Updates on Safety of Covid -19 Vaccines

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Disclosures (COI)

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Lecturer : Menarini, Pfizer, Glenmark, AstraZeneca

Roadmap

- Vaccination period / definition of terms.
- Vaccines used in the program.
- Data on Adverse Events
- Summary

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Reports of Suspected Adverse Reaction to COVID-19 Vaccines (01 March 2021 to 31 October 2022)

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

Introduction

- The presentation is is a summary of AEFI following COVID-19 vaccination from 01 March 2021 up to 31 October 2022 as published in the PFDA.
- 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), vaccination sites, hospitals, patients/consumers, and EUA holders.
- 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, verification and validation may be done, which may change the assessment.

Introduction

- Adverse reaction reports are necessary for the safety assessment of the vaccines, making sure that the benefits always outweigh the risks.
- **Seven (7) vaccines under Emergency Use Authorization** (EUA) are currently being used in the vaccination program: **CoronaVac**, **Vaxzevria** (AstraZeneca), Sputnik V/Sputnik Light, **Comirnaty, Spikevax** (Moderna), Janssen COVID-19 Vaccine, and COVID-19 Vaccine Sinopharm.

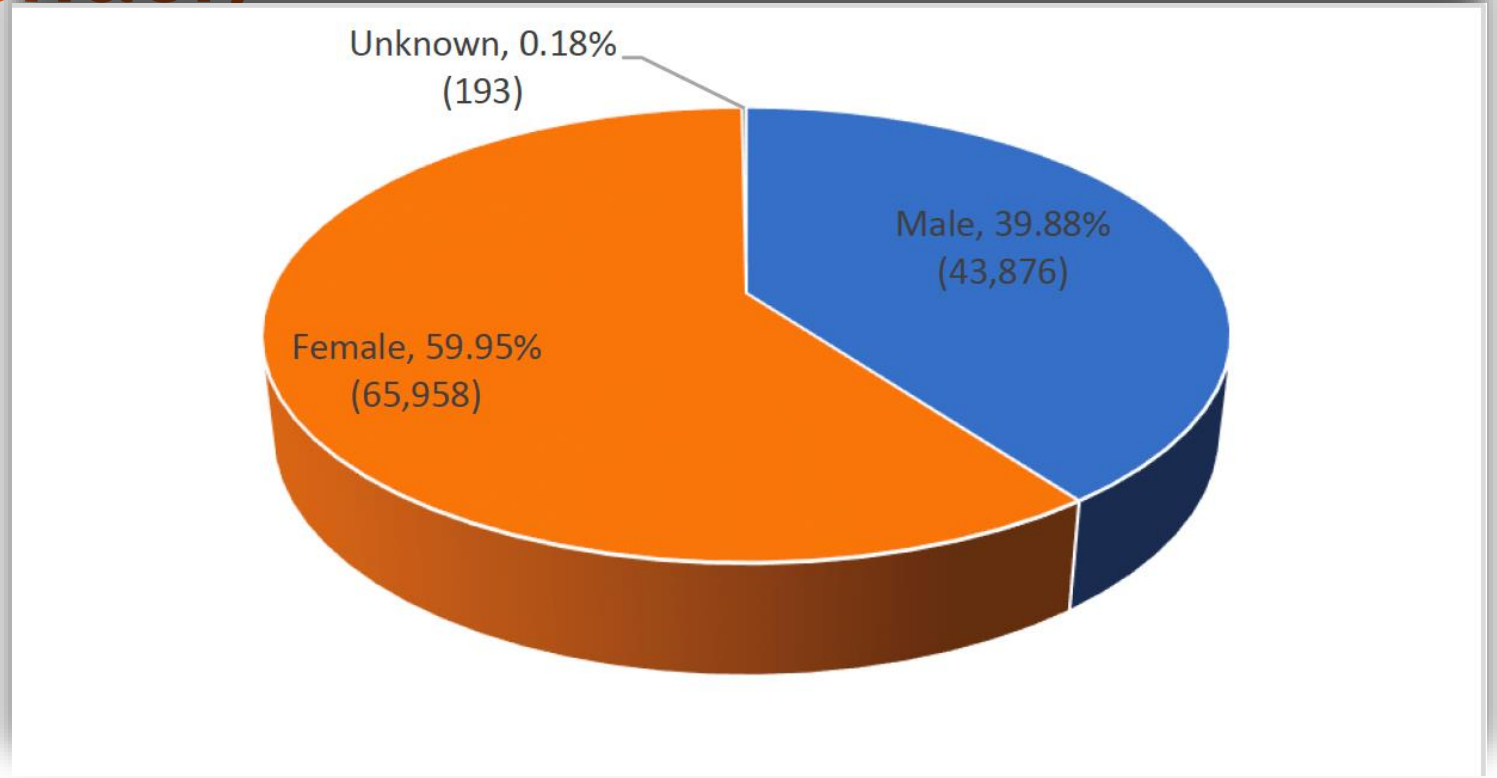
Data on vaccination and suspected adverse reaction reports

