



# Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 March to 12 September 2021)

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## 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 12 September 2021.
- Seven (7) 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, 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), 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 12 September 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. It is possible for several persons to experience the same adverse event but for the report to be serious for one person and non-serious for another person. 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 in their product labels.

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.

Seven (7) vaccines are currently used in the immunization program. These include CoronaVac, COVID-19 Vaccine AstraZeneca, Sputnik V, Comirnaty, COVID-19 Vaccine Moderna, Janssen COVID-19 Vaccine, and COVID-19 Vaccine Sinopharm. 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 [eight \(8\) COVID-19 vaccines with 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 & Sputnik Light)
- 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 Sinopharm BIBP/Wuhan)

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 Sinopharm BIBP/Wuhan are inactivated vaccines. All are administered in two doses within an interval of a few weeks except for Janssen COVID-19 Vaccine and Sputnik Light, which is administered as a single-dose.

### Statistics regarding reports of suspected adverse reactions

As of 12 September 2021, more than 39 million doses of COVID-19 vaccines (either CoronaVac, COVID-19 Vaccine AstraZeneca, Sputnik V, Comirnaty, COVID-19 Vaccine Moderna, Janssen COVID-19 Vaccine, or COVID-19 Vaccine Sinopharm) were already administered. Nearly 17 million individuals are now fully vaccinated (either given a single-dose or 2-dose vaccine course) while more than nine (9) million are partly vaccinated waiting for their second dose to be administered. A total of 62,777 suspected adverse reaction reports were received, evaluated, and analyzed by the FDA. To disaggregate, 25,023 have been reported for CoronaVac, 30,569 for COVID-19 Vaccine AstraZeneca, 665 for Sputnik V, 2,805 for Comirnaty, 1,074 for COVID-19 Vaccine Moderna and, 2,628 for Janssen COVID-19 Vaccine, and 13 for COVID-19 Vaccine Sinopharm.

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

Indicators	Value
Total number of doses administered	39,229,200
No. of fully vaccinated individuals	16,923,110
No. of individuals partly vaccinated	9,011,851
No. of suspected adverse reaction reports	<b>62,777</b> (0.16% of doses administered)
No. of suspected serious adverse reaction reports	<b>2,341</b> (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 up until 12 September 2021.

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

Vaccine	Date started	Total vaccine doses administered <sup>b</sup>	Number of fully vaccinated individuals <sup>b</sup>	Number of individuals partly vaccinated	Total number of reports <sup>a</sup>	Reports of non-serious events	Reports of serious events
CoronaVac	01 Mar 2021	22,198,456	8,826,666	4,545,124	25,023	23,900	1,123
AstraZeneca	07 Mar 2021	6,388,935	2,125,071	2,138,793	30,569	29,828	741
Sputnik V	04 May 2021	335,037	67,549	199,939	665	654	11
Comirnaty	13 May 2021	3,855,937	1,625,094	605,749	2,805	2,661	144
Moderna	30 June 2021	2,640,804	649,847	1,341,110	1,074	1,024	50
Janssen	20 July 2021	3,628,871	3,628,871	-	2,628	2,358	270
Sinopharm	August 2021	181,160	12	181,136	13	11	2
<b>TOTAL</b>		<b>39,229,200</b>	<b>16,923,110</b>	<b>9,011,851</b>	<b>62,777</b>	<b>60,436</b>	<b>2,341</b>

Data source: <sup>a</sup>VigiFlow, <sup>b</sup>NVOC daily report as 6PM, 12 September 2021

Notes: Additional information may become available in individual cases, which may change the figures presented

<sup>b</sup>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

<sup>c</sup>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. Click [here](#) to show disaggregated data.

