Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 March to 16 May 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 16 May 2021.
- Four (4) vaccines under Emergency Use Authorization (EUA) are currently being used in the vaccination program: CoronaVac, COVID-19 Vaccine AstraZeneca, Sputnik V, and Comirnaty.
- 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 16 May 2021. As per benefit-risk assessment, these reports do not provide a basis for revising the current recommendations regarding use of the COVID-19 vaccines.

The reports received have no indications of new safety concerns. The reported reactions are generally in line with what is described in the product information and labels. Most of the 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.

CoronaVac is currently being used for the elderly population aged 60 years old and above. The benefit on its use outweighs the risks considering the increasing need to protect the elderly population despite the limited availability of vaccines. The FDA posed no objection to its use in elderly.

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.

Four (4) vaccines are now in use the immunization program. These include CoronaVac, COVID-19 Vaccine AstraZeneca, Sputnik V, and Comirnaty.

COVID-19 vaccines with Emergency Use Authorization in the Philippines

At present, there are seven (7) COVID-19 vaccines granted 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)

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; Sputnik V uses the same technology having two (2) different (dose) components of viral vectors; and CoronaVac and Covaxin 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 16 May 2021, more than two (2) million individuals have received their first dose of COVID-19 vaccines (either CoronaVac, COVID-19 vaccine AstraZeneca, Sputnik V, or Comirnaty). Over 700,000 individuals have received their second dose of either CoronaVac or COVID-19 vaccine AstraZeneca. An aggregate of 32,754 suspected adverse reaction reports were received, evaluated, and analyzed by the FDA.

Demographics

The figures provide a descriptive overview of the population reporting adverse reactions from COVID-19 vaccines. Figure 1. and Figure 2. shows the distribution of reports by gender and age.

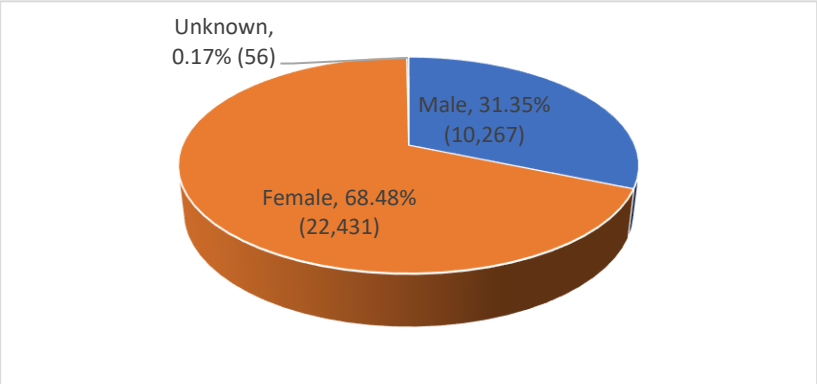

Figure 1. Report distribution by gender

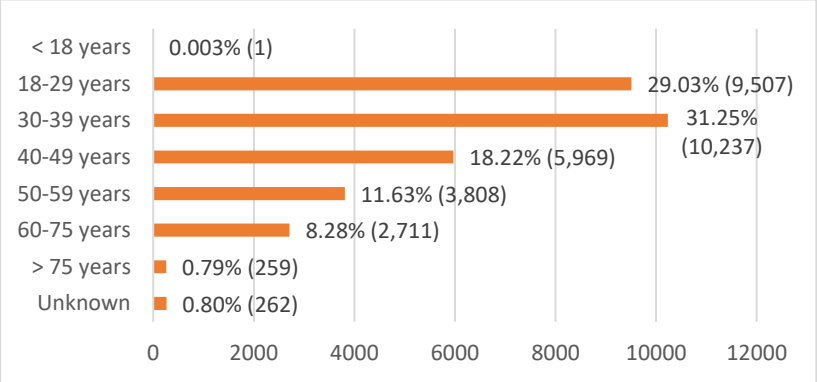

Figure 2. Report distribution by age

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. This may be attributed to the coverage of priority groups of senior citizens and individuals with comorbidities.

[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

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 16 May 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	1,552,586	709,737	12,565	12,339	226
AstraZeneca	697,813	9,865	20,044	19,816	228
Sputnik V	14,967	0	100	99	1
Comirnaty	16,907	0	45	45	0
TOTAL	**2,282,273**	**719,602**	**32,754**	**32,299**	**455**

Data source: [a]VigiFlow, [b]NVOC daily report as 6PM, 16 May 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.