Indicators	Value
Total number of doses administered	168,421,865
No. of fully vaccinated individuals	73,549,560
No. of individuals with booster shots	20,594,592
No. of suspected adverse reaction reports	**110,027** (0.07% of doses administered)
No. of suspected serious adverse reaction reports	**10,184** (0.006% of doses administered)

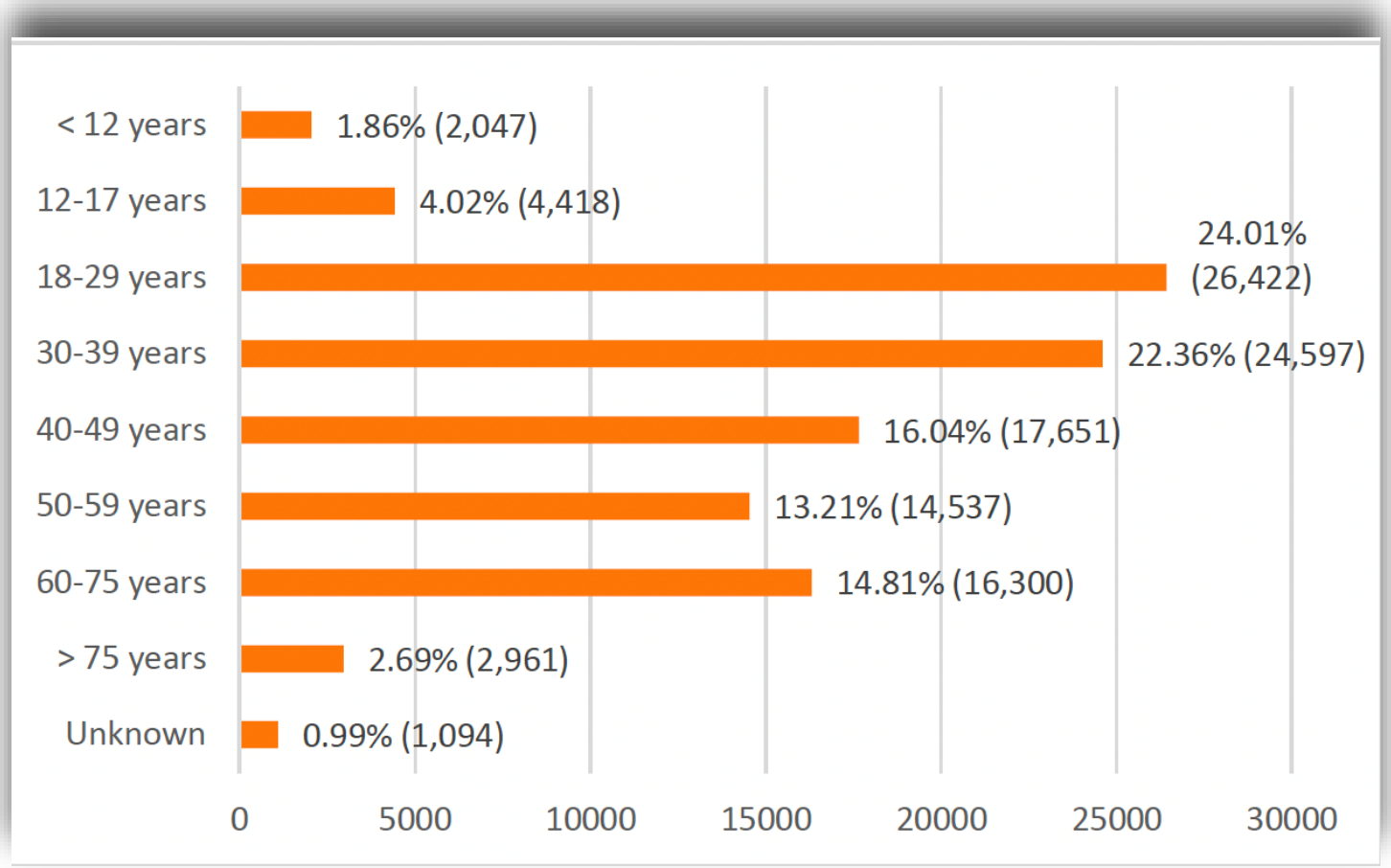
Distribution of reports of adverse reactions for each vaccine

