Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 March to 04 July 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 04 July 2021.
- Five (5) vaccines under Emergency Use Authorization (EUA) are currently being used in the vaccination program: CoronaVac, COVID-19 Vaccine AstraZeneca, Sputnik V, Comirnaty, and COVID-19 Vaccine Moderna.
- 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 04 July 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 of other countries, information on the very rare and serious adverse events of thrombosis and thrombocytopenia and in some cases accompanied by bleeding has been revised under the special warning and precautions for use.

On 18 June 2021, the European Medicines Agency (EMA) published a new safety update (with continuing assessment) on the use of Comirnaty, COVID-19 Vaccine Moderna, Janssen COVID-19 Vaccine, and COVID-19 Vaccine AstraZeneca. This is regarding a small number of cases of myocarditis and pericarditis after Comirnaty vaccination in Israel. The cases were mostly male individuals below 30 years old, symptoms starting few days after second dose of vaccination. Most of the cases were mild and resolved within a few days. Relative to this, USFDA announced the revision of patient and provider factsheets for the mRNA vaccines Moderna and Comirnaty (Pfizer-BioNTech) on 25 June 2021.

Five (5) vaccines are currently used in the immunization program. These include CoronaVac, COVID-19 Vaccine AstraZeneca, Sputnik V, Comirnaty, and COVID-19 Vaccine Moderna. 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 04 July 2021, more than 11.3 million doses of COVID-19 vaccines (either CoronVac, COVID-19 vaccine AstraZeneca, Sputnik V, Comirnaty, or COVID-19 vaccine Moderna) were already administered. More than 8.5 million individuals have received their first dose of the vaccine while over 2.7 million individuals have completed their vaccine doses or considered as fully vaccinated. A total of 47,918 suspected adverse reaction reports were received, evaluated, and analyzed by the FDA. To disaggregate, 18,789 have been reported for CoronaVac, 27,530 for COVID-19 Vaccine AstraZeneca, 551 for Sputnik V, and 1,048 for Comirnaty.

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 04 July 2021.

Table 1. Distribution of reports of adverse reactions for each vaccine

Vaccine	Number vaccinated with first dose[b]	Number vaccinated with second dose[b]	Total number of reports[a]	Reports of non-serious events	Reports of serious events
CoronaVac	5,476,471	2,289,042	18,789	18,269	520
AstraZeneca	2,185,820	471,836	27,530	27,018	512
Sputnik V	112,886	14,776	551	546	5

Comirnaty	1,039,744	93,251	1,048	1,012	36
Moderna	24,203	0	0	0	0
TOTAL	**8,515,770**	**2,791,797**	**47,918**	**46,845**	**1,073**

Data source: [a]VigiFlow, [b]NVOC daily report as 6PM, 04 July 2021
Notes: Additional information may become available in individual cases which may change the figures presented
[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.

Table 2. Data on vaccination and suspected adverse reaction reports

Indicators	Value
No. of individuals who have received at least one dose of the vaccine	8,515,770
No. of individuals fully vaccinated	2,791,797
Total number of doses administered	11,307,567
No. of suspected adverse reaction reports	47,918 (0.42% of doses administered)
No. of suspected serious adverse reaction reports	1,073 (0.009% of doses administered)

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.

