21.8614
Premenstrual syndrome	20.3278	11.97781
Oligomenorrhoea	14.29911	10.44386
Menstrual discomfort	13.53291	5.561068
Menstruation delayed	11.84715	10.08448
Hypomenorrhoea	11.10052	7.561653
Menstrual cycle management	10.3487	1.404279
Dysmenorrhoea	9.67558	8.66264
Menstrual disorder	7.196782	6.49236
Menstruation irregular	6.716901	6.136435
Menstruation normal	4.51097	1.385468
Premenstrual dysphoric disorc	3.42303	1.355849
Amenorrhoea	3.40617	3.059794
Premenstrual headache	1.990134	0.436046
Menstrual headache	0.398027	0.024895
Menstrual clots	0.199013	0.018045
Menorrhagia	0.043365	0.029359

Figure 14: Related Symptom Consistency (COVID monovalent : menstrual bleeding)

COVID 19 monovalent vaccines have the **highest LCI** for "heavy menstrual bleeding" compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term "menstrual bleeding".

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	40.60019279561212
DF	0.4936069508371545
UNK	0.4835309725815476
EBZR	0.4597087641934416
COVID19-2	0.0877079615080846
HPV9	0.0811439470461163
SMALLMNK	0.0177095701916733
HPV4	0.0129545496860474
HPVX	0.0088905807834269
FLUX	0.0056252350128059

Figure 15: Related Symptom Consistency (All vaccines : "heavy menstrual bleeding")

4.9 PRR for Aneurysm

. COVID 19 monovalent vaccines generate a safety signal for 4 symptoms of aneurysm (LCI >= 2).

SYMPTOM	PRR	LCI
Aortic aneurysm rupture	9.1546154	2.22225239
Aneurysm ruptured	6.8659615	2.50570841
Ruptured cerebral aneurysm	5.7315853	2.31527877
Cerebral endovascular aneurysm repair	4.7763211	0.62103889
Carotid artery aneurysm	4.3782943	1.02953167
Cardiac aneurysm	3.9802676	1.42406775
Splenic artery aneurysm	3.9802676	0.50950491
Aortic aneurysm	3.6727014	2.36551416
Retinal aneurysm	3.5822408	0.4538301
Aneurysm	2.6866806	1.74999496
Intracranial aneurysm	2.5208361	1.71520389
Vertebral artery aneurysm	2.3881605	0.28750413
Aortic aneurysm repair	2.1891472	0.48522079
Mesenteric artery aneurysm	1.1940803	0.1242032
Coronary artery aneurysm	0.7076031	0.31269178
Carotid aneurysm rupture	0.1990134	0.01804507

Figure 16: Related Symptom Consistency (COVID monovalent : aneurysm)

COVID 19 monovalent vaccines have the **highest LCI** for ”aneurysm” compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term ”aneurysm”.

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	1.7499949624077962
DTAP	0.6497312666109415
DTAPIPV	0.5951285509900395
PNC	0.4367601218395199
COVID19-2	0.3950493675286447
FLU3	0.3693400501733465
RV1	0.3276805924782505
FLU(H1N1)	0.2239520440558244
HEPA	0.1813667825901106
PNC13	0.1201387973398535

Figure 17: Related Symptom Consistency (All vaccines : ”aneurysm”)

4.10 PRR for Arteriosclerosis

. There are 10 "arteriosclerosis" symptoms listed in the database, and COVID 19 monovalent vaccines generate a safety signal for 4 of them (LCI >= 2).

SYMPTOM	PRR	LCI
Aortic arteriosclerosis	7.960535	4.560661
Arteriosclerosis	2.82599	2.10181
Arteriosclerosis coronary artery	6.368428	3.636487
Carotid arteriosclerosis	11.01207	3.480296
Cerebral arteriosclerosis	4.908997	1.513587
Iliac artery arteriosclerosis	inf	
Mesenteric arteriosclerosis	inf	
Renal arteriosclerosis	inf	
Renal artery arteriosclerosis	0.796054	0.07218
Vertebral artery arteriosclerosis	inf	

Figure 18: Related Symptom Consistency (COVID monovalent : arteriosclerosis)

COVID 19 monovalent vaccines have the **highest LCI** for "arteriosclerosis" compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term "arteriosclerosis".

