Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 March 2021 to 31 July 2023)

Contents

About the report

- A summary is presented below of all received suspected adverse reaction reports following COVID-19 vaccination from 01 March 2021, the date when the first vaccine became available, up to **31 July 2023**.

- Seven (7) vaccines under Emergency Use Authorization (EUA) are currently being used in the vaccination program: CoronaVac, Vaxzevria (AstraZeneca), Sputnik V/ Sputnik Light, Comirnaty (Pfizer-BioNTech)/ Comirnaty Original/Omicron BA.4-5, Spikevax (Moderna), Janssen COVID-19 Vaccine, and COVID-19 Vaccine Sinopharm.

- **Data are based on VigiFlow**, the national database of adverse reactions in the Philippines. It includes reports from various epidemiology surveillance units (ESUs) of the Department of Health (DOH), vaccination sites, hospitals, patients/consumers, and EUA holders.

- Symptoms or diseases that occur after vaccination are reported if there is a *suspicion* of a possible link. However, it **cannot be assumed that there is a causal relationship between the suspected adverse reaction and the vaccine**.

- This report contains all suspected adverse reactions regardless of any possible causal relationship.

- Additional information may become available in individual case reports at any time, verification and validation may be done, which may change the assessment and figures presented.

- Adverse reaction reports are necessary for the safety assessment of the vaccines, **making sure that the benefits always outweigh the risks**.

- Reports are constantly reviewed and **monitored for the possible emergence/identification of unknown adverse reactions also known as signal**. If a signal is identified, the FDA and DOH perform investigations, regulatory actions, and timely communication.

- Due to the lifting of the state of public health emergency throughout the Philippines due to COVID-19, the report will be published quarterly until the end of the year then as needed thereafter.

FOREWORD

The Philippine FDA reminds the readers of this report that the benefits of the vaccines in preventing severe and critical disease caused by COVID-19 far outweigh any current known adverse reactions in most of the vaccinated individuals.

Relative to the mandate of the FDA, being the regulatory agency that ensures the safety of medicines including vaccines, a summary of reports is provided for transparency. Any specific part of the report should not be interpreted independently but must be concluded based on the benefits versus the risks on the use of the vaccines as described herein.

A report of adverse reaction does not necessarily mean that the vaccine caused the reaction. Causality assessment must be conducted to evaluate the relationship of the adverse reaction and vaccine administered. A **mere suspicion** may also be reported. Undiagnosed illness, underlying comorbidities, and pre-existing medical conditions can cause symptoms similar to adverse reactions. These conditions may also aggravate possible adverse reactions from vaccines. The reported numbers should not be used to determine and compare the safety of different vaccines.

Like any other vaccines, COVID-19 vaccines may cause adverse reactions in some people while others may not experience any adverse reaction. It is possible for several people to experience the same adverse event. The severity of adverse events differs from one person to another. The report may be serious for one person and non-serious for others. Most of the reported reactions are generally the same and listed in the product information and labels. Such reports are minor adverse reactions, which include body pain, chills, fatigue, fever, headache, nausea, and pain in the injection site. These usually appear on the first or second day of vaccination and may last for 2-3 days. Most people tolerate these adverse reactions while others experience greater discomfort.

Serious adverse reactions have also been reported. The FDA together with other public health partners are continuously monitoring the adverse events experienced by the vaccinees as more people are being vaccinated with COVID-19 vaccines. Such monitoring will provide reassurance that the vaccines are safe and effective for use.

Considering the post-authorization experience on the use of COVID-19 vaccines, Vaxzevria (AstraZeneca) and Janssen COVID-19 Vaccine updated their labels and included that individuals who have experienced thrombosis with thrombocytopenia syndrome (TTS) and capillary leak syndrome (CLS) are contraindicated in the use of these vaccines. In addition, special warnings and precaution for use of these vaccines were updated to include information on hypersensitivity and anaphylaxis, anxiety-related reactions, coagulation disorders, capillary leak syndrome, Guillain-Barré syndrome (GBS), and transverse myelitis.

The labels of mRNA vaccines Spikevax (Moderna) and Comirnaty (Pfizer-BioNTech) included special warnings and precautions on hypersensitivity and anaphylaxis, myocarditis and pericarditis, anxiety-related reactions, thrombocytopenia, and coagulation disorders.

The immunization program expanded its coverage to include adolescent individuals (12 to 17 years old) on the second week of October 2021. Comirnaty, Spikevax, Coronavac, and Covovax are the vaccines with EUA for the said population. Vaccination further expanded its coverage to include children ages 5-11 years last February 2022. Comirnaty, CoronaVac, and Spikevax are the vaccines approved for use in such population. However, Comirnaty is the only vaccine currently used.

Seven (7) vaccines are currently used in the immunization program. Supplies of vaccines are either procured by the government and/or private sector or supplied under the COVAX facility.

COVID-19 vaccines with Emergency Use Authorization in the Philippines

At present, the FDA granted nine (9) COVID-19 vaccines with emergency use authorization:

- Pfizer-BioNTech COVID-19 mRNA Vaccine (nucleoside modified) [Comirnaty]; Tozinameran + Famtozinameran [Comirnaty Original/Omicron BA.4-5]
- AstraZeneca COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria]
- COVID-19 Vaccine (Vero Cell), Inactivated [CoronaVac]
- Gam-COVID-Vac [Sputnik V & Sputnik Light]
- COVID-19 Vaccine (Ad26.COV2-S [recombinant]) [Janssen COVID-19 Vaccine]
- COVID-19 Vaccine (Whole Virion Inactivated Corona Virus vaccine) [Covaxin]
- Moderna COVID-19 mRNA Vaccine (nucleoside modified) [Spikevax]; Elasomeran + Imelasomeran [Spikevax Bivalent Original/Omicron BA.1]
- Inactivated COVID-19 Vaccine (Vero Cell) [COVID-19 Vaccine Sinopharm BIBP/Wuhan]
- COVID-19 Vaccine (SARS-CoV-2 rS Protein Nanoparticle [Recombinant]) [Covovax]

Various vaccine platforms have been approved for use in the Philippines. Comirnaty and Spikevax are mRNA vaccines; Vaxzevria and Janssen COVID-19 Vaccine are non-replicating viral vector vaccines while Sputnik V uses the same technology having two (2) different (dose) components of viral vectors, and Sputnik Light having a single dose component; CoronaVac, Covaxin, and COVID-19 Vaccine Sinopharm BIBP/Wuhan are inactivated vaccines; and Covovax is a protein subunit vaccine. Primary series are administered either in two doses (three doses for immunocompromised individuals) with an interval of a few weeks or single-dose using Janssen COVID-19 Vaccine or Sputnik Light. Booster shots are administered as homologous or heterologous using only approved vaccines as listed above.

Statistics regarding reports of suspected adverse reactions

As of 31 July 2023, more than 181.6 million doses of COVID-19 vaccines (CoronaVac, Vaxzevria, Sputnik V/Sputnik Light, Comirnaty, Spikevax, Janssen COVID-19 Vaccine, COVID-19 Vaccine Sinopharm) were administered. A total of 113,002 suspected adverse reaction

reports were received, evaluated, and analyzed by the FDA. *Table 1* and *Table 2* provide the data of adverse reaction reports and distribution of the total number of reports of adverse reactions for each vaccine, respectively.

Table 1. Data on vaccination and suspected adverse reaction reports

Indicators	Value
Total number of doses administered	181,645,251
No. of fully vaccinated individuals	78,443,972
No. of individuals with booster shots	23,811,248
No. of suspected adverse reaction reports	**113,002** (0.06% of doses administered)
No. of suspected serious adverse reaction reports	**10,727** (0.006% of doses administered)

Distribution of reports of adverse reactions for each vaccine

Data shown below are cumulative reports from the start of the vaccination program on 01 March 2021 until 31 July 2023.

