Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 March to 01 August 2021)

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 01 August 2021.
- Six (6) vaccines under Emergency Use Authorization (EUA) are currently being used in the vaccination program: CoronaVac, COVID-19 Vaccine AstraZeneca, Sputnik V, Comirnaty, COVID-19 Vaccine Moderna, and Janssen COVID-19 Vaccine.
- 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), 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, 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, investigations, regulatory actions, and timely communication is performed by the FDA.
- A weekly report is published to summarize reported adverse reactions to the COVID-19 vaccines.

Summary

This report is based on an assessment of adverse reaction reports received by 01 August 2021. As per benefit-risk assessment, these reports do not provide a basis for revising the current recommendations regarding the use of COVID-19 vaccines.

A report of adverse reaction does not necessarily mean that the vaccine caused the reactions. A mere suspicion may also be reported. Undiagnosed illness, underlying comorbidities, and pre-existing medical conditions unrelated to vaccination can be factors in reporting adverse reactions. The relative numbers should not be used to compare the safety of different vaccines.

Like any other vaccines, COVID-19 vaccines may cause adverse reactions in some people. Most of the reported reactions are generally in line with what is described 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 experience 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 Vaccine AstraZeneca and Janssen COVID-19 Vaccine of other countries, information on the very rare and serious adverse events of thrombosis and thrombocytopenia and in some cases accompanied by bleeding have been revised under the special warning and precautions for use.

The label of mRNA vaccines Moderna and Comirnaty (Pfizer-BioNTech) have been revised to include imposition of the European Medicines Agency and the USFDA to include safety information on myocarditis and pericarditis.

Six (6) vaccines are currently used in the immunization program. These include CoronaVac, COVID-19 Vaccine AstraZeneca, Sputnik V, Comirnaty, COVID-19 Vaccine Moderna, and Janssen COVID-19 Vaccine. COVID-19 Vaccine AstraZeneca and Comirnaty are supplied under COVAX facility.

COVID-19 vaccines with Emergency Use Authorization in the Philippines

At present, the FDA granted eight (8) COVID-19 vaccines under emergency use authorization:

- Pfizer-BioNTech COVID-19 Vaccine (Comirnaty)
- ChAdOx1-S [recombinant] (COVID-19 Vaccine AstraZeneca)
- SARS-CoV-2 Vaccine (Vero Cell), Inactivated (CoronaVac)
- Gam-COVID-Vac (Sputnik V)
- Ad26.COV2-S [recombinant] (Janssen COVID-19 Vaccine)
- Whole Virion Inactivated Corona Virus (Covaxin)
- COVID-19 mRNA Vaccine [nucleoside modified] (COVID-19 Vaccine Moderna)
- Inactivated COVID-19 Vaccine (Vero Cell) (COVID-19 Vaccine BIBP/Sinopharm)

Various vaccine platforms have been approved for use in the Philippines. Comirnaty and COVID-19 Vaccine Moderna are mRNA vaccines; COVID-19 Vaccine AstraZeneca 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 CoronaVac, Covaxin, and COVID-19 Vaccine BIBP/Sinopharm are inactivated vaccines. All are administered in two doses within an interval of a few weeks except for Janssen COVID-19 Vaccine, which is administered as a single-dose.

Statistics regarding reports of suspected adverse reactions

As of 01 August 2021, more than 20.8 million doses of COVID-19 vaccines (either CoronaVac, COVID-19 vaccine AstraZeneca, Sputnik V, Comirnaty, COVID-19 vaccine Moderna, or Janssen COVID-19 Vaccine) were already administered. More than 11.7 million individuals have been partly vaccinated (received only one dose of a two-dose vaccine course) while over 9.1 million individuals have completed their vaccine doses (either a single-dose or both doses of 2-dose vaccine) or considered as fully vaccinated. A total of 53,629 suspected adverse reaction reports were received, evaluated, and analyzed by the FDA. To disaggregate, 21,446 have been reported for CoronaVac, 28,699 for COVID-19 Vaccine AstraZeneca, 606 for Sputnik V, 1,883 for Comirnaty, 317 for COVID-19 Vaccine Moderna, and 678 for Janssen COVID-19 Vaccine.