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	2.1018104286546557
LYME	0.8407786980888983
COVID19-2	0.7547083775695479
FLUX	0.5678254798067737
HEP	0.4710906289034329
FLU(H1N1)	0.3657455404994079
FLUA3	0.3415303199295558
PPV	0.279926564103761
FLU3	0.270833168151906
SMALL	0.1865702031888377

Figure 19: Related Symptom Consistency (All vaccines : "arteriosclerosis")

COVID 19-2 bivalent generates a safety signal for 1 of them - renal artery arterioslerosis only (LCI = 3.41) . No other vaccine in the database generates a safety signal for arteriosclerosis

4.11 PRR for Ischaemia

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There are 40 "ischaemic" symptoms listed in the database, and COVID 19 monovalent vaccines generate a safety signal for 8 of them (LCI >= 2).

SYMPTOM	PRR	LCI
Peripheral ischaemia	9.552642	4.903816635
Cerebellar ischaemia	9.154615	1.23627562
Ischaemic cerebral infarction	8.637181	4.582070772
Colitis ischaemic	8.048986	4.121657367
Ischaemic stroke	7.731164	6.425317684
Ischaemic cardiomyopathy	7.695184	2.411122273
Intestinal ischaemia	7.164482	3.789927106
Ischaemic hepatitis	4.875828	1.759580675
Spinal cord ischaemia	4.577308	1.079157386
Ischaemic limb pain	4.378294	0.56524642
Ischaemia	3.980268	2.767538215
Renal ischaemia	3.980268	0.509504909
Transient ischaemic attack	3.980268	3.518613112
Ocular ischaemic syndrome	3.582241	0.453830104
Optic ischaemic neuropathy	2.798626	1.932528007
Reversible ischaemic neurological deficit	2.487667	0.865761426
Cerebral small vessel ischaemic disease	2.447127	1.629371536
Retinal ischaemia	2.255485	0.946924061
Myocardial ischaemia	2.015325	1.583238159
Subendocardial ischaemia	1.990134	0.232498832
Cerebral ischaemia	1.959119	1.533411211
Brain stem ischaemia	1.691614	0.569198977
Hypoxic-ischaemic encephalopathy	1.094574	0.686032985
Necrosis ischaemic	0.530702	0.118774564
Gastrointestinal ischaemia	0.398027	0.024894852

Figure 20: Related Symptom Consistency (COVID vax : ischaemia)

COVID 19 monovalent vaccines have the **highest LCI** for ”ischaemia” compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term ”ischaemia”.

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	2.76753821531799
FLUX	0.8118015892042142
RV1	0.6158696836257412
YF	0.4618656878827125
COVID19-2	0.3235025359860619
LYME	0.2720198780710751
FLU3	0.2515361662609795
PNC13	0.2257958980234841
SMALL	0.2146632331827159
FLU(H1N1)	0.118332884005833

Figure 21: Related Symptom Consistency (All vaccines : ”ischaemia”)

Besides COVID 19 monovalent vaccines, other vaccines have symptoms for ischaemia that are significant at the 5% level. These are COVID Bivalent and RV1 with 3 symptoms each; DTP, DTPIPV, FLUA3, HIBV, JEV, LYME, MEN, TBE

1. **COVID bivalent** has a safety signal for myocardial ischaemia (LCI = 4.21), reversible ischaemic neurological deficit (LCI = 2.21), and transient ischaemic attack (LCI = 2.25). The strongest effect is myocardial ischaemia, which is consistent with the cardiovascular effects associated with COVID vaccines.

2. **RV1** has a safety signal for retinal ischaemia (LCI = 2.21), gastro-intestinal ischaemia (LCI = 27), and ischemic necrosis (LCI = 33.57). The strongest effect here is intestinal ischaemia.