Table 2. Distribution of reports of adverse reactions for each vaccine

Vaccine	Date started	Total vaccine doses administered [b]	Total number of reports[a]	Reports of non-serious events	Reports of serious events
CoronaVac	01 Mar 2021	48,734,507	37,305	33,838	3,467
AstraZeneca	07 Mar 2021	23,931,246	37,894	35,816	2,078
Sputnik V/ Sputnik Light	04 May 2021	1,584,507	922	866	56
Comirnaty	13 May 2021	77,024,785	23,766	20,848	2,918
Moderna	30 June 2021	21,605,790	7,011	6,089	922
Janssen	20 July 2021	7,654,344	5,661	4,465	1,196
Sinopharm	25 Aug 2021	1,110,072	443	353	90
TOTAL		**181,645,251**	**113,002**	**102,275**	**10,727**

Data source: [a]VigiFlow, [b]DOH (as of 19 March 2023)
Notes: Additional information may become available in individual cases, which may change the figures presented.
Data concerning various vaccines are not directly comparable. COVID-19 vaccines profile varies, they have not been used for equal periods of time and they have been administered to number of people with different profiles including various age and sex.

Demographics

The figures below provide a descriptive overview of the population who have experienced adverse reactions to COVID-19 vaccines. Figure 1 and Figure 2 show the distribution of reports by gender and age. Click here to show disaggregated data.

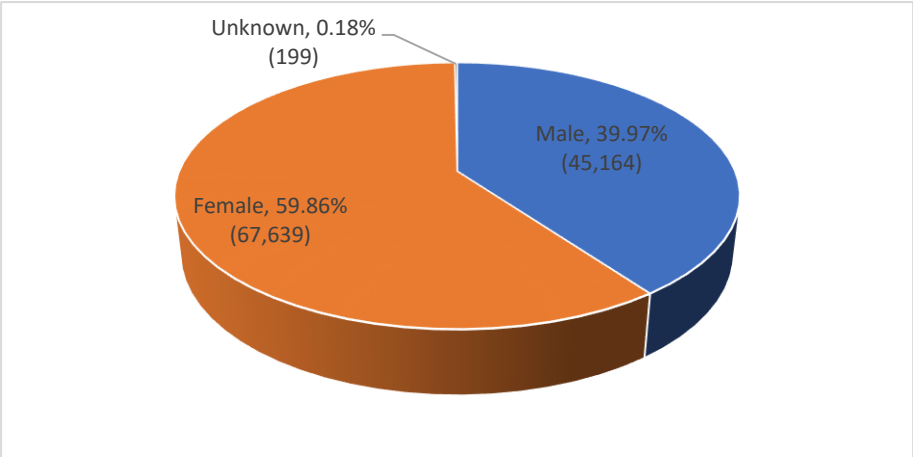

Figure 1. Report distribution by gender

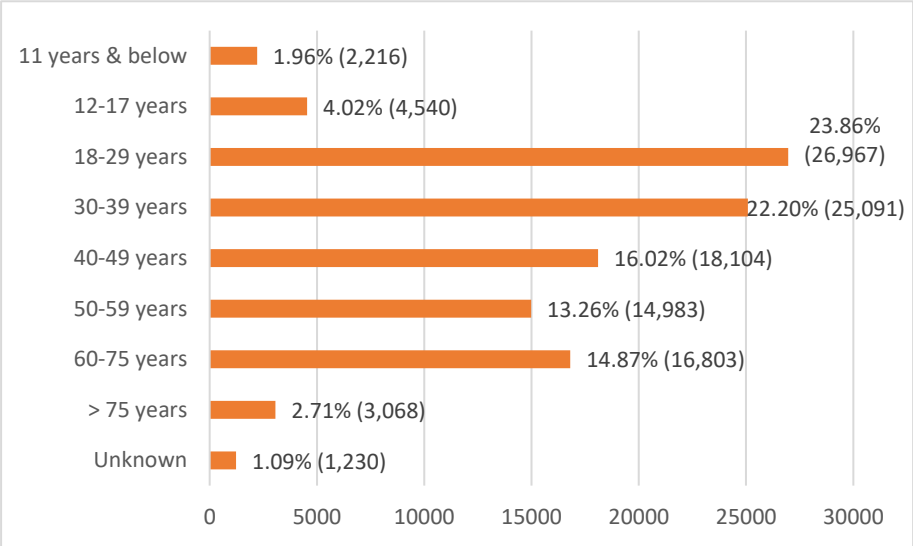

Figure 2. Report distribution by age

The early phase of the vaccination program is intended for the frontline health workers, thus, the high number in the female and younger population might be associated with the data that our health system is dominated by female (75%) and young adults under the age of 35 (65%).[1]

The increasing number of reports from the age group 40 years and above may be attributed to the coverage of priority groups of senior citizens and individuals with comorbidities. The reports also include adolescents and children since their age population is already included in the vaccination coverage.

Relative to the inclusion of the frontline personnel in the priority groups, the observed increasing number of reports in the male population may be attributed to the vaccine coverage and statistics that more males are employed than females (6 in every 10).[2]

[1] University of the Philippines Population Institute (UPPI) and Demographic Research and Development Foundation, Inc. (DRDF). (2020, August). Human Resource for Health in the Time of the COVID-19 Pandemic: Does the Philippines Have Enough? (UPPI/DRDF Research Brief No. 8). Retrieved from https://www.uppi.upd.edu.ph/sites/default/files/pdf/COVID-19-Research-Brief-08.pdf.

[2] "Employment Situation in July 2018," Philippine Statistics Authority, January 30, 2019, https://psa.gov.ph/statistics/survey/labor-and-employment/labor-force-survey/title/Employment%20Situation%20in%20July%202018.

Pregnant women and lactating mothers

Pregnant women are included in the A3 priority group for COVID-19 vaccination. Pregnancy is not a contraindication to getting the COVID-19 vaccine (except for the Gamaleya vaccine which shall not be administered to the pregnant and breastfeeding populations). They are considered to have a low risk of contracting COVID-19; however, studies have shown that pregnant women have a higher risk of having severe COVID-19 infection compared to non-pregnant women thus the benefits of getting vaccinated outweigh the risks.[3,4]

As of 31 July 2023, 579 suspected adverse reaction reports were received from pregnant women. Out of these reports, 325 reports were tagged as serious and 254 reports were non-serious. The most reported adverse reactions from pregnant women include labor pain, vaccination/injection site pain, back pain, myalgia, and pyrexia and COVID-19.

Breastfeeding is vital to the health of infants and their mothers. COVID-19 vaccination is also recommended for breastfeeding mothers. Limited data is available on the effects of the vaccine on milk production and excretion.[3,4]

As of 31 July 2023, 196 reports were received from the group of lactating mothers. Eighteen (18) reports were tagged as serious and 178 reports were tagged as non-serious. The most reported adverse reactions from lactating mothers include pyrexia, headache, vaccination/injection site pain, malaise, and myalgia.

Overall, data suggests that the benefits of receiving a COVID-19 vaccine outweigh any known or potential risks of vaccination during pregnancy and lactation.

Vaccination in children

The roll out for vaccinating adolescent population (12-17 years old) started last 15 October 2021 initially for those with co-morbidities and expanded to include all adolescents (with or without co-morbidities) on 02 November 2021. Comirnaty, Spikevax, Coronavac, and Covovax are the vaccines with EUA for the adolescent population.

As of 31 July 2023, 4,540 reports were received: 469 reports were tagged as serious (386 hospitalizations), 4,069 reports were tagged as non-serious, and two (2) reports with no tag whether serious or non-serious. The most common reported reactions are pyrexia, dizziness, vaccination/injection site pain, headache, and rash.