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 and AstraZeneca. It is very rare (0.002% for CoronaVac and 0.001% for AstraZeneca from local data) and occurs only in a few vaccinated individuals. It usually happens in people with a history of severe vaccine reactions. Severe allergic reactions 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 the vaccine. Epinephrine is readily available in all vaccination sites.

Increased blood pressure
Blood pressure increased has been continuously reported as one of the top adverse reaction 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 history of hypertension, symptomatic hypertension, and base 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 Sison, Divinagracia & Nailes (2019), the latest data on prevalence of hypertension is 28%; 9% of which are unaware that they have hypertension. The BP control rate of 20% may be attributed to the increasing reports of blood pressure increased. Anxiety during vaccination may also cause elevation in blood pressure levels.[2]

[2] *Immunization stress-related response (ISRR) - A synopsis*
https://www.who.int/immunization/sage/meetings/2019/april/2_A_synopsis_of_ISRR_Draft_SAGE.PDF?ua=1

Reports involving death
As of 09 May 2021, 91 fatal events were received. Most of these events occurred in people with multiple existing comorbidities. There were cases of confirmed COVID-19 infections leading to severe cases with fatal outcome. Another cause of deaths was cardiovascular disease which belongs to the three leading causes of death in the Philippines (PSA 2020). An independent committee assessed 37 of these events as coincidental events or not related to the vaccine, three (3) cases were indeterminate, and two (2) were unclassifiable. Other cases are still under investigation and are continuously being reviewed.

To date, there were no reports of fatal events directly associated with the use of the vaccines currently in use.

Confirmed COVID-19 infections
Reports included 292 confirmed COVID-19 infections. Most of the reported infections were asymptomatic cases. There were 16 severe cases with a fatal outcome which, upon assessment, were not related to the use of the vaccine. These cases were attributable to the number of daily COVID-19 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.

Number of suspected adverse reactions per category

A total of 32,754 case reports containing 79,166 suspected adverse reactions were received from the start of the vaccination program. More than one suspected adverse reactions 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*	4,442
Cardiac symptoms *E.g. Palpitations, bradycardia*	452
Ear symptoms *E.g. Ear swelling, vertigo*	18
Endocrine symptoms *E.g. Goiter*	1
Examinations *E.g. Increased blood pressure, increased heart rate*	4,157
Eye symptoms *E.g. Eye itchiness, blurred vision*	122
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	1,383
Hepatobiliary symptoms *E.g. Jaundice*	1
Immune system symptoms *E.g. Allergic reactions*	104
Infections *E.g. Cold symptoms*	617
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	79
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities*	907
Neurological symptoms *E.g. Dizziness, headache, syncope*	3,747
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	695
Psychiatric symptoms *E.g. Feeling anxious*	45
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	10
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	6
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	1,377
Skin symptoms *E.g. Cold sweat, rash, redness*	2,058
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	22
Vascular symptoms *E.g. Flushes, low blood pressure*	689