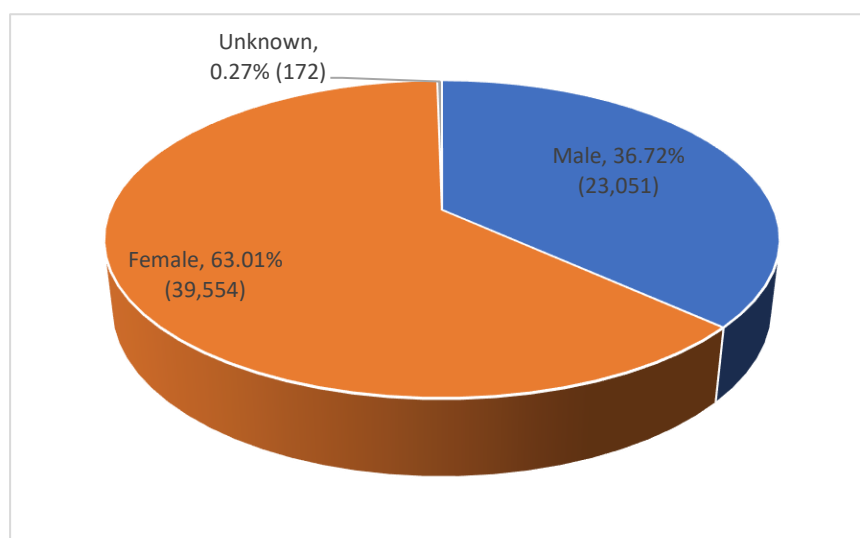


Figure 1. Report distribution by gender

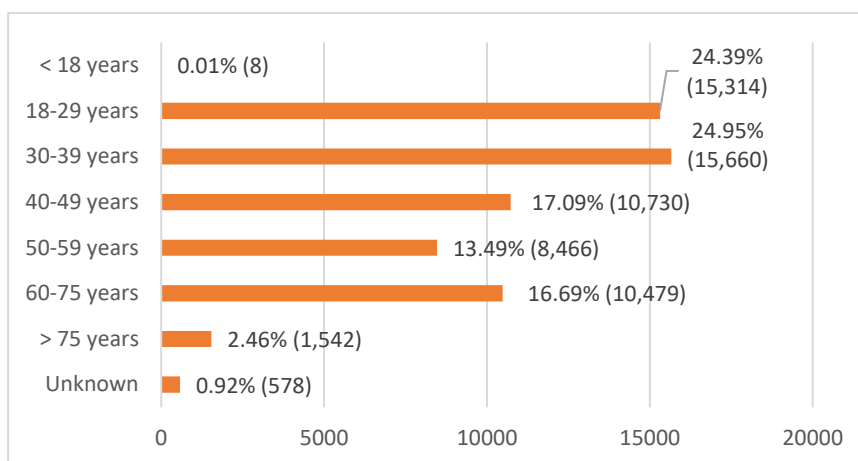


Figure 2. Report distribution by age

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%).<sup>1</sup> 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).<sup>2</sup>

<sup>1</sup> 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>

<sup>2</sup> 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 6.42 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 unaware. The BP control rate, with or without medications, is 36%. Only about 25% of hypertensive individuals monitor blood pressure at home.<sup>3</sup> This study explains the increase in blood pressure observed in most vaccinated individuals.

<sup>3</sup> 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-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:<sup>4</sup>

- 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

Five (5) cases of thrombosis 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.

<sup>4</sup> 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 1,320 confirmed reports of COVID-19 infections. Most of the reported infections were asymptomatic cases. There were 116 severe cases which 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 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.

Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience the following symptoms after vaccination:<sup>5</sup>

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

Four (4) 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.

<sup>5</sup> *Comirnaty and Spikevax: possible link to very rare cases of myocarditis and pericarditis*  
<https://www.ema.europa.eu/en/news/comirnaty-spikevax-possible-link-very-rare-cases-myocarditis-pericarditis>

### **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):<sup>6</sup>

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

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.

<sup>6</sup> COVID-19 Vaccine Janssen: Contraindication in individuals with previous capillary leak syndrome and update on thrombosis with thrombocytopenia syndrome  
<https://www.ema.europa.eu/en/medicines/dhpc/covid-19-vaccine-janssen-contraindication-individuals-previous-capillary-leak-syndrome-update>

### **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.

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:<sup>7</sup>

- double vision or difficulty moving eyes
- difficulty swallowing, speaking, or chewing
- coordination problems and unsteadiness
- difficulty walking
- tingling sensations in the hands and feet
- weakness in the limbs, chest, or face
- problems with bladder control and bowel function

Nine (9) cases of GBS have been reported. Two (2) cases have been assessed as product related reactions (as per published literature), two (2) cases are indeterminate meaning there is insufficient evidence that the vaccine caused the reaction, and five (5) 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.