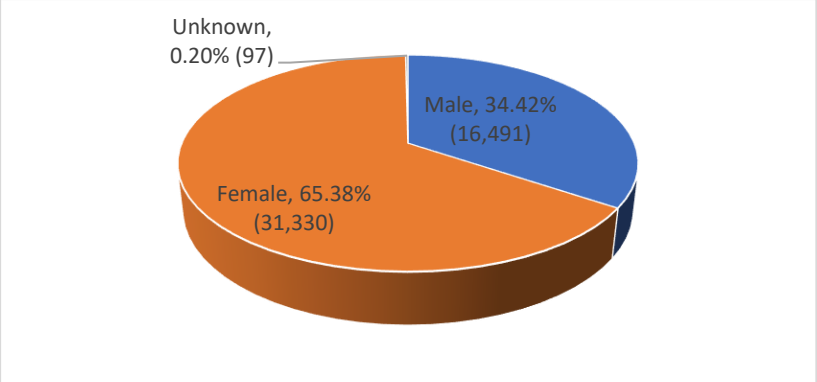

Figure 1. Report distribution by gender

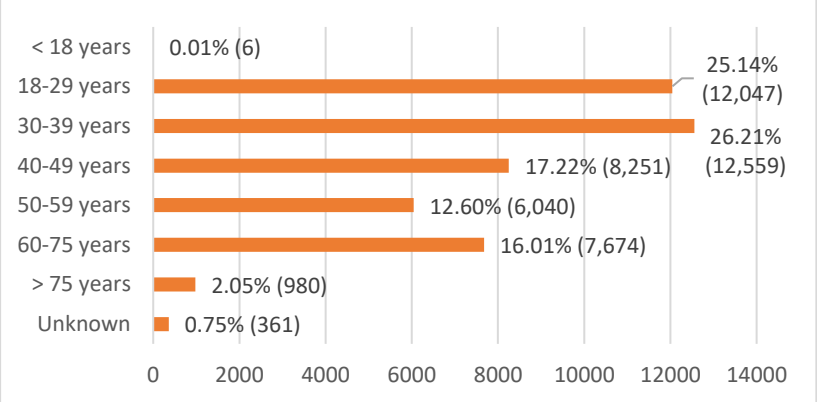

Figure 2. Report distribution by age

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, and Comirnaty. It occurs only 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 population increases. The current reporting rate for anaphylaxis is 18.93 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/*

Confirmed COVID-19 infections

There were 522 confirmed reports of COVID-19 infections. Most of the reported infections were asymptomatic cases. There were 27 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.

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. The expert committee reviews and assesses whether the vaccine caused the reaction. Based on the reports received the hospitalization reporting rate is 5.39 per 100,000 doses administered. Commonly reported causes of hospitalization include pyrexia, cough, dyspnea, and headache.

Reports involving death

As of 04 July 2021, 382 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 23 years and above. The mean age of the fatal cases was 64.60 years. 73.30% (280) of the fatal cases were from age group 60 years and above, 20.94% (80) from age group of 40-59 years, 5.24% (20) from age group 20-39 years, and 0.52% (2) 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 172 of these case reports as coincidental events or not related to the vaccine, 12 cases were indeterminate, and nine (9) were unclassifiable. Other cases are still under investigation and are continuously being reviewed.

Number of suspected adverse reactions per category

A total of 47,918 case reports consisting of 106,643 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*	7,017
Cardiac symptoms *E.g. Palpitations, bradycardia*	602
Ear symptoms *E.g. Ear swelling, vertigo*	28
Endocrine symptoms *E.g. Adrenal insufficiency, goiter*	3
Examinations *E.g. Increased blood pressure, increased heart rate*	8,008
Eye symptoms *E.g. Eye itchiness, blurred vision*	176
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	1,964
Hepatobiliary symptoms *E.g. Jaundice*	1
Immune system symptoms *E.g. Allergic reactions*	127
Infections *E.g. Cold symptoms*	931
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	158
Musculoskeletal symptoms	1,185

E.g. Back pain, joint pain, pain in extremities	
Neurological symptoms *E.g. Dizziness, headache, syncope*	4,982
Pregnancy, puerperium, and perinatal conditions *E.g. Abortion*	2
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	42
Psychiatric symptoms *E.g. Feeling anxious*	75
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	19
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	18
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	2,054
Skin symptoms *E.g. Cold sweat, rash, redness*	2,759
Social circumstances *E.g. Hearing disability, walking disability*	3
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	27
Vascular symptoms *E.g. Flushes, low blood pressure*	295