Vaccination in children ages 5 to 11 started last 07 February 2022. Initially, Comirnaty is the only vaccine used in this age group. CoronaVac and Spikevax have also been authorized by the FDA to be used in individuals 6 years and above. Comirnaty for children ages 5 to 11 has a different formulation compared with the Comirnaty used in 12 years and older. Only 10-

[3] "COVID-19 vaccines and pregnancy, breastfeeding, fertility," World Health Organization, last updated September 9, 2022, https://www.who.int/westernpacific/emergencies/covid-19/information-vaccines.

[4] "Pregnancy or Breastfeeding," Center for Disease Control and Prevention, updated July 14, 2022, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html#anchor_1628692463325.

µg/dose is needed for active immunization to prevent COVID-19 caused by SAR-CoV-2 in children aged 5 to 11 years.

As of 31 July 2023, 2,216 reports were received: 239 reports were tagged as serious (208 hospitalizations), 1,976 reports are tagged as non-serious, and one (1) report with no tag whether serious or non-serious. The most common reported reactions are pyrexia, vaccination/injection site pain, rash, vomiting, and headache.

Booster shots

The roll out of vaccination for the booster shots (third or additional doses) started last 17 November 2021 initially for healthcare workers then senior citizens, immunocompromised, and individuals with comorbidities at high risk of developing severe COVID-19 on 22 November 2021. The general population ages 18 years and above who completed their vaccine doses may also receive booster shots, which started last 03 December 2021.

Individuals eligible for booster shots have the option of receiving a homologous or heterologous booster dose given that they have completed their primary dose series at least 3 months (initially 6 months) after getting the second dose of either CoronaVac, Vaxzevria, Sputnik V, Comirnaty, or Spikevax and at least 2 months (initially 3 months) for Janssen COVID-19 vaccine and Sputnik Light. The interval for the administration of booster doses was shortened effective 22 December 2021.

As of 31 July 2023, 6,489 suspected adverse reaction reports were received: 928 reports were tagged as serious, and 5,561 reports were tagged as non-serious. The most common reported adverse reactions include vaccination/injection site pain, pyrexia, headache, malaise, and cough.

The roll out for second booster started last 25 April 2022 for the immunocompromised population. On 18 May 2022, the second booster was made available to senior citizens and frontline healthcare workers. The vaccination further expanded its second booster coverage last 26 July 2022 to include adults 50 years old and up and adults ages 18-49 with comorbidities. The vaccines authorized by the FDA for second booster are Comirnaty, Spikevax, CoronaVac, Sinopharm, and Vaxzevria. Second booster shots shall be administered at least four (4) months after the first booster shot.

As of 31 July 2023, 1,533 suspected adverse reaction reports were received: 142 reports were tagged as serious, and 1,391 reports were tagged as non-serious. The most common reported adverse reactions include vaccination/injection site pain, pyrexia, headache, malaise, and chills.

The adolescent population must be given additional protection, especially now as they slowly transition to full face-to-face classes. The vaccination rollout for the administration of the first booster dose vaccine for adolescents aged 12–17 years including immunocompromised and healthy individuals started last June 23, 2022. Comirnaty and Spikevax are the vaccines currently used in this age group. The dose interval of the primary series and booster dose is

at least 28 days and five-months for immunocompromised and healthy individuals, respectively.

On 21 June 2023, the rollout for the 3rd booster with COVID-19 Vaccine Pfizer Bivalent or Comirnaty Original/Omicron BA.4-5 started. The rollout employed a phased approach where adults aged 18 years and above who belong to A1 (healthcare workers) and A2 (senior citizens) groups are prioritized. Other groups will be made eligible following the availability of stocks. The 3rd booster or the bivalent booster shall be given to eligible individuals at least four (4) to six (6) months from the 2nd booster dose.

As of 31 July 2023, 321 suspected adverse reaction reports to the bivalent booster dose were received: one (1) report was tagged as serious, 318 reports were tagged as non-serious, and two (2) reports with no tag whether serious or non-serious. The most common reported adverse reactions include vaccination/injection site pain, headache, pyrexia, arthralgia, and chills and fatigue.

For the pediatric population, as of 31 July 2023, there are 150 suspected adverse reaction reports received from the first booster dose: 18 reports were tagged as serious, and 132 reports were tagged as non-serious. The most common reported adverse reactions include pyrexia, vaccination site pain, headache, dizziness, and rash. For the second booster, there is one (1) reported non-serious suspected ADR.

National Vaccination Days

With the aim of increasing COVID-19 vaccination coverage nationwide, a series of National Vaccination Days (NVD) were held since the roll-out. During the vaccination days, reports of suspected adverse reaction were monitored and continuously reported and evaluated together with all other reports.

Roll out in pharmacies and clinics

The COVID-19 vaccination program aims to reach more Filipinos through its vaccination roll out in pharmacies and clinics that started last 20 January 2022 initially for booster shots. High-risk groups and children below 18 years old are not qualified to be vaccinated in drugstores while clinics may give shots to high-risk group such as senior citizens and individuals with co-morbidities. Initially, CoronaVac and COVID-19 Vaccine AstraZeneca were the only vaccines utilized in these settings.

Reports of suspected serious adverse reaction

Adverse reactions experienced after vaccination are considered serious when it resulted to any of the following criteria:

- In-patient hospitalization/prolongation of existing hospitalization
- Significant disability/incapacity
- Life-threatening (e.g., anaphylaxis) and death

- Birth defect or congenital malformations
- Considered to be medically important event

Hypersensitivity including severe allergic reactions
Severe allergic reactions have been reported on the use of COVID-19 vaccines including CoronaVac, COVID-19 Vaccine AstraZeneca, Sputnik V, Comirnaty, COVID-19 Vaccine Moderna, Janssen COVID-19 Vaccine, and COVID-19 Vaccine Sinopharm. It only occurs in a few vaccinated individuals. It usually happens in people with a history of severe vaccine reactions. Severe allergic reactions (anaphylaxis) generally occur soon after vaccination and are usually managed with Epinephrine in combination with other medicines. Thus, vaccinees are observed for at least 15 minutes after receiving their vaccine. Epinephrine is readily available in all vaccination sites in case of anaphylaxis.

The proportion of reported side effects of severe allergic reactions to COVID-19 vaccines proved to be statistically rare as the number of vaccinated populations increases. The current reporting rate for anaphylaxis is 1.79 per million doses administered.

Increased blood pressure
Blood pressure (BP) increased has been continuously reported as one of the top adverse reactions to all vaccine platforms. Monitoring BP has been part of the screening process for COVID-19 vaccination program in the country. The program recommends monitoring BP only in vaccine recipients with a history of hypertension, symptomatic hypertension, and based on the clinical judgement of the physician on the vaccination site. This is in relation to the recommendations of the Philippine Heart Association and Philippine Society of Hypertension on elevated blood pressure readings during COVID-19 vaccination.

According to PRESYON 4 (Philippine Heart Association Report on the Study of Hypertension), a nationwide hypertension survey conducted in January to April 2021, the prevalence of hypertension in the Philippines alarmingly increased to 37% in 2021 among adults 18 years old and above from 28% (2013). Out of this 37%, 19% are aware of having hypertension while 18% are undiagnosed. The BP control rate, with or without medications, is 36%. Only about 25% of hypertensive individuals monitor blood pressure at home.[5] This study explains the increase in blood pressure observed in most vaccinated individuals.

Thrombosis-thrombocytopenia syndrome
Thrombosis-thrombocytopenia syndrome (TTS) are cases of unusual blood clots with low blood platelets. Following cases of TTS from other countries, COVID-19 Vaccine AstraZeneca and Janssen COVID-19 Vaccine revised their label to include warnings related to thrombosis with thrombocytopenia, a very rare side effect following vaccination.

Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience any sign of blood clots and low blood platelet such as:[6]

[5] Philippine Heart Association, "PRESYON 4 – Nationwide 2021 Hypertension Survey Results," Facebook video, Press Conference on June 16, 2021, https://www.facebook.com/philheart.org/videos/159433679504182/.
[6] "AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets," European Medicines Agency, April 7, 2021, https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood.

