

# Safety Monitoring of COVID-19 Vaccines in Hong Kong

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This page contains data of adverse event reports up to and including 7 March 2021

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## 1. Pharmacovigilance system in Hong Kong

The Department of Health has put in place a pharmacovigilance system for COVID-19 immunization, including receiving reports of Adverse Events Following Immunization (“AEFIs”)<sup>1</sup> related to the COVID-19 vaccines used in Hong Kong from healthcare professionals and pharmaceutical industries.

Pursuant to the requirements of the Prevention and Control of Disease (Use of Vaccines) Regulation, Cap. 599K to monitor any adverse event that occurs to the recipient associated with the administration of the relevant vaccine, the Director of Health appointed the Expert Committee on Clinical Events Assessment Following COVID-19 Immunization (“Expert Committee”) to provide independent assessment of potential causal link between AEFIs and COVID-19 vaccines used in Hong Kong and to provide expert advice to the Government on safety-related matters.

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<sup>1</sup> According to World Health Organization, Adverse Events Following Immunization refers to any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

The Department of Health also partners with the University of Hong Kong to conduct an active surveillance programme for Adverse Events of Special Interest (“AESIs”)<sup>2</sup> related to COVID-19 vaccines.

This page provides regular updated information on the number of doses of COVID-19 vaccines administered and reports of adverse events following COVID-19 immunization. For press statements related to adverse events of COVID-19 vaccines, please click [here](#).

## 2. Summary report

The information of adverse events provided below is based on the reports received from healthcare professionals via the COVID-19 Vaccine Adverse Event on-line Reporting System (link click [here](#)). In addition, healthcare professionals are encouraged to report 15 items (link click [here](#)) of serious or unexpected AEFIs for close monitoring of the safety of the vaccines.

Currently, the Government Vaccination Programme provides two different types of COVID-19 vaccines, namely:

1. Inactivated virus technology platform - CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated by Sinovac Biotech (Hong Kong) Limited; and
2. mRNA technology platform - Comirnaty COVID-19 mRNA Vaccine (BNT162b2) Concentrate for Dispersion for Injection by Fosun Pharma in collaboration with the German drug manufacturer BioNTech.

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<sup>2</sup> According to the World Health Organization, Adverse Event of Special Interest (“AESI”) is a predefined and predefined medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further specific studies. The list of AESI is available at [https://www.drugoffice.gov.hk/eps/do/en/healthcare\\_providers/adr\\_reporting/index.html](https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html)

Up to and including 7 March, 2021, a total of 93, 025 people had received the COVID-19 vaccines. During the same period, the Department of Health had received a total of 71 AEFI reports.

### CoronaVac vaccine

<b>Cumulative number of doses of COVID-19 vaccine administered</b>	<b>91,818</b>
<b>Cumulative number of adverse events following immunization (AEFI) reports received</b>	<b>69 (0.075% of all doses administered)</b>

### Comirnaty vaccine

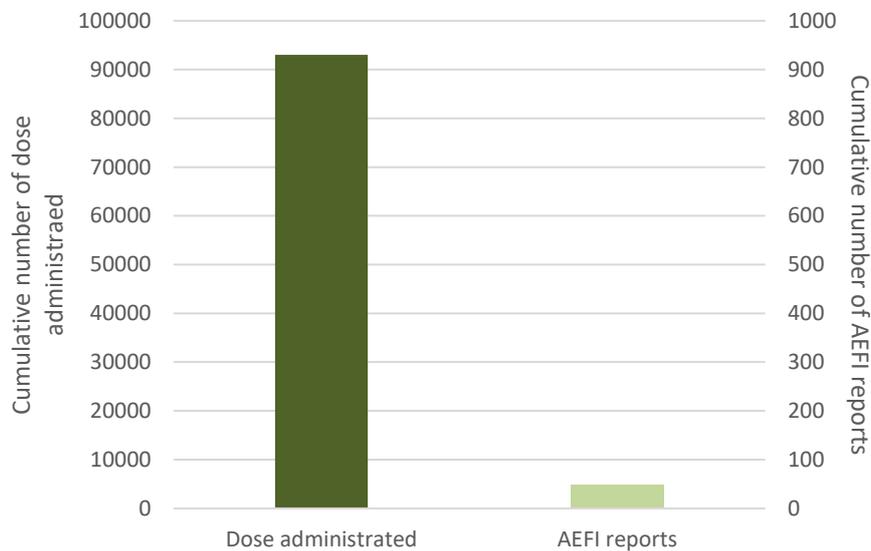
<b>Cumulative number of doses of COVID-19 vaccine administered</b>	<b>1,207</b>
<b>Cumulative number of adverse events following immunization (AEFI) reports received</b>	<b>2 (0.166% of all doses administered)</b>

## 3. Statistics and charts

The below information gives an overview of the total number of AEFI reports received and the proportion of AEFI. Up to and including 7 March, 2021, the Department of Health received 71 AEFI reports related to CoronaVac vaccine and Comirnaty vaccine including 47 reports of hospitalization and 2 reports of death case.

