Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 to 21 March 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 21 March 2021.
- Two (2) vaccines under Emergency Use Authorization (EUA) are currently being use in the vaccination program: the SARS-CoV-2 Vaccine (Vero Cell) Inactivated, [CoronaVac] and COVID-19 Vaccine AstraZeneca.
- Data are based on VigiFlow, the national database of adverse reactions in the Philippines. It includes reports from hospitals and various epidemiology surveillance units (ESUs) of the Department of Health.
- 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 21 March 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 new indications of unexpected adverse reactions. 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 sites. These usually appear on the first or second day after vaccination and may last for 2-3 days. Most people tolerate these adverse reactions while others experience greater discomfort.

COVID-19 vaccines with emergency use authorization in the Philippines

At present, there are four (4) COVID-19 vaccines granted emergency use authorization:

- Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)
- ChAdOx1-S [recombinant] (COVID-19 Vaccine AstraZeneca)
- SARS-CoV-2 Vaccine (Vero Cell), Inactivated (CoronaVac)
- Gam-COVID-Vac (Sputnik V)

Pfizer-BioNTech COVID-19 vaccine is an mRNA vaccine, COVID-19 Vaccine AstraZeneca and Sputnik V are viral vectors, and CoronaVac is an inactivated vaccine. All are administered in two doses within an interval of a few weeks.

Statistics regarding reports of suspected adverse reactions

As of 21 March 2021, more than 360,000 individuals were vaccinated with their first dose of Coronavac and COVID-19 vaccine AstraZeneca. A total of 11,003 suspected adverse reaction reports were received, evaluated, and analyzed by the FDA.

Demographics

To provide a descriptive overview of the population reporting adverse reactions from COVID-19 vaccines.

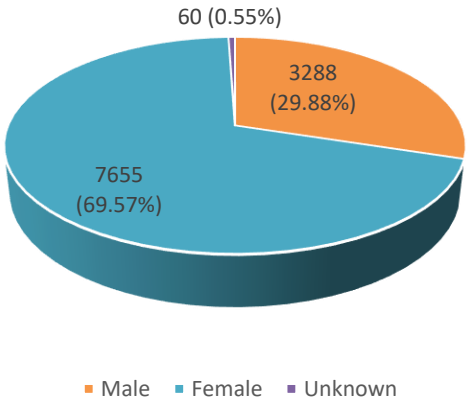

Figure 1. Report distribution by gender

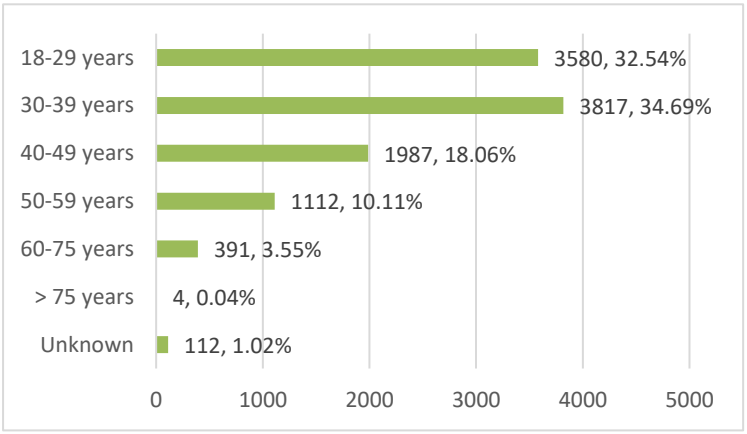

Figure 2. Report distribution by age

Since the early phase of the vaccination program is the frontline health workers, 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 (65%) under the age of 35.[1]

[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 up until 21 March 2021.