- shortness of breath
- chest pain
- leg swelling
- persistent abdominal (belly) pain
- neurological symptoms, such as severe and persistent headaches or blurred vision
- tiny blood spots under the skin beyond the site of the injection

Thirteen (13) cases of thrombosis and two (2) cases of thrombosis-thrombocytopenia have been reported. Two (2) cases of thrombosis-thrombocytopenia has been assessed as product related reaction (as per published literature) and 13 cases of thrombosis are currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Confirmed COVID-19 infections

There were 4,862 confirmed reports of COVID-19 infections. Most of the reported infections were asymptomatic cases. There were 258 severe cases that resulted in a fatal outcome. Most of the fatal reports have not yet completed their vaccination course. Upon assessment, these cases were not related to the use of the vaccine, but these were actual COVID-19 natural infections.

The vaccines currently being used in the COVID-19 vaccination program are non-replicating viral vector, inactivated, and mRNA vaccines. It does not contain any live virus and therefore does not cause COVID-19 infection in vaccine recipients.

Inflammation of the heart

Myocarditis is an inflammation of the heart muscle that may present as chest pain, palpitations, arrhythmias, and/or symptoms of heart failure while pericarditis is an inflammation of the pericardial sac that surrounds the heart and fixes it to the mediastinum. Cases of myocarditis and pericarditis on the use of mRNA vaccine, such as Comirnaty and COVID-19 Vaccine Moderna, have been reported in many countries including the US, UK, Germany, and Israel. Most of the cases are young male. The US FDA announced the revision of fact sheets for Comirnaty and COVID-19 Vaccine Moderna suggesting increased risk of myocarditis and pericarditis following vaccination. EMA's safety committee has also concluded that myocarditis and pericarditis can occur in very rare cases following Comirnaty and COVID-19 Vaccine Moderna.

Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience the following symptoms after vaccination:[7]

- breathlessness
- a forceful heartbeat that may be irregular
- chest pain

[7] "Comirnaty and Spikevax: possible link to very rare cases of myocarditis and pericarditis," European Medicines Agency, July 9, 2021, https://www.ema.europa.eu/en/news/comirnaty-spikevax-possible-link-very-rare-cases-myocarditis-pericarditis.

Thirty-one (31) cases of myocarditis and four (4) cases of pericarditis have been reported. Fourteen (14) cases of myocarditis and one (1) case of pericarditis have been assessed as product related reactions (as per published literature) and 17 cases of myocarditis together with three (3) cases of pericarditis are currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Capillary Leak Syndrome

Capillary leak syndrome is a very rare, serious condition that causes fluid leakage from small blood vessels (capillary), resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood, and low blood levels of albumin. Several cases were reported on the use of COVID-19 Vaccine AstraZeneca and Janssen COVID-19 Vaccine. The EMA's safety committee recommended contraindication in individuals with previous capillary leak syndrome and inclusion of capillary leak syndrome as a new side effect in the product information for both products.

Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience the following symptoms days after vaccination, which may occur together with feeling faint (due to low blood pressure):[8]

- rapid swelling of the arms and legs
- sudden weight gain

One (1) case of capillary leak syndrome has been reported. It has been assessed as a product related reaction (as per published literature). The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Guillain-Barré syndrome

Guillain-Barré syndrome (GBS) is a rare, autoimmune disorder in which a person's own immune system damages the nerves, causing muscle weakness and sometimes paralysis. An increased risk for GBS has been observed following vaccination with Janssen COVID-19 Vaccine in the US. The US FDA has announced the revision of fact sheets for Janssen COVID-19 Vaccine to include the observed risk for GBS. EMA's safety committee considered that a causal relationship between Janssen COVID-19 Vaccine and GBS is possible. COVID-19 Vaccine AstraZeneca already updated their product information.

Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience signs and symptoms suggestive of GBS such as:[9]

- double vision or difficulty moving eyes
- difficulty swallowing, speaking, or chewing
- coordination problems and unsteadiness
- difficulty walking

[8] "Vaxzevria: EMA advises against use in people with history of capillary leak syndrome," European Medicines Agency, June 11, 2021, https://www.ema.europa.eu/en/news/vaxzevria-ema-advises-against-use-people-history-capillary-leak-syndrome.

[9] "COVID-19 Vaccine Janssen: Guillain-Barré syndrome listed as a very rare side effect," European Medicines Agency, July 22, 2021, https://www.ema.europa.eu/en/news/covid-19-vaccine-janssen-guillain-barre-syndrome-listed-very-rare-side-effect.

- tingling sensations in the hands and feet
- weakness in the limbs, chest, or face
- problems with bladder control and bowel function

Thirty-five (35) cases of GBS have been reported. Thirteen (13) cases have been assessed as product related reactions (as per published literature), six (6) cases are indeterminate meaning there is insufficient evidence that the vaccine caused the reaction, two (2) cases as coincidental or not related to the vaccine, and 14 are currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Bell's palsy

Bell's palsy is a form of temporary facial paralysis or weakness on one side of the face. It results from dysfunction of facial nerve, which directs the muscles on one side of the face. Cases have been reported in several people in Hong Kong, Canada, and UK on the use of CoronaVac, Comirnaty, and COVID-19 Vaccine Moderna. The overall number of these reports is relatively small. In relation to this, CoronaVac vaccination fact sheet was revised to include bell's palsy as a very rare adverse reaction in Hong Kong while Comirnaty product information was revised in Canada. COVID-19 Vaccine Moderna already contains this safety information.

Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience any combination of the following symptoms:[10]

- uncoordinated movement of the muscles that control facial expressions, such as smiling, squinting, blinking, or closing the eyelid
- loss of feeling in the face
- headache
- tearing from the eye
- drooling
- lost sense of taste on the front two-thirds of the tongue
- hypersensitivity to sound in the one ear
- inability to close an eye on one side of the face

Thirty-eight (39) cases of bell's palsy have been reported. Fourteen (14) cases have been assessed as product related reactions (as per published literature), four (4) cases are indeterminate meaning there is insufficient evidence that the vaccine caused the reaction, two (2) cases as coincidental or not related to the vaccine, and 19 cases are currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Immune thrombocytopenia

Immune thrombocytopenia is an autoimmune condition in which the immune system mistakenly targets blood cells called platelets that are needed for normal blood clotting. Very rare cases have been reported internationally after receiving the Janssen COVID-19 Vaccine

[10] "Health Canada updates Pfizer-BioNTech COVID-19 vaccine label to reflect very rare reports of Bell's Palsy," Health Canada, August 6, 2021, https://recalls-rappels.canada.ca/en/alert-recall/health-canada-updates-pfizer-biontech-covid-19-vaccine-label-reflect-very-rare-reports.

and the COVID-19 Vaccine AstraZeneca. The product information for both vaccines have been recommended to update the imposition of the European Medicines Agency to include safety information on immune thrombocytopenia.