Vaccine	Date started	Total vaccine doses administered [b]	Total number of reports [a]	Reports of non-serious events	Reports of serious events
CoronaVac	01 Mar 2021	46,292,981	36,631	33,204	3,427
AstraZeneca	07 Mar 2021	22,208,188	37,566	35,578	1,988
Sputnik V/ Sputnik Light	04 May 2021	1,115,717	885	838	47
Comirnaty	13 May 2021	70,857,671	22,240	19,606	2,634
Moderna	30 June 2021	19,720,871	6,768	5,923	845
Janssen	20 July 2021	7,185,701	5,500	4,343	1,157
Sinopharm	25 Aug 2021	1,040,736	437	351	86
TOTAL		**168,421,865**	**110,027**	**99,843**	**10,184**

Demographics (gender)



Demographics (age)



Pregnant women and lactating mothers

- Overall, data suggests that the benefits of receiving a COVID-19 vaccine outweigh any known or potential risks of vaccination during pregnancy and lactation.

Vaccination in children

- The roll out for vaccinating adolescent population (12-17 years old) started last 15 Oct

- As of 31 October 2022, 4,418 reports were received: 435 reports were tagged as serious (358 hospitalizations) and 3,983 reports were tagged as non-serious. The most common reported reactions are pyrexia, dizziness, vaccination/injection site pain, headache, and rash.

Vaccination in children

- Vaccination in children ages 5 to 11 started last 07 February 2022. Initially, Comirnaty is the only vaccine used in this age group. CoronaVac and Spikevax has also been authorized by the FDA to be used in individuals 6 years and above.

- As of 31 October 2022, 2,047 reports were received: 180 reports were tagged as serious (157 hospitalizations), 1,866 reports are tagged as non-serious, and one (1) report with no tag whether serious or non-serious. The most common reported reactions are vaccination/injection site pain, pyrexia, rash, vomiting, and headache.

Hypersensitivity including severe allergic reactions

- The proportion of reported side effects of severe allergic reactions to COVID-19 vaccines proved to be statistically rare as the number of vaccinated populations increases.
- The current reporting rate for anaphylaxis is 1.94 per million doses administered.

Increased blood pressure

- Blood pressure (BP) increased has been continuously reported as one of the top adverse reactions to all vaccine platforms. Monitoring BP has been part of the screening process for COVID-19 vaccination program in the country.