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

Vaccine	Date started	Vaccinated Individual[b] (cumulative)	Total number of reports[a]	Reports of non-serious events	Reports of serious events
CoronaVac	01 Mar 2021	205,290	4,194	3,926	105
AstraZeneca	07 Mar 2021	163,759	6,808	6,402	91
TOTAL		**369,049**	**11,003**	**10,328**	**196**

Data source: [a]VigiFlow, [b]NVOC daily report as 6PM, 21 March 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 resulted to 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

Number of suspected adverse reactions per category

There were 21,460 suspected adverse reactions reported from the 11,003 reports received. 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*	1,566
Cardiac symptoms *E.g. Palpitations, bradycardia*	191
Examinations *E.g. Increased blood pressure, increased heart rate*	773
Ear symptoms *E.g. Ear swelling, vertigo*	3
Eye symptoms *E.g. Eye itchiness, blurred vision*	52
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	477
Hepatobiliary symptoms *E.g. Jaundice*	1
Immune system symptoms *E.g. Allergic reactions*	75
Infections *E.g. Cold symptoms*	108
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	17
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities*	245
Neurological symptoms *E.g. Dizziness, headache, syncope*	1,396
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	37
Psychiatric symptoms *E.g. Feeling anxious*	6
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	1
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	1
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	437
Skin symptoms *E.g. Cold sweat, rash, redness*	934
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	11
Vascular symptoms *E.g. Flushes, low blood pressure*	283