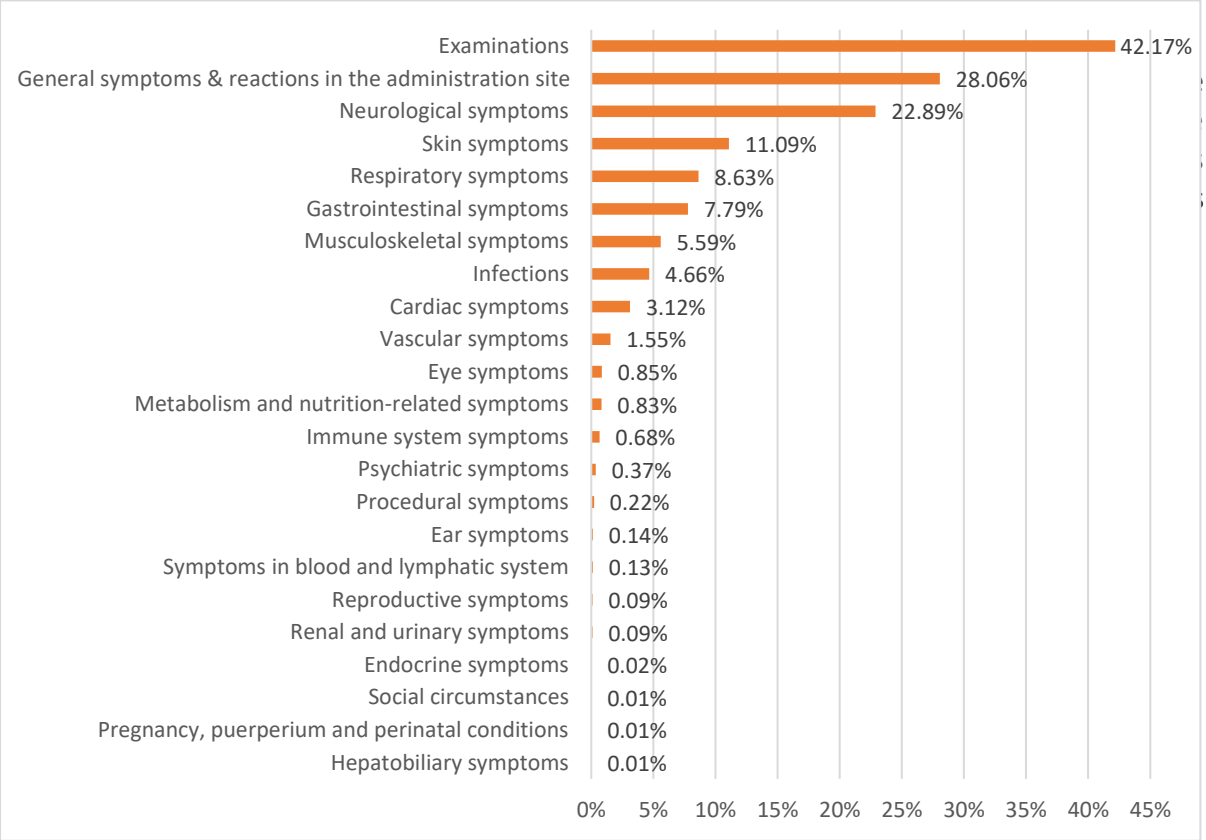

Figure 3. Suspected adverse reaction distribution by SOC for inactivated vaccine

Reactions to non-replicating viral vector vaccines

- COVID-19 vaccine AstraZeneca
- Sputnik V

Classification	Number of suspected reactions
General symptoms & reactions in the administration site *E.g. Pain and reaction in the injection site, chills, discomfort*	37,260
Cardiac symptoms *E.g. Palpitations, bradycardia*	583
Ear symptoms *E.g. Ear swelling, vertigo*	39
Endocrine symptoms *E.g. Adrenal insufficiency, goiter*	2
Examinations *E.g. Increased blood pressure, increased heart rate*	4,801
Eye symptoms *E.g. Eye itchiness, blurred vision*	350
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	3,678
Hepatobiliary symptoms *E.g. Jaundice*	2
Immune system symptoms *E.g. Allergic reactions*	207
Infections *E.g. Cold symptoms*	1,050
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	532
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities*	7,875
Neurological symptoms *E.g. Dizziness, headache, syncope*	13,142
Pregnancy, puerperium, and perinatal conditions *E.g. Abortion*	1
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	31
Psychiatric symptoms *E.g. Feeling anxious*	53
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	15
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	26
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	1,886
Skin symptoms *E.g. Cold sweat, rash, redness*	2,471
Social circumstances *E.g. Hearing disability, walking disability*	1
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	44