- According to PRESYON 4 (Philippine Heart Association Report on the Study of Hypertension), a nationwide hypertension survey conducted in January to April 2021, the prevalence of hypertension in the Philippines alarmingly increased to 37% in 2021 among adults 18 years old and above from 28% (2013). Out of this 37%, 19% are aware of having hypertension while 18% are undiagnosed. The BP control rate, with or without medications, is 36%. Only about 25% of hypertensive individuals monitor blood pressure at home.

Thrombosis-thrombocytopenia syndrome

- Thrombosis-thrombocytopenia syndrome (TTS) are cases of unusual blood clots with low blood platelets. Following cases of TTS from other countries, COVID-19 Vaccine AstraZeneca and Janssen COVID-19 Vaccine revised their label to include warnings related to thrombosis with thrombocytopenia, a very rare side effect following vaccination.
- Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience any sign of blood clots and low blood platelet such as:
  - shortness of breath
  - chest pain
  - leg swelling
  - persistent abdominal (belly) pain
  - neurological symptoms, such as severe and persistent headaches or blurred vision
  - tiny blood spots under the skin beyond the site of the injection

Thrombosis-thrombocytopenia syndrome

- Thirteen (13) cases of thrombosis have been reported. Causal link to all cases are currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Confirmed COVID-19 infections

- There were 4,749 confirmed reports of COVID-19 infections. Most of the reported infections were asymptomatic cases. There were 256 severe cases that resulted to a fatal outcome. Most of the fatal reports have not yet completed their vaccination course. Upon assessment, these cases were not related to the use of the vaccine, but these were actual COVID-19 natural infections.

Inflammation of the heart

- Myocarditis is an inflammation of the heart muscle that may present as chest pain, palpitations, arrhythmias, and/or symptoms of heart failure while pericarditis is an inflammation of the pericardial sac that surrounds the heart and fixes it to the mediastinum.
- Cases of myocarditis and pericarditis on the use of mRNA vaccine, such as Comirnaty and COVID-19 Vaccine Moderna, have been reported in many countries including the US, UK, Germany, and Israel.

Inflammation of the heart

- Most of the cases are young male.
- The US FDA announced the revision of fact sheets for Comirnaty and COVID-19 Vaccine Moderna suggesting increased risk of myocarditis and pericarditis following vaccination. EMA's safety committee has also concluded that myocarditis and pericarditis can occur in very rare cases following Comirnaty and COVID-19 Vaccine Moderna.

Inflammation of the heart

- Nineteen (19) cases of myocarditis and two (2) cases of pericarditis have been reported. Five (5) cases of myocarditis have been assessed as product related reactions (as per published literature) and 14 cases including two (2) cases of pericarditis are currently being reviewed. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Capillary Leak Syndrome

- Capillary leak syndrome is a very rare, serious condition that causes fluid leakage from small blood vessels (capillary), resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood, and low blood levels of albumin.

- Several cases were reported on the use of COVID-19 Vaccine AstraZeneca and Janssen COVID-19 Vaccine. The EMA's safety committee recommended contraindication in individuals with previous capillary leak syndrome and inclusion of capillary leak syndrome as a new side effect in the product information for both products.

Capillary Leak Syndrome

- Vaccinated individuals should watch out for the said adverse event and seek immediate medical assistance if they experience the following symptoms days after vaccination, which may occur together with feeling faint (due to low blood pressure):8
    - rapid swelling of the arms and legs
    - sudden weight gain
- One (1) case of capillary leak syndrome has been reported. It has been assessed as indeterminate meaning there is insufficient evidence that the vaccine caused the reaction. The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Guillain-Barré syndrome

- Guillain-Barré syndrome (GBS) is a rare, autoimmune disorder in which a person's own immune system damages the nerves, causing muscle weakness and sometimes paralysis.

- An increased risk for GBS has been observed following vaccination with Janssen COVID-19 Vaccine in the US. The US FDA has announced the revision of fact sheets for Janssen COVID-19 Vaccine to include the observed risk for GBS. EMA's safety committee considered that a causal relationship between **Janssen** COVID-19 Vaccine and GBS is possible. COVID-19 Vaccine **AstraZeneca** already updated their product information.