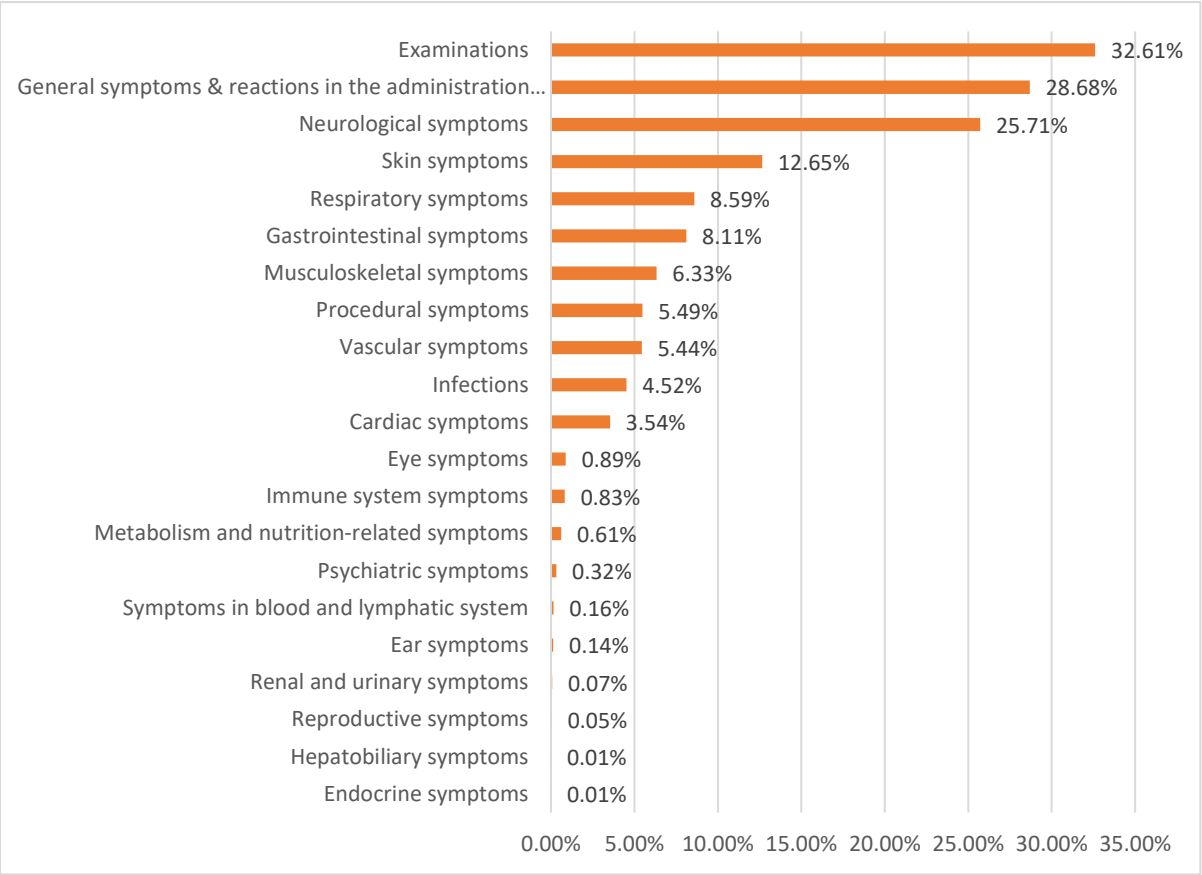

Figure 3. Suspected adverse reaction distribution by SOC for inactivated vaccine

As shown in Figure 3, the SOC containing the greatest number of events were general symptoms and reactions in the administration site (4,442), followed by examinations (4,157), neurological symptoms (3,747), skin symptoms (2,058), gastrointestinal symptoms (1,383), respiratory symptoms (1,377), musculoskeletal symptoms (907), procedural symptoms (695) vascular symptoms (689), and infections (617).

The top reported events are:

- blood pressure increased (32.13%)
- headache (15.30%)
- vaccination/injection site pain (14.24%)
- dizziness (8.64%)
- pyrexia (8.14%)
- rash (7.95%)
- vaccination related malaise (5.50%)
- pruritus (5.09%)
- nausea (3.83%)
- cough (3.76%)

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*	24,976
Cardiac symptoms *E.g. Palpitations, bradycardia*	368
Ear symptoms *E.g. Ear swelling, vertigo*	24
Examinations *E.g. Increased blood pressure, increased heart rate*	1,820
Eye symptoms *E.g. Eye itchiness, blurred vision*	257
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	2,800
Hepatobiliary symptoms *E.g. Jaundice*	1
Immune system symptoms *E.g. Allergic reactions*	163
Infections *E.g. Cold symptoms*	793
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	403
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities*	6,714
Neurological symptoms *E.g. Dizziness, headache, syncope*	10,677
Pregnancy, puerperium, and perinatal conditions *E.g. Abortion*	1
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	5.563
Psychiatric symptoms *E.g. Feeling anxious*	35
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	6
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	16
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	1,240
Skin symptoms *E.g. Cold sweat, rash, redness*	1,769
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	31
Vascular symptoms *E.g. Flushes, low blood pressure*	492