Vascular symptoms *E.g. Flushes, low blood pressure*	283

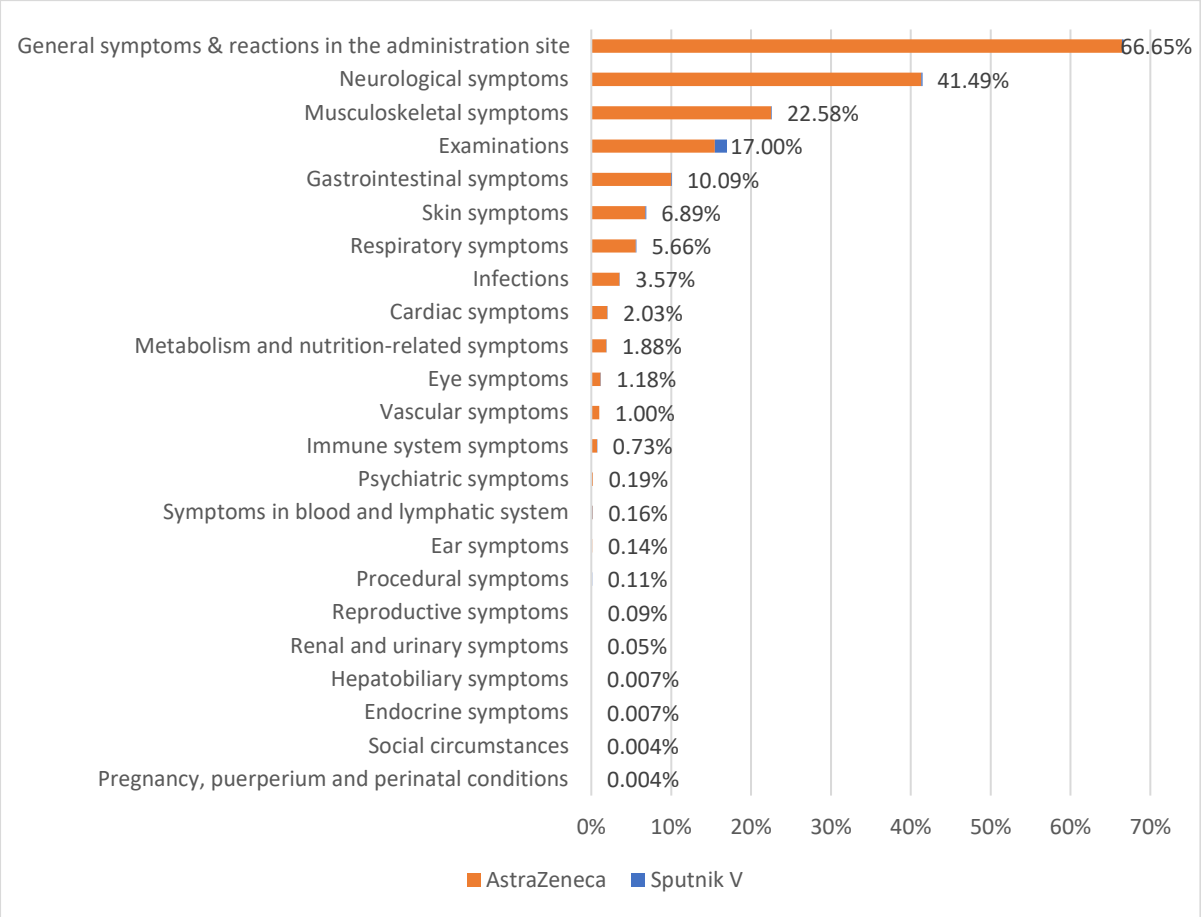

Figure 4. Suspected adverse reaction distribution by SOC for viral vector vaccines

As shown in Figure 4, the SOC which consists of the greatest number of reports were general symptoms and reactions in the administration site (18,717), followed by neurological symptoms (11,651), musculoskeletal symptoms (6,342), examinations (4,774), gastrointestinal symptoms (2,834), skin symptoms (1,935), respiratory symptoms (1,590), infections (1,002), and cardiac symptoms (569), and metabolism and nutrition-related symptom (528).