Vaccinated individuals should seek immediate medical assistance if they experience the following symptoms after vaccination:[11]

- unexplained bleeding
- unexplained bruising
- small purplish spots beyond the site of vaccination
- shortness of breath
- chest pain
- leg pain and/or swelling
- persistent abdominal pain

Twelve (12) cases of immune thrombocytopenia have been reported. Six (6) cases have been assessed as product related reactions (as per published literature), three (3) cases are indeterminate meaning there is insufficient evidence that the vaccine caused the reaction, one (1) case as coincidental or not related to the vaccine, and two (2) cases are currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Encephalitis and acute disseminated encephalomyelitis

Encephalitis is inflammation of the brain caused by an infection (such as a virus or bacteria), medication, or immune system malfunction while Acute Disseminated Encephalomyelitis (ADEM) is an autoimmune neurological disorder characterized by brief but widespread attacks of inflammation (swelling) in the brain and spinal cord. Cases of encephalitis have been reported in association with Vaxzevria, Comirnaty, and Moderna after vaccination. Causal relationship of these conditions with Vaxzevria has not been confirmed, and further data will be compiled and assessed.[12]

Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience signs and symptoms suggestive of encephalitis such as:[13]

- confusion or disorientation
- seizures or fits
- changes in personality and behavior
- difficulty speaking
- weakness or loss of movement in some parts of the body
- loss of consciousness

[11] "Health Canada is updating the labels of the Janssen and Vaxzevria (AstraZeneca) COVID-19 vaccines," Health Canada, last modified November 9, 2021, https://recalls-rappels.canada.ca/en/alert-recall/health-canada-updating-labels-janssen-and-vaxzevria-astrazeneca-covid-19-vaccines.

[12] Covid-19 Vaccines Safety Update. European Medicines Agency. (2021, June 18). https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-vaxzevria-previously-covid-19-vaccine-astrazeneca-18-june-2021_en.pdf

[13] Encephalitis. National Health Service. (2019, December 3). https://www.nhs.uk/conditions/encephalitis/

Six (6) cases of encephalitis have been reported. One (1) case has been assessed as product related reaction (as per published literature), three (3) cases as coincidental or not related to the vaccine, and two (2) cases are currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Heavy menstrual bleeding

Heavy menstrual bleeding is described by an increased or heavy blood flow and/or longer duration than usual. Cases of heavy menstrual bleeding have been reported in women who received mRNA vaccines (Comirnaty and Spikevax). The product information for such vaccines has been revised to include heavy menstrual bleeding.[14] Most cases appeared to be non-serious and temporary in nature.

Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience signs and symptoms of heavy menstrual bleeding such as:[15,16]

- Heavy bleeding and longer duration of menses than usual
- Bleeding between periods or irregular vaginal bleeding
- Any vaginal bleeding after menopause
- Menstrual flow with blood clots the size of a quarter or larger
- Heavy menstrual flow that keeps you from doing the things you would do normally
- constant pain in the lower part of the stomach during your periods

Twenty-eight (28) cases of heavy menstrual bleeding have been reported locally. Out of the 28 cases, nine (9) cases were tagged as serious. Two (2) cases have been assessed as coincidental or not related to the vaccine and the remaining cases are currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Transverse Myelitis

Transverse myelitis is a rare neurological disorder caused by inflammation to the spinal cord, that interrupts communication between nerve cells in the spinal cord and the body, which can result in paresthesia or altered sensations such as burning, tickling, pricking, numbness, coldness or tingling sensation.~~,~~ Bladder and bowel dysfunction, pain, and weakness are also seen in Transverse Myelitis. [16] It is a rare occurrence with few cases reported from the use of COVID-19 vaccines AstraZeneca and Janssen. The product information has been updated to include Transverse Myelitis as a potential side effect following the recommendation of EMA's safety committee.

[14] Covid-19 Vaccines Safety Update. European Medicines Agency. (2022, November 10). https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccines-safety-update-10-november-2022_en.pdf

[15] Centers for Disease Control and Prevention. (2022, August 17). Heavy Menstrual Bleeding. Centers for Disease Control and Prevention. https://www.cdc.gov/ncbddd/blooddisorders/women/menorrhagia.html

[16] HPRA Safety Update. Health Products Regulatory Authority . (2021, October 7). https://www.hpra.ie/docs/default-source/default-document-library/safety-update-covid-19-vaccines-overview-of-national-reporting-experience-(15072021).pdf?sfvrsn=4

Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience signs and symptoms of Transverse Myelitis such as:[17]

- Develop weakness in the arms or legs
- Sensory symptoms (such as tingling, numbness, pain or loss of pain sensation)
- Problems with bladder or bowel function

Two (2) cases of transverse myelitis have been reported. One (1) case has been assessed as product related reaction (as per published literature) and one (1) case is currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Cases of hospitalization

One of the criteria for serious adverse reaction is hospitalization or extended hospital stay. Reports of suspected adverse reaction that results in hospitalization **does not necessarily mean that vaccine caused the reaction**. An Expert Committee reviews and assesses whether the vaccine caused the reaction. Based on the reports received, the hospitalization-reporting rate is 4.13 per 100,000 doses administered. Commonly reported causes of hospitalization include pyrexia, cough, dyspnea, and headache.

Reports of fatal events

Another criterion for serious adverse reaction is when the case has resulted in fatal outcome regardless of the causality. As of 31 July 2023, 2,837 reports of fatal events were received. **The reports of fatal outcome do not necessarily mean that the vaccine caused the events**. Underlying conditions or pre-existing medical conditions causing fatal events are usually coincidental on the use of the vaccine. It is expected that reports of fatal events will rise as the vaccination program covers more people including those with undiagnosed illness, underlying comorbidities, and pre-existing medical conditions.

The mean age of the fatal cases was 59.17 years. 56.47% (1,602) of the fatal cases were from age group 60 years and above, 27.46% (779) from age group of 40-59 years, 12.72% (361) from age group 18-39 years, 1.90% (54) from age group 12-17 years of age, 0.60% (17) from the age group 5-11 years, and 0.85% (24) were not identified to what age group they are classified. The reports with fatal events were accounted to about 0.002% of the total vaccine doses administered.

Most of these events occurred in persons with multiple existing comorbidities. These include cardiovascular diseases, ischemic heart diseases, cerebrovascular diseases, cancer, diabetes, and infections including pneumonia. According to the Philippine Statistics Office, such comorbidities are also the top leading causes of mortality in the Philippines. There were cases of confirmed COVID-19 infections leading to severe cases with fatal outcomes which also ranks among leading causes of death registered in year 2021.

[17] JCOVDEN, INN-COVID-19 vaccine (Ad26.COV2-S [recombinant]) Summary of Product Characteristics. European Medicines Agency. (n.d.). https://www.ema.europa.eu/en/documents/product-information/jcovden-previously-covid-19-vaccine-janssen-epar-product-information_en.pdf

Number of suspected adverse reactions per category

A total of 113,002 case reports consisting of 239,534 suspected adverse reactions were received from the start of the vaccination program. More than one suspected adverse reaction might be reported in a single case. Suspected adverse reactions were coded using the Medical Dictionary for Regulatory Activities (MedDRA) terminology to allow international comparison of reports.

The data presented below are categorized by System Organ Class (SOC), the highest in the hierarchy of MedDRA. They are grouped by manifestation site (e.g., gastrointestinal, cardiac) and etiology (e.g., infections, examinations).

Reactions to inactivated vaccines

- CoronaVac
- COVID-19 Vaccine Sinopharm

Classification	Number of suspected reactions
General symptoms & reactions in the administration site *E.g. Pain and reaction in the injection site, chills, discomfort, fever, fatigue*	16,089
Cardiac symptoms *E.g. Palpitations, bradycardia, tachycardia*	1,037
Congenital, familial, and genetic disorder *E.g. Polycystic kidney*	6
Ear symptoms *E.g. Ear swelling, vertigo, tinnitus, ear discomfort*	65
Endocrine symptoms *E.g. Adrenal insufficiency, goiter, thyroid symptoms*	6
Examinations *E.g. Increased blood pressure, increased heart rate, blood glucose increased, SARS-CoV-2 test*	13,238
Eye symptoms *E.g. Eye itchiness, blurred vision, eye pain, eye swelling*	301
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting, dry mouth, lip swelling*	4,486
Hepatobiliary symptoms *E.g. Jaundice*	30
Immune system symptoms *E.g. Allergic reactions, hypersensitivity*	199
Infections *E.g. Cold symptoms, rhinitis*	4,852
Metabolism and nutrition-related symptoms *E.g. Decreased appetite, increased appetite, starvation, dehydration*	576
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities, muscle pain, muscle spasms*	2,606
Neoplasm *E.g. Liver cancer, endometrial cancer, uterine myoma*	17