Table 1. Data on vaccination and suspected adverse reaction reports.

Indicators	Value
No. of individuals partly vaccinated	11,747,581
No. of fully vaccinated individuals	9,115,963
Total number of doses administered	20,863,544
No. of suspected adverse reaction reports	**53,629** (0.26% of doses administered)
No. of suspected serious adverse reaction reports	**1,439** (0.007% 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 up until 01 August 2021.

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

Vaccine	Date started	Number of individuals partly vaccinated[b]	Number of fully vaccinated individuals[b]	Total number of reports[a]	Reports of non-serious events	Reports of serious events
CoronaVac	01 Mar 2021	7,044,592	5,093,246	21,446	20,722	724
AstraZeneca	07 Mar 2021	3,124,335	908,113	28,699	28,098	601
Sputnik V	04 May 2021	249,708	64,167	606	598	8
Comirnaty	13 May 2021	1,252,739	1,099,189	1,883	1,795	88
Moderna	30 June 2021	76,207	23,528	317	312	5
Janssen	20 July 2021	-	1,927,720	678	665	13
TOTAL		**11,747,581**	**9,115,963**	**53,629**	**52,190**	**1,439**

Data source: [a]VigiFlow, [b]NVOC daily report as 6PM, 01 August 2021
Notes: Additional information may become available in individual cases, which may change the figures presented
[b]An individual is considered partly vaccinated if they have received only one dose of a two-dose vaccine course. An individual is considered fully vaccinated if they have received a single-dose vaccine or both doses of a two-dose vaccine
[c]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. shows the distribution of reports by gender and age.

