Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 to 14 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 on when the first vaccine became available, up to 14 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 from the VigiFlow, the national database of adverse reactions in the Philippines. This also include 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 14 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 three (3) 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)

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

Statistics regarding reports of suspected adverse reactions

As of 14 March 2021, nearly 200,000 individuals were vaccinated with their first dose of Coronavac and COVID-19 vaccine AstraZeneca. A total of 4,182 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.

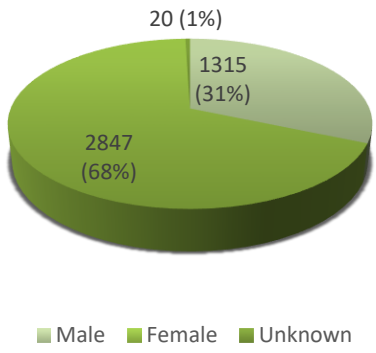

Figure 1. Report distribution by gender

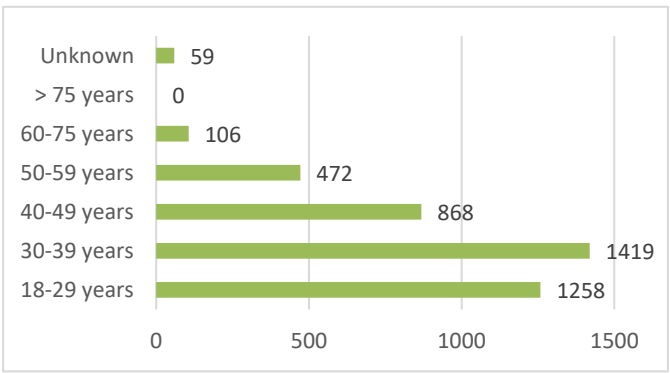

Figure 2. Report distribution by age

Distribution of reports of adverse reactions for each vaccine

Data shown below are cumulative reports from the start of the vaccination program up until 14 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	No. of serious reports involving death	No. of serious reports other than death
CoronaVac	01 Mar 2021	155, 212	2888	2738	-	68
AstraZeneca	07 Mar 2021	44, 492	1294	1198	-	27
TOTAL		**199, 704**	**4182**	**3937**	-	**95**

Data source: [a]VigiFlow, [b]NVOC daily report
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:

- Inpatient in 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

Out of the 95 serious reports, a total of 217 reactions were reported.

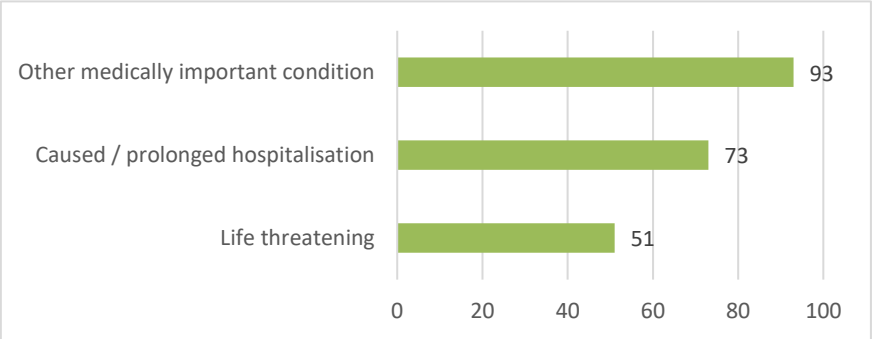

Figure 3. Report distribution by seriousness criteria

Number of suspected adverse reactions per category

There were 7,506 adverse reactions reported out of the 4,182 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, 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*	985
Cardiac symptoms *E.g. Palpitations, bradycardia*	141
Examinations *E.g. Increased blood pressure, increased heart rate*	607
Eye symptoms *E.g. Eye itchiness, blurred vision*	40
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	327
Hepatobiliary symptoms *E.g. Jaundice*	1
Immune system symptoms *E.g. Allergic reactions*	46
Infections *E.g. Cold symptoms*	57
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	7
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities*	114
Neurological symptoms *E.g. Dizziness, headache, syncope*	945
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	8
Psychiatric symptoms *E.g. Feeling anxious*	4
Reproductive symptoms *E.g. Vaginal bleeding*	1
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	297
Skin symptoms *E.g. Cold sweat, rash, redness*	732
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	8
Vascular symptoms *E.g. Flushes, low blood pressure*	204

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 individuals vaccinated. 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 this events or reactions on the 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*	1511
Cardiac symptoms *E.g. Palpitations, bradycardia*	19
Examinations *E.g. Increased blood pressure, increased heart rate*	99
Ear symptoms *E.g. Ear swelling, vertigo*	1
Eye symptoms *E.g. Eye itchiness, blurred vision*	14
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	121
Immune system symptoms *E.g. Allergic reactions*	36
Infections *E.g. Cold symptoms*	19
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	14
Musculoskeletal symptoms *E.g. Back pain, joint pain, pain in extremities*	339
Neurological symptoms *E.g. Dizziness, headache, syncope*	486
Procedural symptoms *E.g. Procedural hypertension, vaccination adverse reaction*	7

Psychiatric symptoms *E.g. Feeling anxious*	2
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	70
Skin symptoms *E.g. Cold sweat, rash, redness*	183
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	1
Vascular symptoms *E.g. Flushes, low blood pressure*	61

Hypersensitivity including severe allergic reactions

Hypersensitivity including severe allergic reactions to COVID-19 vaccine AstraZeneca have been identified to be biologically possible. AstraZeneca initiated the revision of their labelling. A second dose of the vaccine should not be given to those who have experienced severe allergic reaction (anaphylaxis) to the first dose of COVID-19 vaccine AstraZeneca.

Thromboembolic events

Several vaccination programs in the European Union including Italy and Denmark temporarily suspend the use of COVID-19 vaccine AstraZeneca due to fatal events of blood clots. There is no evidence that the vaccine caused the events. No issues or events have been found that could have impact the product quality, safety or efficacy.

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.