Neurological symptoms *E.g. Dizziness, headache, syncope*	10,112
Pregnancy, puerperium, and perinatal conditions *E.g. Abortion, hemorrhage*	115
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	242
Psychiatric symptoms *E.g. Feeling anxious, insomnia, nervousness, disorientation*	185
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	105
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	133
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	8,181
Skin symptoms *E.g. Cold sweat, rash, redness*	4,657
Social circumstances *E.g. Hearing disability, walking disability*	3
Surgical and medical procedures *E.g. Tumor debulking, nasolabial flap*	35
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	66
Vascular symptoms *E.g. Flushes, low blood pressure*	456

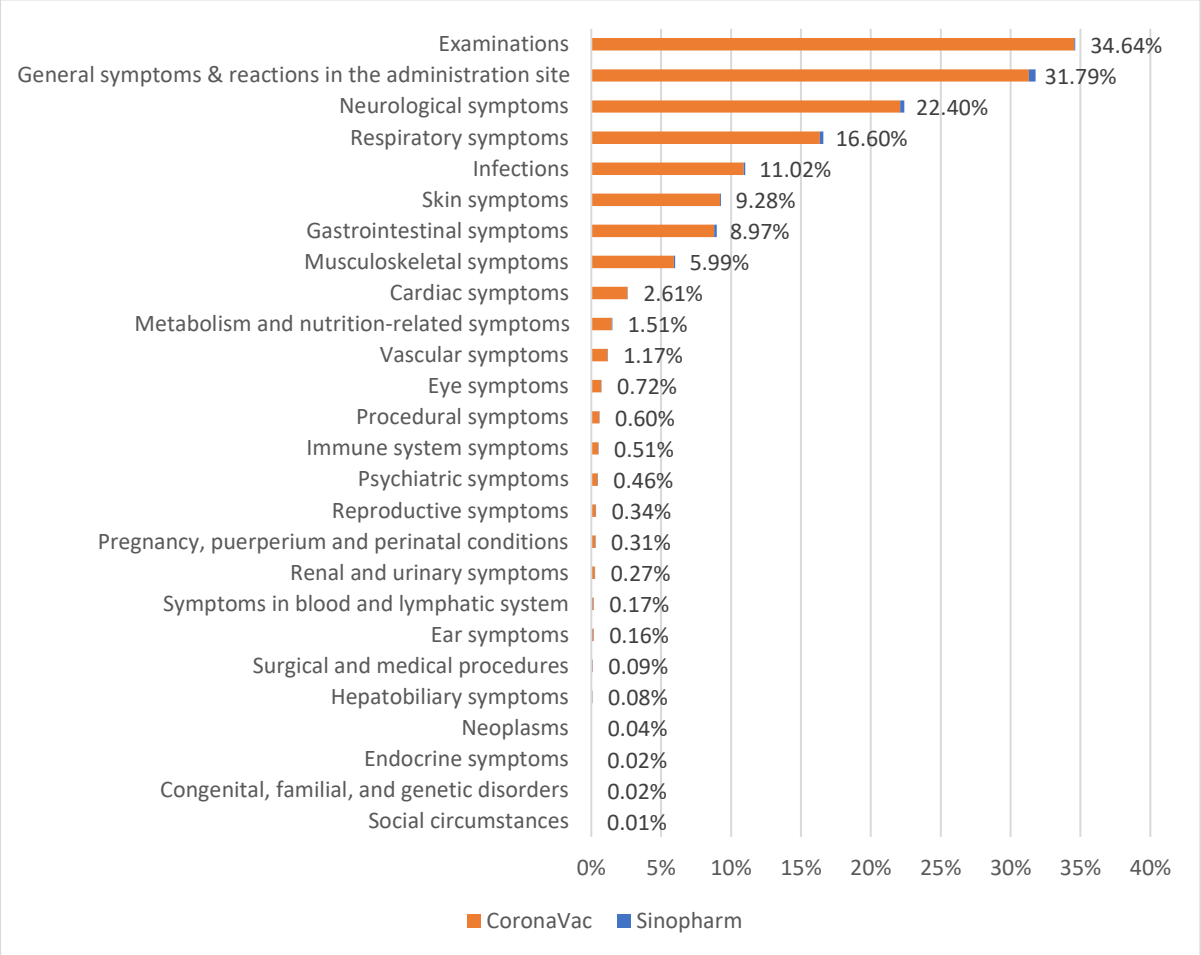

Figure3. Suspected adverse reaction distribution by SOC for inactivated vaccine

As shown in Figure 3, the SOC which consists of the greatest number of reports were examinations (13,074), followed by general symptoms and reactions in the administration site (11,999), neurological symptoms (8,457), respiratory symptoms (6,264), infections (4,160), skin symptoms (3,504), gastrointestinal symptoms (3,386), musculoskeletal symptoms (2,262), cardiac symptoms (986), and metabolism and nutrition-related symptoms (568).

The top reported events for CoronaVac are:

- blood pressure increased (34.21%)
- pyrexia (13.80%)
- headache (12.18%)
- cough (10.85%)
- vaccination/injection site pain (10.29%)
- dizziness (6.69%)
- rash (6.26%)
- nasopharyngitis (5.90%)
- COVID-19 (5.36%)
- dyspnea (5.29%)

The top reported events for COVID-19 Vaccine Sinopharm are:

- pyrexia (20.54%)
- cough (13.09%)
- dizziness (10.16%)
- headache (9.71%)
- vaccination/injection site pain (9.03%)
- COVID-19 (5.64%), dyspnea (5.64%), fatigue (5.64%)
- rash (4.97%)
- nasopharyngitis (4.74%)
- abdominal pain (4.29%), blood pressure increased (4.29%), diarrhea (4.29%)
- asthenia (3.84%), chills (3.84%)

Reactions to non-replicating viral vector vaccines

- COVID-19 vaccine AstraZeneca (Vaxzevria)
- Sputnik V
- Janssen COVID-19 Vaccine

Classification	**Number of suspected reactions**
General symptoms & reactions in the administration site *E.g. Pain and reaction in the injection site, chills, discomfort, fever, fatigue*	48,797
Cardiac symptoms *E.g. Palpitations, bradycardia, tachycardia*	927
Congenital, familial, and genetic disorder *E.g. Polycystic kidney*	22
Ear symptoms *E.g. Ear swelling, vertigo, tinnitus, ear discomfort*	78
Endocrine symptoms *E.g. Adrenal insufficiency, goiter, thyroid symptoms*	8

Examinations *E.g. Increased blood pressure, increased heart rate, blood glucose increased, SARS-CoV-2 test*	7,600
Eye symptoms *E.g. Eye itchiness, blurred vision, eye pain, eye swelling*	565
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting, lip swelling*	6,032
Hepatobiliary symptoms *E.g. Jaundice*	46
Immune system symptoms *E.g. Allergic reactions, hypersensitivity*	288
Infections *E.g. Cold symptoms, rhinitis*	4,470
Metabolism and nutrition-related symptoms *E.g. Decreased appetite, increased appetite, starvation, dehydration*	897
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities, muscle pain, muscle spasms*	9,920
Neoplasms *E.g. Liver cancer, endometrial cancer, uterine myoma*	34
Neurological symptoms *E.g. Dizziness, headache, syncope*	18,580
Pregnancy, puerperium, and perinatal conditions *E.g. Abortion, hemorrhage*	257
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	762
Product issues *E.g. Device issue*	1
Psychiatric symptoms *E.g. Feeling anxious, insomnia, nervousness, disorientation*	147
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	126
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	141
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	6,471
Skin symptoms *E.g. Cold sweat, rash, redness*	4,087
Social circumstances *E.g. Hearing disability, walking disability*	3
Surgical and medical procedures *E.g. Tumor debulking, nasolabial flap*	54
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	123
Vascular symptoms *E.g. Flushes, low blood pressure*	474