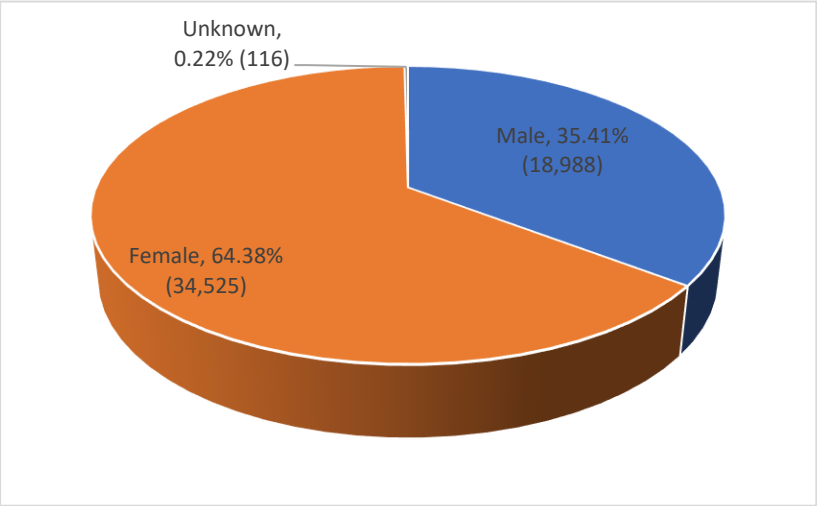

Figure 1. Report distribution by gender

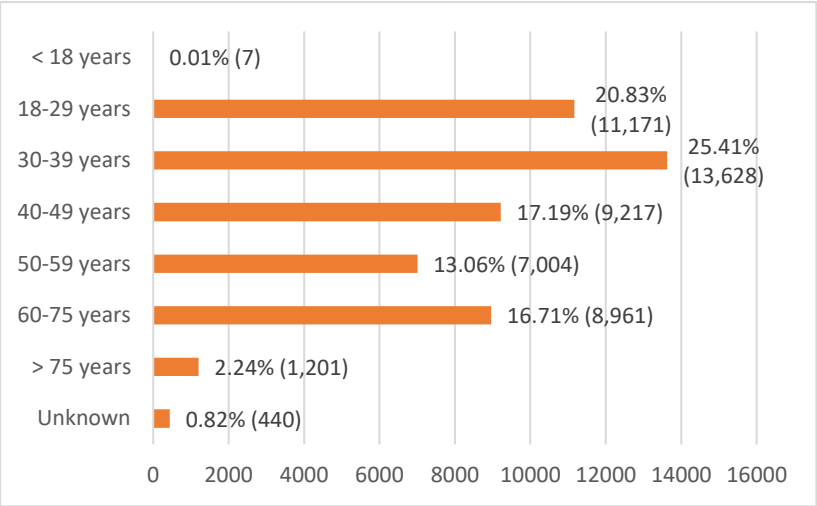

Figure 2. Report distribution by age

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] An increasing number of reports from the age group 40 years and above have been observed in the past few weeks of the vaccination program. This may be attributed to the coverage of priority groups of senior citizens and individuals with comorbidities.

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] *Human Resource for Health in the Time of the COVID-19 Pandemic: Does the Philippines Have Enough?* *https://www.drdf.org.ph/sites/default/files/pdf/COVID-19-Research-Brief-08.pdf*
[2] Employment situation in July 2018, *Philippine Statistics Authority* *https://psa.gov.ph/statistics/survey/labor-and-employment/labor-force-survey/title/Employment%20Situation%20in%20July%202018*

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, AstraZeneca, Sputnik V, Comirnaty, and Janssen COVID-19 Vaccine. 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 11.79 per million doses administered.

Increased blood pressure

Blood pressure increased has been continuously reported as one of the top adverse reactions to all vaccine platforms. Monitoring blood pressure has been part of the screening processes for COVID-19 vaccination program in the country. The program recommends monitoring blood pressure 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 unaware. The blood pressure (BP) control rate, with or without medications, is 36%. Only about 25% of hypertensive individuals monitor blood pressure at home.[3]

The recent study explains the increase in blood pressure observed in most vaccinated individuals.

[3] *Sison, J.A. (2021, May). Press Conference on PRESYON 4 – Nationwide 2021 Hypertension Survey Results [Video file]. Retrieved from https://www.facebook.com/philheart.org/videos/159433679504182/*

Thrombosis with thrombocytopenia syndrome

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 with COVID-19 vaccine AstraZeneca should watch out for the said adverse event and seek immediate medical assistance if they experience any signs of blood clots and low blood platelet such as[4]:

- 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

[4] *AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood*

Confirmed COVID-19 infections
There were 737 confirmed reports of COVID-19 infections. Most of the reported infections were asymptomatic cases. There were 65 severe cases which resulted to a fatal outcome. 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 does not cause COVID-19 infection in vaccine recipients.

Inflammation of the heart
Myocarditis is an inflammation of the heart muscle that may present 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 Moderna COVID-19 vaccines 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.

Two (2) cases of myocarditis have been reported. Causal link of such cases to the vaccination are 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 vaccines AstraZeneca and Janssen. The EMA's safety committee recommended inclusion of capillary leak syndrome in the product information for both products.

No case of capillary leak syndrome has been reported on the use of COVID-19 vaccines in the Philippines as of this time. 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 for 42 days 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 recommended no change on the labeling of COVID-19 vaccines AstraZeneca as their data neither confirms nor rules out possible association with the vaccine.

Three (3) cases of GBS have been reported and are currently reviewed for causal link to the vaccination. 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 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 4.10 per 100,000 doses administered. Commonly reported causes of hospitalization include pyrexia, cough, dyspnea, and headache.

Reports involving death

As of 01 August 2021, 526 fatal events were received. Reports of fatal events does 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 vaccinees reported to have fatal events were aged 20 years and above. The mean age of the fatal cases was 65.25 years. 74.71% (393) of the fatal cases were from age group 60 years and above, 19.96% (105) from age group of 40-59 years, 4.75% (25) from age group 20-39 years and 0.57% (3) were not identified to what age group they are classified.