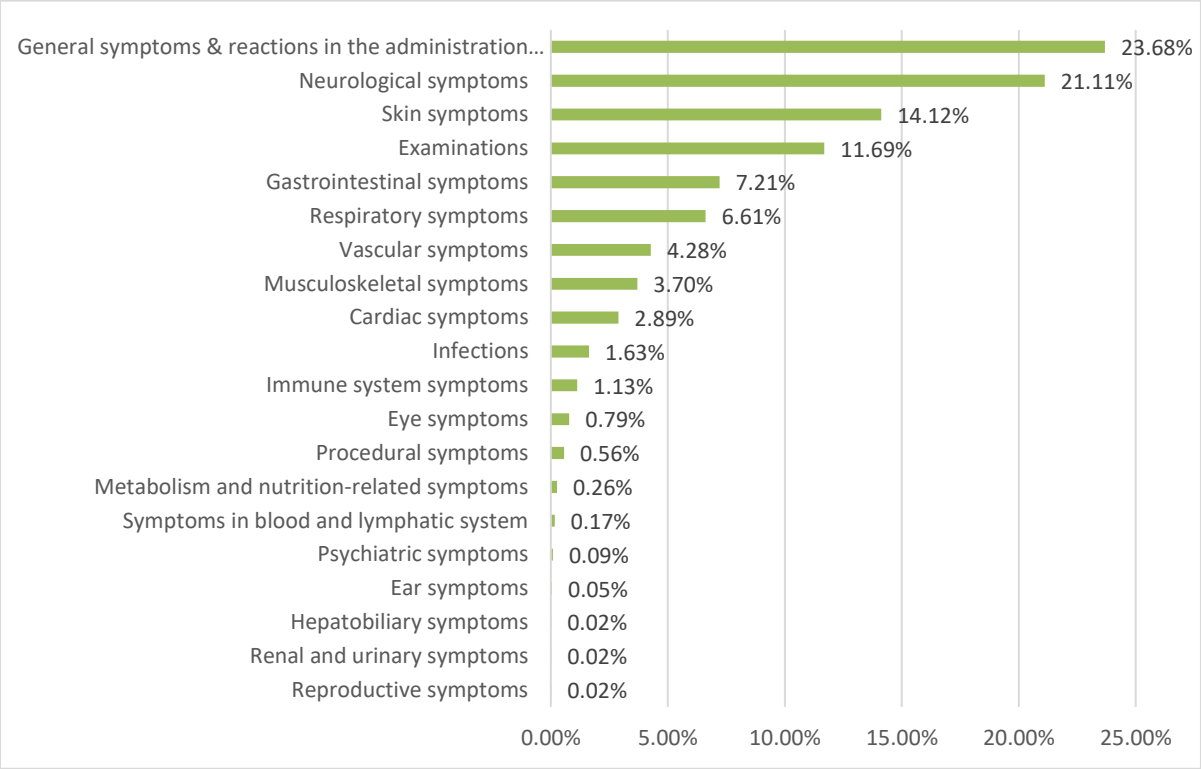

Figure 3. Suspected adverse reaction distribution by SOC for inactivated vaccine

General symptoms and reactions in the administration site comprised of 23.68% of overall reported reactions to inactivated vaccine, followed by neurological symptoms (21.11%) and skin symptoms (14.12%). The top reported events under the said SOCs are:

- General: Injection/vaccination site pain (7.89%), pyrexia (4.38%), fatigue (2.36%)
- Neurological: Headache (10.37%), dizziness (7.18%)
- Skin: Rash (7.05%), pruritus (4.34%), erythema (1.56%)

Severe allergic reactions following immunization with inactivated virus vaccine

Severe allergic reactions have been reported on the use of CoronaVac. It is very rare and occurs only in a few vaccinated individuals. It typically occurs in people who are known to have had severe vaccine reactions in the past. Severe allergic reactions generally occur soon after vaccination and is 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.

An increasing number of reports of severe allergic reactions was noted on the use of such vaccine. Experts are now looking into these events/reactions and their causal link with the vaccine.

Increased blood pressure

It was observed that high blood pressure is one of the most reported adverse reactions to inactivated vaccine during the vaccination program. The prevalence of hypertension in the

Philippines is 19.2% (2018). Anxiety in vaccinated individuals may also affect elevation in blood pressure level. The causal link with the vaccine needs further analysis.

Reactions to viral vector vaccine

- COVID-19 vaccine AstraZeneca

Classification	Number of suspected reactions
General symptoms & reactions in the administration site *E.g. Pain and reaction in the injection site, chills, discomfort*	7,376
Cardiac symptoms *E.g. Palpitations, bradycardia*	109
Congenital, familial, and genetic symptoms *E.g. Deficiency on specific receptor antagonist*	1
Examinations *E.g. Increased blood pressure, increased heart rate*	526
Ear symptoms *E.g. Ear swelling, vertigo*	6
Eye symptoms *E.g. Eye itchiness, blurred vision*	61
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	729
Immune system symptoms *E.g. Allergic reactions*	106
Infections *E.g. Cold symptoms*	93
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	90
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities*	1,712
Neurological symptoms *E.g. Dizziness, headache, syncope*	2,754
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	146
Psychiatric symptoms *E.g. Feeling anxious*	6
Renal and urinary symptoms *E.g. Urine coloring yellow, urine frequency*	1
Reproductive symptoms *E.g. Vaginal bleeding, vaginal spotting*	2
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	291
Skin symptoms *E.g. Cold sweat, rash, redness*	661
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	5