3. **DTP** has a safety signal for Hypoxic-ischaemic encephalopathy (LCI = 5.36) and for Ischaemic necrosis (LCI = 19.21)

4. **DTPIPV** has a safety signal for Hypoxic-ischaemic encephalopathy (LCI = 56.02)

5. **FLUA3** has safety signals for ischaemic cardiomyopathy (LCI = 2.26) and brain stem ischaemia (LCI = 6.58)

6. **HIBV** has a safety signal for Hypoxic-ischaemic encephalopathy (LCI = 4.86)

7. **JEV** has a safety signal for cerebral ischaemia (LCI = 2.79)

8. **LYME** has a safety signal for cerebral ischaemia (LCI = 2.24)

9. **MEN** has a safety signal for retinal ischaemia (LCI = 4.64)

10. **TBE** has a safety signal for myocardial ischaemia (LCI = 11.69)

4.12 PRR for Haematoma

. COVID monovalent vaccines generate safety signals for 4 symptoms of haematoma (LCI >= 2).

SYMPTOM	PRR	LCI
Subdural haematoma	3.900662	2.679124
Vaccination site haematoma	3.393702	2.425025
Cerebral haematoma	4.450663	2.401835
Spontaneous haematoma	4.726568	2.297102

Figure 22: Related Symptom Consistency (COVID monovalent : haematoma)

4.13 PRR for Phlebitis

. COVID monovalent vaccines generate safety signals for 4 symptoms of phlebitis (LCI >= 2).

SYMPTOM	PRR	LCI
Thrombophlebitis superficial	29.73828	14.1072
Phlebitis superficial	11.27742	3.565845
Thrombophlebitis	9.937829	6.940298
Phlebitis deep	5.174348	0.676871
Phlebitis	3.607512	2.781025
Periphlebitis	2.388161	0.287504
Papillophlebitis	0.995067	0.193051
Phlebitis infective	0.398027	0.024895
Portal vein phlebitis	0.199013	0.018045

Figure 23: Related Symptom Consistency (COVID monovalent : phlebitis)

COVID 19 monovalent vaccines have the **highest LCI** for ”phlebitis” compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term ”phlebitis”.

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	2.781024564628459
TYP	1.6939632493085284
HPVX	1.4039983377294951
DF	1.0618517322890593
PPV	0.719234565282857
HEP	0.5500919249363815
HEPAB	0.4250540186239369
SMALLMNK	0.406298550223827
PNC13	0.2425770785893736
VARCEL	0.2046484066783061

Figure 24: Related Symptom Consistency (All vaccines : ”phlebitis”)

4.14 PRR for Fibrin D Dimer

Biomarkers for thrombosis include the D-dimer test.

VAX_TYPE	PRR	LCI
COVID19-2	5.03321549	4.407369049
COVID19	3.724552044	3.340005204
UNK	1.381082434	0.990135348
PNC15	6.893029878	0.973384893
FLUA4	1.624082326	0.609413054
PNC20	1.389623358	0.448113561
FLU4	0.358228778	0.222459306
RSV	1.391798187	0.196104613
FLUX	0.251582761	0.139207051
FLUC4	0.378911881	0.122159492
VARZOS	0.147689345	0.098019135
PNC13	0.214179753	0.089096888
YF	0.311296792	0.04384269
FLUX(H1N1)	0.246669024	0.034739684
PPV	0.073045294	0.030385427
HPV9	0.118313373	0.029579087
FLU3	0.061490549	0.029294002
TYP	0.192332327	0.027086571
HEPAB	0.145186321	0.02044651
RAB	0.124095709	0.017476183
HPV2	0.08090634	0.011393701
HPV4	0.030461658	0.007615415
TDAP	0.027019262	0.003804927
6VAX-F	0	0
ADEN_4_7	0	0
ANTH	0	0

Figure 25: Related Biomarker Consistency (All vaccines : D-dimer)

COVID 19 monovalent vaccines have the **highest LCI** for "fibrin D dimer increased" compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term "fibrin D dimer increased".