<sup>7</sup> COVID-19 Vaccine Janssen: Guillain-Barré syndrome listed as a very rare side effect  
<https://www.ema.europa.eu/en/news/covid-19-vaccine-janssen-guillain-barre-syndrome-listed-very-rare-side-effect>

### **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 3.53 per 100,000 doses administered. Commonly reported causes of hospitalization include pyrexia, cough, dyspnea, and headache.

### Reports involving death

As of 12 September 2021, 879 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 64.49 years. 71.67% (630) of the fatal cases were from age group 60 years and above, 19.91% (175) from age group of 40-59 years, 6.83% (60) from age group 20-39 years and 1.59% (14) 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 261 of these case reports as coincidental events or not related to the vaccine, 19 cases were indeterminate, and 14 were unclassifiable. Other cases are still under investigation and are continuously being reviewed.

## Number of suspected adverse reactions per category

A total of 62,777 case reports consisting of 138,948 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 vaccines

- CoronaVac
- COVID-19 Vaccine Sinopharm

Classification	Number of suspected reactions
General symptoms & reactions in the administration site <i>E.g. Pain and reaction in the injection site, chills, discomfort, fever, fatigue</i>	10,163
Cardiac symptoms <i>E.g. Palpitations, bradycardia, tachycardia</i>	817

Ear symptoms <i>E.g. Ear swelling, vertigo, tinnitus, ear discomfort</i>	37
Endocrine symptoms <i>E.g. Adrenal insufficiency, goiter, thyroid symptoms</i>	3
Examinations <i>E.g. Increased blood pressure, increased heart rate, blood glucose increased, SARS-CoV-2 test</i>	10,087
Eye symptoms <i>E.g. Eye itchiness, blurred vision, eye pain, eye swelling</i>	223
Gastrointestinal symptoms <i>E.g. Abdominal pain, diarrhea, nausea, vomiting, dry mouth, lip swelling</i>	2,642
Hepatobiliary symptoms <i>E.g. Jaundice</i>	2
Immune system symptoms <i>E.g. Allergic reactions, hypersensitivity</i>	169
Infections <i>E.g. Cold symptoms, rhinitis</i>	1,966
Metabolism and nutrition-related symptoms <i>E.g. Decreased appetite, increased appetite, starvation, dehydration</i>	297
Musculoskeletal symptoms <i>E.g. Back pain, joint pain, pain in extremities, muscle pain, muscle spasms</i>	1,694
Neoplasm <i>E.g. Liver cancer, Endometrial cancer</i>	2
Neurological symptoms <i>E.g. Dizziness, headache, syncope</i>	6,817
Pregnancy, puerperium, and perinatal conditions <i>E.g. Abortion, hemorrhage</i>	3
Procedural symptoms <i>E.g. Procedural hypertension, vaccination adverse reaction</i>	64
Psychiatric symptoms <i>E.g. Feeling anxious, insomnia, nervousness, disorientation</i>	104
Renal and urinary symptoms <i>E.g. Urine coloring yellow, urine frequency</i>	33
Reproductive symptoms <i>E.g. Vaginal bleeding, vaginal spotting</i>	34
Respiratory symptoms <i>E.g. Cough, nasal congestion, throat irritation</i>	3,899
Skin symptoms <i>E.g. Cold sweat, rash, redness</i>	3,598
Social circumstances <i>E.g. Hearing disability, walking disability</i>	3
Surgical and medical procedure <i>E.g. Tumor debulking, nasolabial flap</i>	1
Symptoms in blood and lymphatic system <i>E.g. Pain in the lymph nodes</i>	31
Vascular symptoms <i>E.g. Flushes, low blood pressure</i>	360