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. There were cases of confirmed COVID-19 infections leading to severe cases with fatal outcomes. An independent committee assessed 231 of these case reports as coincidental events or not related to the vaccine, 17 cases were indeterminate, and 12 were unclassifiable. Other cases are still under investigation and are continuously being reviewed.

Number of suspected adverse reactions per category

A total of 53,629 case reports consisting of 118,132 suspected adverse reactions were received from the start of the vaccination program. More than one suspected adverse reaction may 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 vaccine

- CoronaVac

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*	8,179
Cardiac symptoms *E.g. Palpitations, bradycardia, tachycardia*	698
Ear symptoms *E.g. Ear swelling, vertigo, tinnitus, ear discomfort*	32
Endocrine symptoms *E.g. Adrenal insufficiency, goiter, thyroid symptoms*	3
Examinations *E.g. Increased blood pressure, increased heart rate, blood glucose increased, SARS-CoV-2 test*	8,985
Eye symptoms *E.g. Eye itchiness, blurred vision, eye pain, eye swelling*	196
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting, dry mouth, lip swelling*	2,228
Hepatobiliary symptoms *E.g. Jaundice*	1
Immune system symptoms *E.g. Allergic reactions, hypersensitivity*	156
Infections *E.g. Cold symptoms, rhinitis*	1,257
Metabolism and nutrition-related symptoms *E.g. Decreased appetite, increased appetite, starvation, dehydration*	198
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities, muscle pain, muscle spasms*	1,388
Neoplasm *E.g. Liver cancer*	2
Neurological symptoms *E.g. Dizziness, headache, syncope*	5,676
Pregnancy, puerperium, and perinatal conditions *E.g. Abortion, hemorrhage*	2
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	53
Psychiatric symptoms *E.g. Feeling anxious, insomnia, nervousness, disorientation*	87
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	25
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	25
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	2,667
Skin symptoms *E.g. Cold sweat, rash, redness*	3,127
Social circumstances *E.g. Hearing disability, walking disability*	3

Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	28
Vascular symptoms *E.g. Flushes, low blood pressure*	326