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	6.405048675714032
UNK	0.7833600658862089
COVID19-2	0.7297726848185703
HEPAB	0.4034464867253254
HPVX	0.2468411966827329
FLUA4	0.2090352942070869
DF	0.1869991974827937
SMALL	0.1442240633668641
RAB	0.1236922652655843
HPV4	0.118669267426925

Figure 26: Related Symptom Consistency (All vaccines : "fibrin D dimer increased")

4.15 PRR for Anticoagulant Therapy

VAX_TYPE	PRR	LCI
COVID19-2	5.03321549	4.407369049
COVID19	3.724552044	3.340005204
UNK	1.381082434	0.990135348
PNC15	6.893029878	0.973384893
FLUA4	1.624082326	0.609413054
PNC20	1.389623358	0.448113561
FLU4	0.358228778	0.222459306
RSV	1.391798187	0.196104613
FLUX	0.251582761	0.139207051
FLUC4	0.378911881	0.122159492
VARZOS	0.147689345	0.098019135
PNC13	0.214179753	0.089096888
YF	0.311296792	0.04384269
FLUX(H1N1)	0.246669024	0.034739684
PPV	0.073045294	0.030385427
HPV9	0.118313373	0.029579087
FLU3	0.061490549	0.029294002
TYP	0.192332327	0.027086571
HEPAB	0.145186321	0.02044651
RAB	0.124095709	0.017476183
HPV2	0.08090634	0.011393701
HPV4	0.030461658	0.007615415
TDAP	0.027019262	0.003804927

Figure 27: Related Treatment Consistency (All vaccines : anticoagulant therapy)

COVID 19 monovalent vaccines have the **highest LCI** for ”anticoagulant therapy” compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term ”anticoagulant therapy”.

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19-2	4.407369049388642
COVID19	3.3400052038399752
UNK	0.9901353481308304
PNC15	0.973384892553476
FLUA4	0.6094130536436922
PNC20	0.4481135605362943
FLU4	0.2224593064598993
RSV	0.1961046131145436
FLUX	0.1392070506820427
FLUC4	0.1221594919885762

Figure 28: Related Symptom Consistency (All vaccines : ”anticoagulant therapy”)

4.16 PRR for Thrombectomy

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VAX_TYPE	PRR	LCI
RSV	13.54172147	1.90363459
COVID19	5.233314752	3.53871583
COVID19-2	3.296675531	1.998409595
DTP	2.513638168	0.353194921
FLUN3	1.4347815	0.201594225
FLUC4	1.228231427	0.172571397
UNK	1.147240659	0.368361981
HPV2	0.787191083	0.110601459
HPV4	0.446797768	0.143457766
6VAX-F	0	0
ADEN_4_7	0	0
ANTH	0	0
BCG	0	0
CEE	0	0
CHOL	0	0
DF	0	0
DPP	0	0
DT	0	0
DTAP	0	0
DTAPH	0	0
DTAPHEPBIP	0	0
DTAPIPV	0	0
DTAPIPVHIB	0	0
DTIPV	0	0
DTOX	0	0
DTPHEP	0	0

Figure 29: Related Treatment Consistency (All vaccines : thrombectomy)

COVID 19 monovalent vaccines have the **highest LCI** for "thrombectomy" compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term "thrombectomy".

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	3.5387158302822046
COVID19-2	1.998409594606402
RSV	1.9036345903830476
UNK	0.3683619813084125
DTP	0.3531949213315853
FLUN3	0.2015942248452252
FLUC4	0.1725713972379512
HPV4	0.1434577657090684
HPV2	0.1106014593704187

Figure 30: Related Symptom Consistency (All vaccines : "thrombectomy")

4.17 PRR for Catheters

. COVID monovalent has signficant high disproportionality for the use of catheters (LCI >= 2).

VAX_TYPE	PRR	LCI
Catheterisation cardiac	6.413367	4.962255
Catheterisation cardiac abnormal	3.151045	2.333804
Arterial catheterisation	9.353629	2.271988
Catheter directed thrombolysis	8.358562	2.023327
Catheterisation cardiac normal	2.144922	1.604303
Central venous catheterisation	1.477292	1.087603
Vascular catheterisation	6.368428	0.844535
Bladder catheterisation	1.027288	0.82006
Catheter removal	4.776321	0.621039
Catheter placement	0.861037	0.613729
Transcatheter aortic valve implant	4.378294	0.565246
Biliary catheter insertion	2.786187	0.342784
Bladder catheter replacement	1.592107	0.338085
Catheter site haemorrhage	1.061405	0.281582
Bladder catheter removal	1.19408	0.241
Catheter site pain	1.592107	0.177944
Arterial catheterisation normal	1.19408	0.124203
Bladder catheter permanent	0.796054	0.07218
Bladder catheter temporary	0.796054	0.07218
Catheter culture positive	0.398027	0.024895
Catheter site discharge	0.398027	0.024895
Swan ganz catheter placement	0.398027	0.024895
Ureteral catheterisation	0.398027	0.024895
Catheter site erythema	0.199013	0.018045

Figure 31: Related Treatment Consistency (COVID monovalent : catheters)

COVID 19 monovalent vaccines have the **highest LCI** for ”arterial catheterisation” compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term ”arterial catheterisation”.