The cumulative number of doses of COVID-19 vaccines administered and the cumulative number of AEFI reports received are shown in Figure 1.

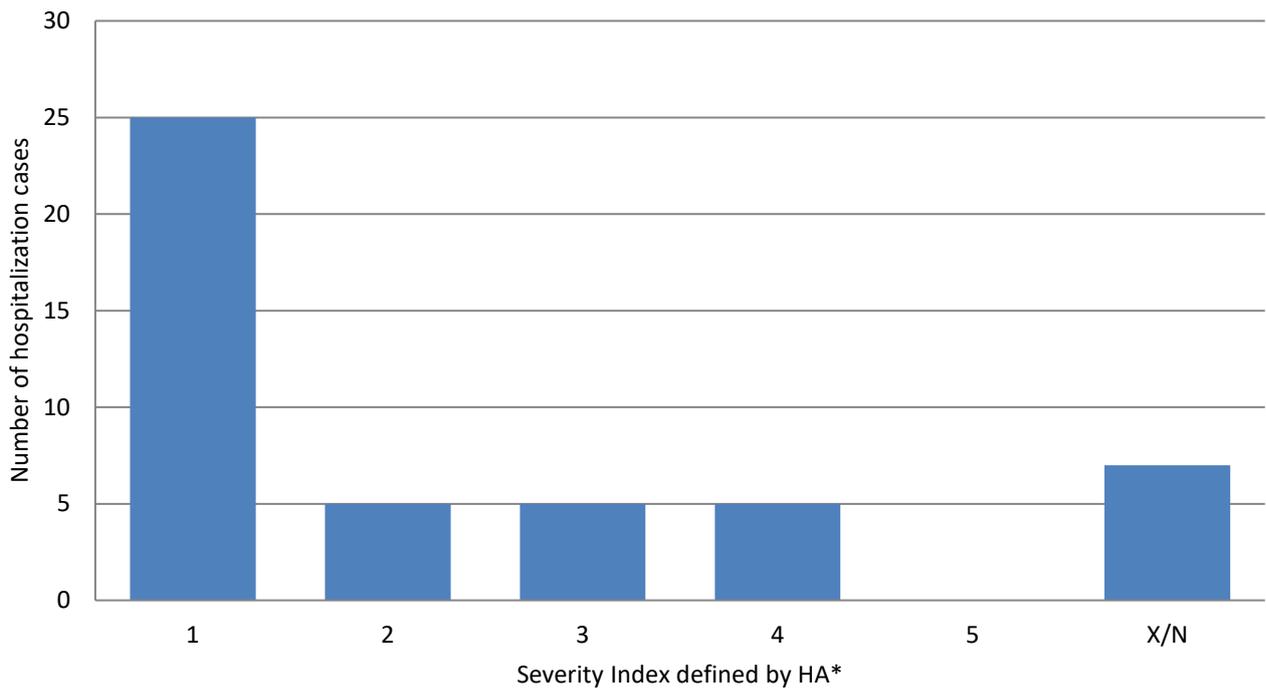
Figure 1. Cumulative number of dose of COVID-19 vaccines administered and cumulative number of AEFI reports received up to and including 7 March 2021



## Hospitalization

There were 47 reports of hospitalization received from the Hospital Authority (HA). The cases involved 30 males and 17 females, age ranged from 30 to 90 years old. The distribution of the severity index of these cases as defined by HA are as follow:

Figure 2. Hospitalization cases reported by Hospital Authority (HA)



\* Severity index defined by HA:

1 = Incident occurred but no injury sustained.

2 = Minor injury.

3 = Temporary morbidity.

4 = Significant morbidity.

5 = Major permanent loss of function / disability

X/N = Not known or Not applicable

Except for two cases admitted to the intensive care unit (ICU), a case with provisional diagnosis of Bell's palsy and a case with provisional diagnosis of stroke, the other cases were mainly presented with chest discomfort, chest pain, diarrhoea, dizziness, fever, headache, malaise, numbness, palpitation, rash, shortness of breath, tachycardia, vomiting, and weakness.

Assessment of these reports is ongoing, the information may be subjected to change when further information is available.

Adverse events reported are not necessarily caused by the vaccine. As a whole population, people with acute medical conditions with various severity are admitted to the hospitals every day. With the commencement of

the vaccination programme, among those patients with acute medical conditions, there will be those that have received vaccines and reports of such cases might increase with the increasing vaccination uptakes. It is important for the surveillance system in place to monitor these adverse events following COVID-19 vaccination and to conduct causality assessments based on scientific and objective approach to ensure that any untoward outcome would not go unnoticed.

## Other Reports

Apart from the reports of hospitalization and death cases, 22 other reports were received.

Based on the 20 AEFI reports associated with CoronaVac, the three most frequently reported events are:

Description of Events	Number of Events*
1. Headache	5
2. Dizziness	3
3. Urticaria	3

\*One report may have more than one event.