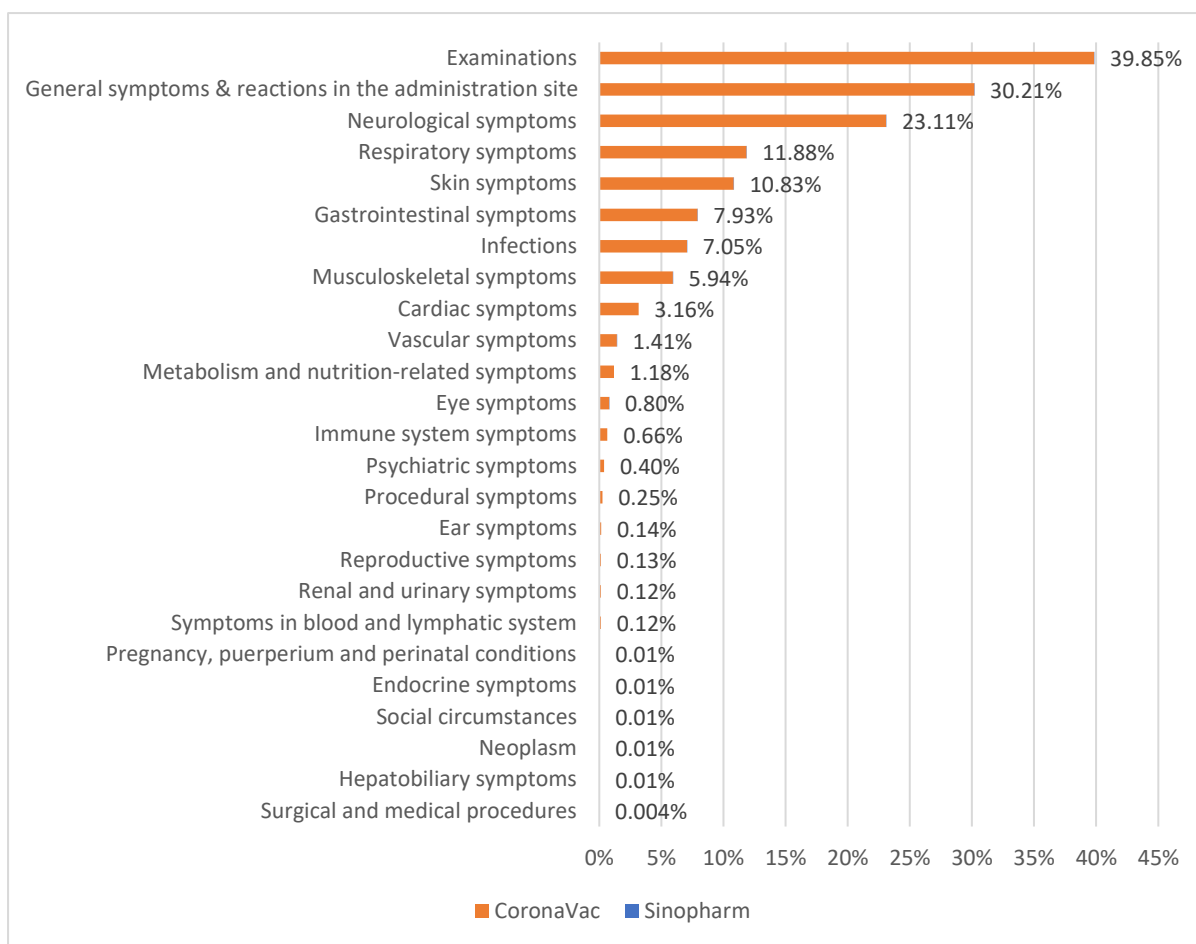


Figure 3. Suspected adverse reaction distribution by SOC for inactivated vaccine

As shown in Figure 3, the SOC which consists of the greatest number of reports were examinations (9,977), followed by general symptoms and reactions in the administration site (7,562), neurological symptoms (5,786), respiratory symptoms (2,974), skin symptoms (2,712), gastrointestinal symptoms (1,985), infections (1,766), musculoskeletal symptoms (1,486), cardiac symptoms (791), and vascular symptoms (353).