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

- pyrexia (40.90%)
- headache (36.02%)
- vaccination/injection site pain (25.01%)
- malaise (23.84%)
- myalgia (17.58%)
- chills (17.54%)
- blood pressure increased (15.51%)
- fatigue (13.15%)
- arthralgia (8.56%)
- dizziness (6.37%)

The top reported events for Sputnik V are:

- blood pressure increased (73.32%)
- heart rate increased (6.17%)
- headache (4.54%), pyrexia (4.54%)
- rash (4.17%)
- dizziness (3.81%)
- vaccination/injection site pain (3.09%)
- dyspnoea (2.18%)
- pruritus (2.00%)
- cough (1.81%)
- chest pain (1.27%), chills (1.27%)

Reactions to mRNA vaccine

- Comirnaty

Classification	Number of suspected reactions
General symptoms & reactions in the administration site *E.g. Pain and reaction in the injection site, chills, discomfort*	444
Cardiac symptoms *E.g. Palpitations, bradycardia*	37
Ear symptoms *E.g. Ear swelling, vertigo*	2
Examinations *E.g. Increased blood pressure, increased heart rate*	538
Eye symptoms *E.g. Eye itchiness, blurred vision*	15
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	115
Immune system symptoms *E.g. Allergic reactions*	3
Infections *E.g. Cold symptoms*	32
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	14
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities*	85
Neurological symptoms *E.g. Dizziness, headache, syncope*	257
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	5
Psychiatric symptoms *E.g. Feeling anxious*	4
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	2
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	4
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	115

Skin symptoms *E.g. Cold sweat, rash, redness*	109
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	4
Vascular symptoms *E.g. Flushes, low blood pressure*	14