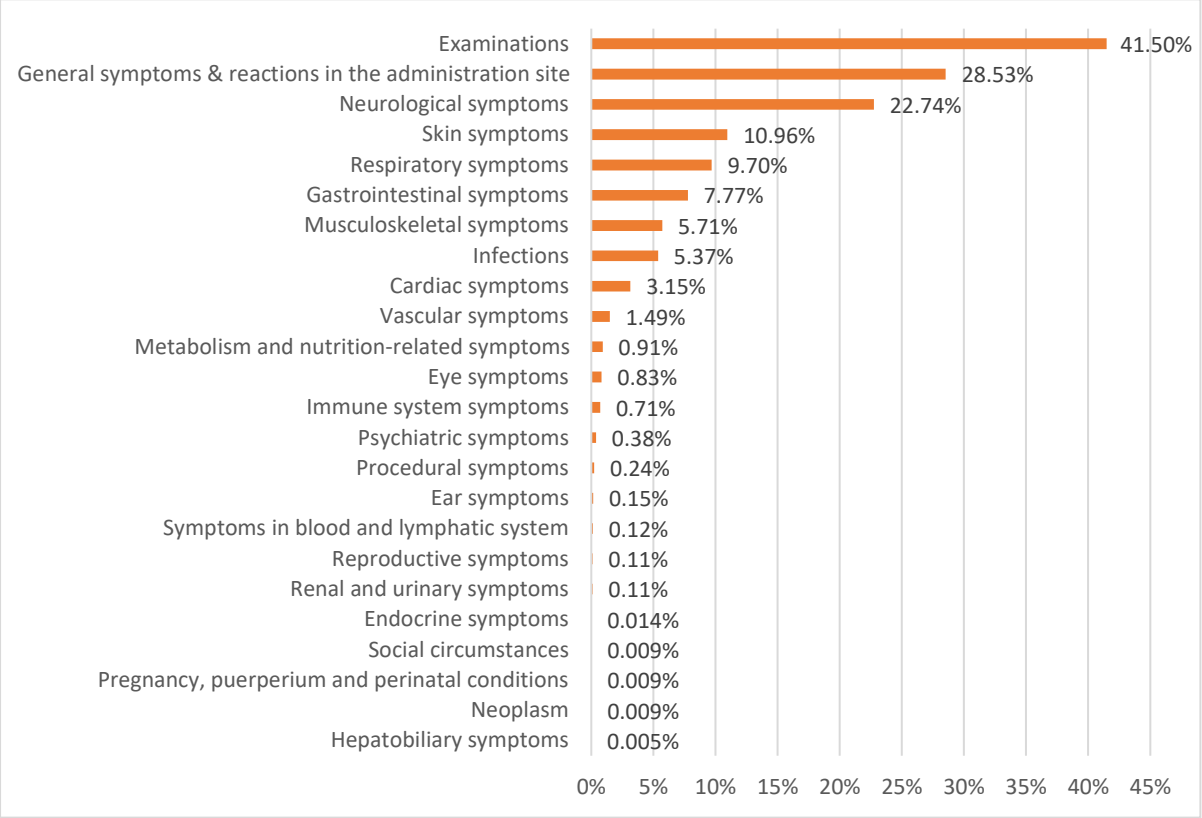

Figure 3. Suspected adverse reaction distribution by SOC for inactivated vaccine

As shown in Figure 3, the SOC which consists of the greatest number of reports were examinations (8,899), followed by general symptoms and reactions in the administration site (6,119), neurological symptoms (4,877), skin symptoms (2,351), respiratory symptoms (2,080), gastrointestinal symptoms (1,666), musculoskeletal symptoms (1,224), infections (1,152) cardiac symptoms (676), and vascular symptoms (320).

The top reported events are:

- blood pressure increased (41.05%)
- headache (13.39%)
- vaccination/injection site pain (11.44%)
- pyrexia (9.37%)
- dizziness (7.26%)
- rash (7.12%)
- cough (5.07%)
- malaise (5.02%)
- pruritus (4.52%)
- nasopharyngitis (3.46%)

Reactions to non-replicating viral vector vaccines

- COVID-19 vaccine AstraZeneca
- 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*	38,639
Cardiac symptoms *E.g. Palpitations, bradycardia, tachycardia*	617
Ear symptoms *E.g. Ear swelling, vertigo, tinnitus, ear discomfort*	41
Endocrine symptoms *E.g. Adrenal insufficiency, goiter, thyroid symptoms*	3
Examinations *E.g. Increased blood pressure, increased heart rate, blood glucose increased, SARS-CoV-2 test*	5,592
Eye symptoms *E.g. Eye itchiness, blurred vision, eye pain, eye swelling*	383
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting, lip swelling*	3,917
Hepatobiliary symptoms *E.g. Jaundice*	2
Immune system symptoms *E.g. Allergic reactions, hypersensitivity*	235
Infections *E.g. Cold symptoms, rhinitis*	1,214
Metabolism and nutrition-related symptoms *E.g. Decreased appetite, increased appetite, starvation, dehydration*	563
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities, muscle pain, muscle spasms*	8,157
Neurological symptoms *E.g. Dizziness, headache, syncope*	13,754
Pregnancy, puerperium, and perinatal conditions *E.g. Abortion, hemorrhage*	7
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	46
Psychiatric symptoms *E.g. Feeling anxious, insomnia, nervousness, disorientation*	64
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	20
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	28
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	2,120
Skin symptoms *E.g. Cold sweat, rash, redness*	2,670
Social circumstances *E.g. Hearing disability, walking disability*	1

Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	51
Vascular symptoms *E.g. Flushes, low blood pressure*	297