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	2.2719878650703387
COVID19-2	0.2168509664813578
HEP	0.1626118641787255

Figure 32: Related Symptom Consistency (All vaccines : ”arterial catheterisation”)

4.18 PRR for Stents

. Both COVID monovalent and COVID bivalent have high disproportionality for the use of stents (LCI >= 2).

VAX_TYPE	PRR 1	LCI 1
Stent placement	4.426058	2.939576
Coronary arterial stent insertion	2.905595	2.087972
Ureteral stent insertion	5.307023	1.641741
Vascular stent thrombosis	10.3487	1.404279
Arterial stent insertion	4.975334	1.178442
Bile duct stent insertion	2.985201	0.682654
Vascular stent stenosis	5.174348	0.676871
Venous stent insertion	2.786187	0.342784
Cerebral artery stent insertion	1.592107	0.177944
Stent removal	1.592107	0.177944
Aortic stent insertion	1.592107	0.177944
Vascular stent insertion	1.592107	0.177944
Pancreatic stent placement	0.796054	0.07218
Brain stent insertion	0.398027	0.056065

Figure 33: Related Treatment Consistency (COVID monovalent : stents)

VAX_TYPE	PRR 2	LCI 2
Pancreatic stent placement	37.70573	3.4189001
Coronary arterial stent insertion	3.568365	2.1259839
Cerebral artery stent insertion	18.85286	2.1071276
Stent removal	18.85286	2.1071276
Venous stent insertion	10.77306	1.3254191
Vascular stent stenosis	5.800881	0.7588355
Bile duct stent insertion	4.713216	0.6250378
Arterial stent insertion	2.90044	0.393582
Stent placement	1.008849	0.3761728
Ureteral stent insertion	1.795511	0.2471158

Figure 34: Related Treatment Consistency (COVID bivalent : stents)

COVID 19 monovalent vaccines have the **highest LCI** for ”cerebral artery stent insertion” and for ”coronary artery stenosis” compared to all other vaccines. You can check this yourself by using Safety Signal and entering the singular term ”cerebral artery stent insertion” or ”coronary artery stenosis”

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19-2	2.107127618043306
COVID19	0.1779437428434439

Figure 35: Related Symptom Consistency (All vaccines : ”cerebral artery stent insertion”)

Vaccine	Lower Confidence Limit of Proportional Reporting Ratio
COVID19	3.297568919566692
FLUR4	1.1221163430889052
UNK	0.8463241200954622
COVID19-2	0.2266992852602195
FLUX	0.0713273987718301
FLU4	0.065610601466475
PPV	0.0456344961077383
FLU3	0.0274249413502128

Figure 36: Related Symptom Consistency (All vaccines : ”coronary artery stenosis”)

5 Summary

This pilot study provides a publicly accessible dataset where anyone can check the safety signals for any vaccine. Safety signals are defined by the magnitude of the PRR (PRR > 2) where the lower confidence interval of the PRR is also greater than or equal to 2 (LCI $>= 2$). High PRR scores are confirmed by consistency of the PRR across multiple samples, related symptoms, indicators and treatments. In the demonstration example, I find that COVID 19 vaccines show the highest disproportionality for thrombosis, and this is confirmed by elevated PRR scores for related symptoms and treatments.

COVID 19 vaccines are strongly associated with severe vascular disease characterised by occlusion of blood vessels, and weakening and rupture of blood vessel walls

Occlusion takes the form of thombosis, embolism, infarction. Occlusion leads to ischaemia and localised haematoma. Weakeneing and rupture of blood vessels leads to haemorrhages, bleeding and strokes.

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