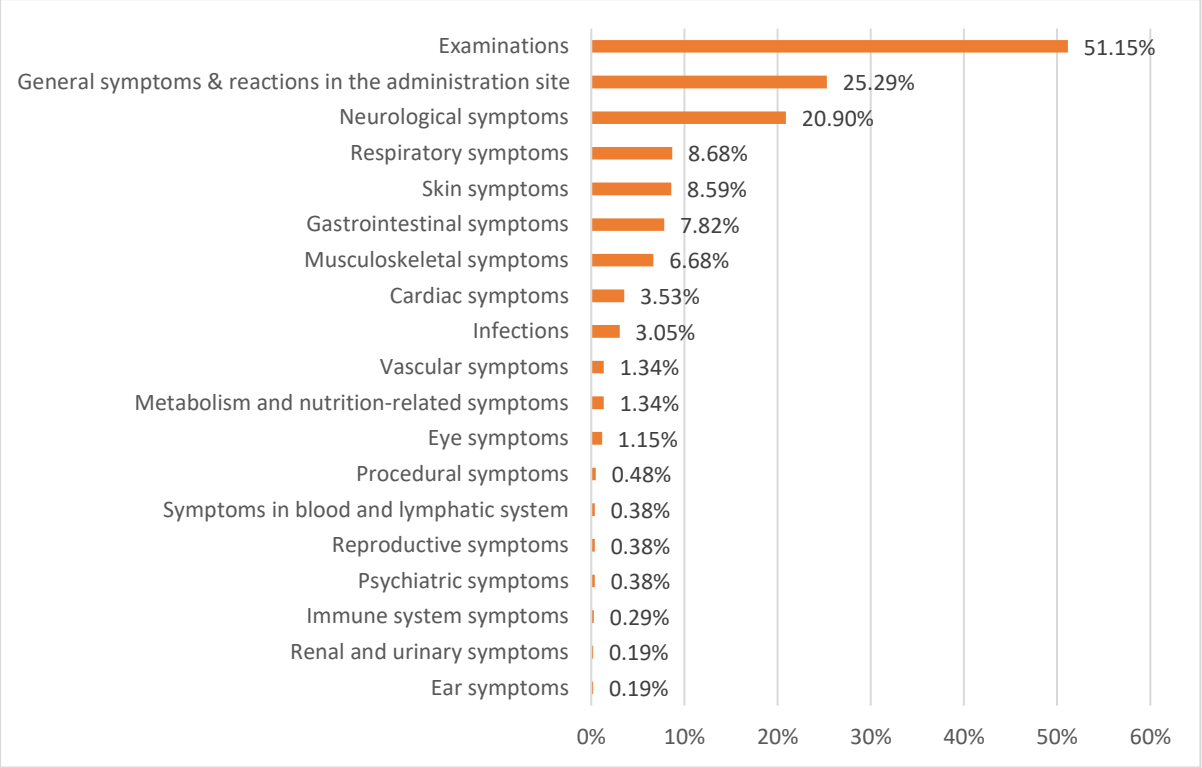

Figure 5. Suspected adverse reaction distribution by SOC for mRNA vaccine

As shown in Figure 5, the SOC which consists of the greatest number of reports were examinations (536), followed by general symptoms and reactions in the administration site (265), neurological symptoms (219), respiratory symptoms (91), skin symptoms (90), gastrointestinal symptoms (82), musculoskeletal symptoms (70), cardiac symptoms (37), and infections (32), and metabolism and nutrition-related symptoms (14) and vascular symptoms (14).

The top reported events are:

- blood pressure increased (49.14%)
- pyrexia (13.07%)
- headache (10.78%)
- dizziness (8.68%)
- vaccination/injection site pain (8.11%)
- malaise (5.82%)
- rash (5.34%)
- cough (3.91%), dyspnea (3.91%)
- nausea (3.82%)
- chills (3.34%)

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 (81.07%)*, although there were few cases who have *recovered but with sequalae (0.03%)*. A little over 10% of cases are *recovering/resolving* while less than 1% have *not recovered/not resolved* at the time of reporting. A proportion of 0.80% were reported with fatal outcomes as discussed in the section Reports involving death.

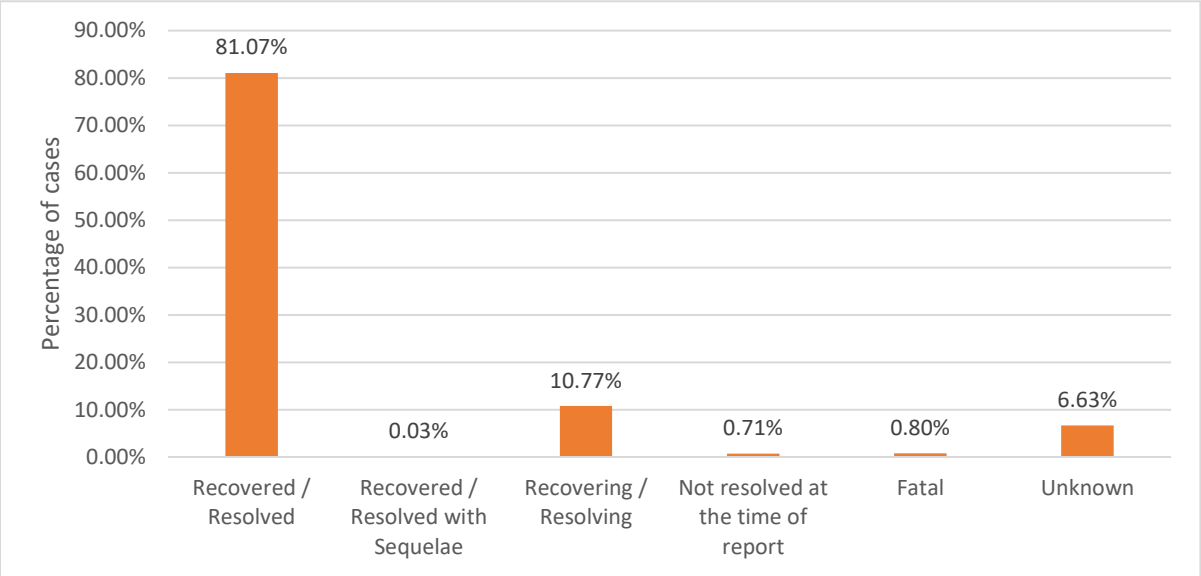

Figure 6. Case outcome

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
  - Moderna – COVID-19 Vaccine Moderna
- FDA online reporting system

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