Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Reports of suspected adverse reactions to COVID-19 vaccines (01 to 07 March 2021)

Key points:

- The vaccination program in the Philippines started last 01 March 2021 prioritizing the frontline workers in health facilities. The inactivated SARS-CoV-2 Vaccine (Vero Cell) under the brand name CoronaVac developed by Sinovac Lifesciences Co., Ltd. was the first vaccine to arrive and used in the implementation of the program. The COVID-19 Vaccines AstraZeneca from the COVAX facility are currently being distributed in health facilities.
- The Food and Drug Administration (FDA), in close cooperation with the Department of Health (DOH) will continuously monitor reports of suspected adverse reactions.
- The summary presented below are the reports on adverse reactions to COVID-19 vaccines particularly the use of CoronaVac since it is the only vaccine currently in use.
- The figures are taken from the VigiFlow as it is the identified national database of adverse reaction in the Philippines.
- Symptoms or diseases that occur after vaccination are reported, it cannot be assumed that the use of the vaccine have causal relationship with suspected adverse reactions.
- Additional information may become available in individual case reports which may change the figures presented.
- Data concerning various vaccines are not directly comparable. COVID-19 vaccines profile varies. Some vaccines are more widely use compared to others, they have not been used for equal periods of time, and they have been administered to number people with different profiles including various age and sex.
- The known adverse reactions of the vaccines are listed in their respective product information.

Summary

Adverse reactions to COVID-19 vaccine are reported by health facilities as reported in heatl facilities. Alternatively, vaccinees may also report directly to the FDA or vaccine manufacturers. All reports regardless of the originating platform will be recorded in the national database of adverse reactions. Reporting of one adverse event in multiple platform is discouraged to avoid duplication of reports.

Reports of adverse reaction are necessary for the safety assessment of the COVID-19 vaccines This allows program implementors to constantly evaluate that the benefits still outweigh the known and potential risks.

Data shown below are cumulative reports from the roll-out of the vaccination program since 01 March 2021. Most reports are minor adverse reactions which include headache, fever, fatigue, chills, nausea, body pain and pain in the injection sites. These usually appear on first or second day after receiving the vaccine. The reactions are reported to lats around 2-3 days.

COVID-19 vaccines under emergency use in the Philippines

Presently, three (3) COVID-19 vaccines were approved under 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 with a few weeks interval.

Statistics of reports as of 07 March 2021

As of 07 March 2021, over 35,000 individuals received their first dose of COVID-19 vaccine. Their second dose is scheduled for administration after four (4) weeks.

A total of 351 cases of suspected adverse reaction were reported.

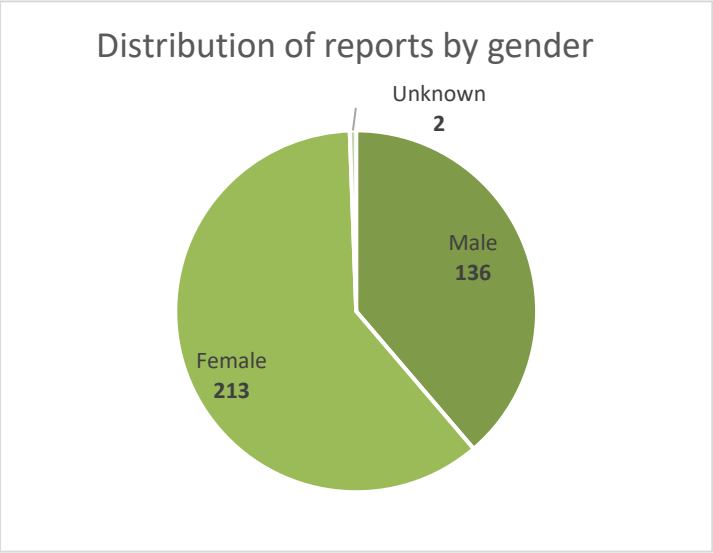

Figure 1. Percentage distribution of patients according to gender

Distribution of reports by age

Age group	No. of Reports
18-29 years	66
30-39 years	132
40-49 years	93
50-59 years	48
60-75 years	11
≥75 years	0
Unknown	1

Table 2. Age distribution of patients in the reports

Distribution of reports of adverse reactions for each vaccine

	Date started	Vaccinated (cumulative)	Total number of reports	Reports of non-serious events	No. of serious reports involving death	Serious reports other than death
CoronaVac	01 Mar 2021	35,669	344	333	-	7
AstraZeneca	-	-	-		-	-
TOTAL		35,669	344	333	-	7

Table 3. Distribution of reports according to vaccine and seriousness of the reaction

Reported adverse reaction are classified as serious adverse events when resulted in any of the following:

- Inpatient hospitalization/ prolongation of existing hospitalization
- Disabilities
- Life-threatening (e.g. anaphylaxis) and/or death
- Birth defect or congenital malformations
- Considered to be medically important event

Reported adverse reactions

Classification	Number of suspected reactions
General symptoms and reaction in the administration site *E.g. Pain and rection in the injection site, chills, discomfort*	171
Neurological symptoms *E.g. dizziness, headache, syncope*	112
Examinations *E.g. Increased blood pressure, increased heart rate*	76
Skin symptoms *E.g. Cold sweat, redness, rash,*	58

Musculoskeletal symptoms *E.g. Joint pain, back pain, pain in extremities*	29
Gastrointestinal symptoms *E.g. Abdominal pain, diarrhea, nausea, vomiting*	26
Respiratory symptoms *E.g. Cough, nasal congestion, throat irritation*	26
Vascular symptoms *E.g. Flushes, low blood pressure*	15
Cardiac symptoms *E.g. Palpitations*	13
Immune system symptoms *E.g. Allergic reactions*	9
Eye symptoms *E.g. Eye itchiness , blurred vision*	6
Symptoms in blood and lymphatic system *E.g. Pain in the lymph nodes*	4
Infections *E.g. Cold symptoms*	3
Metabolism and nutrition-related symptoms *E.g. Decreased appetite*	3
Psychiatric symptoms *E.g. Feeling anxious*	1

Serious allergic reactions following immunization with inactivated virus vaccine

Serious allergic reactions have been reported on the use of CoronaVac. Severe allergic reactions are generally very rare occurring only in few people vaccinated. It often occurred in people known to have had severe vaccine reactions in the past. It usually occurs soon after vaccination and can be treated with Epinephrine. Hence, observation post-vaccination for at least 15 minutes is necessary. Epinephrine is readily available in all immunization sites.