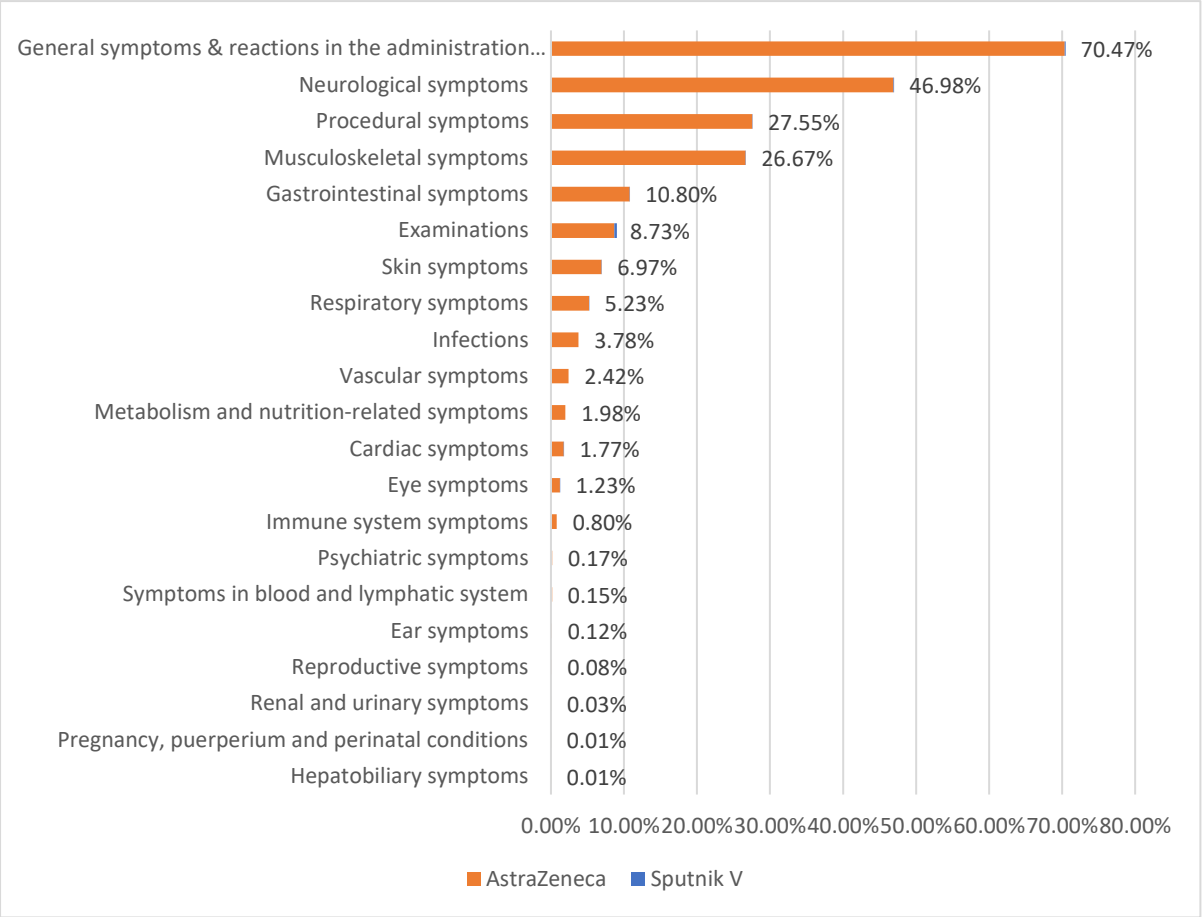

Figure 4. Suspected adverse reaction distribution by SOC for viral vector vaccines

As shown in Figure 4, the SOC containing the greatest number of events were general symptoms and reactions in the administration site (24,976), followed by neurological symptoms (10,677), musculoskeletal symptoms (6,714), procedural symptoms (5,563), gastrointestinal symptoms (2,800), skin symptoms (1,796), examinations (1,820), skin symptoms (1,796), respiratory symptoms (1,240), infections (793), and vascular symptoms (492).

The top reported events are:

- pyrexia (46.79%)
- headache (41.11%)
- vaccination related malaise (27.69%)
- vaccination/injection site pain (26.79%)
- myalgia (20.76%)
- chills (19.87%)
- fatigue (14.84%)
- arthralgia (10.22%)
- blood pressure increased (8.65%)
- pain (6.79%)

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*	13
Cardiac symptoms *E.g. Palpitations, bradycardia*	2
Ear symptoms *E.g. Ear swelling, vertigo*	1
Examinations *E.g. Increased blood pressure, increased heart rate*	34
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	2
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities*	2
Neurological symptoms *E.g. Dizziness, headache, syncope*	6
Vascular symptoms *E.g. Flushes, low blood pressure*	689