Guillain-Barré syndrome

- Thirty (30) cases of GBS have been reported. Ten (10) cases have been assessed as product related reactions (as per published literature), five (5) cases are indeterminate meaning there is insufficient evidence that the vaccine caused the reaction, and 15 are currently being reviewed.
- The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Bell's palsy

- Bell's palsy is a form of temporary facial paralysis or weakness on one side of the face. It results from dysfunction of facial nerve, which directs the muscles on one side of the face.
- Cases have been reported in several people in Hong Kong, Canada, and UK on the use of CoronaVac, Comirnaty, and COVID-19 Vaccine Moderna.
- CoronaVac vaccination fact sheet was revised to include bell's palsy as a very rare adverse reaction in Hong Kong while Comirnaty product information was revised in Canada. COVID-19 Vaccine Moderna already contains this safety information.

Bell's palsy

- Thirty-two (32) cases of bell's palsy have been reported. Nine (9) cases have been assessed as product related reactions (as per published literature), two (2) cases are indeterminate meaning there is insufficient evidence that the vaccine caused the reaction, two (2) cases as coincidental or not related to the vaccine, and 19 cases are currently being reviewed.
- The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Immune thrombocytopenia

- Immune thrombocytopenia is an autoimmune condition in which the immune system mistakenly targets blood cells called platelets that are needed for normal blood clotting.
- Very rare cases have been reported internationally after receiving the Janssen COVID-19 Vaccine and the COVID-19 Vaccine AstraZeneca. The product information for both vaccines have been recommended to update the imposition of the European Medicines Agency to include safety information on immune thrombocytopenia.

Immune thrombocytopenia

- Nine (9) cases of immune thrombocytopenia have been reported. Three (3) cases have been assessed as product related reactions (as per published literature), three (3) cases are indeterminate meaning there is insufficient evidence that the vaccine caused the reaction, two (2) cases as coincidental or not related to the vaccine, and one (1) case is currently being reviewed.
- The FDA together with the Epidemiology Bureau of the DOH shall continue to monitor vaccine safety ensuring that the benefits always outweigh the risks.

Cases of hospitalization

- One of the criteria for serious adverse reaction is hospitalization or extended hospital stay. Reports of suspected adverse reaction that results in **hospitalization does not necessarily mean that vaccine caused the reaction.** An Expert Committee reviews and assesses whether the vaccine caused the reaction.

- Based on the reports received, the hospitalization-reporting rate is 4.24 per 100,000 doses administered. Commonly reported causes of hospitalization include pyrexia, cough, dyspnea, and headache.