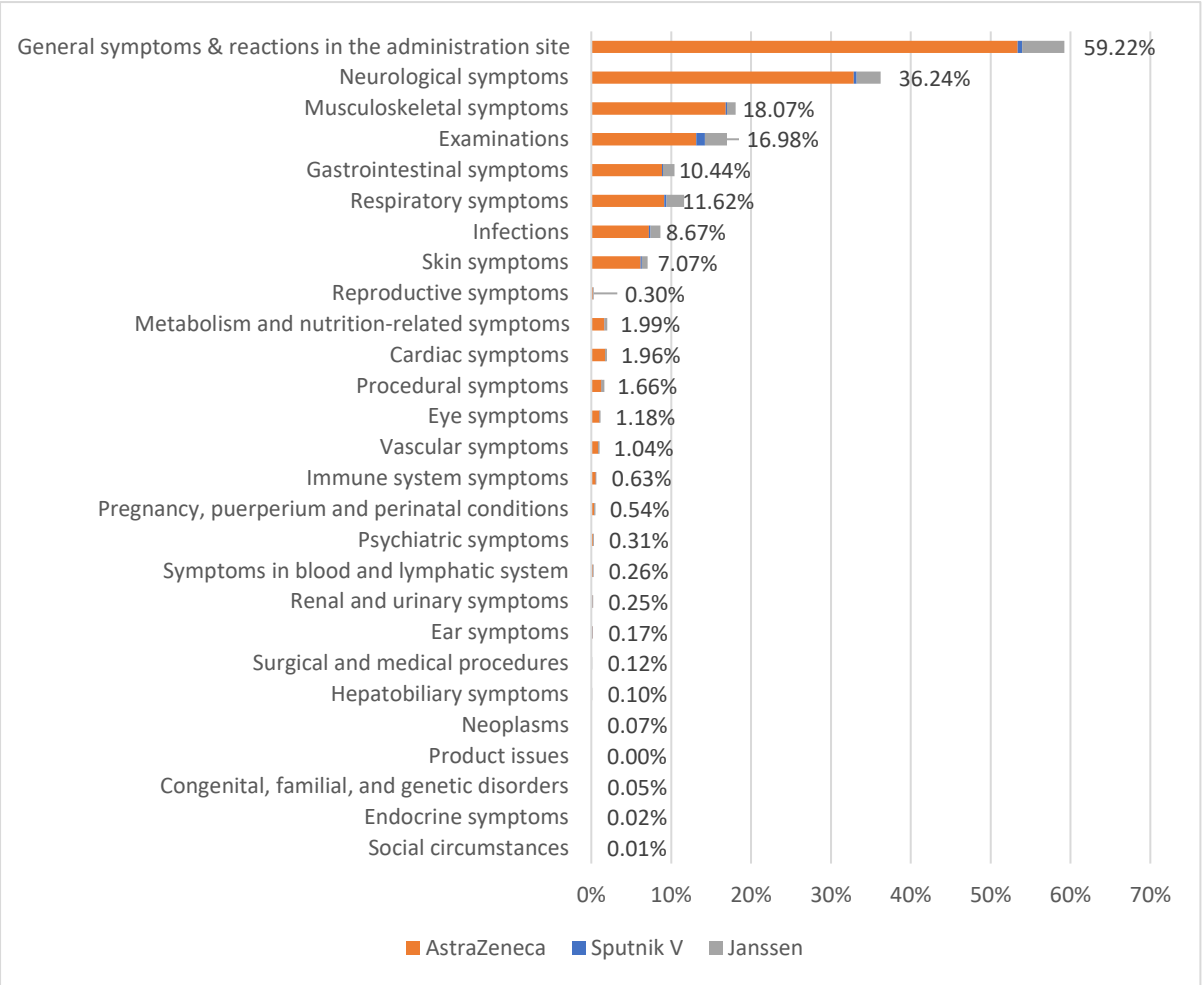

Figure 4. Suspected adverse reaction distribution by SOC for viral vector vaccines

As shown in Figure 4, the SOC which consists of the greatest number of reports were general symptoms and reactions in the administration site (26,341), followed by neurological symptoms (16,120), musculoskeletal symptoms (8,037), examinations (7,550), respiratory symptoms (5,170), gastrointestinal symptoms (4,643), infections (3,856), skin symptoms (3,144), metabolism and nutrition-related symptom (885), and cardiac symptoms (872).

The top reported events for COVID-19 Vaccine AstraZeneca are:

- pyrexia (38.25%)
- headache (31.27%)
- vaccination/injection site pain (21.71%)
- malaise (19.83%)
- chills (15.07%)
- blood pressure increased (14.94%)
- myalgia (14.30%)
- fatigue (10.75%)
- arthralgia (7.15%)
- dizziness (6.41%)

The top reported events for Sputnik V are:

- blood pressure increased (46.64%)

- pyrexia (14.64%)
- headache (8.89%)
- cough (7.92%)
- vaccination/injection site pain (6.07%)
- dizziness (5.64%)
- nasopharyngitis (5.53%)
- rash (5.21%)
- COVID-19 (4.23%)
- dyspnea (4.12%)

The top reported events for Janssen COVID-19 Vaccine are:

- blood pressure increased (20.51%)
- pyrexia (17.38%)
- vaccination/injection site pain (14.27%)
- cough (10.49%)
- headache (9.89%)
- dyspnea (7.75%)
- dizziness (6.20%)
- malaise (4.80%)
- COVID-19 (4.52%)
- hypoesthesia (4.43%)

Reactions to mRNA vaccines

- Comirnaty
- COVID-19 Vaccine Moderna (Spikevax)

Classification	Number of suspected reactions
General symptoms & reactions in the administration site *E.g. Pain and reaction in the injection site, chills, discomfort, fever, fatigue*	21,574
Cardiac symptoms *E.g. Palpitations, bradycardia, tachycardia*	870
Congenital, familial, and genetic disorder *E.g. Skull malformation*	13
Ear symptoms *E.g. Ear swelling, vertigo, tinnitus, ear discomfort*	73
Endocrine symptoms *E.g. Adrenal insufficiency, goiter, thyroid symptoms*	9
Examinations *E.g. Increased blood pressure, increased heart rate, blood glucose increased, SARS-CoV-2 test*	5,269
Eye symptoms *E.g. Eye itchiness, blurred vision, eye pain, eye swelling*	334
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting, lip swelling*	4,651
Hepatobiliary symptoms *E.g. Jaundice*	43

Immune system symptoms *E.g. Allergic reactions, hypersensitivity*	198
Infections *E.g. Cold symptoms, rhinitis*	3,280
Metabolism and nutrition-related symptoms *E.g. Decreased appetite, increased appetite, starvation, dehydration*	423
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities, muscle pain, muscle spasms*	3,053
Neoplasms *E.g. Liver cancer, endometrial cancer, uterine myoma*	23
Neurological symptoms *E.g. Dizziness, headache, syncope*	9,342
Pregnancy, puerperium, and perinatal conditions *E.g. Abortion, hemorrhage*	281
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	428
Psychiatric symptoms *E.g. Feeling anxious, insomnia, nervousness, disorientation*	185
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	130
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	210
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	5,477
Skin symptoms *E.g. Cold sweat, rash, redness*	4,211
Social circumstances *E.g. Hearing disability, walking disability*	10
Surgical and medical procedure *E.g. Chemotherapy*	182
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	189
Vascular symptoms *E.g. Flushes, low blood pressure*	358