Vascular symptoms *E.g. Flushes, low blood pressure*	169

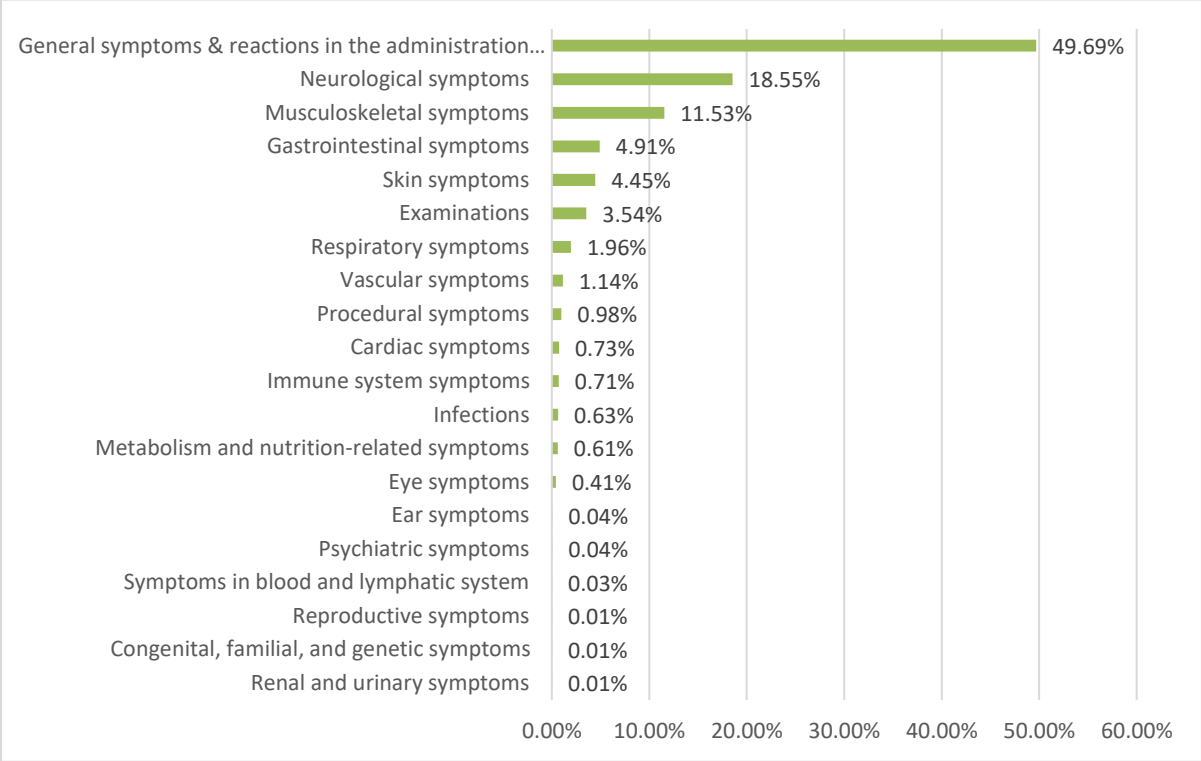

Figure 4. Suspected adverse reaction distribution by SOC for viral vector vaccine

General symptoms and reactions in the administration site comprised of 49.69% of overall reported reactions to viral vector vaccine, followed by neurological symptoms (18.55%) and musculoskeletal symptoms (11.53%). The top reported events under the said SOC are:

- General: Fever (17.21%) chills (8.04%), injection/vaccination site pain (5.15%), malaise (4.45%)
- Neurological: headache (14.32%), dizziness (2.26%)
- Musculoskeletal: muscle pain (6.38%), joint pain (3.52%)

Hypersensitivity including severe allergic reactions

Hypersensitivity including severe allergic reactions to COVID-19 vaccine AstraZeneca have been identified to be biologically possible. AstraZeneca revised the labeling of their product to reflect the changes that the second dose of the vaccine should not be given to those who have experienced a severe hypersensitivity reaction to the first dose of COVID-19 vaccine AstraZeneca.

Thromboembolic events (clotting risk)

The European Medicines Agency (EMA) concluded the following in their preliminary review for the signal of blood clots last 18 March 2021:

- the benefits of the vaccine in combating the still widespread threat of COVID-19 (which itself results in clotting problems and may be fatal) continue to outweigh the risk of side effects;
- the vaccine is not associated with an increase in the overall risk of blood clots (thromboembolic events) in those who receive it;
- there is no evidence of a problem related to specific batches of the vaccine or to particular manufacturing sites;
- however, the vaccine may be associated with very rare cases of blood clots associated with thrombocytopenia, i.e. low levels of blood platelets (elements in the blood that help it to clot) with or without bleeding, including rare cases of clots in the vessels draining blood from the brain (CVST).

Source: https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots

Reporting of suspected adverse reactions following vaccination

Individuals who 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 manufacturers
- FDA online reporting system

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