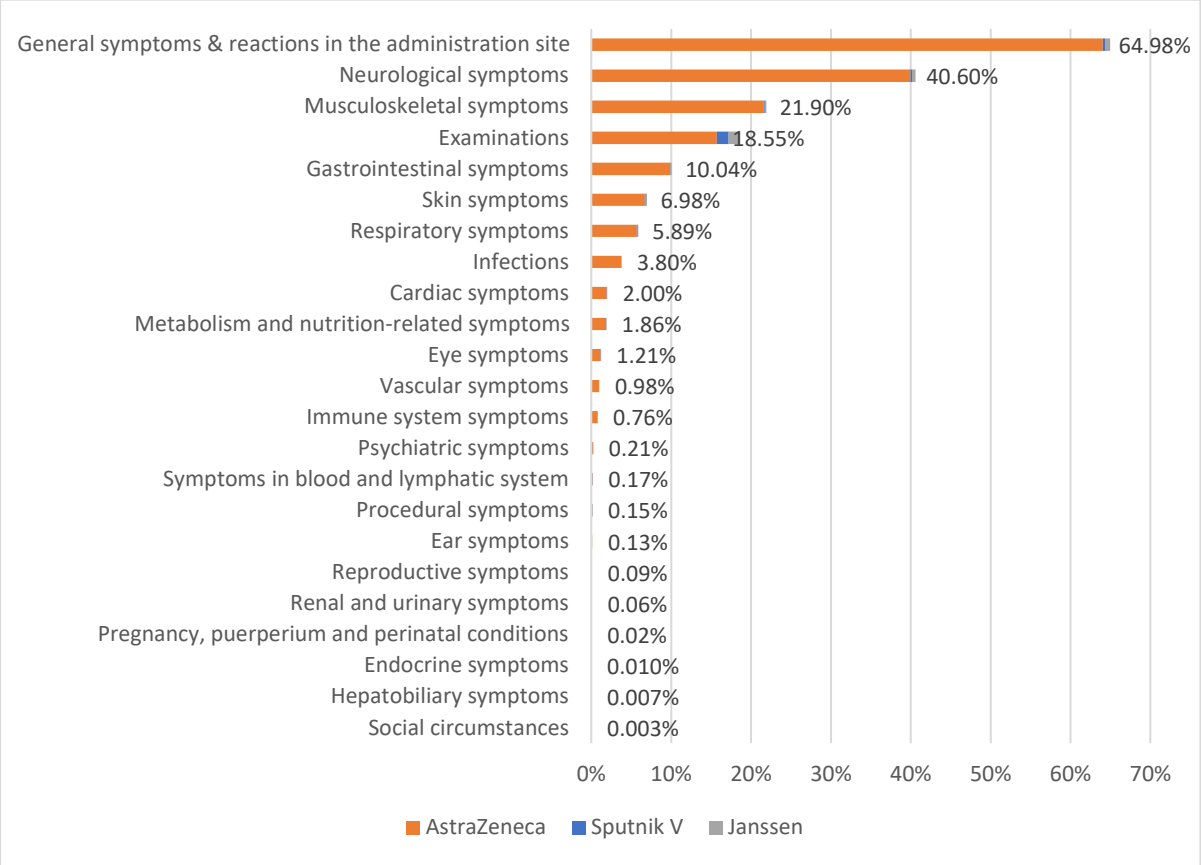

Figure 4. Suspected adverse reaction distribution by SOC for viral vector vaccines

As shown in Figure 4, the SOC which consists of the greatest number of reports were general symptoms and reactions in the administration site (19,483), followed by neurological symptoms (12,173), musculoskeletal symptoms (6,567), examinations (5,561), gastrointestinal symptoms (3,010), skin symptoms (2,093), respiratory symptoms (1,765), infections (1,139), cardiac symptoms (599), and metabolism and nutrition-related symptom (559).