The top reported events for CoronaVac are:

- blood pressure increased (39.49%)
- headache (13.48%)
- pyrexia (11.41%)
- vaccination/injection site pain (11.09%)
- rash (7.21%)
- cough (7.01%)
- dizziness (6.95%)
- malaise (5.10%)
- nasopharyngitis (4.35%)
- pruritus (4.32%)

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

- dizziness (30.77%)
- cough (23.08%), fatigue (23.08%), nausea (23.08%)
- chills (15.38%), pruritus (15.38%)

## Reactions to non-replicating viral vector vaccines

- COVID-19 vaccine AstraZeneca
- Sputnik V
- Janssen COVID-19 Vaccine

<b>Classification</b>	<b>Number of suspected reactions</b>
General symptoms & reactions in the administration site <i>E.g. Pain and reaction in the injection site, chills, discomfort, fever, fatigue</i>	41,929
Cardiac symptoms <i>E.g. Palpitations, bradycardia, tachycardia</i>	706
Congenital, familial, and genetic disorder <i>E.g. Polycystic kidney</i>	1
Ear symptoms <i>E.g. Ear swelling, vertigo, tinnitus, ear discomfort</i>	55
Endocrine symptoms <i>E.g. Adrenal insufficiency, goiter, thyroid symptoms</i>	3
Examinations <i>E.g. Increased blood pressure, increased heart rate, blood glucose increased, SARS-CoV-2 test</i>	6,320
Eye symptoms <i>E.g. Eye itchiness, blurred vision, eye pain, eye swelling</i>	453
Gastrointestinal symptoms <i>E.g. Abdominal pain, diarrhea, nausea, vomiting, lip swelling</i>	4,407
Hepatobiliary symptoms <i>E.g. Jaundice</i>	4
Immune system symptoms <i>E.g. Allergic reactions, hypersensitivity</i>	249
Infections <i>E.g. Cold symptoms, rhinitis</i>	1,760
Metabolism and nutrition-related symptoms <i>E.g. Decreased appetite, increased appetite, starvation, dehydration</i>	668
Musculoskeletal symptoms <i>E.g. Back pain, joint pain, pain in extremities, muscle pain, muscle spasms</i>	8,711
Neurological symptoms <i>E.g. Dizziness, headache, syncope</i>	15,247
Pregnancy, puerperium, and perinatal conditions <i>E.g. Abortion, hemorrhage</i>	8
Procedural symptoms <i>E.g. Procedural hypertension, vaccination adverse reaction</i>	121
Psychiatric symptoms <i>E.g. Feeling anxious, insomnia, nervousness, disorientation</i>	88
Renal and urinary symptoms <i>E.g. Urine coloring yellow, urine frequency</i>	35
Reproductive symptoms <i>E.g. Vaginal bleeding, vaginal spotting</i>	41
Respiratory symptoms <i>E.g. Cough, nasal congestion, throat irritation</i>	3,065
Skin symptoms <i>E.g. Cold sweat, rash, redness</i>	3,175
Social circumstances <i>E.g. Hearing disability, walking disability</i>	1

Surgical and medical procedure <i>E.g. Tumor debulking, nasolabial flap</i>	2
Symptoms in blood and lymphatic system <i>E.g. Pain in the lymph nodes</i>	61
Vascular symptoms <i>E.g. Flushes, low blood pressure</i>	350