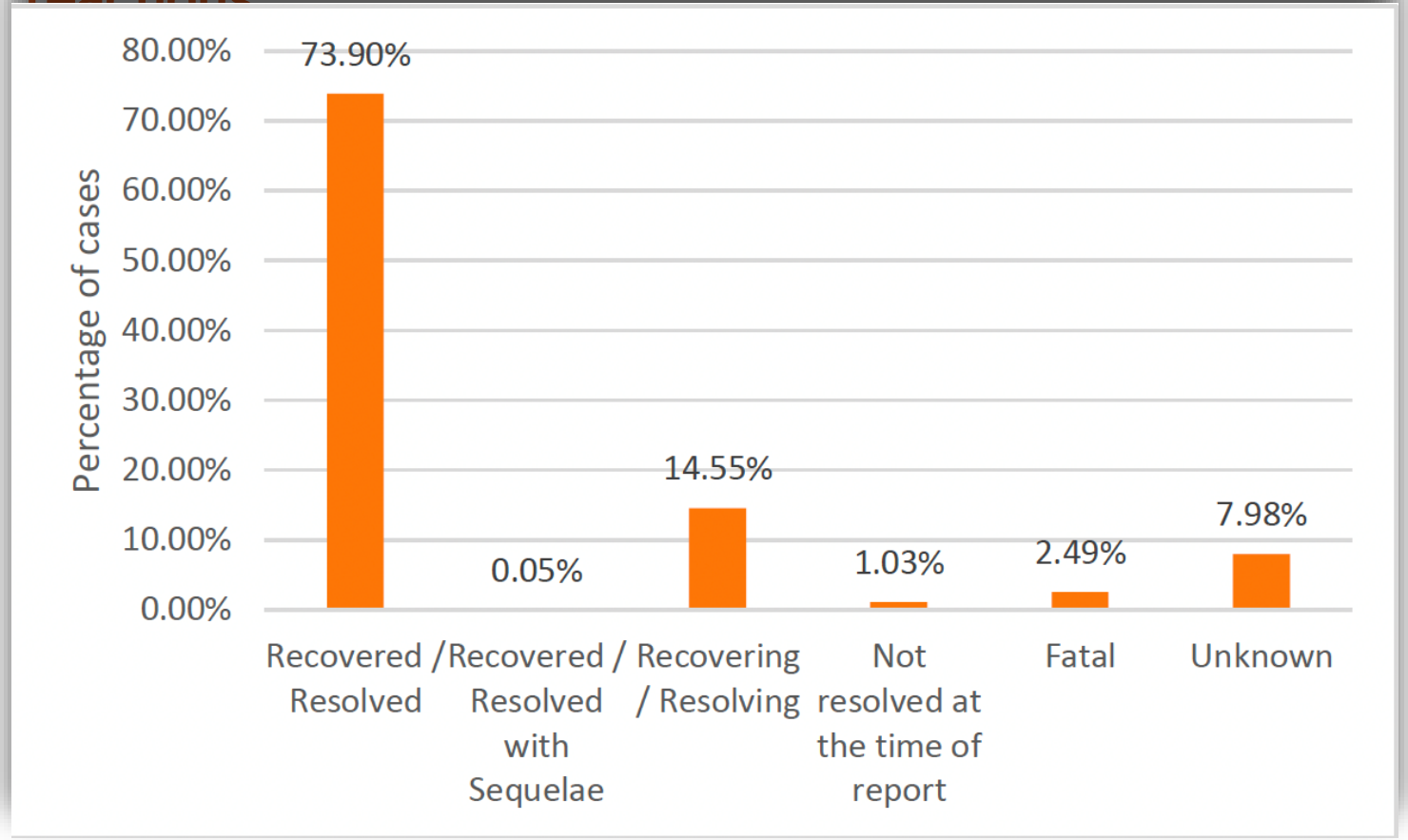
Reports of fatal events

- Another criteria for serious adverse reaction is when the case has resulted to fatal outcome regardless of the causality. As of 31 October 2022, 2,741 reports of fatal events were received. **The reports of fatal outcome do not necessarily mean that the vaccine caused the events.** Underlying conditions or pre-existing medical conditions causing fatal events are usually coincidental on the use of the vaccine. It is expected that reports of fatal events will rise as the vaccination program covers more people including those with undiagnosed illness, underlying comorbidities, and pre-existing medical conditions.

Reports of fatal events

- Most of these events occurred in persons with multiple existing comorbidities. These include cardiovascular diseases, ischemic heart diseases, cerebrovascular diseases, cancer, diabetes, and infections including pneumonia. According to the Philippine Statistics Office, such comorbidities are also the top leading causes of mortality in the Philippines. There were cases of confirmed COVID-19 infections leading to severe cases with fatal outcomes which also ranks among leading causes of death registered in year 2021.

Outcome of suspected adverse reactions



The overall risk-benefit evaluation of the vaccines

Based on the current available data, the benefits of the vaccines in the prevention of COVID-19 and severity of the disease outweighs any current known adverse reactions in the majority of the vaccinated individuals.

Thank you very much for kind attention