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

- pyrexia (40.55%)
- headache (35.54%)
- vaccination/injection site pain (24.55%)
- malaise (23.21%)
- chills (17.33%)
- myalgia (17.14%)
- blood pressure increased (16.15%)
- fatigue (12.85%)
- arthralgia (8.39%)
- dizziness (6.39%)

The top reported events for Sputnik V are:

- blood pressure increased (68.48%)
- pyrexia (6.93%)
- headache (5.94%)
- heart rate increased (5.78%)
- rash (4.79%)
- dizziness (4.13%)
- vaccination/injection site pain (3.30%)
- dyspnoea (2.81%)
- cough (2.64%)
- pruritus (2.15%)

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

- blood pressure increased (59.29%)
- pyrexia (15.63%)
- headache (13.27%)
- vaccination/injection site pain (10.03%)
- dizziness (5.46%)
- malaise (4.87%)
- rash (4.72%)
- chills (4.57%)
- myalgia (4.42%)
- arthralgia (3.69%), nausea (3.69%)

Reactions to mRNA vaccines

- Comirnaty
- COVID-19 Vaccine Moderna

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*	1,435
Cardiac symptoms *E.g. Palpitations, bradycardia, tachycardia*	58
Ear symptoms *E.g. Ear swelling, vertigo, tinnitus, ear discomfort*	3
Examinations *E.g. Increased blood pressure, increased heart rate, blood glucose increased, SARS-CoV-2 test*	754
Eye symptoms *E.g. Eye itchiness, blurred vision, eye pain, eye swelling*	30
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting, lip swelling*	241
Immune system symptoms *E.g. Allergic reactions, hypersensitivity*	17
Infections *E.g. Cold symptoms, rhinitis*	126

Metabolism and nutrition-related symptoms *E.g. Decreased appetite, increased appetite, starvation, dehydration*	35
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities, muscle pain, muscle spasms*	271
Neurological symptoms *E.g. Dizziness, headache, syncope*	609
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	7
Psychiatric symptoms *E.g. Feeling anxious, insomnia, nervousness, disorientation*	11
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	3
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	6
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	351
Skin symptoms *E.g. Cold sweat, rash, redness*	300
Social circumstances *E.g. Hearing disability, walking disability*	1
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	11
Vascular symptoms *E.g. Flushes, low blood pressure*	35