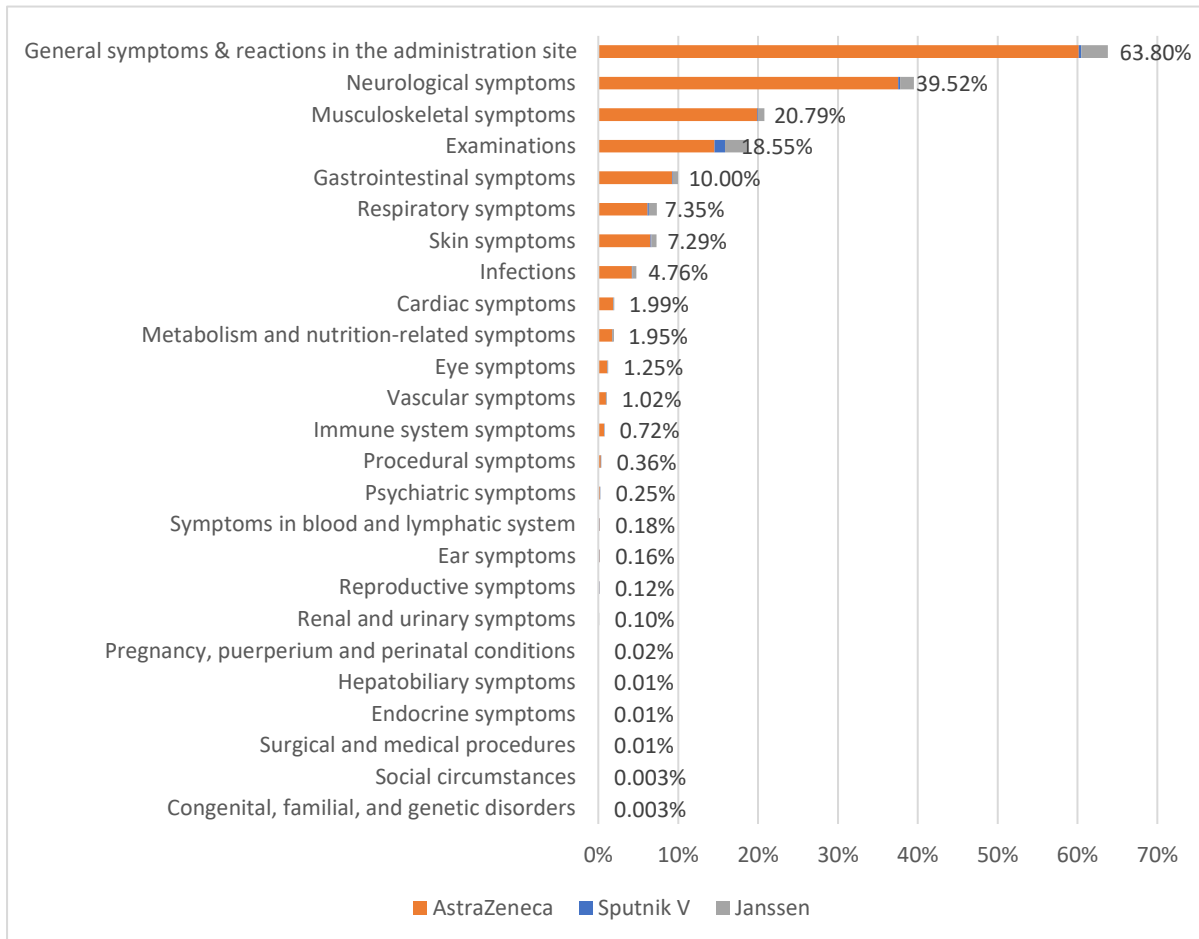


Figure 4. Suspected adverse reaction distribution by SOC for viral vector vaccines

As shown in Figure 4, the SOC which consists of the greatest number of reports were general symptoms and reactions in the administration site (21,605), followed by neurological symptoms (13,383), musculoskeletal symptoms (7,039), examinations (6,281), gastrointestinal symptoms (3,385), respiratory symptoms (2,488), skin symptoms (2,468), infections (1,610), cardiac symptoms (675), and metabolism and nutrition-related symptom (661).

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

- pyrexia (40.73%)
- headache (35.08%)
- vaccination/injection site pain (23.90%)
- malaise (22.63%)
- chills (17.03%)
- myalgia (16.46%)
- blood pressure increased (15.88%)

- fatigue (12.43%)
- arthralgia (8.17%)
- dizziness (6.45%)

The top reported events for Sputnik V are:

- blood pressure increased (63.01%)
- pyrexia (8.87%)
- headache (7.67%)
- rash (5.56%)
- heart rate increased (5.26%)
- cough (4.36%)
- dizziness (4.06%)
- vaccination/injection site pain (3.76%)
- dyspnea (2.86%)
- chills (2.71%)

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

- blood pressure increased (33.64%)
- pyrexia (20.36%)
- vaccination/injection site pain (15.30%)
- headache (11.95%)
- cough (8.49%)
- malaise (5.90%)
- rash (5.67%)
- dizziness (5.40%)
- myalgia (4.83%)
- dyspnea (4.72%)