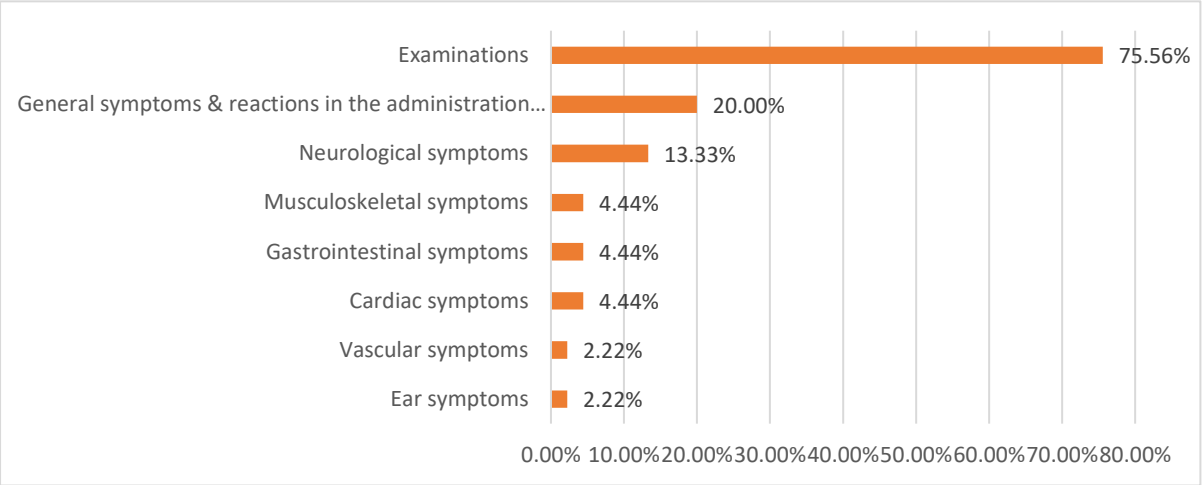

Figure 5. Suspected adverse reaction distribution by SOC for mRNA vaccine

As shown in Figure 5, the SOC containing the greatest number of events were examinations (34) followed by general symptoms and reactions in the administration site (13), and neurological symptoms (6).

The top reported events are:

- blood pressure increased (75.56%)
- headache (11.11%)
- pyrexia (11.11%)
- pain (6.67%)
- chills (4.44%)
- myalgia (4.44%)

Outcome of suspected adverse reactions

The outcome of cases of suspected adverse reactions to COVID-19 vaccines is shown in Figure 5. Overall, most of the reported cases have *recovered/resolved*, although there were few cases who have *recovered but with sequalae*. 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 0.23% were reported with fatal outcome as discussed in the section Reports involving death.

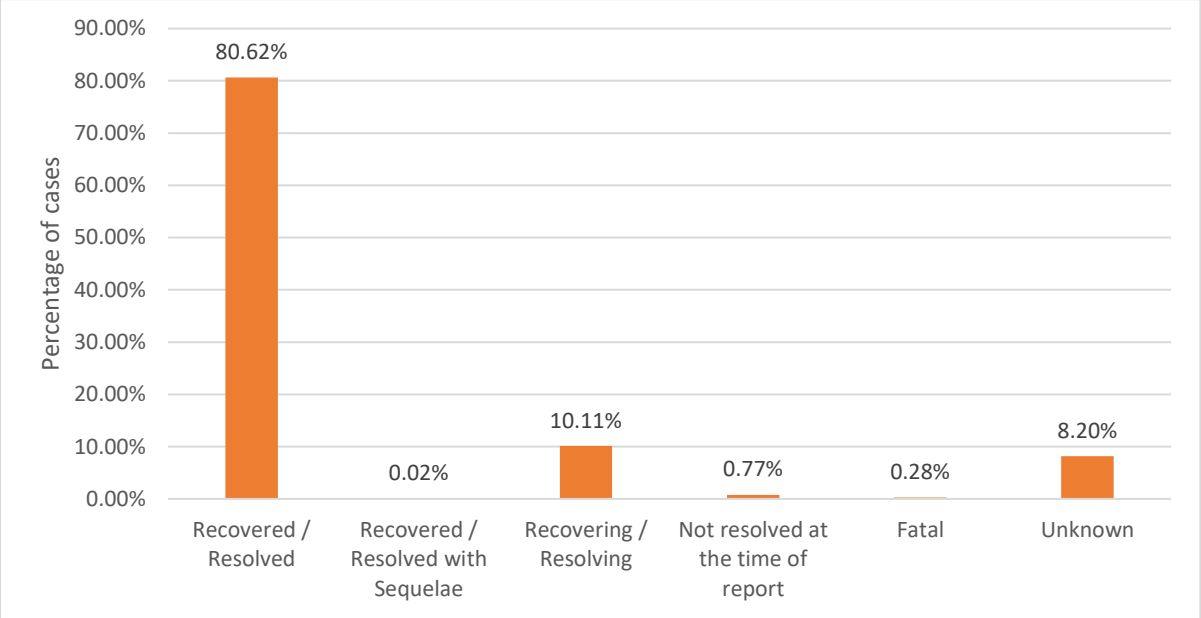

Figure 5. Case outcome

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
- FDA online reporting system

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