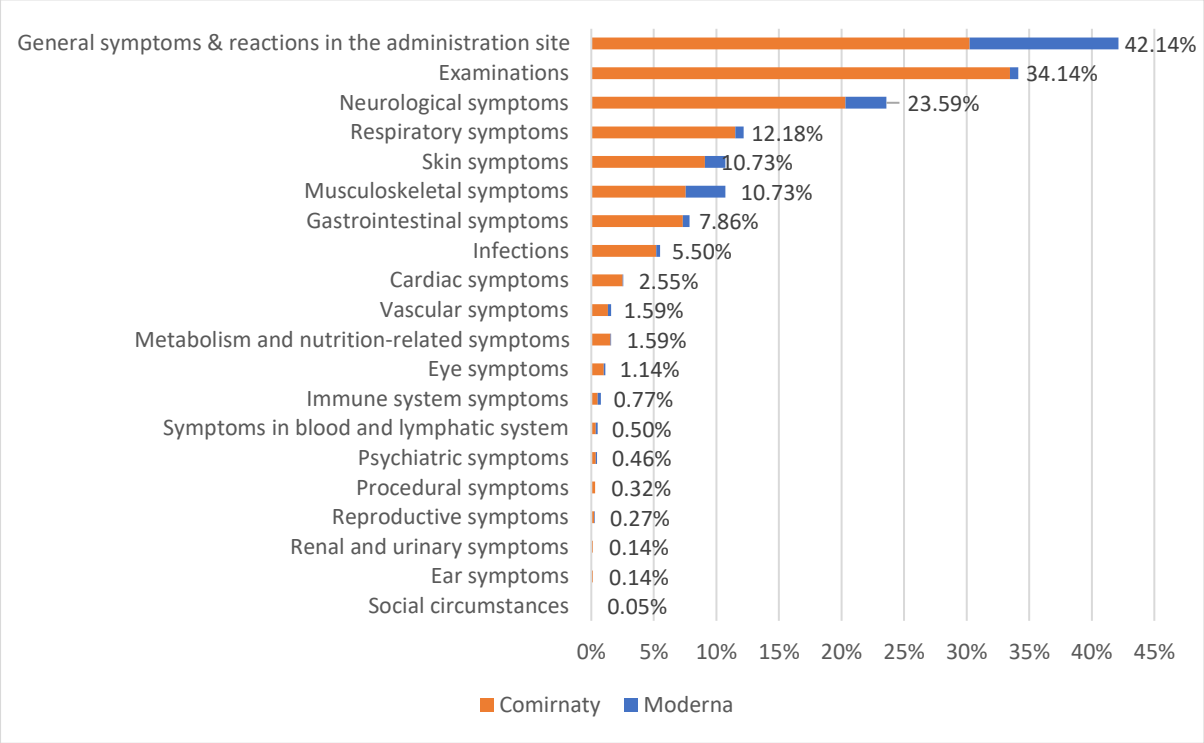

Figure 5. Suspected adverse reaction distribution by SOC for mRNA vaccine

As shown in Figure 5, the SOC which consists of the greatest number of reports were general symptoms and reactions in the administration site (927), followed by examinations (751), neurological symptoms (519), respiratory symptoms (268), musculoskeletal symptoms (236),

skin symptoms (236), gastrointestinal symptoms (173), infections (121), cardiac symptoms (56), and metabolism and nutrition-related symptoms (35).

The top reported events for Comirnaty are:

- blood pressure increased (37.76%)
- pyrexia (20.18%)
- headache (14.13%)
- vaccination/injection site pain (9.13%)
- dizziness (8.55%)
- cough (8.02%)
- malaise (7.49%)
- rash (7.22%)
- dyspnoea (5.20%)
- chills (4.51%)

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

- vaccination/injection site pain (56.15%)
- pyrexia (17.35%)
- headache (16.72%)
- limb discomfort (9.15%)
- malaise (8.52%)
- myalgia (7.89%)
- fatigue (5.99%)
- chills (5.36%)
- blood pressure increased (4.42%), pain (4.42%)
- vaccination site swelling (4.10%)

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 (79.98%)*, although there were few cases who have *recovered but with sequalae (0.03%)*. A little over 11% of the cases are *recovering/resolving* while less than 1% have *not recovered/not resolved* at the time of reporting. A proportion of 0.98% were reported with fatal outcomes as discussed in the section Reports involving death.

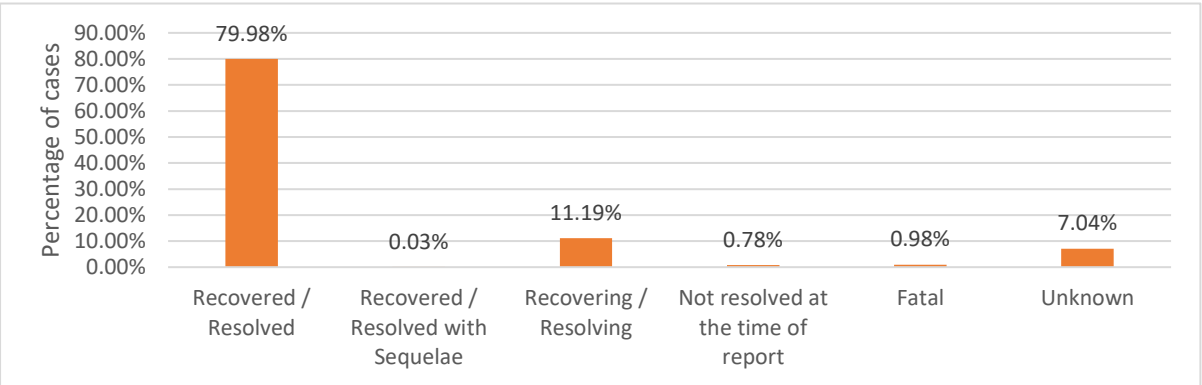

Figure 6. Case outcome

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
    - AstraZeneca – COVID-19 Vaccine AstraZeneca
    - Gamaleya – Sputnik V
    - Pfizer – Comirnaty
    - Zuellig – COVID-19 Vaccine Moderna
    - Johnson & Johnson – Janssen COVID-19 Vaccine
- FDA online reporting system

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