### Reactions to mRNA vaccines

- Comirnaty
- COVID-19 Vaccine Moderna

Classification	Number of suspected reactions
General symptoms & reactions in the administration site <i>E.g. Pain and reaction in the injection site, chills, discomfort, fever, fatigue</i>	2,941
Cardiac symptoms <i>E.g. Palpitations, bradycardia, tachycardia</i>	124
Ear symptoms <i>E.g. Ear swelling, vertigo, tinnitus, ear discomfort</i>	11
Examinations <i>E.g. Increased blood pressure, increased heart rate, blood glucose increased, SARS-CoV-2 test</i>	1,240
Eye symptoms <i>E.g. Eye itchiness, blurred vision, eye pain, eye swelling</i>	48
Gastrointestinal symptoms <i>E.g. Abdominal pain, diarrhea, nausea, vomiting, lip swelling</i>	470
Immune system symptoms <i>E.g. Allergic reactions, hypersensitivity</i>	26

<b>Infections</b> <i>E.g. Cold symptoms, rhinitis</i>	312
<b>Metabolism and nutrition-related symptoms</b> <i>E.g. Decreased appetite, increased appetite, starvation, dehydration</i>	67
<b>Musculoskeletal symptoms</b> <i>E.g. Back pain, joint pain, pain in extremities, muscle pain, muscle spasms</i>	558
<b>Neurological symptoms</b> <i>E.g. Dizziness, headache, syncope</i>	1,253
<b>Pregnancy, puerperium, and perinatal conditions</b> <i>E.g. Abortion, hemorrhage</i>	1
<b>Procedural symptoms</b> <i>E.g. Procedural hypertension, vaccination adverse reaction</i>	13
<b>Psychiatric symptoms</b> <i>E.g. Feeling anxious, insomnia, nervousness, disorientation</i>	21
<b>Renal and urinary symptoms</b> <i>E.g. Urine coloring yellow, urine frequency</i>	3
<b>Reproductive symptoms</b> <i>E.g. Vaginal bleeding, vaginal spotting</i>	10
<b>Respiratory symptoms</b> <i>E.g. Cough, nasal congestion, throat irritation</i>	732
<b>Skin symptoms</b> <i>E.g. Cold sweat, rash, redness</i>	524
<b>Social circumstances</b> <i>E.g. Hearing disability, walking disability</i>	2
<b>Symptoms in blood and lymphatic system</b> <i>E.g. Pain in the lymph nodes</i>	24
<b>Vascular symptoms</b> <i>E.g. Flushes, low blood pressure</i>	48