Based on the 2 AEFI reports associated with Comirnaty, the three most frequently reported events are:

Description of Events	Number of Events*
1. Abdominal pain	1
2. Diarrhoea	1
3. Numbness	1

\*One report may have more than one event.

## 4. Specific reports

### Death

As at 7 March, 2021, the DH had received 2 death case reports with history of COVID-19 immunization.

- The first case involved a 63-year-old man who suffered from acute shortness of breath with cough and attended Queen Elizabeth Hospital on 28 February, 2021. The patient's condition deteriorated rapidly and he eventually succumbed in the same day. The patient was a heavy smoker, had history of diabetes mellitus, hypertension, hyperlipidemia, obesity and suspected ischemic heart disease. He had received a dose of CoronaVac vaccine on 26 February, 2021. The Expert Committee conducted a causality assessment based on the algorithm of the WHO and all available information, including the medical conditions and history of the patient with relevant clinical data, vaccine information and preliminary autopsy findings of serious coronary heart disease. The Expert Committee considered that the patient's outcome was not directly associated with COVID-19 vaccination. However, the full autopsy report would be required for the Expert Committee to conclude the causality assessment. For further details, please refer to <https://www.info.gov.hk/gia/general/202103/03/P2021030300753.htm>
- In 2019, there were 3,740 deaths due to ischaemic heart diseases, including acute myocardial infarction<sup>^</sup>. The crude death rate was 49.82 per 100,000 population.
- The second case involved 55-year-old woman who had history of hypertension and hyperlipidaemia, suffered from acute stroke on March 5, 2021. She was admitted to Caritas Medical Centre (CMC) for treatment and was later transferred to Kwong Wah Hospital for further treatment. Subsequently, she had cardiac arrest and eventually passed away on March 6, 2021. She had received a dose of CoronaVac COVID-19 vaccine on March 2, 2021. Based on all available information, including the medical conditions and history of the patient with relevant clinical data, vaccine information and

preliminary autopsy findings of aortic dissection, the Expert Committee considered that the deceased's outcome was not directly associated with COVID-19 vaccination. However, the full autopsy report would be required for the Expert Committee to conclude the causality assessment. For further details, please refer to <https://www.info.gov.hk/gia/general/202103/08/P2021030800778.htm>

- In 2019, there were 368 deaths due to aortic aneurysm and dissection, including aortic dissection<sup>^</sup>. The crude death rate was 4.90 per 100,000 population.

<sup>^</sup>Tables on Health Status and Health Services 2019, Department of Health February 2021 ([supplementary\\_table2019.pdf \(dh.gov.hk\)](#)).

## **Admission to Intensive Care Unit**

- As at 7 March, 2021, the DH had received 2 reports involving patients with history of COVID-19 immunization admitted to Intensive Care Unit.
- The first case was about an 80-year-old man who has history of diabetes, carotid atherosclerosis, hypertension and stroke. He complained of chest pain on March 6 and attended the Accident and Emergency Department of CMC for treatment. The patient did not respond well to treatment and was transferred to the ICU for further management. The provisional diagnosis was acute coronary syndrome. He received a dose of CoronaVac COVID-19 vaccine on March 1, 2021. The Expert Committee considered that the patient's outcome was not directly associated with COVID-19 vaccination. However, the Expert Committee will require more clinical information during treatment to conclude the causality assessment.
- The second case was about a 72-year-old woman who has history of diabetes, hyperlipidaemia, hypertension and hypothyroidism, and received a dose of CoronaVac COVID-19 vaccine on March 6, 2021. She felt malaise after vaccination and skipped two doses of regular insulin. Her general condition decreased on March 7, 2021 and she was admitted to Prince of Wales Hospital for treatment. She was suspected of having severe diabetic ketoacidosis and transferred to the ICU for further treatment. Provisional diagnosis was diabetes, complicated with hyperosmolar hyperglycemic state. The Expert

Committee considered that the patient's situation was due to her underlying diseases and skipping of her regular insulin.

- For further information, please refer to <https://www.info.gov.hk/gia/general/202103/08/P2021030800778.htm>

## **Bell's palsy**

- A 69-year-old man with history of hypertension vaccinated with CoronaVac vaccine on 6 March, 2021. Two hours after the vaccination, he developed left eye discomfort and could not close the left eye completely. He attended the Accident and Emergency Department of Ruttonjee Hospital on 7 March, 2021 for treatment. Provisional diagnosis was Bell's palsy. He was discharged on 8 March, 2021. The Expert Committee noted the case and will conduct assessment when more clinical information is available.

## **Stroke**

- A 74-year-old man with history of diabetes, hypertension and hyperlipidaemia presented with left-sided weakness and slurred speech on 7 March, 2021 and was admitted to Tuen Mun Hospital. He had received a dose of CoronaVac COVID-19 vaccine on 1 March, 2021. Provisional diagnosis was stroke. His condition was stable. The Expert Committee noted the case and will conduct assessment when more clinical information is available.

12 March 2021