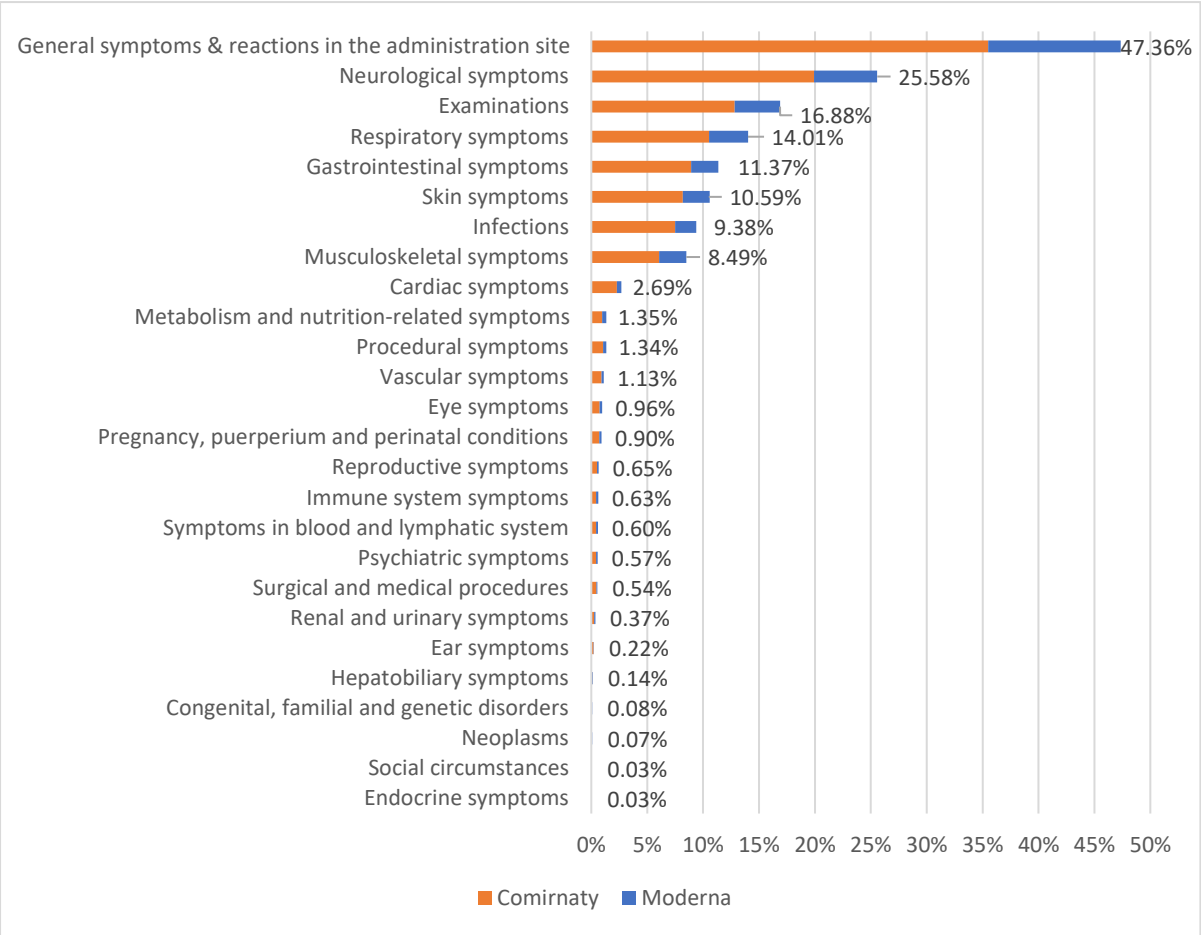

Figure 5. Suspected adverse reaction distribution by SOC for mRNA vaccine

As shown in Figure 5, the SOC which consists of the greatest number of reports were general symptoms and reactions in the administration site (14,575), followed by neurological symptoms (7,872), examinations (5,195), respiratory symptoms (4,313), gastrointestinal symptoms (3,499), skin symptoms (3,260), infections (2,886), musculoskeletal symptoms (2,614), cardiac symptoms (827), and metabolism and nutrition-related symptom (416).

The top reported events for Comirnaty are:

- pyrexia (20.21%)
- vaccination/injection site pain (20.18%)
- blood pressure increased (15.03%)
- headache (13.01%)
- dizziness (9.23%)
- cough (8.01%)
- rash (7.43%)
- malaise (6.91%)
- nasopharyngitis (5.46%)
- dyspnea (5.00%)

The top reported events for COVID-19 vaccine Moderna are:

- pyrexia (27.63%)
- vaccination/injection site pain (19.48%)

- blood pressure increased (16.07%)
- headache (14.53%)
- cough (8.94%)
- dizziness (7.39%)
- chills (7.10%)
- rash (6.53%)
- malaise (6.16%)
- dyspnea (5.72%)

Outcome of suspected adverse reactions

The outcome of cases of suspected adverse reactions to COVID-19 vaccines is shown in Figure 6. Overall, most of the reported cases have *recovered/resolved (73.51%)*, although there were few cases who have *recovered but with sequalae (0.05%)*. Over 14% of the cases are *recovering/resolving* while more than 1% have *not recovered/not resolved* at the time of reporting. A proportion of 2.51% were reported with fatal outcomes as discussed in the section reports involving death.

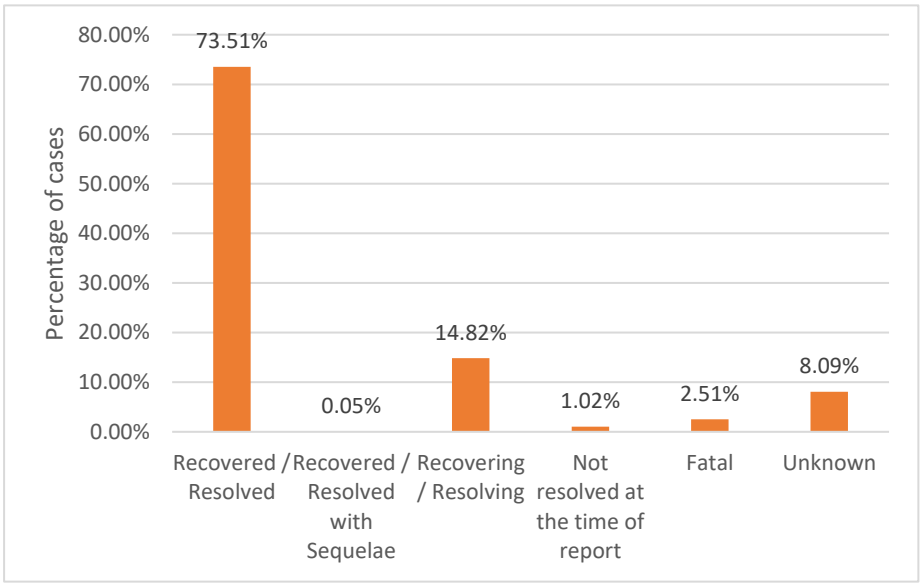

Figure 6. Case outcome

The overall risk-benefit evaluation of the vaccines

Based on the current available data, the benefits of the vaccines in the prevention of COVID-19 and severity of the disease outweighs any current known adverse reactions in most of the vaccinated individuals.

Reporting of suspected adverse reactions following vaccination

Individuals who have received their COVID-19 vaccination shots can report any suspected adverse reaction to any of the following:

- Immunization site where you were vaccinated
- Directly to the vaccine manufacturer or emergency use authorization holder
    - Sinovac – CoronaVac & Covaxin
    - AstraZeneca – COVID-19 Vaccine AstraZeneca
    - Gamaleya – Sputnik V & Sputnik Light
    - Pfizer – Comirnaty
    - Zuellig – COVID-19 Vaccine Moderna
    - Johnson & Johnson – Janssen COVID-19 Vaccine
    - Faberco – Covovax
- FDA online reporting system

Kindly **report only to one** of the abovementioned options to avoid duplication of reports.