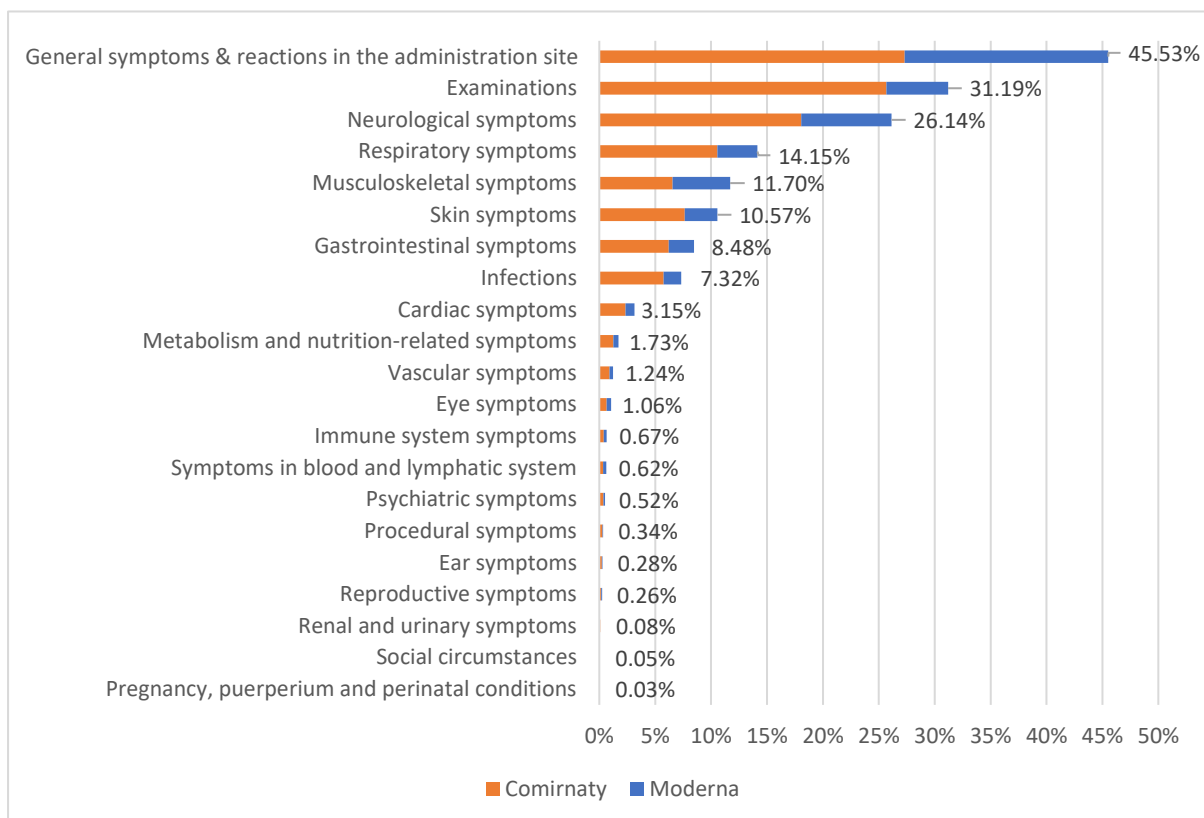


Figure 5. Suspected adverse reaction distribution by SOC for mRNA vaccine



As shown in Figure 5, the SOC which consists of the greatest number of reports were general symptoms and reactions in the administration site (1,766), followed by examinations (1,210), neurological symptoms (1,014), respiratory symptoms (549), musculoskeletal symptoms (454), skin symptoms (410), gastrointestinal symptoms (329), infections (284), cardiac symptoms (122), and metabolism and nutrition-related symptoms (67).

The top reported events for Comirnaty are:

- blood pressure increased (34.01%)
- pyrexia (22.10%)
- headache (14.90%)
- vaccination/injection site pain (9.45%)
- cough (9.13%)
- dizziness (8.02%)
- rash (7.34%)
- malaise (6.49%)
- nasopharyngitis (5.35%)
- chills (5.10%)

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

- vaccination/injection site pain (34.08%)
- pyrexia (31.94%)
- headache (22.63%)
- blood pressure increased (18.53%)
- chills (11.27%)
- malaise (10.24%)
- cough (8.19%)
- pain (8.01%)
- myalgia (7.73%)
- dizziness (6.98%)

## 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* (77.81%), although there were few cases who have *recovered but with sequelae* (0.03%). Over 12% of the cases are *recovering/resolving* while less than 1% have *not recovered/not resolved* at the time of reporting. A proportion of 1.40% were reported with fatal outcomes as discussed in the section reports involving death.

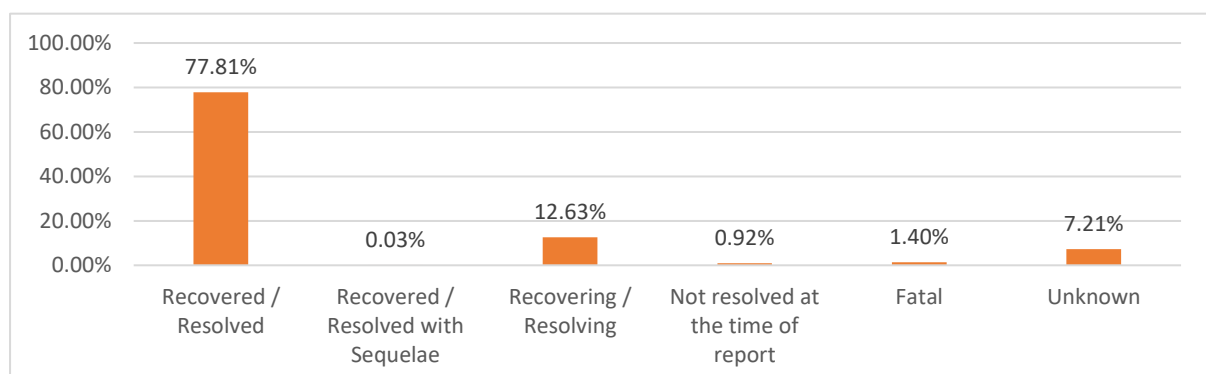


Figure 6. Case outcome

## 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.